

Tuesday, 1 December 2020

(10.00 am)

SIR BRIAN LANGSTAFF: Ms Richards, before we begin today, let me just say a few words first, if you bear with me Professor Ludlam, to the general public and others who are watching this remotely. For this week, and the next, the Inquiry will be turning its spotlight on clinicians who worked in Edinburgh and Glasgow. This is a UK-wide public inquiry. It has already considered the centres in Cardiff, Oxford Birmingham, Swansea, Sheffield and London and some other centre in England. Belfast is yet to come.

But if the spotlight of the Inquiry this week is on Edinburgh and Scotland, there is a spotlight in the world today on AIDS. Today is World AIDS Day. No-one could doubt the serious threat that Covid-19 poses to all of us. Indeed, it's the reason we have to take the evidence in the manner which reduces the risks. But we should not forget, even as deaths from Covid approach 1.5 million worldwide, that nearly 33 million people worldwide have so far died of AIDS. Any untimely death is a tragedy. It is not a statistic.

A death from AIDS often involves long drawn out suffering, not just for the person infected. The main

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oath.

You will be watched by around about a couple of hundred thousand -- sorry, couple of hundred -- I beg your pardon, I mustn't add noughts where they don't belong -- a couple of hundred people who are watching remotely. It will be there or thereabouts. It varies a little bit during the day but it's a fairly constant number, and they will be watching, of course, all week because you will be with us all week.

We will take a break mid-morning. I'm grateful to you for agreeing to sit for the whole day today. The other three days we'll finish round about lunchtime to give you a break overnight because it's a long time to give evidence and we appreciate that

CHRISTOPHER ARMSTRONG LUDLAM, affirmed

Questioned by MS RICHARDS

Q. Professor Ludlam, are you able to see and hear me?

A. Good morning Ms Richards. Yes, I can see you and hear you. Thank you.

Q. Before we start with the main part of your evidence the Inquiry has received this morning a document apparently co-authored by you and Professor Lowe. It's entitled The Scottish Perspective on Healthcare Organisation Management of Pandemics and Management of Haemophilia Care, and it purports to be on behalf of

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task of this Inquiry is to determine how and why so many being treated by the NHS suffered like this. The proportion of the global number may be small, though significant, but each and every one who suffered or continues to suffer is a real person, not simply a statistic, wherever they are in the UK. You might like to know that my team and I will never forget that.

So, as I say, Professor Ludlam, today we are talking about Scotland. Let me just set the scene for you before I ask you to take the oath. You, I understand, are on your own in a room in Edinburgh, I think, at your solicitors; is that right?

THE WITNESS: That's correct, yes.

SIR BRIAN LANGSTAFF: Your counsel, Mr Reid, and your solicitor are in a separate room; is that correct?

THE WITNESS: Yes, that's correct -- next door.

SIR BRIAN LANGSTAFF: Here, because you won't be able to see much more than me and Ms Richards when she asks you questions, there is a very large hearing chamber which is largely empty. There are four counsel, the counsel team, in it; there is Soumik, who is there to make sure that we and the general public see the right documents; and we have three other people in the room, one of whom is Mary who will now ask you to take the

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Scottish Haemophilia Centre Directors past and present and their territorial health boards and refers to some further 42 other documents.

Professor Ludlam, so that you understand, I've not had time to read it, the Chair has not seen it and no Core Participant or recognised legal representative will have done so because it arrived with the Inquiry only this morning.

In circumstances where the rule 9 request for a statement was sent to you on 12 December last year, are you able to assist us with why this document is being sent to the Inquiry now?

A. I think we -- I and I think my colleague, Professor Lowe, have been very busy providing our statements, the full statements that we made. I recently, over the last two weeks, have been reading some of the many documents that have been sent electronically to me in relation to the Inquiry and from the Inquiry. It has taken quite a little while to put together this document and to get it supported from -- or to send it round to my colleagues and ex-colleagues in Scotland. I'm sorry it's arrived at this late date. It's because of all the consultation to make sure that we have given a fair summary of how we see Scottish healthcare being rolled out over the

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1 last 50 or more years.

2 **Q.** The Inquiry --

3 **A.** I'm sorry that it has arrived so late. I had

4 anticipated, I had asked for it to be sent in sooner.

5 It was out of my control with the central legal

6 office, who were primarily overseeing this.

7 **Q.** The Inquiry has been careful to ask for individual

8 statements from individual Haemophilia Centre

9 Directors, rather than collective documents or

10 submissions. Are you able to tell us who asked you to

11 produce this document?

12 **A.** I think it arose out of a discussion probably between

13 Professor Lowe and the team at the central legal

14 office.

15 **Q.** You'll understand, Professor Ludlam, that I'm not

16 going to be asking you questions about it because not

17 only have I not seen it but our system provides that

18 any statement should be seen by the very significant

19 number of Core Participants and their recognised legal

20 representatives so they can suggest questions and

21 no-one else will have seen this document as yet.

22 **SIR BRIAN LANGSTAFF:** Can I raise a more fundamental

23 issue. What is the nature of the document? Is it

24 evidence or is it in effect submission?

25 **MS RICHARDS:** That's a question for you, professor.

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1 persuade me about the nature of Scottish healthcare

2 and whether it did or didn't go wrong; if it did go

3 wrong, why and where; if it did things right, why and

4 where; if the rest of the UK might have benefited by

5 doing what Scotland did, we shall learn from that too.

6 But the right place for that is at the end for

7 submission, where submissions will be dealt with in

8 a manner we have yet to finally determine but I would

9 expect them to be shared by others, you can see what

10 others are saying, answer it, they can see what you're

11 saying and answer it. That's the fair and proper way

12 of doing it.

13 It seems to me it is entirely wrong -- and the

14 CLO ought to have realised this -- entirely wrong for

15 this document to be produced now. It looks as

16 though -- I'm sure it wasn't intended this way -- it

17 looks as though it's an attempt to pre-empt some of

18 the discussion. Well, it isn't and Ms Richards will

19 ask you the questions that she had in mind. I don't

20 expect this document to have any further currency in

21 this inquiry. You can revise it as much as you like

22 before the end. I won't read it until then because

23 I don't see any proper evidential basis for doing so.

24 If your counsel wishes to persuade me

25 otherwise, I'm prepared to listen and will do so

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1 **THE WITNESS:** Oh, I'm sorry. It is a submission in that

2 it's a description --

3 **SIR BRIAN LANGSTAFF:** Just pause there. Can I explain

4 clearly, so that you understand and in particular the

5 CLO who plainly played a part in producing this

6 document so late in the day, what the right place for

7 submission is. In an inquiry like this, the purpose

8 of hearing evidence from you is to take evidence.

9 Now, some of that evidence may, naturally does,

10 involve someone expressing their own views where they

11 are relevant to the question which is being asked, but

12 it's question driven, this is an inquiry asking its

13 own questions of witnesses who will be able to say

14 what the facts are. You are not called as an expert,

15 even though you have obviously expertise, which is why

16 you have been in the position you have, and great

17 expertise too, judging in particular by the number of

18 documents and articles which you yourself have been

19 responsible for. But this is not the right place to

20 make a submission particularly when only part of the

21 evidence is in.

22 In due course, there will be a chance for you

23 to advise the CLO, no doubt, and to discuss with them

24 if you wish -- matter for you -- what they want to say

25 to me at the end of the day and they may want to

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1 tomorrow afternoon, once you have finished your

2 evidence, if he wants to say anything to me about it.

3 But, for the moment, I'm not very happy that the

4 document is put forward. I don't necessarily blame

5 you for it but you are party to it, and I won't read

6 it and I shall expect to have submissions in the

7 proper place at the end of the hearing. Thank you.

8 **MS RICHARDS:** Professor Ludlam, I'm going to start by

9 asking you about your career. You undertook house

10 officer work at the Royal Infirmary in Edinburgh in

11 1971 to 1972. Did that work involve the treatment of

12 patients with bleeding disorders?

13 **A.** With the six months of medicine in Professor

14 Girdwood's unit that involved some general medicine,

15 but the ward was the ward that received patients with

16 bleeding disorders, yes.

17 **Q.** So how much experience did you have in that time of

18 working with patients with bleeding disorders?

19 **A.** It was mainly at an operational level dealing mostly

20 with in-patients, admitting them to the ward if they

21 needed to come into a bed, and putting up drips on

22 them, arranging investigations, their general medical

23 management. As a house officer, I had very little

24 part in deciding, if you like, their management.

25 **Q.** Was Dr Davies at that point the director of the

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1 haemophilia centre in Edinburgh?

2 **A.** Dr Davies and Professor Girdwood, I think they were

3 joint directors.

4 **Q.** Your CV tells us between 1972 and 1975 you were an MRC

5 junior research fellow in the Department of

6 Therapeutics at the Royal Infirmary. Briefly can you

7 tell us what that entailed.

8 **A.** Yes. As a student, I did a project in the Blood

9 Transfusion Centre in the hospital setting up an assay

10 for a blood clotting factor and I became quite

11 interested as a result of that in blood clotting.

12 I became particularly interested in platelets, which

13 I'm sure you are aware are small cells in the blood

14 that stop you bleeding, and there was an opportunity

15 to do some research.

16 I applied for the job, it was as a three-year

17 job, partly because it gave me some security for three

18 years because most junior hospital doctors are only

19 for a year. I'd just got married, my wife had an

20 interesting and a good job and we didn't want to move

21 round the country, so if I was able to get

22 a three-year post, that was advantageous.

23 The work I did was on platelet aggregation and

24 I became particularly interested in platelet-specific

25 proteins and it was in the setting up of an assay for

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1 I did, in fact, a lot of acute medicine, a little bit

2 of haematology, in those three years but it was really

3 a way of getting general medical experience in

4 a general medical ward.

5 **Q.** You moved to Cardiff in 1975 and you worked under

6 Professor Bloom in the haemophilia centre in Cardiff

7 as a senior registrar from 1975 to 1979.

8 **A.** That's correct.

9 **Q.** How much time did you spend treating patients with

10 bleeding disorders during those years?

11 **A.** The training I received in Cardiff was in a rotation

12 around the department and like most departments of

13 haematology the vast bulk of the work, clinical work,

14 is malignant work, leukaemias and lymphomas and so

15 a lot of my time was spent doing that work, both at

16 outpatients and up on the ward.

17 We rotated about every six months but six

18 months was also spent in the laboratory reporting

19 blood films and bone marrows and about six months was

20 spent taking responsibility as a senior registrar for

21 the blood bank.

22 The time spent in coagulation might have been

23 probably about a year I'd be attached specifically to

24 Professor Bloom but because of my interest in clotting

25 and I was able to continue a little bit of my work

11

1 one of those that I learnt the importance of

2 collaborating with other people to solve problems.

3 I did a little bit of work also with some of

4 the DDAVP analogues and that's how I became interested

5 in DDAVP because at this time Dr Cash was doing his

6 original work with DDAVP demonstrating that it not

7 only caused a rise in Factor VIII but also increase

8 the dissolution of blood clots and it was his work

9 that led on to Professor Mannucci using DDAVP in the

10 treatment of haemophilia that he published in 1977.

11 That's a well-known paper.

12 **Q.** Is it right to say that that work between 1972 and

13 1975 was essentially laboratory work rather than

14 clinical work?

15 **A.** No. More than half the time I would think would be

16 clinical work. I helped manage the patients in the

17 ward. There were two wards; there's a male and female

18 ward. I was doing out-patient clinics both in general

19 medicine and a specialist one in haematology. I had

20 responsibility as the what we call the on-call waiting

21 registrar, so all the emergency medical admissions

22 came to Accident and Emergency. On the days when our

23 unit was responsible for them, I was down in casualty

24 seeing them. I was the person overnight who had to

25 deal with all the acute medicine that came in. So

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1 activity there, I was, if you like, more familiar with

2 what was going on in the coagulation laboratory

3 because of my interest. So although I may only have

4 spent perhaps a year attached to Professor Bloom's

5 service, I was more in touch with what was happening

6 in clotting in general I think it would be fair to

7 say.

8 **Q.** What, if anything, do you recall of Professor Bloom's

9 approach to treatment and the use of factor

10 concentrates?

11 **A.** Professor Bloom was a very cautious individual.

12 I remember him talking to me on a number of occasions

13 about the Bournemouth hepatitis outbreak that occurred

14 in 1974 and how patients when they were first exposed

15 particularly to American concentrates got hepatitis

16 and, as I'm sure you will recall, at least one patient

17 died shortly after receiving a treatment. A goodly

18 number of patients developed overt and quite serious

19 hepatitis, many more developed asymptomatic hepatitis,

20 and it was very, very thoroughly investigated as you

21 will recall by a Dr Craske. He did a superb piece of,

22 sort of, viral epidemiology in investigating the

23 outbreak leading to several very important

24 publications.

25 This was clearly a very important event.

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1 I didn't, if you like, appreciate it at the time. It
 2 was Professor Bloom talking about it that really drew
 3 my attention to it, he was -- so he was cautious about
 4 US American concentrates. We used cryoprecipitate, we
 5 used NHS Factor VIII, we used latterly commercial
 6 Factor VIII. The difficulty sometimes was when you
 7 went to the fridge to get the Factor VIII out you
 8 weren't quite sure what was going to be there and,
 9 particularly in terms of NHS Factor VIII, the
 10 deliveries were very, as far as I could see, irregular
 11 and you couldn't predict when the next one was going
 12 to be. It seemed a bit spasmodic and not terribly
 13 satisfactory, but that was -- I think the Factor VI II
 14 came through the local Blood Transfusion Service,
 15 where of course I had an attachment.

16 **Q.** Were there patients in Cardiff during your time the re
 17 on home treatment?

18 **A.** There were. I think it started in about 1976 or '77.
 19 A haemophilia sister was appointed, and I think it was
 20 she who took forward the sort of home treatment
 21 arrangements for patients. I can't remember before
 22 that whether there was home treatment.

23 **Q.** Were there patients receiving prophylactic treatmen
 24 in Cardiff during the years that you were there?

25 **A.** There might well have been short-term prophylaxis. In

13

1 haemophilia centre at the Edinburgh Royal Infirmary in
 2 that year.

3 **A.** Yes.

4 **Q.** You remained in that post until you retired from th
 5 NHS in 2011?

6 **A.** That's correct, yes.

7 **Q.** Now, your statement refers to there having been
 8 another consultant colleague at that time but is it
 9 right to say that, insofar as bleeding disorder
 10 patients were concerned, decisions about treatment,
 11 product usage testing and so on, those decisions were
 12 your responsibility?

13 **A.** Yes.

14 **Q.** You were a member of the UKHCDO throughout your tim
 15 at the Edinburgh Royal Infirmary and you were, in
 16 fact, a member of the Reference Centre Directors group
 17 from 1980.

18 **A.** Yes.

19 **Q.** You were on the Hepatitis Working Party, which was led
 20 by Dr Craske, also from 1980?

21 **A.** Yes.

22 **Q.** And on the AIDS group from its inception in 1985?

23 **A.** Yes, as were all the other Reference Centre Directo rs.

24 **Q.** You were Chair of UKHCDO from 1996 to 1999?

25 **A.** Yes.

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1 other words, if a patient had had a series of bleed
 2 into an individual joint, an individual knee or elbow,
 3 in fairly quick succession, one of the ways of tryi ng
 4 to settle the joint down would be to give Factor VI II
 5 injections every other day, or perhaps every day, for
 6 two or three weeks to let the joint settle down and
 7 heal up. You then stopped the prophylaxis. So tha
 8 was short-term prophylaxis and I'm sure that we use
 9 that for some patients.

10 **Q.** Did Professor Bloom remain someone to whom you turn ed
 11 for advice in the later part of your career once yo
 12 were in Edinburgh?

13 **A.** Very much so. He was a world authority on
 14 haemophilia. He was very well informed. I respected
 15 his opinion. He was a very conscientious individua l.
 16 He's a very kind person and, while I'm talking abou
 17 him, if I may, I would fully endorse what
 18 Dr Saad Ismail had to say about Professor Bloom and
 19 the respect that he held him in. I couldn't have put
 20 it better myself.

21 **Q.** I may ask you some further questions about the exte nt
 22 to which you and Professor Bloom discussed matters as
 23 we go through the various issues.

24 Picking up your career in 1980, you became
 25 consultant haematologist and director of the

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1 **Q.** You were on The Haemophilia Society's Medical Advis ory
 2 Panel from 1989 to 1992?

3 **A.** Yes.

4 **Q.** You provided an expert report on HIV infection in
 5 haemophiliacs as part of the Haemophilia HIV
 6 Litigation, I think. Was that at the request of th
 7 Department of Health in England?

8 **A.** No, I think it was on behalf of the English health
 9 authorities.

10 **Q.** Since your retirement in 2011, you have advised
 11 a number of pharmaceutical companies. Your stateme nt
 12 tells us they are Ipsen, Sobi, Roche and BioMarin?

13 **A.** That's correct, yes.

14 **Q.** I want to ask you next about the Edinburgh Centre a nd
 15 my questions are going to focus on 1980 to about 1987
 16 for the most part in this regard. Can you recall how
 17 and when the centre in Edinburgh became a reference
 18 centre or treated as if it were a reference centre?

19 **A.** The situation in Scotland was slightly different from
 20 England. In Scotland, there were haemophilia centres
 21 in Edinburgh, Dundee, Inverness, Glasgow Royal
 22 Infirmary and Glasgow Children's Hospital York Hill ,
 23 and they were called Regional Haemophilia Centres and
 24 they were all considered to be, if I can put it thi
 25 way, equal. There wasn't any tiering of the system at

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1 all. I think you may be coming to the issue about how
2 the directors of Glasgow and Edinburgh came to be o
3 the reference centre committee.

4 There were some discussions with the Scottish
5 Home and Health Department in early 1980s, 1980 or
6 1981, because Dr Forbes and I were keen to attend t he
7 Reference Centre Directors meetings and the Scottis
8 Government, Scottish Home and Health Department, wa
9 keen that all haemophilia centres in Scotland shoul
10 be seen as equal and that there shouldn't be seen t
11 be a two-tier system of Edinburgh and Glasgow and t he
12 smaller centres. So a way of circumventing this wa
13 that Dr Forbes and I could attend the Reference Cen tre
14 Director meetings.

15 Q. Just --

16 A. Is that clear? I'm sorry --

17 Q. We'll just look at a couple of documents to see if
18 that assists. Soumik, could we have HCDO0000405,
19 please. HCDO0000405.

20 Temporary technical problem in terms of sharing
21 the document screen with you, doctor. We'll just s ort
22 that out, I hope. Do you want to try again, Soumik

23 Can you see the document, professor?

24 A. I can, yes, thank you.

25 Q. So this is the 10th meeting of UK Haemophilia

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1 suggested that Belfast should be regard as the
2 reference centre for Northern Ireland and that
3 Dr Rizza should write to Dr Mayne, et cetera. This
4 was agreed. It was also agreed that the Department of
5 Health should be asked to put Edinburgh and Glasgow as
6 the Scottish reference centres and Belfast as the
7 Northern Ireland reference centre ..."

8 If we go to the top of the next page, please
9 Soumik, first few lines only:

10 "... in the list of UK haemophilia centres when
11 this was reprinted."

12 Then it says this:

13 "Dr Ludlam asked that the Lothian Health Board
14 should receive a copy of the letter to the Departme nt
15 of Health as this would help him in negotiations with
16 the board."

17 What did you mean by negotiations with the
18 board, professor?

19 A. I think it was trying to establish with the board t he
20 importance of the haemophilia centre and the
21 haemophilia service I was starting or would be
22 starting to develop.

23 Q. So you and Dr Forbes, in any event, attended the
24 Reference Centre Director meetings. Had Dr Forbes
25 been attending them prior to 1980, to your knowledg e?

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1 Reference Centre Directors, 26 October 1980. The l ist
2 of names includes your own, and this would presumab ly
3 have been your first meeting?

4 A. That's correct, yes.

5 Q. If we just turn please, Soumik, to page 6, if we co uld
6 have section 5 downwards please, Soumik, so I can s ee
7 the whole of that.

8 I'm just going to read out the relevant
9 section:

10 "Haemophilia reference centres in Scotland and
11 Northern Ireland. Professor Blackburn said that
12 patients had raised with him the question of
13 haemophilia reference centres in Scotland and North ern
14 Ireland. There were at present no official referen ce
15 centres in either Scotland or Northern Ireland and
16 some patients were very worried about this.
17 Professor Bloom referred to the DHSS leaflet publis hed
18 in 1976. Professor Bloom said that in 1975 to '76 it
19 had been agreed in Scotland that there should not b
20 any officially designated reference centres in
21 Scotland, although unofficially the centres in
22 Edinburgh and Glasgow acted as reference centres.
23 Northern Ireland was included in the Oxford supra
24 region and Belfast was the only haemophilia centre in
25 Northern Ireland. After some discussion it was

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1 A. I'm sorry, I don't know.

2 Q. Then if we go to one further document please, Soumi k,
3 it's PRSE0000144. We can see this is a meeting of
4 directors of the Scottish National Blood Transfusio
5 Service and haemophilia directors, 30 January 1981.

6 If we could just go to page 4, please, Soumik,
7 bottom half of the page, we can see that there is
8 a heading there:

9 "Proposal for recognition of Edinburgh and
10 Glasgow Haemophilia Centres as reference centres. The
11 Chairman reported he had received requests from
12 Professor Bloom Chairman of the Reference Centre
13 Directors group and also from Dr Forbes and Dr Ludl am
14 asking that the haemophilia centres in Edinburgh an
15 Glasgow be designated as official reference centres
16 At the Chairman's invitation Dr Forbes explained th at
17 in England and Wales the designated reference centres
18 were charged with the responsibility for co-ordinating
19 the functioning of the haemophilia service. Many
20 centres England and Wales are relatively small and
21 look to the larger reference centres for guidance and
22 advice. The proposal to designate the two larger
23 centres as reference centres was simply to formalis
24 the present situation whereby the directors of the
25 Edinburgh and Glasgow centres attended meetings of the

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(5) Pages 17 - 20

Reference Centre Directors in the interests of UK co-ordination. Dr Forbes also explained that internationally it was important that certain centres in the UK were recognised as reference centres for training purposes. Members agreed that this link with England and Wales was important and should be maintained and it was confirmed that the directors of the other centres in Scotland, vis Aberdeen, Dundee and Inverness, supported the proposal that Glasgow and Edinburgh should be regarded as reference centres. The Chairman said that the department would wish to support this recommendation in regard to the status of the Edinburgh and Glasgow directors in the UK context but the designation of these two centres as reference centres would require further consideration involving the CAMOs."

Clearly this formalised an arrangement for you and Dr Forbes to attend the Reference Centre Director meetings. Was Edinburgh, as far as you're concerned, ever formally recognised or designated a reference centre?

- A. I don't recall any further correspondence. The CAMOs were the chief area -- chief administrative medical officers, the sort of chief administrative medical officers for each health board and that in my case

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and Aberdeen were senior physicians and haematologists, very experienced, much more experienced than I was in haemophilia care at one level, they had been looking after people with haemophilia for decades. So I was the new kid on the block and so I didn't feel initially that it was my job to be, inverted commas, "overseeing" what happened in these other centres.

As we went through the 1980s, a number of changes occurred. One of them was for the haemophilia directors in Scotland to meet regularly, initially as a subgroup of the Scottish office, SNBTS Haemophilia Directors Group, which you referred to earlier. But from about 1985 I was invited by the Scottish Home and Health Department to chair the Haemophilia Director for Scotland, and so we met every two or three months to discuss issues of mutual interest and concern in running and developing the service.

So, in that way, during the early/mid-1980s, in a sense, there was greater communication and collaboration in Scotland between the haemophilia centres.

- Q. In terms of the actual facilities in Edinburgh when you arrived, you described them in your statement, and I'm not going to ask you to repeat that in any detail,

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would be Lothian and the one for Glasgow would be the Glasgow Health Board.

- Q. Other than involving your attendance at the Reference Centre Director meetings and thus allowing a degree of co-ordination with England and Wales, did being designated as a reference centre have any further significance for you or for the centre?

- A. Yes. It, if you like, increased the expectation that the Edinburgh and Glasgow centres should be seen as centres of excellence and to conform to the health circular for England and Wales HSE764 which set out in some detail the responsibilities of haemophilia centres and I think reference centres in some detail. So it increased the expectation that we would lead haemophilia care, if I can put it that way, as best we could with the resources available. We were a teaching hospital and that put an additional obligation on us to try and be at the forefront of investigations and therapy for haemophilia.

- Q. Did it mean that the smaller centres in Oxford -- sorry, the smaller centres in Scotland looked to Edinburgh and Glasgow for advice and guidance in the same way as these minutes describe smaller centres in England and Wales doing so?

- A. When I was appointed in 1980, the directors in Dundee

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but as I understand it from your statement, and indeed the evidence of others, there was essentially ward 23, as an in-patient ward where patients would be admitted, and a small room at the entrance to the ward. You've described that as suboptimal in relation to patient privacy, arrangements for managing patients and availability of records; is that right?

- A. That is a brief description, yes. There was a room I would think about 20 feet by 12 perhaps, with a sliding door and it said Haemophilia Centre on the outside. Inside was -- the room contained two quite comfortable reclining chairs where people could get infusions, a number of hard chairs, dining-style chairs, where people could sit. It was a moderate-sized room and the patients would come from their home, when they were from home with bleeds and would be treated in this room.

I think it would be helpful to the Inquiry if I was to perhaps say a little bit about the type of bleeding that patients were getting and that we had to manage in the haemophilia centre, because I think the history of what haemophilia was like in the '70s and '80s is almost lost -- personal experience of what it was like in those days.

Severe haemophilia was a dreadful condition.

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It led to great uncertainties in the patients' lives. They didn't know when they were going to bleed, the didn't know how long, if they did bleed, when they did bleed, they were going to have to wait for an ambulance to come up to hospital, they'd have to wait in hospital to get their treatment, they'd get their treatment wait for an ambulance to take them home again. It was a whole day's expedition.

Bleeding into the joints is -- can be extremely painful. An untreated bleed can last ten days or so and requires opiates often to deal with it. There are also bleeds into muscles and that can lead to the destruction of the muscle and the bleeds into the joints leads to destruction of the joints, so that an appreciable number of the patients that I came to look after were very, very disabled. Their joints, particularly their elbows and knees, had very little movement in them. The knees would perhaps have five degrees/ten degrees of movement. They would be bent and people would have to walk with bent knees. The calf muscles would have been destroyed from fibrosis following bleeds into the calf because that was quite common. So these individuals ended up trying to walk on their toes with bent knees, and their arms were disabled because of bleeding into the elbows was

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a bleed. Now, as I'm sure you know, in the last two or three years, there's new therapy in which an injection under the skin once a fortnight stops most people with severe haemophilia from bleeding. So it's a completely transformed condition now. But patients, from small children up into adulthood, can grow up only needing injection once a fortnight and without experiencing bleeding. It is completely different, and I think the morbidity and mortality of the 1970s and 1980s, I think is -- there aren't many people left, if I can put it that way, who remember it firsthand.

Q. Professor Ludlam, can I just take you back to the question of facilities?

A. Yes.

Q. You described the facilities as they were in 1980. Your statement tells us that in 1986 the centre was able to have a suite of rooms at the entrance for ward 45. Can you recall how that was funded?

A. Well, the rooms in ward 45 I don't -- there was minimal costs involved. Another department had moved out of the rooms and I think they may have needed a coat of paint and perhaps some new chairs. But the counselling rooms which we urgently needed as you say, minimal.

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common, led to the destruction of the elbow joint. That became an appreciable problem when patients couldn't get their hands to their mouth to feed themselves.

So the disability was huge and I had the impression that the patients in Edinburgh when I arrived seemed to be rather more disabled than I remembered them in Cardiff. You've already heard about mortality. I experienced that very dramatically the first few years I was in Edinburgh. In 1981, '82 and '83, each year a young man came in with a fatal intracranial bleed and died, a terrible tragedy. That was -- those three patients represented nearly 10 per cent of my patients. It was a dreadful condition, severe haemophilia, that patients and their families -- because, as you know, there may well have been two people, two brothers, for example, in a family, and certainly extended families, uncles, may have had bleeding as well and it really was a terrible condition to have.

Its treatment became, as you know, with prophylaxis in the 1990s, so that children got injections every other day. They grew up virtually without bleeds. They hardly knew what it was to have a bleed. In fact, they didn't recognise when they got

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I'd had to raise money previously to improve the facilities in the haemophilia treatment room in ward 23 because patients there were coming up and in the mornings one would go round and see them and they would sit round in a semicircle, four or five patients, and they would tell you how they had come or what the bleeding problem was. There was no privacy at all. It was awful.

They knew each other, most of them, very well. At that time we had a side ward in the ward of four beds and there was usually a haemophiliac in each bed and so patients would come up, go to the treatment room, get their treatments and then go and see the patients who they knew well in the ward. So there was quite a community there. But, as I indicated in my statement, my first endeavour was to improve the arrangements in this haemophilia room by getting a partition put up so there was a tiny little consulting room where I could see each individual privately and examine them. It also had the advantage that we could keep the medical records, at least the latest volume of medical records, in a couple of filing cabinets there. That was to try and give patients a bit more space and dignity.

Q. In terms of staffing, you didn't have a haemophilia

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sister until 1982 and your statement tells us that clinical assistants and further nursing staff joined in 1986. Your statement then says that there was an associate specialist and further consultant later.

Can you recall when those further posts were filled?

A. We initially, as you say, had clinical assistance. I think we had two appointed about 1985 or '86 and they worked for several years, four, five, six years, perhaps, and I think they left, rotated on to other appointments, and I think we used the funding for the associate -- what became the associate specialist post. The additional consultant post was separately funded.

I wonder if I could go back. I think I have perhaps misunderstood your question about the consulting rooms. Were you asking about consulting rooms for counselling or the move of the haemophilia centre to this new location?

Q. I had asked about the move of the haemophilia centre to the new location in '86, simply how it was funded.

A. I'm sorry because we initially moved to two of the rooms for counselling purposes and then the centre moved a little while later because we were just desperate to try and get the service on to one site

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the haemophilia service was only a very small part of my activity. I was mainly working as a clinical laboratory haematologist with responsibility for diagnosing and treating patients with leukaemia and lymphoma, both as in-patients and as out-patients, and overseeing their chemotherapy. I was involved with doing bone marrow transplants in some of my patients.

So much of my time on the clinical side actually was spent looking after malignant patients not individuals with haemophilia or bleeding disorders. I also had responsibility for overseeing initially the laboratory clotting service, which is a very large workload, and also providing advice around the hospital on patients with any haematological problems, but particularly with thromboses, bleeding, we were -- I was advising general practitioners. They would phone up and ask for advice. There would be other consultants who would phone me up and ask for advice. There was a lot of what one might call multitasking. At the end of the day I had to come and look at the abnormal blood films reports, some of the bone marrow reports that had been sent in during the day.

So haemophilia and clotting was only perhaps one day a week's worth of work if one had to put it in

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That was funded by Lothian Health, as far as I recall. That required some building work and was quite substantial.

Q. Can you recall roughly when the further consultant joined you? Was it in the 1990s?

A. I think it was about 19 ... I'm sorry, probably about 1996, '7 or '8. I provided a statement. With my statement there is an appendix listing the staff and when they were appointed. I could look at it if you wish just now.

Q. No, no, don't worry. In terms of your role, I want to ask you about a paragraph in your witness statement Soumik, it's WITN3428001. If we could go to page 7 please, paragraph 20. If we can just see the whole paragraph 20 thank you. We can see if we pick it up in the third line you say:

"At that time [when you were first appointed] as a consultant my responsibility was to help lead the service, whereas today the emphasis is much more on consultants providing the service."

Can you explain what that distinction is. What was it about your role in 1980 that's different from the role of the modern consultant?

A. What we haven't considered so far are all the other responsibilities that I had as a consultant. Managing

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those sort of terms. I had all these other activities to be responsible for.

Q. Is that the distinction then you are making in paragraph 20?

A. Yes. So to answer your question I, in those days, had to, if you like, have more of a supervisory role and to try and ensure that the systems that were in place were reasonable and fit for purpose and, in particular, in relation to the haemophilia service, the clinical assistants who were appointed in about 1985 or '86 did a lot of the routine review of the appointments, the clinics, if you like, under my supervision. They saw the patients on my behalf. That's the sense in which I was trying to convey that I was overseeing the service.

Nowadays, of course, there are many more consultants and so the consultants would be seeing the patients, if you like, rather than the clinical assistants.

Q. If you were spending very approximately the equivalent of one day a week in relation to patients with clotting disorders in the first half of the '80s, can you assist us with how much time again approximately you were spending on research work?

A. I had a contract, when I took up my appointment the

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university offered me what was called a part-time senior lecturer appointment of two sessions -- that's two half days -- in the week. That was in recognition of the teaching that I was doing which I hadn't mentioned up to now. I was teaching both general medicine on the ward once a week, giving lectures to students and other Health Service staff and trainees.

A lot of the research was squeezed in to whenever you could one would perhaps have lunchtime meetings with people, discuss things. A lot of it was reading and writing that was done out of hours in the evening at the expense of my family, to which I owe a great debt for allowing me to do it. So there weren't any formal sessions that were set aside for university work in those days.

Q. In terms of your research work as a whole, your academic work and research, what proportion of that approximately over your career has related to patients with bleeding disorders?

A. Can you still see me?

Q. Yes.

A. You can?

Q. Yes.

A. Fine. Something's happened to the screen here.

I would say that most of my research for the -- for my

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coagulation in a range of different respects, so I think that is the answer to the question I asked.

Just on the issue of laboratory testing, if we could have, please, Soumik, again, Professor Ludlam's statement, WITN3428001. Professor, is your screen --

SIR BRIAN LANGSTAFF: May I just ask, professor, can you see Ms Richards?

THE WITNESS: Yes, I can. Thank you.

SIR BRIAN LANGSTAFF: So everything's okay with your screen?

THE WITNESS: Yes. It was a temporary glitch for about half a minute.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Can you see the document that's come up on screen now, your statement?

THE WITNESS: I can, yes.

Q. Soumik, could we have page 14, please paragraph 43. If we pick this up in the third line, it says that:

"In addition to previous routine investigations, there was a need to increase the surveillance of the immune and virological status of all patients."

We'll come on to the details of that later in the week, professor. Then you say this:

"As the necessary laboratory investigations

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career has been in relation to blood coagulation and particularly blood safety and immune function, as we may come on to discuss later on. But I've done a significant amount of work, perhaps latterly with other colleagues, particularly those interested in vascular medicine and thrombosis and the endothelial cells. So that's the latter part of my career I was involved with that, but that was using desmopressin for various research studies with a cardiologist, for example.

But during the -- I should perhaps say that my initial work as the MRC research fellow was -- if you like, it was for a research laboratory, research work. I was very fortunate. In those days, I had a full-time technician. I was the youngest researcher in the department. I was given a whole-time technician, it was a luxury you don't get these days, and that allowed me to do the research work but also to spend a lot of my time doing the clinical work that I mentioned earlier.

I'm sorry, I've not been terribly helpful perhaps, have I?

Q. As I understand your answer, professor -- correct me if I'm wrong -- you said that the majority of your research has been related to clotting disorders, blood

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were not available routinely in the NHS, additional resources were sought and acquired to do this from providers of research funds."

Which providers of research funds provided resources to the centre in the 1980s, to enable this kind of laboratory investigation to be undertaken?

A. The Scottish Home and Health Department had a research fund that I applied to and successfully got funding, and also the Medical Research Council, I applied for funding and they supported our work.

Q. Was any funding received in relation to this and the laboratory investigations that you are describing here from pharmaceutical companies?

A. Not that I -- no, I don't think so. No, no, this was -- no, I've no recollection. No, no, this was funded by Scottish Home and Health Department and the Medical Research Council.

Q. Again, focusing on the first half of the 1980s, did you hold regular out-patient clinics at the centre for patients with bleeding disorders?

A. In the first half of the 1980s the clinics were held in the medical out-patient department, I think on a Tuesday afternoon. I think I tried to keep one clinic a month for reviewing patients with haemophilia and, at that time, thanks to my predecessor having had

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a good liaison with a physiotherapist, we had a physiotherapist who came to the clinics and all the patients had their joints measured by goniometry, which was really quite unheard of at the time, and I'm interested it's now come back into fashion the last few years as a way of monitoring patients. My predecessor, Dr Davies, had set this up before I arrived and so we had a physiotherapist who came to my clinics.

As you see, it was in a general medical out-patient department. When we moved into what became the haemophilia centre in the mid-1980s then the patients came to that unit and everything was very much more brought together. That's where we saw the out-patients and the review clinics and the office. It was a very, very much better arrangement.

Q. In the first half of the 1980s, in the out patients as you've described, how often did the regular clinics take place, were they weekly, monthly?

A. Well, I had a clinic every Tuesday and Friday afternoon and on Tuesdays once a month I think I tried to keep the clinic predominantly for people with haemophilia. I could see them on other Tuesdays but Tuesday was also the day when I saw new patients, not just new patients with bleeding disorders or

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Now, again, just dealing with the period 1980 through to 1986/7 and not any later time, what role did the SHHD play in the organisation and delivery of haemophilia services in Edinburgh?

A. Well, the SHHD convened these meetings -- led, if I can put it this way, led -- they invited us to these meetings, and so they were providing, if you like, proactively developing collaboration with blood transfusion and themselves. So they knew what was going on, they knew what our needs were, and it provided, I think, a particularly useful conduit for discussions between haemophilia directors and SNBTS which were so important in trying to provide clotting factor concentrates for treating the patients.

Q. During this period, the first half of the 1980s, how regular or how frequent were the meetings that were organised by SHHD?

A. They were about once a year. They may have been twice a year. They started in the '70s, before my time in Edinburgh, I believe. I think they were about once a year, it might have been twice a year. But in about 1982 it became clear that there was a need to have more frequent meetings and so a subgroup was set up of the haemophilia directors from Edinburgh and Glasgow and some blood transfusion representatives under the

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thrombotic conditions but new patients with leukaemia or lymphoma or just anaemias that general practitioners wanted advice about.

Q. Patients with a severe bleeding disorder, how often did they have regular, scheduled appointments, were they seen six monthly or four monthly or annually, what were the arrangements in 1980?

A. It was a bit variable depending on the particular individual, but it would be -- most of them would be seen at least every six months, people with severe haemophilia. They would be coming up and being reviewed also with their acute bleeds in the haemophilia centre. So one got very used to seeing them on a day-to-day basis, if I can put it that way, as well as at the review clinics.

Q. Then one final question on, as it were, the organisation and structure for haemophilia care at that time. If we go back to page 12 of the statement, please, Soumik, paragraph 36. If we just go down to 36, it says here that:

"The SHHD [so Scottish Home and Health Department] provided the framework for collaboration ... by convening regular meetings to consider arrangements for the provision of the service for patients."

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chairmanship of Dr George MacDonald who was a senior haematologist in Glasgow and co-director of the Glasgow Haemophilia Centre and he convened some meetings to take forward various projects in relation to supply of treatment, particularly for patients between about 1982 or 1983 and '85/'86.

MS RICHARDS: Sir, I note the time and I'm going to move on to a new topic, so is this an appropriate moment for a break?

SIR BRIAN LANGSTAFF: Yes. Just a couple of questions, if I may, just to give me an impression of the service. Where geographically did most of your patients come from? Did those patients in Fife, for instance, go to Dundee?

A. That was one of our difficulties. We served a very large geographical area. Patients in the south of Fife, Kirkcaldy and around there, Dunfermline, came to Edinburgh. We had patients down as far as Berwick-upon-Tweed. So it was a very large area, a population of about a million and a half. So the size of the haemophilia centre is roughly proportional to the population it serves. We were a relatively small haemophilia centre, as haemophilia centres go, compared with some of the ones in Manchester or London that evidence been hearing about in the past. We had

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1 about 40 or 50 people with severe bleeding disorders.
 2 But it was a long journey if you lived in Kirkcaldy
 3 Bleeds often started overnight, you would wake up i
 4 the morning, got a bleed in your knee, phone for
 5 an ambulance, you might wait half an hour/an hour for
 6 an ambulance, you would trundle over to Edinburgh,
 7 an hour and a half or so, possibly picking up other
 8 patients on the way, came to our ward 23, sat in th
 9 haemophilia centre, the one room. Eventually, the
 10 cryoprecipitate would arrive. You probably set the
 11 drip up yourself, because you are pretty good at it,
 12 and when it had run through you would perhaps go round
 13 and see the other people that you knew in the ward.
 14 You would then wait until the ambulance came some t ime
 15 in the afternoon to take you home again. You might
 16 have to come back the following day.

17 I put it in this way because the distances were
 18 long, the bleeding was frequent, it was no way for
 19 young men to grow up. Children needed to be at
 20 school, not coming up for treatment for bleeds.

21 **SIR BRIAN LANGSTAFF:** The same would apply in the Borders,
 22 because the Borders would go to you, I would imagine.
 23 **A.** Yes. We served most of the Borders. Between
 24 Edinburgh and Glasgow there was a sort of watershed
 25 Some of the patients who lived nearer Glasgow

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1 **A.** Well, there are two sorts of -- there was the
 2 supervision of the registrars and a lot of that was
 3 done because they walked around the hospital with m
 4 and we discussed management of patients as we walke
 5 down the corridors between wards. The clinical
 6 assistants I think -- I can't remember the exact
 7 details but I would have told them about haemophili a;
 8 they'd have met the patients; they'd have met the
 9 haemophilia sister who had been in post for two or
 10 three years and become very knowledgeable about
 11 haemophilia. My guess is that I ran the clinics to
 12 begin with and they sat in on them and then when they
 13 were familiar with the way I did things, sort of
 14 investigations we were doing and so on, that they
 15 would take over.

16 But there was very low threshold for coming to
 17 seek my help and opinion. I always used to say to
 18 everyone I kept the door shut to my room to keep th
 19 noise out, not to keep people out because there was
 20 a noisy office outside with typists and phones ringing
 21 and so on.

22 **SIR BRIAN LANGSTAFF:** So it was supervision in the sense
 23 of they could come to you and get advice if they
 24 needed it once they had had a degree of
 25 apprenticeship?

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1 sometimes came to Edinburgh because they had family in
 2 Edinburgh and some of the ones that lived close to
 3 Edinburgh went to Glasgow because they had families
 4 there. It didn't cause us any difficulties. But
 5 there were long distances and Glasgow -- you need t
 6 take this up, if you wish, with Professor Lowe, ser ved
 7 the islands and -- the Highlands and islands. You
 8 know, they were considerable distances and treatmen
 9 and investigation challenges.

10 **SIR BRIAN LANGSTAFF:** Thank you for that. The other
 11 question really arose out of your describing how some
 12 of the treatment was delivered under your supervisi on
 13 and you were describing that as part of a section w hen
 14 counsel was asking you about your routine and you were
 15 saying, as I understood it, that because you had so
 16 much work to do of all sorts of which haemophilia care
 17 was only a part amounting to roughly a day a week, you
 18 would supervise the care rather than provide it
 19 personally.

20 So supervision if I can just have a sense of
 21 what that involved because plainly it wasn't sittin
 22 with the clinical assistant when the clinical
 23 assistant was providing the care, supervising in that
 24 direct sitting on the shoulder-type style.

25 What did it actually involve?

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1 **A.** Yes.

2 **SIR BRIAN LANGSTAFF:** Thank you very much. Now, we're
 3 having a break. At all the breaks that we'll have,
 4 whether it's overnight or whether it's during the day,
 5 the general rule is this and I just want to remind you
 6 of it as I do to all witnesses. You're giving
 7 evidence. You must not discuss your evidence eithe
 8 the evidence you have given or any evidence which you
 9 think you might be asked to give with anyone, whoever
 10 they are, whether it's your solicitor, counsel, you
 11 wife even, with anyone. You can talk about anythin
 12 else you like. Now we'll take a break until let's say
 13 11.45.

14 11.45.

15 **A.** Thank you very much.

16 (11.21 am)

(A short break)

18 (10.45 am)

19 **MS RICHARDS:** Professor Ludlam, I'm going to be asking you
 20 next about product usage and treatment policies in the
 21 period 1980 to 1984.

22 First of all, in terms of the annual returns
 23 that were completed and sent to Oxford, was that yo ur
 24 responsibility at that time?

25 **A.** It was my responsibility. I didn't actually do all

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1 the work for it. I had staff, clerical and other
 2 staff, who did most of the work.
 3 **Q.** Do you know where the annual returns were kept? Th
 4 reason I ask, professor, is that we haven't got any
 5 for Edinburgh Royal Infirmary for the 1980s.
 6 **A.** I'm amazed to hear that. They must -- they should be
 7 in the fairly extensive archives that are with the
 8 health board in the university library. I'm amazed
 9 We -- I can't understand why you haven't got those.
 10 I was obsessional about collecting these things.
 11 It's possible, I suppose, that, if you like,
 12 the top copy was sent off to Oxford and we didn't keep
 13 a photocopy. Photocopiers were not very common in the
 14 early 1980s. I'm sorry, the data you get from the
 15 national database, I think, will be pretty accurate as
 16 a reflection; so I'm sorry I don't have the --
 17 **Q.** Yes, the information that the annual returns would
 18 give us that we don't have from elsewhere, currentl
 19 at least, would be the number of patients actually
 20 treated in a given year but you've estimated that i
 21 your witness statement -- well, you've estimated in
 22 your witness statement, first of all, in paragraph 59,
 23 that you think there are about 40 to 50 patients wi
 24 severe bleeding disorders and approximately 150 to 200
 25 patients with non-severe disorders.

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1 ten you will access them from the blood bank?
 2 **A.** Yes.
 3 **Q.** Am I right in understanding that there was no charg
 4 for those products to the health board or the
 5 hospital; they were effectively free of charge to you?
 6 **A.** Yes.
 7 **Q.** What can you recall in the early 1980s about how PF
 8 allocated concentrates to particular blood banks or
 9 particular geographical regions?
 10 **A.** In the early 1980s I think it was on the basis of the
 11 amount of plasma that the Edinburgh region, which was
 12 South East Scotland, could submit to the Protein
 13 Fractionation Centre for making into Factor VIII
 14 concentrate and other blood products.
 15 **Q.** We will have a look at a couple of documents that
 16 might assist. Soumik, could we first of all have
 17 PRSE0000144. So we can see from the top of the page,
 18 Professor Ludlam, this is a Meeting of Directors of
 19 the Scottish National Blood Transfusion Service and
 20 Haemophilia Directors, 30 January 1981, and we can see
 21 that you are in attendance. Could we go to page 3
 22 please, Soumik.
 23 If we can zoom in on the heading development of
 24 a new approach and the paragraphs beneath that. So we
 25 can see it says there, Professor Ludlam, "Developme nt

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1 **A.** Yes.
 2 **Q.** That's your best recollection.
 3 **A.** Yes.
 4 **Q.** We'll look at one document which may assist. Soumik,
 5 could we have PRSE0004349. If we go to the second
 6 page, please. This is your response to
 7 Professor Bloom's AIDS survey. I'm not asking you
 8 about the detail of that, at least not at the moment,
 9 but we can just see numbers here, how many
 10 haemophiliacs are treated each year at your centre, eg
 11 in 1982, and the answer that's been given is 60
 12 haemophilia A, 16 haemophilia B, seven
 13 von Willebrand's disease. It's not clear, I think,
 14 from the form whether you are giving that informati
 15 for 1982 or 1983 but would that be broadly reflective
 16 of the kind of numbers that were being treated on
 17 an annual basis at that time?
 18 **A.** Yes.
 19 **Q.** Now, in terms of the source of products that you used,
 20 NHS concentrates were supplied to you by the Protei
 21 Fractionation Centre in Liberton; is that right?
 22 **A.** That's where they were manufactured. They were
 23 supplied by the local blood bank in the Royal
 24 Infirmary.
 25 **Q.** So the PFC would provide them to the blood bank and

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1 of a new approach to regional issues of Factor VIII
 2 Concentrate from PFC":
 3 "Mr Watt invited members to consider a proposal
 4 that each region should get back quantities of bloo
 5 products in proportion to the amount of plasma sent to
 6 the PFC for processing, rather than by the present
 7 method whereby Factor VIII was distributed on the
 8 basis of population.
 9 "Haemophilia directors expressed reservations
 10 about this proposal, and the chairman referred to the
 11 central funding of the blood transfusion service in
 12 Scotland compared with the strong regional element in
 13 the English service. In general members agreed tha
 14 Mr Watt should continue to maintain a reserved supply
 15 of Factor VIII at the PFC and were of the view that
 16 while issues of VIII should be related to the amoun
 17 of plasma submitted for processing it was for the
 18 transfusion service to rationalise the collection o
 19 plasma appropriately."
 20 Now, pausing there, professor, it looks from
 21 the first paragraph as though, as at early 1981,
 22 Factor VIII was distributed according to population
 23 rather than amount of plasma sent, and then there's
 24 a proposal to change that. Do you recall that at all?
 25 **A.** I don't recall the change but I recall discussions in

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1 about 1981 in which I remember calculating how much
2 Factor VIII I would receive because I knew how much
3 plasma was being collected in South East Scotland. So
4 I think it did verge towards that system, although
5 there is, in a sense in this paragraph, the suggestion
6 that there could be some movement of supplies around
7 Scotland between health boards.

8 **Q.** We see from this second paragraph, it says
9 "Haemophilia directors expressed reservations about
10 this proposal", can you recall whether you had
11 reservations about it or what those reservations might
12 have been from others?

13 **A.** I think we wanted, as haemophilia directors to offer
14 as good a service as we could to our patients and to
15 be able to offer them as much concentrate as we could,
16 particularly NHS concentrate, and we wanted it to be
17 an equitable service throughout Scotland. Without
18 knowledge of the details, it may be that it was harder
19 to collect plasma from the west of Scotland, per head
20 of the population, perhaps, than in some of the
21 smaller health boards, some of the smaller blood
22 transfusion regions.

23 There's an interesting statistic that
24 I remember from many years ago, it's the number of
25 donations you get in a Blood Transfusion Centre is

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1 it seems to me at the moment, is that it's recognised
2 that in England the blood is collected on a regional
3 basis, and some plasma is then sent into BPL for the
4 production of the various products that come from the
5 plasma. But Mr Watt continued to maintain a reserve
6 supply of Factor VIII, whatever that may mean
7 precisely, and of the view that while issues of
8 Factor VIII should be related to the amount of plasma,
9 in England it was directly proportional to, and the
10 it says this:

11 "... it was for the transfusion service to
12 rationalise the collection of plasma appropriately."

13 One way of reading that, in the light of the
14 context, would be, well, we're not going to impose
15 a system where whatever you send in you get
16 a proportional amount back, but we're going to ask --
17 because it's centrally managed, we're going to ask the
18 Transfusion Service to make sure it gets enough plasma
19 from its particular area in order to produce enough
20 product for that area, so that -- it's a rather
21 different slant on the system.

22 Have I understood it correctly or not, or is
23 that the meaning that you took from it? It looks as
24 though it might have been worded because there had
25 been some disagreement and this is a form of consensus

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1 inversely proportional to the size of the population
2 it serves. In other words, a small population is much
3 more likely per head to give more blood than a larger
4 population. That made large areas perhaps not produce
5 quite as much per head of the population as the
6 smaller areas.

7 **Q.** There is a later letter, May 1982, PRSE00000044,
8 please, Soumik. We can see it is dated 10 May 1982
9 It's from Dr Boulton and it's addressed to you. We
10 just need to look at the last paragraph on this page,
11 please, Soumik for present purposes. We can see from
12 that last paragraph it says:

13 "As you know, this allocation [which is the
14 allocation from PFC] is actually based on the amount
15 of plasma we supply to PFC."

16 Does that suggest that by May 1982 the system
17 has changed so that it's now an amount that's
18 proportionate or is somehow based upon the amount of
19 plasma supplied?

20 **A.** It does. I would agree.

21 **SIR BRIAN LANGSTAFF:** Can we just go back for a moment to
22 PRSE0000144 at page 3. The previous screen, thank
23 you. I'm looking at paragraph 5. I am a little
24 puzzled by what was actually meant by the last
25 sentence. What had been discussed -- the context, as

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1 statement, which could mean different things to
2 different observers. So I'm interested in what you
3 would take from it.

4 **A.** I'm having some difficulty. This last sentence of the
5 paragraph that starts "In general members agreed ..
6 the amount of plasma submitted for processing it was
7 for the transfusion service" -- I agree it says to
8 rationalise the collection of plasma appropriately.
9 I -- my interpretation is that it was up to the PFC to
10 try and top up those haemophilia centres, if I can put
11 it that way, that don't get as much Factor VIII
12 because the plasma from that area is less than
13 elsewhere.

14 **SIR BRIAN LANGSTAFF:** Yes.

15 **A.** Does that help?

16 **SIR BRIAN LANGSTAFF:** Well, it does help. It's just
17 trying to understand what is a slightly impenetrable
18 sentence.

19 **MS RICHARDS:** Yes, sir. It may be that question we will
20 be able to explore further with SNBTS and PFC
21 witnesses in due course.

22 **SIR BRIAN LANGSTAFF:** I'm sure we can but I would be
23 interested to know what the answer is.

24 **MS RICHARDS:** Professor Ludlam, again dealing with source
25 of products, did cryoprecipitate -- did you receive

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1 that through the same route, in other words, supplied
 2 by the PFC to the blood bank in the infirmary and then
 3 obtained by you from there?

4 **A.** No, the cryoprecipitate was prepared by the Blood
 5 Transfusion Service locally in Edinburgh and stored in
 6 the deep freezes of the blood bank in the hospital.
 7 It wasn't from PFC. It's the plasma that wasn't used
 8 for making cryoprecipitate and also the
 9 cryoprecipitate supernatant that was sent to PFC for
 10 processing.

11 **Q.** Then in terms of commercial concentrates and we'll
 12 look at precise proportions in a few minutes, but when
 13 you did use commercial concentrates, what was the
 14 arrangement for their purchase or procurement in the
 15 early '80s?

16 **A.** In the early '80s they were purchased by the Blood
 17 Transfusion Service and Lothian Health Board paid for
 18 the concentrate.

19 **Q.** And who decided which commercial concentrate to
 20 purchase Factorate, Koate, whichever? Whose decision
 21 was that?

22 **A.** I can't remember exactly but what I do remember is
 23 that it was sometimes quite difficult to buy
 24 commercial concentrates in the early 1980s. There was
 25 generally a shortage and the commercial suppliers were

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1 "Lothian Health Board, Area Executive Group,
 2 7th December 1982, case for the appointment of a staff
 3 nurse, Edinburgh Haemophilia Centre."

4 If we look down the page we can see that this
 5 page sets out the case for the appointment of a nurse
 6 dedicated to the haemophilia centre. If we look at
 7 the bottom paragraph we can see it said this:

8 "The case is now promoted as a development
 9 which should be self-financing in that the employment
 10 of a staff nurse would be expected to result in
 11 a significant reduction in the use of Factor VIII and
 12 particularly result in a reduction of the use of
 13 commercial Factor VIII, which is presently required to
 14 supplement the allocation of intermediate ...", it
 15 says Factor VIII there. I think that's probably
 16 supposed to be Factor VIII.

17 Then if we go to the next page please, Soumik,
 18 we can see that from the bottom of the page it's
 19 authored by Dr Ogilvie Community Medicine Specialist.
 20 Then if we go back to the top half of the page we can
 21 see it says:

22 "The present requirement for Factor VIII
 23 concentrate is approximately 130,000 IU per month
 24 while the allocation of Factor VIII from PFC to the
 25 Edinburgh Haemophilia Centre is only 84,000 IU."

55

1 keen to supply the big centres. They had contractual
 2 arrangements with the big centres in England and it
 3 was sometimes quite difficult actually to get hold of
 4 Factor VIII. I'm sorry, I can't remember -- probably
 5 I made the decision. It might have been someone at
 6 the blood transfusion but probably me, and to some
 7 extent it would depend on what was available.

8 **Q.** To what extent in the first half of the 1980s did you
 9 receive visits from representatives of pharmaceutical
 10 companies? We've seen examples in relation to other
 11 centres and I think you'll have seen one document,
 12 professor, showing you being visited by Mr Berry of
 13 Immuno in 1984. Was that a regular feature?

14 **A.** No. They didn't see Edinburgh as a market, as it
 15 were, for their products, so I don't recall receiving
 16 visits.

17 **Q.** We're going to look at a document which was a written
 18 submission or case for the appointment of a dedicated
 19 haemophilia nurse.

20 Soumik, it's LOTH0000216, please. Go to the
 21 next page.

22 We can see there there's an agenda for an Area
 23 Executive Group meeting of the Lothian Health Board
 24 Then if we go on another two pages, please.
 25 You'll see there, Professor Ludlam, a document headed:

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1 So that would suggest a shortfall of some
 2 46,000. Then it said:

3 "The difference has to be made up by the
 4 purchase of commercial Factor VIII at a cost of £2,500
 5 per month. It is considered that the home supervision
 6 of haemophiliacs will significantly reduce the total
 7 demand for Factor VIII since it is frequently
 8 inadequate supervision which results in the need for
 9 hospitalisation and the consequential use of Factor
 10 VIII in high dosage. It is anticipated that the
 11 better supervision of haemophiliacs which could be
 12 achieved by the employment of a staff nurse would
 13 result in at least a 15 per cent reduction in
 14 Factor VIII consumption amounting to a reduction of
 15 about 20,000 IU per month, which is equivalent to a
 16 saving of about 12,000 per year."

17 Then if we skip down a couple of paragraphs it
 18 says:

19 "It is understood that commercial blood
 20 products to treat haemophiliacs to the value of about
 21 40,000 was purchased in the first half of this
 22 financial year", and then there's a recommendation for
 23 the appointment of a staff nurse.

24 I think we know from your statement a staff
 25 nurse was appointed in 1982. This wasn't authored by

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1 you but would the data in here and the arguments in
2 here have come from you, do you think?
3 **A.** I think it's likely that the information came from me
4 about the purchase of Factor VIII, commercial
5 Factor VIII, and the allocations of NHS and
6 commercial, yes.

7 **Q.** So this would suggest that there is a shortfall of PFC
8 of about 46,000 IU in terms of allocation per month
9 and there's also a suggestion that patients are
10 effectively receiving too much Factor VIII and the aim
11 is to reduce the amount of Factor VIII required.

12 Can you perhaps help us with the thinking in
13 relation to that please, professor.

14 **A.** Yes. I was only going to receive funding for this
15 post if it was going to be -- lead to a lower
16 expenditure by the health board on haemophilia and
17 otherwise I wouldn't have got this post. So
18 I suggested that maybe, as is set out here, if
19 patients treated themselves at home because early
20 treatment of bleeds requires less treatment. That'
21 not only well established but it results in the bleed
22 getting better quicker and there being less joint
23 damage. So that's good medicine and you need smaller
24 doses if you treat early. So if people went on to
25 home therapy they might well require less Factor VI II

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1 a bleed, treating it early, would avoid a need for
2 them to come into hospital, would avoid the need for
3 greater use of Factor VIII and, therefore, is less
4 wasteful or less -- uses less Factor VIII than
5 requiring them to come to hospital and have it there.

6 It's the, what is said in the first sentence,
7 how that fits with that because there it says that
8 home supervision of haemophiliacs will significantl
9 reduce the total demand for Factor VIII since it is
10 frequently inadequate supervision that results in the
11 need for hospitalisation. So what was the failure of
12 supervision that resulted in the need for people to
13 come to hospital to treat a bleed? I don't quite
14 understand how that fits with what you've just
15 described.

16 It's not your letter so it may be somebody has
17 misunderstood what you were saying but --

18 **A.** Yes, I'm -- the best I can do to help you is that
19 patients on home treatment sometimes end up treatin
20 themselves for several days on end ineffectively
21 without coming up to hospital. I'm sorry, this --
22 mostly patients treat themselves well at home. It
23 isn't a difficulty but it's important that they are
24 educated properly, that good records are kept, that
25 the arrangements for them collecting or having

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1 than delaying for six or 12 hours to get up to
2 hospital, then requiring more Factor VIII.

3 **Q.** Did the increased supervision of home treatment tha
4 came with the appointment of the haemophilia sister
5 have the result of less Factor VIII being used in t he
6 way anticipated here?

7 **A.** I don't remember. I don't recall looking at the
8 statistics but I was very surprised six months afte
9 this request was granted and the haemophilia sister
10 was in post the Health Board Treasurer wrote to me and
11 asked how much we had spent on commercial Factor VII I.

12 I think the expectation was that I would save,
13 I forget, £10,000 in six months and as the way had
14 worked out because it's very difficult to make
15 predictions in haemophilia I had saved £20,000,
16 apparently, on commercial Factor VIII and so I wrot
17 back to the Health Board Treasurer. I didn't hear
18 from him again.

19 **Q.** We're going to look at the specific figures that we re
20 presented to --

21 **SIR BRIAN LANGSTAFF:** Just one moment before we do. The
22 document on the screen, the second paragraph, I jus
23 want to have a look at that. What you've described
24 I think is that having more patients treating
25 themselves at home early with Factor VIII, recognis ing

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1 delivered their Factor VIII, it all requires to be
2 carefully arranged, let me put it that way.

3 **SIR BRIAN LANGSTAFF:** So it might be that if better
4 supervised they wouldn't run out of the Factor VIII
5 that they keep in their fridge and they will be abl
6 to maintain themselves better at home. Is that the
7 sort of point that is being made?

8 **A.** Yes, it's a mechanistic arrangement.

9 **SIR BRIAN LANGSTAFF:** Yes, I see. Thank you very much.

10 **MS RICHARDS:** Just going to look at the figures in terms
11 of product usage that were supplied to the Penrose
12 Inquiry. Soumik, could we have PRSE0002887, please
13 We can see this is a report dated April 2012 from t he
14 National Haemophilia Database, bleeding disorder
15 statistics for the Penrose Inquiry and if we could go
16 please, Soumik, to page 15.

17 We can see there we have the figures for
18 Edinburgh from the 1969 through to 1977. I'm not
19 going to take you to each and every line,
20 Professor Ludlam, but in an attempt to summarise th is
21 we can see there's a substantial increase in the us
22 of cryoprecipitate from 1970, which is the fourth line
23 down in the table where we see 6,350 units being us ed,
24 and if we go by way of example to the bottom of the
25 page we can see for 1977, third line from the botto m,

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1 cryoprecipitate 640,640 units.
 2 We can see that there are no commercial
 3 concentrates being used at all during this period.
 4 Then if we go over to the next page we can see the
 5 first seven lines give us the information for 1978 and
 6 1979. Again, we can see substantial use of
 7 cryoprecipitate. The figures there in the first an
 8 fifth lines give us the cryoprecipitate figures. W
 9 can see an increasing use of Factor VIII from PFC b ut
 10 still less than cryoprecipitate and again no
 11 commercial concentrates.

12 If we then pick the picture up in 1980, which
 13 is when you took over, professor, which is the eigh th
 14 line down, we can see cryoprecipitate 1,212,470 and
 15 then we see being used Factor VIII, so a commercial
 16 Factor VIII, 164,000 units. We'll ignore the small
 17 amounts of FFP. Then also in 1980 PFC Factor VIII
 18 1.6 million, approximately.

19 So is it right to say in relation to 1980 we
 20 can see a significantly increased use of both
 21 cryoprecipitate and, in particular, factor
 22 concentrates and the first use of commercial
 23 concentrates?

24 A. Yes.

25 Q. If we then carry on it with 1981, we can see there

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1 1982, which is the first time it features here?
 2 A. Oh, I can assure you I undertook some studies in
 3 Cardiff which were published in the British Journal of
 4 Haematology in 1980 with Professor Bloom. The UKHC DO
 5 was kind enough to invite me to give a lecture on its
 6 use at their symposium annual general meeting in
 7 Glasgow in 1980, so I felt I was well up in the
 8 potential use for DDAVP and was using it.

9 Q. If we could have, Soumik, WITN3428044. This is
 10 a table which has been prepared from the data in th
 11 document we've just looked at. It's been prepared by
 12 my colleague Mr Hill and you've seen it, professor.

13 We can see, if we look at the period 1979 to
 14 1980, we see in 1979 the amount of cryoprecipitate
 15 used 694,190 units. That's 78 per cent compared to
 16 22 per cent of the product being Factor VIII
 17 concentrate.

18 1980, we see there a very substantial increase
 19 in cryoprecipitate but a much greater increase in the
 20 use of Factor VIII concentrate and the ratio is now
 21 40 per cent cryo, 60 per cent Factor VIII.

22 1981, we can see the figures there set out and
 23 the ratio is 36 per cent cryoprecipitate, 64 per cent
 24 Factor VIII concentrates.

25 1982, we can seek the figure for cryo -- or the

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1 again the figure in relation to cryoprecipitate
 2 720,000. So that's coming down. We can see some
 3 commercial product being used still, Factor VIII,
 4 442,000 so that's gone up, and PFC Factor VIII
 5 840,000. So a significant increase in that year an
 6 the use of commercial concentrates; is that fair?

7 A. Yes. I'm sorry, I'm having difficulty -- that's
 8 better, thank you.

9 Q. There's a shorter table I can probably take it from ,
 10 if that's easier.

11 A. The shorter table I think would be more helpful if
 12 it's the one that you've sent.

13 Q. We will look at that in just a moment because it
 14 distils this information, but can I just draw your
 15 attention to we see DDAVP with an asterisk featurin
 16 for the first time in 1982. That's what this table
 17 tells us.

18 A. Yes.

19 Q. If we go to the shorter table, W --

20 A. Could I just say about DDAVP that its use is not we ll
 21 recorded by the annual returns, if I can put it tha
 22 way, from all haemophilia centres I think. So the
 23 fact that there's nothing here doesn't indicate tha
 24 none was used.

25 Q. Is it your recollection that DDAVP was used prior t

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1 proportion has gone down again and the actual overall
 2 volume has gone down again. It's now 26 per cent,
 3 69 per cent Factor VIII and then we have some figur es
 4 for DDAVP and FEIBA.

5 1983, we can see significantly less
 6 cryoprecipitate being used, so 341,700 compared to
 7 over 612,000 the year before. It's now 15 per cent as
 8 opposed to 83 per cent factor concentrates again wi th
 9 a small amount of other products. Then 1984 the
 10 figure for cryoprecipitate has gone down to 139,000
 11 which now represents 5 per cent of product usage.
 12 Factor VIII concentrates are 91 per cent and we can
 13 see the figure there is just over 2.5 million units

14 So is it fair to summarise the picture between
 15 1980 and 1984 when you were in charge as being
 16 a decreasing usage of cryoprecipitate and
 17 a significant increase in the use of factor
 18 concentrates?

19 A. Yes.

20 Q. Then if we look at the second table that just gives us
 21 the information of PFC versus commercial product. We
 22 can see 1979, it's 100 per cent PFC, 1980 it's
 23 90 per cent or 9.9 per cent PFC, 9.1 per cent
 24 commercial.

25 We can then see in 1981 there's a significant

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(16) Pages 61 - 64

increase in the amount of commercial used
65.5 per cent PFC, 34.5 per cent commercial. Then the
proportion reduces markedly in 1982, '83 and '84 with
it being 0.5 per cent commercial, 7.9 per cent
commercial and 1.5 per cent commercial in each year

You're happy that represents accurately,
summarises accurately the information that's in the
larger table supplied to the Penrose Inquiry?

A. Yes.

Q. Now, if we just look for ease of reference at one
paragraph in the Penrose report which seeks to
summarise the picture in relation to Edinburgh, it'
PRSE0007002 please, Soumik. If you could try
page 552. No, if we go on, please, about another five
or six pages. It's page 541 using the internal
pagination, in fact, Soumik, at the bottom of the
page, if we go on five pages.

Back one page. That's it. Paragraph 12.20,
I'll just read this aloud, Professor Ludlam:

"Professor Ludlam's predecessor as director of
the Edinburgh Haemophilia Centre Dr Howard Davies made
almost exclusive use of locally-produced therapeutic
materials. Professor Ludlam stated that Dr Davies
avoided the use of imported materials as a matter of
policy, believing those derived from Scottish donor

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produced products believing that the general
population of Scotland was at the time relatively
stable and that the risks associated with the local
donor pool were small. Dr Davies' thinking on this
was he said for its time very sensible, otherwise
I wouldn't have continued it."

Now, I've taken you to that summary of the
evidence really to shortcut the need to go to the more
lengthy exposition in the oral transcripts or in your
various statements for the Penrose Inquiry.

Does that accurately set out in summary form
your understanding of Dr Davies' approach and your own
reversal of Dr Davies' policy in relation to the use
of cryoprecipitate?

A. I don't recall Dr Davies having reservations about the
use of concentrates from large pools of donors but
I certainly remember his view that it was better to
use locally-produced products partly to reduce the
risk of viral infection but also he made a very good
point that the local people with haemophilia may have
a degree of resistance, local resistance to local
viruses that might appear in the blood if I can put it
that way.

But, yes, I moved away from cryoprecipitate
because I wanted to give patients the benefit of

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would be safer. Dr Davies' argument in preference of
locally sourced materials, centred on the risks
associated with hepatitis viruses but appears to have
had a more general basis: both Professor Ludlam and
Dr McClelland stated that Dr Davies was reluctant to
potentially introduce novel viruses to the local
population. Dr Brian McClelland who worked with
Dr Davies early in his, Dr McClelland's, career said
that Dr Davies' policy struck him as eminently
sensible. In relation to imported products he thought
the policy was grounded in elementary biology and that
the further afield the blood came from there was
a certainly incalculable but reasonable grounds to
expect that something new and different and unfamiliar
to the indigenous population might be in that blood."

Then it says this:

"Dr Davies also tended to avoid large pool
concentrates preferring, where possible, to use
cryoprecipitate in the belief that large pools of
donations were more likely to contain transmissible
viruses whatever their source. As noted above, when
Professor Ludlam succeeded Dr Davies he quickly
reversed this part of Dr Davies' policy and moved a
many patients as he could to home therapy with
concentrates. He continued however to prefer locally

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treatment at home because I thought that was very
advantageous.

Q. I think, in fact, the element of this paragraph which
is referring to Dr Davies' avoidance of large pool
concentrates is probably derived from Dr McClelland's
evidence rather than your own, which may explain the
position.

Looking then at the figures that we've looked
at and at that summary of the evidence, is it fair to
say that in the early 1980s that there were the
following three features of your approach. Firstly
you moved from a system based on cryoprecipitate as
the main treatment for haemophilia A to a system of
predominantly PFC Factor VIII concentrates.

A. Yes.

Q. Secondly, you substantially increased the number of
patients on home treatment?

A. Yes.

Q. And, thirdly, you increased usage of factor
concentrates as a whole substantially?

A. Yes.

Q. Would it follow that that substantial increase in the
use of factor concentrates would require more and more
plasma to be collected to supply the concentrates that
you required for the home treatment programme?

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1 A. Yes.

2 Q. And that also resulted in commercial concentrates

3 being used for the first time, albeit only in large

4 number in one particular year?

5 A. No. The concentrates -- the commercial concentrate

6 were used for very specific purposes, almost

7 exclusively. There were a couple of patients who were

8 desperate to have home treatment in about 1980 or

9 '81 -- 1981 or '82, desperate, they lived quite a long

10 way from Edinburgh. They were forever travelling a nd

11 getting speeding fines for coming to Edinburgh to get

12 their treatment and they pleaded with me could I no

13 give them home treatment. So I explained that I could

14 but they would have to have commercial Factor VIII and

15 they were quite happy to accept that.

16 But apart from I think those two individuals,

17 most of the rest of the commercial Factor VIII that

18 was used was used for rather specific reasons which

19 really arose out of the quality of the PFC Factor V III

20 not being suitable for what I was wanting to do.

21 Q. Was the reason for using commercial concentrates fo

22 the individuals, the two individuals you described,

23 because you didn't have enough PFC concentrate?

24 A. Yes.

25 Q. So your preference would still have been for PFC

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1 pattern of our Factor VIII usage, i.e. less cryo, m ore

2 concentrate, and this of course may mean that we

3 should be prepared to ship you more fresh frozen

4 plasma for fractionation."

5 Now, first of all, although this wasn't your

6 letter was that an accurate account of your initial

7 approach in 1980?

8 A. Yes.

9 Q. Is it also accurate that you did, as predicted by

10 Dr Boulton, seek to expand the home therapy program me

11 considerably over the year or two that followed?

12 A. Certainly. When I arrived in Edinburgh there were six

13 patients on home therapy and by 1983, I think, we'd

14 increased the number to about 40 or 45. There is

15 a table in the Penrose report giving the number of

16 patients on home therapy each year, but it went fro

17 about 60 up to about 40 or 45 --

18 Q. From about 6. Sorry, you just said 60.

19 A. 6, I'm sorry.

20 Q. What categories of patients received home therapy i

21 those early years in the 1980s? How did you decide

22 who would have home therapy and who would not?

23 A. It was difficult and it was -- you had to take

24 a number of factors into account. The distance the

25 patients came, the age of the patient, their freque ncy

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1 concentrate if that had been available?

2 A. Oh, yes. Yes, certainly.

3 Q. I just want to explore with you in a little more

4 detail your implementation of the home therapy

5 programme.

6 If we could have please, Soumik, PRSE0000492.

7 So we can see if we just zoom a little closer on th

8 text, thank you, it's a letter of 1 February 1980.

9 It's not from you but it is about you. It's from

10 Dr Boulton to Mr Watt:

11 "Dr Christopher Ludlam, who I am sure you know

12 is the haematologist in place of Dr Davies here,

13 wishes to start an active home therapy programme fo

14 some of his haemophilic patients. He has approache

15 me today with a specific proposition for brothers who

16 are in need of regular Factor VIII therapy", and then

17 there is reference to the precise amounts needed.

18 Then if we go into the next paragraph:

19 "I am anxious to support such a programme as

20 much as possible and feel that you ought to know th at

21 I see no reason to discourage Dr Ludlam from going

22 ahead with this programme. I feel that he is very

23 likely to expand his home therapy programme

24 considerably in the course of the next year and thi

25 may well result in a significant difference in the

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1 of attendance with bleeds, whether they were able t

2 inject themselves or whether the parents would be a ble

3 to inject their children. So it was a variety of

4 issues that needed to be considered.

5 Q. Were they all patients with severe haemophilia A?

6 A. No. Some -- one or two had severe haemophilia B. We

7 had one patient with severe von Willebrand's disease,

8 which requires treatment a bit like severe

9 haemophilia A on occasions. But most of them had

10 severe haemophilia A.

11 Q. Did you have any patients with mild or moderate

12 haemophilia on home treatment programmes?

13 A. Certainly have patients with moderate haemophilia o

14 home treatment and I think, latterly, we might have

15 had some mild patients but mild patients don't blee

16 very often. When they do bleed they may bleed very

17 badly but because people with mild haemophilia don'

18 bleed very often, the patients are not well practis ed

19 at injecting themselves or making up the treatment.

20 So, on the whole, patients with mild haemophilia

21 aren't usually on home therapy.

22 Q. You have said in your witness statement that

23 cryoprecipitate wasn't made available for home

24 treatment principally because of the risk of allerg ic

25 reactions. Now, some other witnesses have placed m ore

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1 emphasis on the convenience of concentrates over
2 cryoprecipitate for home therapy, so can I just
3 explore with you what the concern was about allergi
4 reactions?

5 How common, in fact, were such reactions?

6 **A.** Very common. It was almost -- not quite routine. It
7 was certainly routine with some patients that you have
8 to give them injections, or they gave injections
9 themselves, of antihistamine Piriton before they gave
10 the cryoprecipitate and, on occasions, not
11 infrequently, we would need to give hydrocortisone, if
12 a patient got a reaction, to try and damp down the
13 reaction.

14 I think the reason why I didn't dwell upon the
15 issue of making up the cryoprecipitate is because that
16 was done in the blood bank by the Blood Transfusion
17 Service, so immensely grateful to them for doing that,
18 because it's a very labour-intensive process. But
19 cryoprecipitate reactions were very common. I didn't
20 see a fatality. I have colleagues who have had
21 patients collapse on them a bit like peanut allergy
22 anaphylaxis, requiring adrenaline and hydrocortisone.
23 Reactions were very common and unpleasant.

24 **Q.** What form, typically, did common reactions take?

25 **A.** Feeling unwell, getting a temperature, possibly the

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1 50 per cent of normal and 150 per cent of normal. So
2 the amount of Factor VIII in the cryoprecipitate of
3 each individual donation could vary that much; in
4 other words, a threefold difference. So when you get
5 cryoprecipitate, you really have very little idea o
6 how much, exactly how much, Factor VIII there is in
7 it.

8 I notice one of the witnesses said that they
9 had 60 units per donation in their cryoprecipitate and
10 another said 70. I think on a good day our local
11 blood transfusion, because they had improved the
12 yield, they were potentially up to 100 units. So w
13 really didn't know how much there was in the
14 cryoprecipitate, so you didn't know how much you were
15 actually giving to the patient, which might lead yo
16 to potentially over-treat the patients.

17 **Q.** Did you yourself have any direct experience of usin
18 cryoprecipitate for home treatment?

19 **A.** No.

20 **Q.** Were you aware at the time so 1980, early 1980s, th at
21 cryoprecipitate had been used, it would seem
22 relatively successfully, for home treatment in the
23 Royal Free Hospital and also in the Birmingham area

24 **A.** I knew that people -- a small number of centres had
25 used home treatment. I didn't know anything about the

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1 shakes, a rash, all of which might last several hours
2 or half a day. It didn't usually require the patient
3 to stay in hospital. Occasionally, someone had a bad
4 reaction and we had to ask them to stay but mostly
5 they just felt unwell with it. It was not good.

6 **Q.** If we look at your statement, Professor Ludlam,
7 WITN3428001. If we go to page 37, please, Soumik.
8 Paragraph 100, bottom of the page, you say this, by
9 reference to cryoprecipitate, picking it up in the
10 third line:

11 "Cryoprecipitate transformed the treatment of
12 patients with haemophilia A and allowed most bleeds
13 (in non-inhibitor patients) to be treated
14 effectively."

15 So, notwithstanding your concerns about
16 reactions, cryoprecipitate did achieve the objectiv
17 in relation to most bleeds of treating the bleed, did
18 it not?

19 **A.** By the time the patient reached hospital, in
20 a non-inhibitor patient then cryoprecipitate would
21 usually stop the bleeding. One of the other problems,
22 as I think other witnesses have alluded to, is you
23 didn't actually know how much Factor VIII there was in
24 the cryoprecipitate. The normal plasma level of
25 Factor VIII in the blood donors varies between

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1 details.

2 **Q.** If we just look at the previous page of your
3 statement -- it's paragraph 93, please, Soumik --
4 you'll see in paragraph 3, it says:

5 "During the early 1980s strenuous efforts were
6 made by SNBTS to increase Factor VIII concentrate
7 production and the resulting increase allowed more
8 patients to benefit from home therapy. Donor blood
9 plasma was redirected from cryoprecipitate producti
10 to concentrate manufacture."

11 In relation to that second sentence,
12 Professor Ludlam, whose decision was it to redirect
13 donor blood plasma from cryoprecipitate production to
14 concentrate manufacture?

15 **A.** That was a blood transfusion decision but it was
16 informed and discussed with me and with the other
17 haemophilia directors in Scotland.

18 **Q.** One of the reasons, if not the principal reason for
19 that change of direction, would have been your
20 reversal of Dr Davies' policy and your switch from
21 cryoprecipitate to factor concentrates, presumably?

22 **A.** Yes.

23 **Q.** Then I just want to look with you, professor, at so me
24 correspondence from 1982 about the allocation of
25 factor concentrates in the home therapy programme. If

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1 we pick it up, Soumik, at PRSE0003044, please. This
 2 is a letter we looked at before for a different
 3 purpose and we'll just look back at it in a little
 4 more detail. So this is Dr Boulton writing to you in
 5 May 1982. For the benefit of anyone listening who
 6 doesn't know, can you just confirm to us what
 7 Dr Boulton's position was?
 8 **A.** Yes, he was Deputy Director of the Blood Transfusio
 9 Centre, South East Scotland.
 10 **Q.** We can see he is writing to you in May 1982 with
 11 a table of haemophilia home therapy patients and he's
 12 got 24 names -- this is the last sentence of the first
 13 paragraph, professor -- of whom 20 actually receive
 14 some home therapy this year so far. Then he says:
 15 "My concern is the amount of Factor VIII that
 16 has been issued. The total for the first quarter was
 17 206,800 units. This would be an annual consumption of
 18 827,200 units. This means that for each of the 20
 19 patients, the average annual consumption would be
 20 41,360 units ..."
 21 Then he gives a variation on the figure:
 22 "... obviously pretty close to the UK national
 23 average."
 24 Then he says this:
 25 "However the amount of Factor VIII that we were

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1 Then if we go to the next long paragraph, the
 2 first sentence:
 3 "I feel therefore that you should be warned
 4 that we are now very definitely at the limits of our
 5 production for home therapy and therefore you may
 6 consider the necessity for buying some commercial
 7 product. We do anticipate increasing our return of
 8 plasma to PFC, maybe doubling production by the middle
 9 of 1983. However, this would involve a radical
 10 reorganisation of our plasma procurement programme and
 11 cannot at this stage be relied upon."
 12 Now, we'll look at some later correspondence
 13 from 1982 in a moment but what, if anything, can you
 14 recall about this issue that Dr Boulton was raising
 15 with you, in which he was essentially saying "your
 16 home treatment programme is using up most of our
 17 allocation", and asking you to take the steps there
 18 set out?
 19 **A.** I think this reflects a very well the difficulties --
 20 the difficulties the Blood Transfusion Service were
 21 under in being able to supply Factor VIII concentrate
 22 to me for the patients, the pressure I was under from
 23 the patients, who were very keen indeed to have home
 24 therapy which was commonplace in the rest of the
 25 country, and so I did my best to fulfil that request,

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1 officially issued in the first quarter of this year
 2 was only 261,530 units, although we did get some more
 3 from Inverness ...
 4 "Hence, you will see that your home therapy
 5 programme alone has accounted for about 80 per cent of
 6 our allocation from PFC."
 7 Then we have the passage we looked at earlier,
 8 professor, about the allocation being based on the
 9 amount of plasma supplied.
 10 Then if we go on to the next page -- if we
 11 could just zoom in a little bit closer to make it
 12 easier to read, thank you -- he continues:
 13 "I think that the SNBTS as a whole can just about hold
 14 your requirements so long as the following points are
 15 borne in mind:
 16 "Maximum use is made of the Cryoprecipitate
 17 Programme;
 18 "No more patients are put on home therapy;
 19 "No patients are put on the cold operating
 20 lists;
 21 "We try to borrow from other Regions who may
 22 have lower haemophilic loads, particularly if we are
 23 treating 'their' patients;
 24 "Some of the heaviest users are counselled to
 25 use less."

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1 and to do so I had to juggle -- maybe we're going to
 2 come on to it. There were difficulties in the supply
 3 arrangements in the early 1980s from PFC.
 4 The other thing I think that -- a point that is
 5 very pertinent, is that the -- you can't tell actually
 6 when patients are going to be with haemophilia and
 7 sometimes patients come in with a major bleed and/or
 8 need an operation and suddenly you need 50,000 unit
 9 of Factor VIII that you hadn't anticipated needing.
 10 So there were difficulties on the supply side and there
 11 were difficulties, let me put it this way, in being
 12 able to accurately predict usage.
 13 **Q.** What was the "Cryoprecipitate Programme", in capital
 14 letters there, being referred to by Dr Boulton there?
 15 **A.** That was just the -- I'm not sure why there are
 16 capital letters. There was no formal cryoprecipitate
 17 programme. It was the out-patient, and in-patient
 18 I would hasten to add, treatment with cryoprecipitate,
 19 and one of the ways in which we eked at the PFC
 20 allocation was if patients were in hospital we would
 21 treat them with cryoprecipitate, if they didn't react
 22 too badly to it or didn't get reactions at all, and
 23 save the concentrate for patients to use at home.
 24 **Q.** Did you adopt the points 1, 2, 3 and 5 of this list --
 25 4 is probably not so much for you -- did you try an

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1 use maximum use of cryoprecipitate, not put further
 2 patients on home therapy, not put patients on the cold
 3 operating lists and counsel your patients to use less?
 4 **A.** I'm not sure I'd counsel the patients to use less
 5 because the doses that were being used for home
 6 treatment of bleeds were pretty minimal doses. The
 7 are perhaps a quarter of what one would use nowadays.
 8 I can't remember. I'm sure I had a pause in putting
 9 the number -- putting more patients on home therapy
 10 because there was clearly -- when Dr Boulton wrote
 11 this letter, there was clearly a bit of a crisis.
 12 **Q.** If we just follow through some of the correspondence,
 13 we won't look at all of it, but in 1982. If we go
 14 next to PRSE0003294, please, Soumik. If we zoom in on
 15 the text, it's not the clearest of letters, but
 16 I think it is probably August 1982, because that fits
 17 in with other communications. Again it's from
 18 Dr Boulton:
 19 "I am sorry if I am repeating myself but I just
 20 want to write concerning the present status of
 21 Factor VIII usage.
 22 "In July [not sure whether that's 350 bottles
 23 but the precise amount may not matter] were used,
 24 which is approximately 160 per cent of our monthly
 25 allocation from PFC. We were only able to supply this

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1 what was agreed. Paragraph 6:
 2 "The following was agreed:
 3 "(a) The 200 commercial bottles (or equivalent
 4 ...) should be maintained as the 'bedrock' emergency
 5 stock.
 6 "(b) CL will make additional efforts to keep
 7 within the monthly allocation from PFC.
 8 "(c) FEB [that's Dr Boulton] to continue
 9 exploring the possibilities of obtaining PFC
 10 Factor VIII from other regions -- however he warned
 11 that this would be increasingly difficult and should
 12 not be relied upon.
 13 "(d) FEB warned that there will almost
 14 certainly be a need to buy more commercial Factor VIII
 15 if the current usage pattern continues."
 16 Now, do you recall that meeting or these
 17 discussions with Dr Boulton at this time?
 18 **A.** I recall the discussions and if you could go back one
 19 page -- yes, paragraph 2, Dr Boulton --
 20 **Q.** "FEB reminded CAL that the monthly allocations due
 21 from PFC of Factor VIII is 380 bottles until September
 22 (ie about 84,000 units); then from October the
 23 allocation will be reduced to 330 bottles (about
 24 73,000 units)."
 25 Was that the passage, professor?

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1 amount because of a slight surfeit of Factor VIII from
 2 other regions.
 3 "We have enough to cover normal need for the
 4 next three weeks or so and you have of course got your
 5 commercial stock of high purity Factor VIII and we
 6 have the Speywood material in our deep freeze ... We
 7 must talk soon after my return ..."
 8 So it would appear that the issue about usage
 9 was still a concern to Dr Boulton a couple of months
 10 after his May letter, in August 1982. The Speywood
 11 material was what?
 12 **A.** That would be porcine Factor VIII.
 13 **Q.** Did you use that simply for inhibitor patients or did
 14 you use it at all for inhibitor patients at this time?
 15 **A.** It was only used for patients with inhibitors. It had
 16 a particular place for patients with acquired
 17 haemophilia, but didn't use it for non-inhibitor
 18 patients.
 19 **Q.** If we then just move, still in the same month, to
 20 PRSE0001840, we can see this is the notes of a meeting
 21 with Dr Christopher Ludlam on 23 August at 2 pm.
 22 Again, it would seem likely it's 1982 given the
 23 correspondence, and it's authored by Dr Boulton. We
 24 won't go through the detail of every paragraph. If we
 25 go to the second page please, Soumik, we can pick up

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1 **A.** That was the passage. I noticed it's got two marks
 2 beside it. I don't know what further correspondence
 3 you are going to show but my understanding is that the
 4 allocation would have been 500 bottles per month, and
 5 I could take you to evidence for that but perhaps we
 6 should proceed with your correspondence first.
 7 **Q.** So if we go back to the second page, I just want to
 8 ask you about points (b) and (c) in paragraph 6. It's
 9 said that you have agreed to make additional effort
 10 to keep within the monthly allocation from PFC. As
 11 far as you can recall, did you do so and what were
 12 those efforts?
 13 **A.** I can't remember. It's -- I would try and use as much
 14 cryoprecipitate as I could for treating patients when
 15 they were in hospital and once you put in patients on
 16 home therapy, you are very reluctant -- I don't think
 17 I've ever actually had to do it -- to take them off
 18 home therapy. But, you know, that's the ultimate, or
 19 you buy commercial concentrate and give the patient
 20 home treatment with commercial concentrate. But I, as
 21 you know, have been keen to avoid. So I was between
 22 a rock and a hard place.
 23 **Q.** In relation to point (c), the possibility of obtaining
 24 PFC Factor VIII from other regions, and there is so much
 25 further correspondence which refers to that, we don't

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perhaps need to go through it in detail, but that was something that the correspondence suggests was undertaken by Dr Boulton but did you have discussions with your colleagues in other regions about the repercussions for the treatment of their patients if PFC factor was diverted away from other regions to Edinburgh?

A. I think it would only be redirected from other regions if they appeared to have stock on the shelves that wasn't needed in the very near future. This was a blood transfusion stock control arrangement, if I can put it that way. It wasn't discussed by haemophilia directors.

Q. If we then go to PRSE0003269, we can pick this up in December 1982. This is a further letter from Dr Boulton to you, and he says:

"With your current demand from [X] and [X] at 1500 units and 80 and thousand units 80, each respectively, we will have exhausted our current stock by 7 January."

He says he's arranged for more bottles and "another consignment ... will be arriving for the usual monthly stock". Then he says:

"... if demand for the two lads continues at its current rate, I have a nasty feeling that you will

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PRSE0001487. This is 7 December 1982. It's Dr Boulton to Mr Watt at PFC:

"Dear John

"Just to let you know the latest 'manoeuvres' with regard to our Centre's supply of PFC Factor VI II.

"Christopher Ludlam is beginning to use somewhat less of the PFC material in favour of cryoprecipitate, particularly for the in-patients. It is early days yet but at least it is an encouraging trend."

Then there's a discussion of offers from Glasgow and from Inverness of temporary -- of contributions to provide a temporary increase in reserves.

What, if any, observation do you have on that second paragraph, which suggests that you were being encouraged to try and use more cryoprecipitate, particularly for the in-patients, although it doesn't sound like it was exclusively for in-patients.

A. That's what I was trying to convey by my answer a few minutes ago, that when patients were in hospital, they didn't react to cryoprecipitate, that we would try and treat them with cryoprecipitate rather than Factor VIII concentrate, even though they may have been getting concentrate at home for home therapy. So

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need to use your commercial reserves. Indeed, John Watt informs me today that such an action may well be necessary in view of the anticipated large despatching to the other centres at the beginning of January.

"Finally, I hope you won't feel it an impertinence of me to suggest this, but I would not be too surprised if, in the event of [X] not responding to the conservative therapy, there might be a case for actually suspending Factor VIII therapy.

I'm not asking you to comment on individuals but more the general situation that we see describe here. Dr Boulton expressing a concern that the continued usage is going to exhaust stocks, essentially. Can you recall what, if any, steps were taken in response to these concerns in early 1983?

A. I can't say more than I've already said, I think. I think it likely I wouldn't have put, obviously, more patients starting them on home therapy. I don't recall why Dr Boulton made the suggestion in the penultimate paragraph. It was living in a very difficult environment of a precious limited resource in demand and I was -- I and Dr Boulton were in the middle of it.

Q. We will look at one further letter from December 1982 from Dr Boulton. It's not to you. It's at

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that was a way of trying to conserve the stocks of concentrate.

Q. If we go, finally, to one other letter, PRSE0003653 this is a letter 2 February 1983, so we've moved on a year, and if we just go to the bottom of the page we can see who it's from. So it's Dr McClelland, copied to Dr Boulton, addressed to Mr Watt, and it says this:

"Dear John" --

Sorry, can we see the whole text?

"Following the Joint Meeting of Haemophilia and Transfusion Directors, I've been thinking about the request made by the Chairman that you and I, with Chris Ludlam should review Edinburgh Factor VIII use.

"On reflection, I'm not sure that this meeting can help much, since I am satisfied that Frank Boulton has worked hard and consistently to negotiate a reasonable approach to Factor VIII Provision with Chris. To back up this statement, I am enclosing, with Frank's permission, a selection of correspondence with Chris which documents some of their regular joint sessions on the topic. I really do feel that seeing these, you will agree that one cannot readily accept the implication that Chris was inadequately informed of the supply situation, or that he was forced to purchase and 'stockpile' locally because of SNBTS

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failure to delivery.

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

We don't have, Professor Ludlam, all the correspondence to which this letter -- the earlier correspondence to which this letter refers, but it would appear from this that there were continuing concerns that you were using too much Factor VIII concentrates.

Was that your understanding of the SNBTS view at the time?

- A. That was their view. If this is the last of the letters that you're going to show on this correspondence, could I ask for a document, please, which is PRSE0000028.
- Q. Yes, we didn't have this earlier but I'm hoping we now do have it, Soumik. We do, I think.
- A. This is a letter to John Watt, director of PFC, from John Cash who was the National Medical Director. It's

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bottles and that it was due to fall to 330 bottles. I was, therefore, not getting the supply of PFC material that I felt had been agreed.

Now, there were a number of reasons for that that we could go into but I'm not sure that it's relevant at the moment but that is the difficulty, I was from my perspective promised 500 bottles a month, delivery was much less than that, and that's why there came to be a difficulty.

- Q. How, if at all, was that difficulty resolved?
- A. I think PFC eventually was able to provide more concentrate. I haven't got the figures in front of me although it is interesting of the table you've shown me before of Factor VIII usage this is, I don't know whether you want to look at it, WITN34 -- sorry, 3428044.
- As you will see in the lower table, second column, PFC units, it was 200,000 in 1979, 1.6 million in 1980, 1.6 million in 1982. There was a distinct supply problem in 1981 of PFC Factor VIII. So I think this and, as you can see, the supply improved.
- Q. The latter --
- A. I'm sorry.
- Q. Sorry, carry on.
- A. Table 2, the lower table, is the one I was looking at.

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about supplies of Factor VIII pro rata system.

Perhaps I could read it out:

"I would be most grateful for your thoughts on a difficult problem that is emerging in the Edinburgh Haemophilia Centre. There is no doubt that Chris Ludlam had, by the time we had our pro rata meeting in April 1982 started a very large number of new patients on home therapy. He had done so on the basis that he knew by March 31, 1982, the Edinburgh Haemophilia Centre had sent over 6,000 kilograms of fresh frozen plasma to PFC in that year. He did his sums and concluded that on a pro rata basis he could look forward to a monthly issue, beginning April 1982, of at least 500 bottles per month.

"You will not be surprised to learn that Chris is on schedule -- his monthly consumption is exactly 500 bottles! Unless something can be done then he will have to switch some of his home therapy patients to commercial concentrate", and it goes on about the difficulties, industrial action at PFC.

So as you see in 1982 it was reasonable as a result of discussions that Edinburgh would receive about 500 bottles per month and you'll recall in the previous correspondence you have shown me that Dr Boulton was suggesting my allocation was only 38

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I think you can see that the delivery of PFC material did increase from 1982 to '83 and quite significantly in 1984 but in 1981 there was much less made available.

- Q. What was your understanding of the reasons for any difficulties in providing you with the amount of concentrate that you wanted from PFC?
- A. I'm sorry, the acoustics weren't very good. Could you repeat your question.
- Q. Yes, of course. What was your understanding of the reasons why PFC were not able to provide you with the amount of concentrates that you'd wanted?
- A. I think it was -- I think there were manufacturing difficulties at PFC. I'm sorry, I don't have the plasma supply figures available or in my memory. I don't know whether there was a paucity of supply of plasma from South East Scotland Transfusion Centre.
- Q. In general, in terms of your treatment of patients, whether as outpatients, in-patients or on home treatment, how did the centre -- how did you monitor the amount of Factor VIII usage and keep it to the minimum level necessary?
- A. This was one of the big advantages in having a haemophilia sister because she would see the patients when they would come up to collect further

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1 supply of home treatment, usually about once a month
2 and they would bring with them a record of how they
3 had used their treatment, what the bleeds had been,
4 when they had treated, how much they had given
5 themselves. So that way we monitored how the patients
6 were using the therapy.

7 **MS RICHARDS:** Sir, I note the time. I haven't been
8 keeping my eye on the clock. It is 1.10.

9 **SIR BRIAN LANGSTAFF:** Yes, we will take a break there but,
10 while we still have this document on the screen, if
11 you look at the top table, table 1, just do a quick,
12 rough calculation of the number of units used in 1980
13 compared to the number of units used in 81. There
14 were about 3 million in 1980. 1981, it's about
15 2 million, possibly in fact it's almost exactly
16 2 million, I think. Why the drop? Do you remember
17 Why were you using less?

18 **A.** I -- well, it illustrates, I think, two points. One
19 is that demand or usage goes up and down and is a bit
20 unpredictable. The other, and we've not discussed
21 this, but why the Factor VIII, the commercial
22 Factor VIII, was being used. In 1980, we had two
23 patients who went for surgery and they ran into very
24 severe post operative problems arising -- I treated
25 them with PFC Factor VIII concentrate. Unfortunately,

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1 refreshment and stretch your legs and the same for us
2 and for those who are watching. So 2.10.

3 **(1.15 pm)**

4 **(Luncheon Adjournment)**

5 **(2.10 pm)**

6 **SIR BRIAN LANGSTAFF:** Yes.

7 **MS RICHARDS:** Professor Ludlam, we have covered your
8 treatment policy in the early 1980s towards patients
9 with severe haemophilia A. In relation to patients
10 with moderate haemophilia A, do I understand from your
11 statement and your evidence that such patients may
12 well have been treated with factor concentrates but
13 some may have received cryoprecipitate depending upon
14 their presentation?

15 **A.** In the early 1980s, they would have been treated when
16 they come up to hospital probably with
17 cryoprecipitate. If they went on to home treatment
18 they would be treated with concentrate in general.

19 **Q.** In relation to patients who had mild haemophilia A,
20 your statement suggests DDAVP, cryoprecipitate and
21 concentrate might all have been used. Can you outline
22 what the general approach was for the treatment of
23 patients with mild haemophilia A?

24 **A.** Yes. It was to avoid using blood products if
25 possible. It would depend on the event whether DDAVP

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1 they ran into what's called hyperviscosity syndrome,
2 which I hadn't come across in treating haemophilia
3 before because in Cardiff I'd been used to using much
4 higher purity concentrates.

5 The PFC concentrates were of relatively low
6 purity and when you give twice or thrice daily
7 injections for a week or two on end, what happens is
8 the fibrinogen level increases and the fibrinogen
9 level also increases as a response to the stress of
10 the operation.

11 These two patients had operations a week apart
12 and after about ten days, the first one started
13 bleeding from this hyperviscosity system, which as
14 I say I had never experienced and I was perplexed as
15 to why the patient was bleeding despite a reasonable
16 Factor VIII level, and eventually I realised it was
17 this hyperviscosity and so both these patients had to
18 be plasma phoresed, have their plasma exchanged, and
19 I had to buy in commercial concentrate, high purity or
20 much higher purity commercial concentrate, to rescue
21 these two patients, post operative patients, from
22 their bleeding difficulties.

23 **SIR BRIAN LANGSTAFF:** I see. Thank you very much. We
24 will take a break now. We will take a break until
25 2.10 if that's long enough for you to get bite or

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1 would be suitable and that would depend upon the basal
2 Factor VIII level of the patient, how they responded
3 previously to desmopressin, DDAVP, because the
4 response varies quite markedly between patients but
5 within a patient the response is usually reasonably
6 consistent. So if it was, for example, a tooth
7 extraction in someone who had a basal Factor VIII
8 level of 15 or 20 per cent then it is likely that
9 desmopressin would give quite a satisfactory response.

10 On the other hand, if the patient required
11 major surgery then one I would probably have used
12 concentrate, might have used cryoprecipitate, it
13 depends a bit on the nature of the surgery and its
14 duration but concentrate would be reserved for severe
15 bleeding episodes.

16 **Q.** So is this right: in terms of order of priority, and
17 I appreciate we're talking in generalities, but for
18 the mild haemophiliac with haemophilia A, DDAVP if
19 possible, cryoprecipitate would be the next
20 choice, next safest choice if DDAVP was not an option,
21 and then concentrates, would that be the third choice,
22 for example, for something such as major surgery when
23 the others are not an option?

24 **A.** Concentrate might come in front of cryoprecipitate if
25 you had a severe bleed or for surgery.

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- 1 Q. Why?
- 2 A. Because one would need to be -- you need to aim for
- 3 specific Factor VIII levels or responses for surgery
- 4 for it to be carried out without excessive bleeding
- 5 whereas with cryoprecipitate, as I was mentioning
- 6 before lunch, you didn't quite know how much was in
- 7 the bag. Anyway, it was relatively impure and it
- 8 would be easy to overload the patient's circulation if
- 9 you were doing this giving them three infusions a day.
- 10 Q. Forgive me, I didn't make my question sufficiently
- 11 clear. I understand your answer in relation to major
- 12 surgery but, if you had something that did not require
- 13 surgery but was a significant bleed, why would
- 14 concentrates potentially take precedence over
- 15 cryoprecipitate in terms of the options for treatment
- 16 for a mild haemophiliac?
- 17 A. Mild haemophiliac with a mild bleed, that wasn't
- 18 treated with -- treatable with desmopressin, then it
- 19 is possible, likely perhaps, they would receive
- 20 cryoprecipitate. It depends a bit on what their past
- 21 history was.
- 22 Q. Moving from haemophilia A to von Willebrand's disease,
- 23 in the first half of the 1980s what was your treatment
- 24 policy in relation to patients with von Willebrand's?
- 25 A. Von Willebrand's disease comes in many different

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- 1 Q. Did you have a specific policy in the early 1980s in
- 2 relation to the treatment of children and, if so, what
- 3 was it?
- 4 A. For children with severe haemophilia it would be my
- 5 aim to try treating them with cryoprecipitate. That
- 6 can be quite a challenge with a one or two year old
- 7 child because of the volume that needed to be given
- 8 and by the viscosity of the cryoprecipitate,
- 9 considerably more viscous than concentrate. So purely
- 10 a practical problem but a real practical problem of
- 11 giving an infusion into a small child with delicate
- 12 veins and often the arms of small children are a bit
- 13 chubby and if the needle comes out of the vein, then
- 14 you get a haematoma, in addition to the one that
- 15 you're trying to treat.
- 16 So it's not easy to give cryoprecipitate to
- 17 small children but if it seemed feasible, then that's
- 18 what I would think of doing first. If it's a child
- 19 with severe haemophilia, they are likely to need
- 20 treatment relatively frequently and, if you like, the
- 21 benefits of using cryoprecipitate, as far as hepatitis
- 22 is concerned, diminish and, therefore, concentrate
- 23 becomes perhaps a more acceptable form of therapy,
- 24 particularly I would be using PFC concentrate for
- 25 treating a child. A child with severe haemophilia

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- 1 varieties, sort of type 1, 2 and 3, and they respond
- 2 rather differently to desmopressin. I don't want to
- 3 go into all the details unless you want me to but, if
- 4 possible, I would use DDAVP but many of the patients
- 5 with von Willebrand's disease who bled did not respond
- 6 because of the type of von Willebrand's disease they
- 7 had. Type 2 often didn't respond well or DDAVP was
- 8 contraindicated, as in type 2B. So cryoprecipitate
- 9 was used, perhaps as the principle form of certain
- 10 blood product therapy for treating von Willebrand's
- 11 disease.
- 12 Q. In relation to patients with haemophilia B, the table
- 13 that we looked at earlier would tend to suggest -- the
- 14 table from the report that was prepared for the
- 15 Penrose Inquiry would tend to suggest that Factor I
- 16 was the consistent treatment used, PFC Factor IX for
- 17 patients with haemophilia B; is that correct?
- 18 A. That's correct, yes.
- 19 Q. To what extent was fresh frozen plasma used by you in
- 20 the early 1980s for haemophilia B patients, if at all?
- 21 A. I can't recall using it. That doesn't mean to say
- 22 that we didn't use it but I don't -- haemophilia B is,
- 23 as you will know, about a fifth the incidence of
- 24 haemophilia A, so there are many fewer patients.
- 25 I don't remember using fresh frozen plasma.

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- 1 might get on to concentrate use at a youngish age for
- 2 those reasons.
- 3 Q. In terms of your home treatment programme -- we
- 4 discussed the approximate figures of patients that you
- 5 had on home treatment earlier -- what proportion of
- 6 those, as far as you can recall, were children?
- 7 A. Very few. We were a small centre. By 1983 there
- 8 might have been four or five children on home
- 9 treatment something like that, four, five or six.
- 10 Q. At what age did you contemplate putting the child on
- 11 to home treatment.
- 12 A. It depended very much on the child, and the home
- 13 circumstances, and the enthusiasm of the parents, and
- 14 actually how easy it was to find veins on the child
- 15 But I can think of some children just now who were
- 16 probably about 8 or 9 years' old who were treated by
- 17 a parent.
- 18 Q. Now, we've heard from some clinicians that they
- 19 adopted a policy of batch dedication. The material
- 20 you produced for the Penrose Inquiry suggests that in
- 21 Edinburgh such a system was introduced only in or
- 22 around late 1984. Is that right?
- 23 A. I think that probably is correct if that's what the
- 24 evidence is to the Penrose Inquiry then I think that
- 25 is better than my memory at the moment.

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(25) Pages 97 - 100

1 Q. If we have a look at PRSE0000046, so this is
2 a document you authored for the Penrose Inquiry called
3 "Edinburgh haemophilia treatment policy". If we go to
4 page 6 please, Soumik, it should be the last
5 paragraph. You said this:

6 "In an attempt to reduce recipient exposure to
7 multiple batches of Factor VIII a batch dedication
8 system was devised in 1984. In this there were three
9 parallel batches of Factor VIII concentrate, which
10 were given to patients based on their surname, i.e.
11 individuals with a surname beginning with a letter in
12 the first third of the alphabet were given concentrate
13 from bin 1, middle third of the alphabet from bin 2
14 and the last third of the alphabet from bin 3. This
15 simple to operate system reduce the batch exposure of
16 an individual patient by about one third."

17 That's not quite the batch dedication system
18 some other clinicians have described but, first of
19 all, is it right based on that to say that it was only
20 devised in 1984.

21 A. I think -- that is the evidence that I gave ten years
22 ago. I have no reason to believe it's not true. What
23 I would say is that to have a batch dedicated system
24 like this you need to have larger stocks of
25 concentrate in the fridge and you have seen from the

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1 sometimes concurrently. I believe that at one time
2 there was a policy of issuing a whole batch to
3 a single transfusion centre. I understand recently
4 that batches may have been divided and sent to several
5 centres. As a result of this apparent change in
6 policy it is possible for one rogue batch of
7 Factor VIII to potentially contaminate a huge number
8 of haemophiliacs. One reason why there may have been
9 a change in distribution policy may be because of the
10 size of a batch has increased markedly over the last
11 few years. I am further assured that at least
12 Edinburgh BTS would have the capacity to store at
13 least one complete batch."

14 Now, this is being raised in November 1984 and
15 the reference to recent endeavours is presumably
16 a reference to your discovery that a batch had
17 infected a number of your patients with HTLV-III,
18 which we'll come on to at a later stage in your
19 evidence, professor.

20 A. Yes.

21 Q. Was there any other reason why this issue of batch
22 dedication couldn't have been introduced earlier,
23 particularly given that this suggests that Edinburgh
24 SNBTS could store a complete batch?

25 A. I can't at the moment think why it wasn't introduced

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1 discussion we had before lunch that it was a bit of
2 a hand to mouth existence of Factor VIII was never
3 very plentiful and there was not a great deal to be
4 had in the fridge at the best of times and, therefore,
5 it would have been quite impossible to have had
6 a batch dedication system earlier.

7 Q. Carry on.

8 A. The other issue which is a little bit related is if
9 a whole batch is to come to, shall we say, bin 1 that
10 might be a very large amount of Factor VIII,
11 potentially 1,000 bottles, whereas in the normal
12 distribution system that might be split between three
13 haemophilia centres, and I know at one point in
14 Scotland we were trying to avoid arrangements where
15 a batch was split between haemophilia centres because
16 that way you got more patients exposed. So it was
17 a little bit complicated and I tried to explain why it
18 was difficult to introduce earlier than 1984.

19 Q. We'll look at one letter which may refer to the point
20 you've just made, professor. It's SBT0000322_044
21 please, Soumik. This is a letter from you to Dr Perry
22 at the PFC, 12 November '84, so in late 1984:

23 "As a result of our recent endeavours it has
24 become apparent that many of our haemophiliacs are
25 receiving Factor VIII from several different batches,

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1 before 1984, except it was, as I say, a hand to mouth
2 existence and you've got to have three batches to fill
3 three bins and there just weren't three batches
4 available. There were occasions when there was very
5 little Factor VIII concentrate at all on the shelves
6 in Edinburgh. It was sufficiently bad that stocks
7 could run low and I remember one event where actually
8 they ran out and the duty officer for PFC had to be
9 got out of bed in the middle of the night to top up
10 the supply in the blood bank. That's extremely
11 uncommon and a rare occurrence but it illustrates the
12 supply difficulties.

13 SIR BRIAN LANGSTAFF: I understand the supply difficulties
14 but I was going to ask you apropos your earlier answer
15 the question that Ms Richards has just asked, why not
16 earlier? Another way of putting it is this: what was
17 it about 1984 that made a difference do you think,
18 that made it possible to have a system when it wasn't
19 possible before?

20 A. Because I think the supply of Factor VIII concentrate
21 from PFC was greater than it had been previously. The
22 difficulties were really I think in 1982 and beginning
23 of 1983. I think towards the end of '83 and '84 there
24 was a more plentiful supply. But I don't have the
25 figures in my head. That's my recollection.

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

2 **MS RICHARDS:** Professor Ludlam, that might explain why it

3 was 1984 and not earlier, but why was it only it would

4 seem late 1984 rather than early 1984 when this system

5 was introduced?

6 **A.** Without seeing the details of the supply, usage and

7 stock levels, I can't be more specific than I have

8 been.

9 **Q.** I'll move on then to another topic which is looking at

10 your knowledge of hepatitis and some particular

11 matters relating to hepatitis. We start, professor

12 with you telling us what you learnt in your general

13 medical training and then in your specific haematology

14 training about the risks of viral transmission from

15 blood and blood products.

16 **A.** I suppose I had a slightly unusual and traumatic

17 introduction to hepatitis in that as a student in

18 1969/1970 I lived through, as a clinical medical

19 student, the hepatitis outbreak in the Edinburgh renal

20 unit which was a very major catastrophic event in

21 which about 30 staff got hepatitis, four members of

22 staff died, four patients died.

23 The research laboratory I was working in for my

24 project as a student that I mentioned earlier, one of

25 the other workers in this rather small laboratory had

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1 70-something got hepatitis, and then there was

2 a question of how many viruses were involved in the

3 non-A, non-B and, as you know, John Craske suggests

4 that there were probably at least -- well, there were

5 two at least, there may have been more.

6 So that was my introduction certainly in

7 Cardiff to hepatitis and how devastating it could be

8 and how prevalent it could become from concentrates.

9 **Q.** How generally in the 1970s and 1980s did you keep

10 yourself informed about developments in medical and

11 scientific knowledge, in particular what journals did

12 you routinely read?

13 **A.** Apart from the British Medical Journal, I relied on

14 The Lancet for general medicine, British Journal of

15 Haematology, sometimes I would look at Blood and

16 sometimes Thrombosis and Haemostasis, which was the

17 principal clotting journal at that time. I think

18 those are the --

19 **Q.** Other clinicians have mentioned the New England

20 Journal of Medicine.

21 **A.** Yes.

22 **Q.** Is that something which you read at the time?

23 **A.** Didn't take it regularly. It's known as a journal --

24 at least I was told it's the journal of positive

25 results. I read it from time to time in the library,

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1 a needle stick injury when she was working with

2 developing a test for hepatitis B. She got hepatitis

3 and died from it at the age of 20, so that was my

4 introduction to hepatitis.

5 **Q.** I think, we'll check the precise figures but I've

6 certainly seen documents which suggest it was 11

7 patients who died and one member of staff but we'll

8 check the precise figures, professor, in the interests

9 of accuracy.

10 What then in particular in relation to your

11 haematology training and your work under

12 Professor Bloom in Cardiff did you learn further about

13 hepatitis?

14 **A.** I remember Professor Bloom talking on several

15 occasions to me about the Bournemouth hepatitis

16 outbreak that had been in the spring of 1974 and how

17 many patients had become affected and infected by

18 hepatitis at that time, both hepatitis B and non-A,

19 non-B, and that as you know was well and very

20 thoroughly investigated by Dr Craske very

21 painstakingly.

22 I think part of John Craske's extraordinary

23 epidemiology he did persevered, followed up nationally

24 large numbers of patients, I think there were about

25 370 patients that he got details of, and of those

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1 certainly.

2 **Q.** In terms of other sources of information, so other

3 than journals, you obviously had information available

4 to you through UKHCDO, which we'll explore in some

5 detail later. What other sources did you have? What

6 regular meetings or occasions might there be at which

7 you might receive or exchange information relevant to

8 discussions of hepatitis or, indeed in later years,

9 HIV?

10 **A.** It would mainly, I think, be scientific meetings.

11 There was much less -- many fewer gatherings, I think,

12 of people. One would hear by word of mouth talking to

13 colleagues, outside speakers would come to Cardiff

14 when I was there and we had speakers in Edinburgh when

15 I was in the department. There were meetings in the

16 hospital, general medical meetings in the hospital,

17 which might be about any medical or surgical or

18 obstetric gynaecological problems.

19 I think -- there was no internet in those days.

20 I think those were the main routes of medical

21 education, you know, apart from annual general

22 meetings for the British Society of Haematology, and

23 so on.

24 **Q.** We have heard evidence from other clinicians, and we

25 will look later with you at one particular document,

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1 of the Haemostasis Club. Was that something you
 2 Newcastle about and participated in?
 3 **A.** I knew about it. It was London-based grouping, mainly
 4 of sort of academic clotologists who I think met on
 5 evening a month, and they had speakers. I remember
 6 going to one meeting because I was in London and there
 7 were perhaps two or three speakers and a discussion
 8 over a couple of hours between 7.00 and 9.00 in the
 9 evening.
 10 **Q.** How much knowledge of hepatology did you have in 1980
 11 when you took up your post in Edinburgh?
 12 **A.** I wouldn't in any way consider myself a hepatologis
 13 or having any particularly specialist knowledge of the
 14 liver. Many of the clotting factors are made in th
 15 liver, and so liver disease produces a whole variet
 16 of abnormalities of the clotting system, with which
 17 I was familiar. I suppose I had a general medical
 18 knowledge of liver disease. I was obviously aware of
 19 some of the current thinking in terms of hepatitis and
 20 liver disease in haemophilia.
 21 **Q.** Could we have on screen please, Soumik,
 22 LOTH0000031_027. We can see if we just go a little
 23 closer to the text please, Soumik, this is a letter
 24 from you, dated 28 April 1980. It's to Dr Craske and
 25 you're accepting an invitation to serve on the

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1 hepatologist is away in the States at present but h
 2 returns in a fortnight. As I have no practical
 3 experience of the technique for liver biopsy I am
 4 obviously entirely dependent upon his co-operation.
 5 I shall consult him as soon as he returns but
 6 I anticipate that he will be happy to help."
 7 Then I don't think we need to look at the
 8 second page particularly. It talks about some work
 9 that Louise Stirling, who I think was your consulta nt
 10 colleague, was undertaking.
 11 Can I ask you, if we go back to that third
 12 paragraph, why was it that you were drawing to
 13 Dr Craske's attention what you call this almost uni que
 14 group of haemophiliacs?
 15 **A.** Well, he was a virologist and I -- I didn't know hi
 16 at that stage, so I didn't know whether or what he
 17 knew about the local situation in Edinburgh and the
 18 patients who I looked after.
 19 **Q.** It might be thought somewhat unusual to describe
 20 patients, humans, as "useful material for a variety of
 21 studies in relation to liver disease". Why were yo
 22 viewing your patients in that light?
 23 **A.** I agree it is perhaps not the best wording. I suppose
 24 I was distinguishing the patients who I was looking
 25 after, in comparison to the other centres who were

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1 Hepatitis Working Party of UKHCDO. I just wanted t
 2 ask you a couple of questions arising out of the terms
 3 of this letter. You say in the second paragraph:
 4 "Thank you for the invitation to serve on the
 5 Working Party. I am very happy to accept your kind
 6 offer. Like most clotologists most of my training has
 7 been in the treatment of haemophilia from the bleeding
 8 point of view and I have relatively little knowledg
 9 of hepatology. This however is obviously an
 10 increasingly important area; I am anxious to learn and
 11 I hope I may be of some help to the project."
 12 Then you go on to say this:
 13 "I am very conscious of the almost unique group
 14 of haemophiliacs we have in Edinburgh because they
 15 have never received commercial concentrate. They are
 16 therefore, as you are aware, useful material for
 17 a variety of studies in relation to liver disease.
 18 There are various pressures working against keeping
 19 our patients free of non-NHS concentrates but I am
 20 doing my utmost to resist these. I think that the
 21 Liver Biopsy Project is very worthwhile and I hope to
 22 be able to contribute patients to this. I do not
 23 think that we have any patients who have clinical
 24 stigmata of chronic hepatitis so that the study wou ld
 25 be entirely for research purposes. Unfortunately our

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1 studying the livers of patients -- I'm thinking
 2 particularly the Royal Free and perhaps Sheffield -
 3 and those patients were much more likely to have be en
 4 treated with commercial products. I've no idea
 5 exactly what John Craske knew about how patients we re
 6 treated in different parts of the country.
 7 **Q.** I'm going to come back to questions of research later
 8 in the week, professor, but to avoid the need to go
 9 back to this document, did you contribute patients to
 10 the Liver Biopsy Project that's discussed here?
 11 **A.** No, and I think it's interesting that the hepatolog ist
 12 was away when Dr Craske wrote to me because our
 13 hepatologist was at that time was Dr Niall Finlayson,
 14 a very distinguished hepatologist who actually became
 15 President of the College of Physicians in Edinburgh
 16 He is, I would say, a conservative investigator fro
 17 the point of view of invasive investigations and when
 18 he came back from his holiday I suspect if I discus sed
 19 this with him he said to me, "Well, Christopher, they
 20 may have liver disease but if we do biopsies, how i
 21 it going to change their management", which I think is
 22 very pertinent.
 23 The other thing, as has been made explicit
 24 earlier from other witnesses, there was the
 25 very unfortunate death of a patient following a liver

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biopsy at the Royal Free and, internationally, Lou Aledort reported in his 1985 study that one patient had died from a liver biopsy. So, overall, there was a 1 per cent mortality from an investigation and if you didn't have haemophilia your chance of dying was about 1 in 10,000, I think. So it was a much increased risk. One would need to have a good reason for doing biopsies at that time and particularly what are called blind biopsies, where the hepatologist puts a needle where he thinks the live is in through between two ribs to take out a small sample. We did liver biopsies much later on in the 1990s but by a very different technique, which mayb we will come on to think about later on.

For those reasons, we never did any biopsies in the 1980s.

Q. Still in 1980 with a different document HCDO0000257_108, please. HCDO0000257_108. This is 8 October 1980, a letter from you to Miss Spooner a the Oxford Haemophilia Centre:

"Herewith another set of yellow peril forms. I think this is our third episode this year!"

These are obviously forms you were submitting to the Oxford Haemophilia Centre for its data collection purposes. What were the "yellow peril

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I can't help more than that.

Q. I want to ask you about a comment you are recorded as having made a number of years later in 2000 about non-A, non-B hepatitis. It's at ARCH0003312_020. If we just zoom in to start with at the top half of the page, Soumik, thank you.

We can see it is a note of a meeting held on 10 February 2000 to discuss the information require to assist in the examination of the circumstances surrounding the safety of SNBTS blood products from hepatitis C, and we can see that there are Government representatives there. The Deputy Chief Medical Officer is there. You are there. Professor Lowe is there. There are other haemophilia directors there as well.

If we go please to the second page it's a document we might need to come back to for other purposes later but if we go to the very bottom of the second page, please, you can see at point 4 it says

"Professor Ludlam explained that until the late 1980s the perceptions were that non-A, non-B hepatitis was a mild non-progressive condition. The first serious study on liver [if you go to the top of the next page] biopsy having been undertaken in 1985."

In fairness, I should also note that Dr Keel is

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forms", as you called them?

A. There were forms -- UKHCDO had forms for reporting episodes of hepatitis, and so if we had an episode of hepatitis we would complete one of these forms and send it in to Oxford.

Q. So third episode this year, as at October 1980. Can you recall anything about whether this was hepatitis B or non-A, non-B hepatitis or a mixture of both?

A. Almost certainly non-A, non-B hepatitis but I can't be certain.

Q. Just before we look at some of the medical literature about non-A, non-B hepatitis, do you recall whether when you were in Cardiff with Professor Bloom you had seen the World in Action programme Blood Money, in late 1975?

A. I don't think I had or I did see it at that time. I'd just moved to Cardiff with my family and I don't know whether even if it was shown on Welsh television. It may just have been shown in England but I don't recall seeing it in 1975.

Q. Do you recall whether Professor Bloom ever mentioned it to you or raised it with you?

A. I don't. I think if it had been on and available in Cardiff we would have heard about it and would have watched it, so I suspect it wasn't but I'm sorry

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recorded confirming that was also her understanding and there was reference by Dr Watson to the test for the virus.

But I just wanted to ask you about what you said there. Is that still your view of the perception in the 1980s that until the late 1980s the perception was it was a mild non-progressive condition?

A. I wonder if the page could go back to the --

Q. Yes, of course. Sorry, bottom of the previous page Soumik. Very bottom, thank you. It's the last two lines, professor?

A. This is an inaccurate summary of my perceptions. I probably should say mid-1980s would be slightly more accurate, but I was well aware of the Sheffield study of 1978 showing a range of liver pathologies and I was aware of the other papers by Mannucci and from Manchester questioning the progressiveness of it, but by mid-1980s with the study from Sheffield, the one from Lou Aledort and the one from Klaus Shimff in Heidelberg it was clear it was progressive, so this is not a true reflection of my knowledge at that time.

Q. So can I take you back to 1980. I hope it's not too artificial an exercise to ask you to tell us what you think your understanding was of the seriousness and nature of non-A, non-B hepatitis in 1980 when you took

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1 up your post.

2 **A.** In people with haemophilia many had intermittent

3 elevations of their liver enzymes, particularly the ir

4 ALT, which we called hepatitis, and the view -- my

5 view and I think a widely held view was that we wer

6 very uncertain about its seriousness, whether it wa

7 a serious problem or not, but the general overall

8 feeling was it's not terribly serious.

9 Now, that obviously changed but in 1980/81/82

10 our view was that liver enzymes had been

11 intermittently raised for a long time in people wit

12 haemophilia and we didn't see much clinical evidenc

13 of liver disease in our patients.

14 **Q.** Bearing in mind that in 1980 we had had

15 Professor Preston's Sheffield study and Mannucci's

16 study wasn't I think published until 1982, what was

17 the basis for your perception in 1980 that it was mild

18 and non-progressive?

19 **A.** Well, there wasn't clinical evidence in patients of

20 liver disease and a whole variety of clinical

21 manifestations of liver disease that are well

22 described. There was the Mannucci paper I think of

23 about 1978 that didn't show very much in the way of

24 serious hepatitis. I think it was more a lack of

25 evidence about it's progressiveness that led us to

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1 a view that applied to all patients at all but it was

2 one of the possibilities.

3 So it may be biopsies were more safely

4 undertaken in non-haemophiliacs for reasons that we

5 discussed a few minutes ago and that people were

6 reluctant to assess patients with haemophilia by

7 biopsy, which is one of the ways of assessing

8 a progression.

9 **Q.** Do you recall whether you had any discussions with

10 Professor Bloom after the publication of

11 Professor Preston's Sheffield study in 1978?

12 **A.** I don't. I don't remember, no.

13 **Q.** I am going to ask you to look at a Hepatitis Workin

14 Party document. It's from 1978 so it's before you

15 were a director and before you joined the Hepatitis

16 Working Party. It's CBLA0000831, please Henry, so

17 it's a 1978 report. You can see that at the top, and

18 if it assists, Professor Ludlam, I can tell you it was

19 discussed at a meeting of Reference Centre Director

20 in September 1978 which was attended by

21 Professor Bloom. It was also, as it happens, atten ded

22 by Dr Davies although obviously you weren't in

23 Edinburgh at that time.

24 If we could just go please, Soumik, to page 5

25 we can see there the heading "Chronic hepatitis", s

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1 believe that it's possible that it might not be

2 progressive and it became clear that there was a wide

3 range of ways in which it -- rates at which it did

4 progress between different people.

5 **Q.** I understand, professor, that there may have been

6 limited evidence, that there may have been

7 uncertainty, there may not have been proof, but

8 bearing in mind that there are and we can look at some

9 of the papers if we need to but there are a number of

10 papers in the '70s which all have the possibility that

11 non-A, non-B hepatitis might progress to a chronic

12 condition, might be responsible for liver disease

13 which suggests that it may need to be viewed in

14 a similar way to hepatitis B.

15 Why the assumption in the absence of evidence

16 one way or another, perhaps, that it was mild and

17 non-progressive?

18 **A.** I think the -- sorry, the evidence was accumulating in

19 other areas about its progressiveness non-A, non-B

20 hepatitis. It was unclear what the aetiological ag ent

21 was, whether all non-A, non-B hepatitis was a singl

22 entity, whether, in fact, it had a viral aetiology at

23 all. There was a line of thought which suggested t hat

24 some episodes might be an allergic reaction to

25 Factor VIII concentrates. I don't think -- it wasn't

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1 if we see the bottom half of the page please, Soumik.

2 There's a reference in the second paragraph under that

3 heading to:

4 "In the last few months we have received

5 reports of patients in several haemophilia centres who

6 are thought to have evidence of chronic liver

7 disease", and then you will see, professor, the

8 paragraph talks about the question of liver biopsy and

9 the controversy of that and each director having to

10 make up their own mind.

11 Then if we pick it up at the last two lines it

12 says:

13 "I [that's Dr Craske] have recently visited the

14 Department of Medicine at the University of North

15 Carolina at Chapel Hill during a visit to the USA and

16 had the [go over the page, top paragraph please]

17 opportunity to discuss the problem with Dr Roberts and

18 his colleagues. They have carried out almost 100

19 liver biopsies on patients with chronically elevate

20 serum transaminases in a collaborative study and

21 nearly 50 per cent of these have histological changes

22 compatible with cirrhosis, chronic active or chroni

23 persistent hepatitis. These patients have had up t

24 ten years of treatment with freeze-dried Factor VII

25 concentrates of different brands. There is

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controversy as to whether these changes are the sequel to acute virus hepatitis or are due to some other cause but Dr Roberts and many other physicians are of the opinion that virus hepatitis is the main factor. The elucidation of this problem therefore remains the most urgent one from the patients' point of view."

First of all, in 1978, you are not a consultant but occupying a fairly senior position, you were senior registrar to Professor Bloom. Would you see routinely any of the minutes of reference centre director meetings or any of the reports, such as this produced by Dr Craske? Did he share them with his colleagues in Cardiff?

A. No, I wouldn't have seen this. I should add that, although I was a senior registrar, I wasn't a senior registrar to Professor Bloom. I was senior registrar in haematology, and most of my time would be spent outwith haemophilia and Professor Bloom. I might be on a leukaemia part of the service or the laboratories.

No, I've only seen these minutes or this report relatively recently, and I'm surprised that if Harold Roberts had overseen 100 liver biopsies, I don't recall them being published, which is rather unusual, because he was a very eminent haematologist and

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SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: -- and it talks about chronic hepatitis. We cannot be confident it is exactly the same report. There is then reference to a November meeting, which would be the AGM probably, from the Reference Centre Director minutes, I can check the precise dates, and then it would have been a Hepatitis Working Party report.

SIR BRIAN LANGSTAFF: So he may well have presented it more than once?

MS RICHARDS: Certainly, we have seen in later years, in the early 1980s, it's quite common that Dr Craske presents a report, sometimes it's updated and changes slightly, but it is quite common for it to be presented at the Working Party to the Reference Centre Directors and to the general meeting, the AGM.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: So it is possible that that's a report that was refined post the September meeting.

SIR BRIAN LANGSTAFF: I fully understand. Thank you very much. Just for the benefit of those who may be trying to follow and track down documents that may help.

A. Could I interject, please? Dr Craske often dated his reports at the end. I just wondered if you turn to the end of the report you might find a date.

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whether these came -- saw the light of days in Lou Aledort's study in 1985, I'm not sure. But I don't recall the publication of -- specifically of the results from Chapel Hill.

Q. I'm going to show you a couple of other documents -

SIR BRIAN LANGSTAFF: Before you do that, can you just confirm for me the date of this. You said September 1978. The reason I ask is that I have a note it was November but I haven't ascribed an actual day of the month to it so I may be wrong.

MS RICHARDS: Sir, the meeting of the Reference Centre Directors was 15 September 1978.

SIR BRIAN LANGSTAFF: The Hepatitis Working Party?

MS RICHARDS: There's reference in it to a report from Dr Craske which looks likely to have been this report. That's the reason for ascribing that --

SIR BRIAN LANGSTAFF: I have a note that it was entered in a report saying this --

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: -- to the Haemophilia Centre Directors Hepatitis Working Party November 1978.

MS RICHARDS: It's possible, sir. In the latter part of 1978 there was a Reference Centre Directors meeting on 15 September at which he certainly did produce a report --

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MS RICHARDS: Yes. 20 August 1978.

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

MS RICHARDS: Thank you, professor. I'm going to show you two further documents, Professor Ludlam, which you would not have seen at the time BART0002487. This is a letter dated 27 April 1979, it's from Dr Kernoff who, as you know, was a Reference Centre Director at Dr Colvin who was not but was director at The Royal London. If we go to the second page under paragraph 2 "Types of therapeutic material available", you will see about 10/12 lines into that paragraph, Professor Ludlam, it says this:

"Not only is" --

I will pick it up earlier than that:

"Not only is commercial concentrate expensive,

but there are both clinical and moral reasons for preferring the NHS material. The clinical reason is the growing awareness of the probability that commercial concentrates have a higher risk of transmitting non-A, non-B hepatitis than NHS material. This is a serious disease with long-term consequences which, as far as is known, is at present much less common in the UK than in those parts of the world - particularly the USA -- where donor blood for commercial concentrates is collected."

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1 I am not going to ask you, at least not at this
 2 stage, about the commercial versus NHS concentrates
 3 issue, but just the characterisation there of non-A
 4 non-B hepatitis. So it's described by Dr Kernoff in
 5 1979 as a serious disease with long-term consequences.
 6 Would you accept that as an accurate characterisation
 7 in the late 1970s early 1980s of non-A, non-B
 8 hepatitis?

9 **A.** I think it is a view and I think it is informed by
 10 probably the study that Professor Preston published
 11 from Sheffield, and I think that Peter Kernoff had
 12 worked before he came to the Royal Free in the
 13 States -- I forget where in the States -- where non-A,
 14 non-B hepatitis is clearly a more common condition.
 15 So he may have had, if you like, a wider knowledge of
 16 non-A, non-B beyond haemophilia. But a very
 17 reasonable view.

18 **MS RICHARDS:** We've heard from others, including I, think,
 19 Professor Tuddenham, who obviously worked with
 20 Dr Kernoff at the Royal Free, but from others as well,
 21 that Dr Kernoff had a particular interest in the
 22 knowledge of hepatitis and we have seen from your
 23 letter to Dr Craske of 1980 that, at least in 1980,
 24 you didn't claim to be any kind of expert in
 25 hepatology. The other document --

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1 post-transfusion (and blood product infusion)
 2 hepatitis in the USA and elsewhere is caused by non-A,
 3 non-B hepatitis viruses which (unlike Hepatitis B)
 4 cannot, at present, be detected by testing donor
 5 blood."

6 Just pausing there before we look at the next
 7 sentence, does that accord with your understanding in
 8 1980 that the vast majority of post-transfusion or
 9 blood product infusion hepatitis by then was caused by
 10 non-A, non-B hepatitis viruses, whatever precisely
 11 they might be?

12 **A.** Yes. My hesitation is in the interpretation of
 13 hepatitis because hepatitis can include -- or one of
 14 the features of hepatitis may be jaundice and after
 15 blood transfusion you can get jaundice from increased
 16 destruction of the red cells, either because they are
 17 older, but more likely if there's been a slight
 18 mismatch in matching the red cells to the patient, or
 19 the patient has developed an antibody to the red cells
 20 and they are more rapidly destroyed. That can give
 21 rise to jaundice, which might be interpreted as
 22 hepatitis.

23 But leaving aside that, I mean, I suppose the
 24 other thing that makes diagnosis of post-transfusio
 25 hepatitis difficult is because many patients get

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1 **SIR BRIAN LANGSTAFF:** Just a moment you were nodding
 2 there, I caught you on the screen, professor? Were
 3 you nodding in agreement that he had or just
 4 acknowledging the point?

5 **A.** I was acknowledging that Dr Kernoff's views were
 6 important views to take into consideration.

7 **SIR BRIAN LANGSTAFF:** Thank you. The reason I ask you,
 8 I'm sorry it's not being pedantic, it's just if it
 9 doesn't go down in the transcript which a nod doesn't,
 10 you understand why --

11 **A.** I do, yes.

12 **MS RICHARDS:** The reason why that might be a particularly
 13 significant letter, Professor Ludlam, is because
 14 Dr Kernoff was someone with this particular knowledge
 15 of and degree of expertise in hepatitis which may not
 16 have been true of all Haemophilia Centre Directors at
 17 the time; is that fair?

18 **A.** I think that's very fair, yes.

19 **Q.** The next document I wanted to show you, again this is
 20 in the category of documents you wouldn't have seen at
 21 the time, WITN0282008 now, this is an internal
 22 Department of Health and Social Security memo from
 23 1980, September 1980. It's the third paragraph I'll
 24 draw your attention to:
 25 "I must emphasise that 90 per cent of all

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1 transfusions because they are ill and their illness
 2 may be causing hepatitis or the drugs they are
 3 receiving may cause hepatitis and these are often
 4 patients who are seriously ill and therefore needing
 5 a transfusion, who are likely to have abnormal liver
 6 tests for a whole variety of reasons, and that's why
 7 it makes it so difficult to distinguish, if I can put
 8 it this way, viral hepatitis from non-viral hepatitis.

9 **Q.** The factors you have just mentioned might relate to
 10 transfusion hepatitis but not presumably generally to
 11 blood product infusion?

12 **A.** Not at this stage, although in the very early days of,
 13 I think, freeze-dried concentrates or cryo,
 14 occasionally a group, I seem to recall -- has been
 15 described anyway -- episodes of red cell destruction
 16 in someone of group A, if they are transfused a lot of
 17 group O blood, for example, that's got lots of high
 18 level of Anti-A in it.

19 **Q.** If we continue with what is being described here in
 20 the department's memo:
 21 "This form of hepatitis can be rapidly fatal
 22 (particularly when acquired by patients with
 23 pre-existing liver diseases) or can lead to
 24 progressive liver damage."
 25 Would you agree that that's an accurate

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1 statement as at 1980?

2 **A.** I think it is, yes.

3 **Q.** Then if we look at the document that you would have

4 seen at the time from 1981, it's PRSE0004847 please

5 Soumik. You will see this is a Lothian Health Board

6 minute or note of a meeting 14 January 1981. There

7 are a number of attendees, including you. I don't

8 need to ask you about the broad detail of the

9 discussion which is about Factor VIII supplies and

10 perhaps touches on some of the matters we talked about

11 this morning but if we go to paragraph 4, please, the

12 note records you saying this:

13 "When using commercial Factor VIII Dr Ludlam

14 pointed out the danger of liver disease, the cause of

15 which was at present being investigated."

16 Was it your view in January 1981 that the

17 danger of liver disease was simply associated with

18 commercial Factor VIII and not NHS Factor VIII or did

19 the minutes simply record your views in a rather

20 compressed fashion?

21 **A.** They record my view about commercial Factor VIII

22 potentially causing liver disease. That doesn't mean

23 to say they didn't also think that NHS Factor VIII

24 could cause problems of the liver.

25 **MS RICHARDS:** That's all I wanted to clarify.

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1 or anywhere else?

2 **A.** I was not a good notetaker, writer in medical records

3 at that time. One of the things that I was taught in

4 Cardiff, not by Professor Bloom but by one of his

5 senior colleagues, was there's no need to write the

6 obvious that you would have done anyway in the case

7 notes, only write positive observations. For example,

8 when you are examining a patient you'd only record

9 that they've got an enlarged spleen. You don't have

10 to record they don't have an enlarged spleen so that

11 someone reading it subsequently can ensure that you

12 have actually assessed the spleen, the assumption

13 being that you would, of course, have assessed the

14 spleen in this particular situation.

15 So I have to say I was not a very good recorder

16 in my case notes of what happened.

17 **Q.** Does that mean then if you did have a conversation

18 with a patient about the risks and benefits of

19 treatment, let's say it was a patient you were seeing

20 for the first time and they were about to receive

21 factor concentrates, whether commercial or NHS, does

22 that mean you wouldn't have recorded that discussion

23 routinely in the records in the early 1980s?

24 **A.** If it was a first-time treatment, the chances are

25 I might have recorded -- I would have talked to the

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1 Sir, I note the time. I still have a few

2 questions on this topic so shall we take a break now

3 and then pick it up after the break?

4 **SIR BRIAN LANGSTAFF:** Yes, indeed. We will take a break

5 until 3.40, professor. 3.40.

6 **A.** Thank you.

7 **(3.18 pm)**

8 **(A short break)**

9 **(3.44 pm)**

10 **MS RICHARDS:** Professor Ludlam, do you agree it's

11 important for patients to be aware of the risks of

12 their treatment?

13 **A.** I think it's important that patients appreciate the

14 benefits and potential side effects of treatment, yes.

15 **Q.** Do you accept that, from 1980, it was your

16 responsibility as the consultant in charge and the

17 director of the haemophilia centre, to provide or

18 ensure that your colleagues provided adequate

19 information to patients about the risks and benefit

20 of treatment?

21 **A.** I think that's reasonable, yes.

22 **Q.** Now, on such occasions or, sorry, on occasions when

23 you discussed the risks and benefits of treatment with

24 patients, did you record such discussions or the

25 provision of information to patients in their records

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1 patient about the risks. I'm not sure whether I would

2 have recorded it or not. I agree it's not good

3 practice and wouldn't be good practice now but I'm not

4 sure that I would have done.

5 **Q.** Does that mean it's less likely still that you would

6 have recorded those discussions in the case of

7 a patient who was not a first-time patient?

8 **A.** I think it likely I wouldn't have done because it

9 would be part of the routine conversation: your liver

10 tests last time you were here were as follows, this is

11 a bit better and worse than it was the time before.

12 **Q.** When you took over from Dr Davies, did you ascertain

13 what information had routinely been provided to

14 Edinburgh patients about the risks of hepatitis?

15 **A.** No, I don't know, except that it seemed to be when

16 I arrived, it seemed to be sort of general knowledge

17 that -- amongst the patients -- that hepatitis was

18 a subject around. The only little bit of evidence

19 I can think of at the moment is Dr Davies, when he set

20 up the home treatment arrangements, as you know there

21 were only a small number of patients, he asked them to

22 sign a form to say that they agreed to treat

23 themselves and that there was the possibility of

24 hepatitis as a result of their therapy.

25 It was certainly also discussed, for example,

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at The Haemophilia Society Scottish meetings. They had meetings of the patient group from time to time and, certainly, I know that at least on one occasion this was referred to. So I think there was a general awareness.

I brought it very explicitly, I think, to all patients' attention, probably in 1980, possibly '81 but I think probably '80, when I gave each patient a little printed slip of paper to put in their haemophilia card -- the haemophilia card was a card that they carried with them that said that they had haemophilia, what kind of haemophilia it was, where they were registered and who to contact in case of emergency. This was a sort of passport for getting treatment readily at another haemophilia centre if they were travelling and they got a bleed, they could if they weren't -- didn't have the treatment with them they could go to the local haemophilia centre.

I gave each patient a little slip of paper printed on it saying "Please give this patient if possible NHS Factor VIII if they come for treatment", or cryoprecipitate, I think particularly NHS, and not to use commercial and that I would be prepared to reimburse them with Factor VIII concentrate from our stock if need be. So I would have explained to

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husbands and wives would go along and I think there would be a talk and afternoon tea, and a sort of social gathering.

Q. Were you present at any Haemophilia Society meeting in the first half of the 1980s at which the risks of hepatitis, and in particular non-A, non-B hepatitis were explicitly discussed?

A. I wasn't personally at any -- I can't recall meetings that I was personally at.

Q. You have referred to the consent form used by Dr Davies. I think that's the form that's at WITN3428006, please, Soumik.

A. I think I also used the same form when I started patients on home therapy.

Q. Is this the form that you're referring to? It's an exhibit to your witness statement?

A. Yes. Yes, and I asked patients -- my predecessor designed it and we had a heap of them so I asked patients to sign them.

Q. It seems quite formal to have it "signature witnessed by", and then space for a witness and occupation of witness. Do you know why Dr Davies introduced that and is that a practice you adhered to?

A. I saw that for the first time just now. I certainly wouldn't have asked for a witness or the occupation of

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patients about hepatitis, each of them individually they would have known at least that way. But it was generally known amongst patients that hepatitis was a feature of haemophilia treatment, and I think most people distinguish between hepatitis B and non-A, non-B, although I would refer to it as hepatitis rather than non-A, non-B hepatitis.

Q. I just want to, as it were, unpick the various sources of information you have referred to there, Professor Ludlam. You referred to Haemophilia Society patient meetings. Are those meetings that you attended?

A. I was invited to some of them to speak. I don't think I was generally invited to their meetings because they were for the patients rather than the treaters. We did have a local haemophilia group for Edinburgh which was quite difficult to keep going, particularly when home treatment became available and there was less campaigning to get more home treatment. It ended up, I seem to recall, with one parent myself and the haemophilia sister gathering one evening and no patients turned up. So it was very difficult to keep a local group going. The Scottish group was quite a strong group and used to meet on a Saturday afternoon, I think it was, every few months and

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a witness. Dr Davies had a degree of formality and correctness about things and I think also it's a reflection of home therapy being something rather unusual. We take it for granted these days, for example, that nurses take blood and give medicines by intravenous injection, as a matter of course, but in the 1980s, the early 1980s, it was unheard of and I had to address the rather formidable nursing hierarchy to enable our newly appointed nurse, haemophilia sister, to be able to take blood from patients. So it was a very different era and, as I say, I haven't noticed that a witness and their occupation were asked for.

Q. Where would this form, once signed by an individual, by a patient -- forget the question of witnesses -- where would it then go? Would it be kept with the patient's medical records or in other records and, if so, where?

A. No, there was a separate file that these went in.

Q. So it wouldn't be part of the patient's medical records?

A. That's my memory, yes.

Q. Then if we look at the text of it, you're right to point out that it refers to hepatitis. It says:

"I understand that there's a risk of reactions

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1 to such materials. I also understand that such
 2 materials may carry the virus of hepatitis and may
 3 constitute a risk to myself and to others."
 4 It doesn't actually descend to specifics about
 5 hepatitis B or non-A, non-B hepatitis, does it?
 6 **A.** No.
 7 **Q.** It doesn't say anything about the seriousness of
 8 hepatitis or the possibility, at least, of developing
 9 a chronic condition or the possibility of liver
 10 disease?
 11 **A.** No, I agree.
 12 **Q.** In terms then of the piece of paper that you provided
 13 to your patients to go in their haemophilia card or
 14 passport, as I think you described it, that piece of
 15 paper -- I don't think we have a sample but some
 16 witnesses, individuals have also made reference to
 17 it -- stated what treatment they were on but that
 18 piece of paper, as I understand from your description,
 19 didn't itself talk about hepatitis at all?
 20 **A.** That's correct. I don't think it referred to
 21 hepatitis, it referred to desirability of the patient
 22 receiving an NHS treatment.
 23 **Q.** If we look at your witness statement -- Soumik, it'
 24 WITN3428001 -- and if we go to page 83, please, in
 25 answer to the question, "Did you take steps to ensure

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1 understand why I ask?
 2 **A.** Yes, I do.
 3 **MS RICHARDS:** Did you actually tell patients that there
 4 was a risk from the factor concentrates, that they
 5 were receiving or about to receive, of developing not
 6 only hepatitis B, which they may have known about
 7 through the vaccination programme in the early 1980
 8 but a risk of developing non-A, non-B hepatitis, or
 9 did you just refer generally, as I think one of your
 10 earlier answers suggested, to hepatitis?
 11 **A.** I referred to hepatitis with the meaning of not what
 12 we're now calling non-A, non-B hepatitis and I would
 13 have referred to hepatitis B as hepatitis B.
 14 **Q.** Did you tell your patients, again we're talking about
 15 the first half of the 1980s predominantly here, that
 16 there was a risk that the factor concentrates could
 17 give rise to chronic hepatitis and the possibility of
 18 progressive liver disease?
 19 **A.** Well, I would certainly have told them that they had
 20 chronic hepatitis. I'm not sure to what extent
 21 I would have said there's a good chance or significant
 22 chance this will be serious, because we didn't -- at
 23 least I didn't -- really know in the early 1980s what
 24 the long-term outlook was likely to be.
 25 **Q.** I understand that you may not have told them there was

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1 patients were informed and educated about the risks of
 2 hepatitis and HIV", and we'll leave aside HIV until
 3 tomorrow, professor, you have provided a number of
 4 answers here. (a) says this, so paragraph 212(a):
 5 "Reminding patients about the risk of viral
 6 infection from using blood products was part of the
 7 routine arrangement for patients and was evident with
 8 the standard blood tests at review clinics and
 9 feedback of the results of these at subsequent
 10 clinics."
 11 Can you explain more what you mean by that?
 12 **A.** Yes. When a patient was reviewed we -- I would have
 13 looked at the results of the liver function tests and
 14 commented on them, I'd have looked at the results of
 15 the hepatitis B tests, I'd have looked at their full
 16 blood count, make sure that they weren't anaemic or
 17 had a raised white count. Those would be the -- and
 18 I would tell the patient what the results were and
 19 discuss them as seemed appropriate.
 20 **Q.** So you would perhaps discuss if there was significant
 21 liver function test abnormalities?
 22 **A.** (Nodded)
 23 **SIR BRIAN LANGSTAFF:** Just a moment, you're nodding again.
 24 **A.** I'm sorry. I was agreeing.
 25 **SIR BRIAN LANGSTAFF:** Yes, I thought you were but you

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1 a good chance of developing something but did you, as
 2 far as you can recall, tell your patients that there
 3 was a risk, if they either started or continued with
 4 treatment with factor concentrates, a risk that that
 5 could result in liver damage?
 6 **A.** Oh, that was clear, yes, that it could result in liver
 7 damage and one advised because of that to patients to
 8 moderate the amount of alcohol they drank.
 9 **Q.** Did you tell them that it could result in serious
 10 liver damage?
 11 **A.** I'm sorry, I can't recall exactly how far and how
 12 severe. It was sufficiently important, the liver
 13 changes/damage that I was perceiving, that I was
 14 advising patients to moderate the amount of alcohol
 15 they drank because that would exacerbate or possibly
 16 exacerbate damage to their liver.
 17 **Q.** Would the kind of conversations that you are
 18 describing take place only where you had a patient who
 19 had, for example, abnormal liver tests or would the
 20 take place with every patient who would be being
 21 treated with factor concentrates irrespective of their
 22 liver function tests?
 23 **A.** It would tend to be with most patients because most
 24 patients at one time or another on concentrate had
 25 abnormal liver function tests. So it was part of the

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standard discussion with the patients.

Q. Could we look at one of the documents you prepared for the Penrose Inquiry. It's PRSE0003062 and if we can go to the second page, please. If we look at the bottom of the second page, last paragraph, you say this:

"It was our policy to inform patients (and parents of children) of all the risks of haemophilia as well as its treatment, including hepatitis because virtually all recipients of blood products were likely to be at risk or suffer from this complication."

I'm just going to show you one other sentence on the next page and then ask you a question. If we can go to the next page, if we look at paragraph (c), if we pick it up five lines down, you say:

"Although it was our policy to inform patients, requiring blood product for the first time, of the risk of hepatitis ..." and then you go on to talk about how it might be expected that information might not be recalled by patients.

Now, can I ask you to clarify was it your policy to inform patients of the risks of hepatitis when they were receiving blood products for the first time, which is what this passage suggests, or was it your policy to inform patients of the risks whenever

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shown earlier Dr Davies was a member of the hepatitis working party so he had an interest in liver diseases and hepatitis and, as I think you probably know, there are a number of studies done in the 1970s and early 1980s in relation to hepatitis B which were initiated by Dr Davies, so he was very well aware and I think he would have shared that with the patients. There were no secrets and he was a very forthcoming individual very engaging, very educative. I learnt a great deal -- one of the reasons I became a haematologist was because of his enthusiasm for haemophilia and for haematology in general.

Q. Does that mean the answer to my question, did you assume that he'd have told them, is yes you did assume that he would have explored the risks or explained the risks of non-A, non-B hepatitis with patients who were coming to you who had previously been seen by Dr Davies?

A. Yes.

Q. Does that mean that you would not yourself have felt it necessary to explain the risks to them again because you would proceed on the basis that that's something your patients already knew?

A. Well, it would be part of the conversation with the patient at a review clinic, and I would judge by how

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they received treatment with blood products?

A. Well, what's up on this page is certainly the case.

One wouldn't -- I wouldn't say to a patient every time they got an infusion of cryoprecipitate or Factor VIII concentrate this may give you hepatitis or may exacerbate the hepatitis you've already got, because that was accepted knowledge by the patient, just like they might develop an anti-Factor VIII antibody which is really a catastrophic thing that the patients don't want to have but which is a complication of treatment. So you don't warn a patient every time you give them an infusion they might get hepatitis from it.

Q. In relation to the patients you were seeing 1980/early 1980s, most of those presumably, apart from young children or people who moved into the area, would be patients who were not new to the centre, they'd be patients who had been seen by and treated by Dr Davies, possibly in some cases for a number of years?

A. Yes.

Q. Did you assume that Dr Davies had told them about the risks of non-A, non-B hepatitis and that it was not necessary for you to do so?

A. Well, I think it was, if I can put it this way, sort of common knowledge amongst patients. As you have

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they responded to what I was telling them about the liver tests. If they looked very surprised that I was showing them some liver test results, then it would indicate to me that maybe they didn't know much about it and I'd tell them more. But mostly patients indicated that well, yes, they knew about this and, yes, thanks for the update.

Q. Am I right in understanding that at this time there was no written information, other than what we've seen in that consent form, there was no written information provided to patients about non-A, non-B hepatitis or hepatitis more generally?

A. I think that's correct, yes. I can't recall any.

Q. If we just look at this passage again that's on the screen, you say -- I'll read the same sentence again but carry on with it. You say:

"Although it was our policy to inform patients requiring blood product for the first time of the risk of hepatitis, if diagnosis of haemophilia was concurrent with an acute painful bleed it is to be expected that information given might not later be recalled", and then in relation to patients you are saying:

"Not only were usually parents having to try and quickly understand about the condition of

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haemophilia, but they usually had a very upset child to comfort. In these stressful circumstances the chance of the information given being recalled would be reduced because of the stress."

You refer to some home Haemophilia Society booklets which we're still trying to track down. I it's the case that because a patient is experiencing an acute bleed or because a parent is dealing with a very upset child that you think they might not be taking in or recalling the information, would you agree it's all the more important to provide that information in writing or to repeat it at later sessions?

A. I don't know that it would be necessarily appropriate to provide it in writing. It is likely that it would be part of the discussion later on, certainly.

Q. In your statement at page 308 -- Soumik, it's -- paragraph 308 -- Soumik, it's WITN3428001 if we go to page 108, please. If we look at paragraph 308 you will see the question that you were asked was referred to witnesses to the Inquiry who had said that they were not given sufficient or any information about the risks of treatment and you say in the last sentence of paragraph 308:

"It is possible that patients may not recollect

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recall. So I would have explained to the staff who came to work in the haemophilia centre what the risks were. They would have sat in with me to begin with seeing patients and I hope it would have become clear what my usual practice was and what was appropriate to say to patients.

Q. Is it possible, even likely, that the reason some patients have said they were not told of the risks of treatment is not that they've forgotten but that those risks were not clearly communicated to them at the time?

A. It is possible. I think it's unlikely. I can think of one or two instances of patients presenting actually *de novo* with an intracranial bleed, for example. Well, I think -- obviously, not in a position to discuss the situation then. But I would hope that most patients, certainly ones that I was directly involved with, would understand the risks of therapy.

Q. There's a further document I am going to invite you to look at, Professor Ludlam. It's HCDO0000270_031. We can see if we look at the top of the page it's minutes of the 12th meeting of the UK Haemophilia Centre Directors' Hepatitis Working Party on September 14th, 1983, and you are recorded as present.

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exactly what they were told, particularly with the passage of many years."

You'll be aware that there are witnesses, patients of yours, who have given evidence to the Inquiry that they weren't informed of the risks of non-A, non-B hepatitis.

Is that your response, that they may not recollect what they've been told?

A. If I was involved in their treatment, I hope I would have explained the situation to them, the risks to them. If they were not treated by me I would hope they would have been but I can't vouch for other doctors.

Q. You told us this morning when describing your work and the various responsibilities that you had that quite a lot of the day-to-day clinical work would have been done by, for example, the registrars under your supervision in the way in which you described to the chair.

Were there any instructions or guidance for such registrars or others, the haemophilia sister, for example, as to what information they should provide to patients about the risks of treatment?

A. I don't think there was any written information or protocols as one might have nowadays that I can

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If we go to the top of the next page you will see it says this:

"With regard to NHS Factor VIII the paper describing the prospective study of NHS and commercial Factor VIII would shortly be submitted for publication and this showed that there was 100 per cent chance of contracting non-A, non-B hepatitis whether the product was made from NHS Factor VIII or commercial sources."

Do you know whether that's a reference to the Fletcher paper that I think you have referred to in your evidence at some stage?

A. I think it is, yes.

Q. Now, I'm not asking you for your comment on whether what's said in that paper is right or not but bearing in mind that at the Hepatitis Working Party in September 1983 it appears to be the view that there's 100 per cent chance of contracting non-A, non-B from NHS factor concentrates as well as commercial, is that something that you told your patients who were receiving predominantly NHS concentrates? Did you tell them you have 100 per cent chance of contracting non-A, non-B hepatitis?

A. I think patients -- all my patients who were regularly receiving NHS concentrates, which was, as you see, virtually all the patients, understood that the

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hepatitis came from NHS concentrates. There was a view prior to this publication that maybe NHS Factor VIII concentrates were safer, from the point of view of hepatitis, than commercial products and some of the work that we did subsequently, I think, bore this out when hepatitis C was discovered and we set up assays for it.

But there was never the suggestion that NHS Factor VIII was, let me put it this way, free of hepatitis, although it had a reputation for being less likely to cause hepatitis than commercial concentrates.

- Q.** You see, Professor Ludlam, your patients -- some of your patients may have thought that, because they were receiving Scottish concentrates -- and some have said this in their evidence to the Inquiry -- because they were receiving Scottish concentrates that's safer. Leave aside completely the question of HIV because we're going to turn to that tomorrow. But now you have in September 1983 something published which is telling clinicians such as yourself that there's 100 per cent chance if you are treated with an NHS factor concentrate you are going to get non-A, non-B hepatitis. Isn't that information which should be shared with patients at that point?

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- Q.** You told us that you may not have recorded in patients' records at the time discussions about the risks of treatment. Would you have recorded in patients' records at the time the fact that they had non-A, non-B hepatitis?
- A.** No. Because it would be obvious from looking at their liver function tests. If they had a particularly acute episode or they were symptomatic from it, yes, one would put that in, but if they came up for a review and their liver tests were slightly different from the previous occasion, it's unlikely I would have written anything, it would have been not, I think, worthy of comment.
- Q.** Is it possible that the conversations that you had with your patients during this time were more along the lines of: you've got some abnormal liver function tests but it's nothing to worry about?
- A.** No, I think it was along the lines of you have got some, what we used to call transaminitis, intermittently raised transaminases, and we don't really understand what the consequences of the seriousness of this is, but in the early 1980s we weren't too concerned.
- Q.** What, if any, steps did you take at the Edinburgh centre in the first half of the 1980s to reduce the

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- A.** But the patients already knew they had hepatitis because when they came to the clinic we discussed the liver function test from the previous visit and, as I was saying a few minutes ago, if one gives the patient results and say they compare them with how they had been for the previous visits. So patients were universally aware, or virtually universally aware, that hepatitis was a feature of treatment with their NHS products.

- Q.** So is this your evidence, that by the time we're talking about here September 1983 all of your patients who were receiving treatment with concentrates knew, as a matter of fact, that they had non-A, non-B hepatitis?

- A.** I would hope that they knew -- I should say they didn't all have evidence of hepatitis. There were a small number of patients who appeared to have normal liver function tests or virtually normal liver function tests persistently, and we now know that there's a group of patients who actually cleared their hepatitis C, as it came to be known. So not all patients had chronic hepatitis. There was about 10 or 15 per cent who cleared the virus and were fortunate in not having persistent and potentially progressive liver disease.

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- risk of your patients being exposed to non-A, non-B hepatitis?
- A.** We discussed right at the beginning about desmopressin and cryoprecipitate for patients who could be adequately treated with those preparations. It would be a matter of trying to avoid blood products as much as possible. My desire not to use, if possible, commercial concentrates was because of the hepatitis risk because it was -- there was good evidence that it might be a separate virus and that it would be as well to, if one could, to avoid patients getting that.
- MS RICHARDS:** Sir, I note the time and I'm going to move on to a separate topic so this might be the most sensible point to end the afternoon's evidence.
- SIR BRIAN LANGSTAFF:** Yes, certainly. There's just one matter, if I may, professor. You mentioned to counsel that you would tend to discuss with those apart from yourself who might administer treatment within your centre, you would discuss with them what to say, in effect and they would shadow you and see how you did it. I gather from what you're saying about knowledge, your knowledge and knowledge generally, of non-A, non-B hepatitis that no-one quite knew how serious it might be. There was a realisation there was a risk it might be serious, there was a thought it might not be.

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1 Would it also follow that no-one -- that the picture
 2 might become clearer as further research was done?
 3 **A.** Yes.
 4 **SIR BRIAN LANGSTAFF:** To what extent during the early
 5 1980s did you tell those who were administering
 6 treatment apart from yourself of any of these changes
 7 that might affect the extent to which or the emphasis is
 8 they put upon what they said to patients?
 9 **A.** I'm sorry, I don't quite understand. You're asking
 10 about research --
 11 **SIR BRIAN LANGSTAFF:** No, I'm not. I'm asking you about
 12 information to patients.
 13 **A.** I'm sorry.
 14 **SIR BRIAN LANGSTAFF:** The question is based on this, that
 15 you're advising patients of what you see as the risk,
 16 or you might be. If you advise them as to the risk
 17 you would advise them as to your best knowledge of the
 18 risk at the time.
 19 **A.** Yes.
 20 **SIR BRIAN LANGSTAFF:** If you tell others who are working
 21 under your supervision broadly what the risks are,
 22 that is the risks at the time you tell them. That may
 23 need to be updated if the situation, generally as to
 24 the knowledge of risk, is changing, mightn't it?
 25 **A.** Yes, I would be discussing with my colleagues more of

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1 came available that would be shared with staff. That
 2 was part of the educational process. We had weekly
 3 meetings in the department and we would discuss recent
 4 papers and we'd have outside speakers and it was an
 5 evolving ambience in which changing views became part
 6 of the fabric.
 7 **SIR BRIAN LANGSTAFF:** Thank you very much. It's been
 8 a longish day for you, so we'll take a break now. The
 9 same rules apply, of course, overnight as do at
 10 lunchtime or any other break, but I wish you a safe
 11 journey back home and look forward to seeing you
 12 tomorrow morning. We start at 10.00, so we will see
 13 you then. Thank you very much.
 14 **A.** Thank you.
 15 **(4.32 pm)**
 16 **(Adjourned until 10.00 am the following day)**
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1 the background, probably, as to how there came to be
 2 a range of risks that this particular person or paper
 3 suggested that it was -- had these risks -- sorry, I'm
 4 getting a bit tired.
 5 **SIR BRIAN LANGSTAFF:** Don't worry.
 6 **A.** I'm sorry, I would explain, for example, to my
 7 registrar that Pierre Mannucci might have had this
 8 view and his papers showed certain things and that
 9 Preston's papers showed other things. I'd have been
 10 discussing at a more in-depth level obviously with the
 11 medical staff than I would with the patients.
 12 **SIR BRIAN LANGSTAFF:** Yes, and what did you do to check
 13 that that -- that the general import of that change in
 14 general view was being told to the patients by people
 15 other than yourself but people for whose advice to the
 16 patients you were responsible.
 17 **A.** I think it was ensuring that the staff who worked with
 18 me were -- if I can put it this way, held the sort of
 19 views that I wanted promulgated. My views, my
 20 prejudices if you like, what I thought about
 21 particular situations, that to caricature it, if you
 22 like, was the party line.
 23 That's the best way I can describe it and it
 24 was my responsibility to keep staff educated with the
 25 changes, as time went by there were -- new information

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