

Friday, 11 February 2022

(9.59 am)

SIR BRIAN LANGSTAFF: Good morning, Dr Dempsey.

THE WITNESS: Good morning, sir.

SIR BRIAN LANGSTAFF: You can hear me, obviously, and you can see me, can you?

THE WITNESS: Yes, I can.

SIR BRIAN LANGSTAFF: Good. Now, let me set the scene for you. You are talking to a very small group of people here in Aldwych House in Central London, but the main audience, who want to hear what you have to say, is listening remotely. There may be 100 or so. I suspect that we will be joined by quite a number from Northern Ireland, for obvious reasons, and they are the people who are particularly interested in what you have to tell us.

You're at the Belfast City Hospital, are you?

THE WITNESS: Right.

SIR BRIAN LANGSTAFF: And present with you in the room is no one?

THE WITNESS: No one at the moment.

SIR BRIAN LANGSTAFF: But in the building there are your legal representatives and a technology expert just in case things go wonky.

THE WITNESS: That's right.

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patients with bleeding disorders?

A. That's right.

Q. Were you working there under Dr Mayne at the Royal Victoria Hospital and Dr Bridges at the Royal Belfast Hospital?

A. Yes, that's right.

Q. Then, I think, for the first half of 1980 had a post in paediatric oncology at the Royal Manchester Children's Hospital; is that right?

A. That's correct.

Q. Then you returned to the Royal Belfast Hospital for Sick Children in August 1980 as a consultant paediatric haematologist, remaining in that role until your retirement in 2008; is that correct?

A. That's correct.

Q. I'm going to ask you a little more about the services and facilities in haematology at the Royal Belfast Hospital for Sick Children with particular reference to the care of children with bleeding disorders. In terms of the staffing is it right to understand that, for a number of years, you were the sole consultant haematologist, and it was rather later on that a paediatric consultant oncologist was appointed?

A. That's right, the paediatric oncologist -- consultant paediatric oncologist joined me in 2000, the year

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SIR BRIAN LANGSTAFF: In a moment, once Mary has invited you to take the oath, the affirmation in your case, Ms Richards will ask you some questions. Mary.

DR STANLEY IAN DEMPSEY (affirmed)

Questioned by MS RICHARDS

MS RICHARDS: Dr Dempsey, can you see and hear me?

A. Yes, I can.

Q. I'm just going to start with an overview of your career. You undertook house officer and senior house officer roles in Belfast City Hospital between 1970 and 1973; is that right?

A. Yes.

Q. Then your statement tells us that between 1973 and 1978 you undertook senior house officer, then registrar, then senior registrar roles in haematology at Belfast City Hospital. What, broadly, did that work entail, what kind of haematological conditions were you involved with?

A. Well, primarily with malignant conditions and general haematology.

Q. In 1978 through to 1979, you were a senior registrar in haematology at the Royal Victoria Hospital and the Royal Belfast Hospital for Sick Children. Was that your first work as a senior registrar with the care of

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2000.

Q. So if we think about the 1980s, there was you, as a single-handed consultant, and then you had the assistance, I think, of a registrar in haematology who presumably changed as they went through their rotations?

A. Yes, a rotating registrar, yes -- sometimes an SHO.

Q. Then your statement explains there was also a part-time clinical medical officer from 1987. What was the role of the clinical medical officer?

A. Well, the clinical medical officer was primarily to assist me in looking after the patients I cared for: children with general haematological conditions, children with malignancies and children with bleeding disorders.

Q. So is it right to understand that there was no -- in the '80s at least or until, I think, 1987, there was no specialist nursing input in relation to haemophilia care?

A. That's correct, there was no specialist nursing.

Q. Was there any -- sorry.

A. Children were seen on paediatric medical wards, they had -- some came to one ward, some came to another. They were spread across two wards in the Children's Hospital, Musgrave Ward and Allen Ward.

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1 Q. To what extent was there social work or physiotherapy
2 availability for children with bleeding disorders in
3 the 1980s.

4 A. Well, there was a physiotherapy department and we
5 could access help there as we needed to. We had no
6 designated physiotherapist. What else did you ask me
7 there?

8 Q. Social work.

9 A. Social work. Yes, we had a Malcolm Sargent social
10 worker who was funded from a charitable source, and
11 she was able to provide some help with patients who
12 had bleeding disorders. But she was there primarily
13 to look after children with malignancies.

14 Q. Your statement says that, essentially, there were --
15 your clinical responsibilities covered children with
16 leukaemia and solid tumours across Northern Ireland,
17 children with bleeding disorders across Northern
18 Ireland and then general haematological clinical
19 issues; is that right?

20 A. Yes, that's right.

21 Q. Then it was in 1987 that the -- rather than patients
22 being seen on the general medical wards, a specialist
23 unit opened?

24 A. That's right, eight beds and a compliment of nursing
25 staff.

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1 Services: Royal Belfast Hospital for Sick Children":
2 "All children with haemostatic disorders are
3 seen at the Children's Hospital. They get transferred
4 to the adult service usually after their 16th
5 birthday."

6 Is that incorrect or did the practice change in
7 terms of the age of transfer?

8 A. That's incorrect. It was 14 when that audit took
9 place. It may have changed subsequently after my
10 retirement. I think there was a move to extend the
11 age range of patients looked after in the Children's
12 Hospital, but I don't know a great deal about that,
13 I think that might have happened after I left. But
14 certainly in 2000, 14 was roughly the cut-off period,
15 the cut-off age for transfer.

16 Q. How -- sorry, carry on.

17 A. Obviously, some children might have been a little over
18 their 14th birthday by the time they were referred.
19 They wouldn't be much under their 14th birthday by the
20 time they were referred.

21 Q. How was the transfer managed or coordinated with the
22 adult centre?

23 A. Well, not as well coordinated as it is apparently now.
24 Generally speaking, I spoke to the parents, advised
25 them about the upcoming transfer, sometime in advance

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1 Q. That -- sorry, carry on.

2 A. So the nursing staff would get to know the patients
3 with bleeding disorders and they had an ability to
4 relate to patients with bleeding disorders, and take
5 an interest in them, in the way that hadn't happened
6 up until then.

7 Q. Now, your statement suggests that you looked after
8 children with bleeding disorders until they were 14,
9 at which point they would be transferred to the adult
10 Haemophilia Centre at the Royal Victoria Hospital.
11 Why was the age of 14 chosen?

12 A. Well, the age of 14 was already established when I was
13 appointed. The Children's Hospital management were
14 quite keen that children shouldn't stay as patients in
15 the Children's Hospital after the age of 14, and the
16 management in the Royal Victoria Hospital was quite
17 keen that the adult hospital shouldn't look after
18 patients younger than age 14. So that was a cut-off
19 that was established before I joined the hospital as
20 a consultant.

21 Q. I'm just going to ask you to look at one document with
22 me on this issue.

23 Sully, could we have WITN4027002, please. This
24 is a 2000 report of an audit visit. If we go to
25 page 3, the top of the page, it says "Paediatric

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1 of the date, talked to them again before the children
2 were transferred, probably spoke to Dr Mayne in the
3 adult unit, and told her that child X was going to be
4 referred across.

5 Then I wrote a fairly extensive referral letter,
6 outlining their history in the Children's Hospital,
7 over the years they'd been attending and gave that
8 tour. Usually the chart went over with the letter for
9 her to look at before she actually saw them over
10 there. That was the extent of the transfer process
11 that we engaged in.

12 Q. So would it be right to understand from that, that
13 there was not any joint decision making in terms of
14 continuity of treatment or what the treatment regime
15 might then be at the adult hospital?

16 A. Well, I didn't know what was going to be in the adult
17 hospital but I did my best to let Dr Mayne know what
18 we'd done in the Children's Hospital. I think it was
19 pretty important that she did know exactly how
20 treatment had progressed, what the particular problems
21 were of that individual child, and all the other
22 aspects of their haematology. I think -- I did do my
23 best to outline that pretty carefully in the letter of
24 referral so that she wouldn't be in any doubt about
25 any of the issues. Obviously if she'd any problems,

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1 she'd have phoned me fairly quickly to clarify
 2 matters.
 3 **Q.** Now your statement tells us that in the 1980s, there
 4 was a small cohort of bleeding disorder patients under
 5 the care of the Royal Belfast Hospital. You've
 6 estimated it was about 12. And you've said they were
 7 all children who were moderately or mildly affected,
 8 with no severely affected patients in the 1980s; is
 9 that correct?
 10 **A.** That's correct, yes.
 11 **Q.** Do you know how that came about? Does that mean there
 12 were no severely affected haemophilic children
 13 receiving care in the 1980s or had some of the
 14 severely affected children already been transferred to
 15 the adult centre at a younger age?
 16 **A.** No. There weren't any children who were severely
 17 affected in Northern Ireland being treated. They
 18 weren't being treated anywhere else; they just weren't
 19 there during the 1980s. But -- (overspeaking) --
 20 **Q.** And that cohort --
 21 **A.** -- when you say 12 children, well, 12 to 14, roughly
 22 12 to 14 children in the unit at that time.
 23 **Q.** Can you recall whether you had any patients at that
 24 time, in the 1980s, with haemophilia B?
 25 **A.** No, we didn't.

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1 six months -- four to six months.
 2 **Q.** What were the arrangements out of hours? So if
 3 somebody had a bleed out of normal hours, what would
 4 happen?
 5 **A.** Well, they would ring the ward they were associated
 6 with and then the nurse would either speak to the SHO
 7 who was on call, the paediatric SHO who was on call,
 8 who would ring me, or they might ring me directly.
 9 And that was the usual arrangement, apart from when
 10 I was on holiday. When I was on holiday, the nursing
 11 staff would ring the paediatric SHO, who would ring
 12 the haematology senior registrar on call, who would
 13 deal with the problem. And if there was a serious
 14 problem, Dr Mayne would be asked for her opinion. So
 15 that was how it operated.
 16 **Q.** Your statement tells us that home treatment was not
 17 introduced until 1990. Why was that?
 18 **A.** Well, that was because the children were very
 19 mildly -- moderately affected. Their attendances were
 20 fairly infrequent, and I didn't arrange for home
 21 treatment then because I thought they weren't severely
 22 enough affected. I thought that while we might be
 23 able to teach the parents the technique of
 24 venepuncture, if there were long gaps between actually
 25 treating the child, their technique might decay and

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1 **Q.** So the patients, were they all haemophilia A or were
 2 there also some with von Willebrand's?
 3 **A.** Mostly haemophilia A. There were some
 4 von Willebrand's.
 5 **Q.** And then I think your statement tells us that from
 6 1990 you began to see both more children and to start
 7 seeing severely affected children; is that right?
 8 **A.** That's right, yes.
 9 **Q.** Now, in the period up to 1987, when the specialist
 10 clinic or specialist unit opened, were there regular
 11 haematology clinics or regular clinics for patients
 12 with bleeding disorders or was it just a question of
 13 patients turned up as and when they had a bleed?
 14 **A.** There were regular clinics held on the ward they were
 15 attached to -- the children were attached to. When
 16 they needed to come in between appointments, they
 17 turned up on that particular ward. They would phone
 18 the ward before they came, and then they would come up
 19 to be seen on that particular ward, have their problem
 20 looked at and attended to on that particular ward.
 21 **Q.** So in terms of the regular clinics, how often, leaving
 22 aside *ad hoc* attendances when there was a bleed, how
 23 often would you usually expect to see your paediatric
 24 patients in that period, 1980 to 1987?
 25 **A.** Well, I think four -- every four months or every

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1 they might have problems. If several weeks elapsed or
 2 maybe a month or two between treatments -- and this
 3 was quite standard with this group of children --
 4 I was worried that the parent who was able to do it
 5 two months ago might find that their ability had
 6 declined in the interim. So I thought probably best
 7 to see them on a periodic basis or see them when they
 8 needed to be seen rather than devolve that
 9 responsibility to the parents.
 10 **Q.** Is it correct to understand the same as the case in
 11 relation to prophylactic treatment, that only became
 12 a feature of treatment at the Royal Belfast Hospital
 13 in the 1990s?
 14 **A.** Well, that only happened in the 1990s when we
 15 had a group of severely affected children who needed
 16 to have prophylactic treatment for their management.
 17 **Q.** Now, the Royal Belfast Hospital for Sick Children was,
 18 as I understand it, an entirely separate hospital from
 19 the Royal Victoria Hospital. Were they on the same
 20 physical site, however?
 21 **A.** They were on the same physical site. They were
 22 separate hospitals. There was a unified management
 23 system operating.
 24 **Q.** What does that mean, a "unified management system", in
 25 practice?

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1 A. Well, there was one -- there was a general manager who
 2 looked after the whole of the Royal site. I think
 3 that's the easiest way to do it. There were obviously
 4 managers at a lower level whose responsibilities
 5 either referred to the Royal Victoria Hospital or to
 6 the Children's Hospital. But there was an overarching
 7 manager for the Royal group, as it was called.

8 Q. You say in your statement you were solely responsible
 9 for clinical decisions and decisions regarding product
 10 selection for your patients, and would it be right to
 11 understand Dr Mayne was responsible for the clinical
 12 decisions and decisions regarding product usage for
 13 her patients?

14 A. Yes, that's right.

15 Q. What extent of interaction did you have with Dr Mayne
 16 in the 1980s?

17 A. Well, Dr Mayne was a respected senior colleague.
 18 She'd been in post for some years before me. We would
 19 see each other periodically. We would generally see
 20 each other at laboratory management meetings, maybe
 21 once a week or every six -- sorry, once a month or
 22 once every six weeks. We would see each other at
 23 meetings about the rotation of junior staff and the
 24 education of junior staff. That sort of -- we'd meet
 25 in that sort of context.

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1 Dr Mayne when she wasn't there.

2 Q. To what extent did you have direct dealings or
 3 interactions with Dr Morris McClelland, the Regional
 4 Transfusion Director of the Northern Ireland Blood
 5 Transfusion Service?

6 A. Well, I knew him, and I related really to him when
 7 I had a need of his service, and very helpful the
 8 Transfusion Service were. I didn't meet him on
 9 a regular basis, no, but he was very helpful around
 10 providing blood products for my patients over the
 11 years, and he bent over backwards to help and look
 12 after them. And I'm referring really now to patients
 13 with malignant disease, who often required a lot of
 14 platelet transfusions and the like.

15 Q. To what extent did you have any regular or ongoing
 16 interactions with other paediatric haematologists
 17 looking after children with haemophilia elsewhere in
 18 the United Kingdom?

19 A. Well, not a great deal but I would meet them at
 20 meetings related to general haematology and
 21 haematological malignancy. People who went to those
 22 meetings often had a remit also looking after children
 23 with haemophilia.

24 Q. Were there any particular paediatric haematologists
 25 looking after children with haemophilia, with whom you

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1 If there were matters relating to haemophilia,
 2 then you could go along to Dr Mayne's office and
 3 discuss them. She was always available for me to ask
 4 about any clinical problem that I had difficulty with,
 5 among my haemophilia patients, and I could ask her and
 6 she was always very willing and obliging with her
 7 help.

8 Q. The blood bank and coagulation laboratory were based,
 9 as I understand your evidence, at the Royal Victoria
 10 Hospital and fell under the responsibility of
 11 Dr Mayne?

12 A. That's right.

13 Q. To what extent did you have ongoing dealings or
 14 a relationship in the 1980s with Professor Bridges?

15 A. Well, Professor Bridges was in charge of the academic
 16 Department of Haematology. He also had
 17 responsibilities for patients with malignant disease,
 18 and for those patients to be looked after on ward 22
 19 at the Royal Victoria Hospital, which is also the ward
 20 where the adult haemophilia patients were looked
 21 after.

22 His remit was entirely around general
 23 haematology and malignant haematology. He wasn't, as
 24 far as I know, involved in the care of adults with
 25 Haemophilia, although I think he probably did cover

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1 had more contact than others?

2 A. Well, I couldn't say, particularly. If I had needed
 3 to consult with a paediatric haematologist about
 4 haemophilia I'd probably have spoken to colleagues in
 5 Glasgow or in York Hill but that didn't arise too
 6 often. We had quite good links with the paediatric
 7 haematology oncology unit in Bristol but I don't know
 8 that they were involved in haemophilia care. I don't
 9 think they were.

10 Q. Now, in terms of the service at the Royal Belfast
 11 Hospital for Sick Children, was it a recognised
 12 haemophilia centre with UKHCDO, did it have a centre
 13 number in the 1980s?

14 A. Well, not that I'm aware of. I think we were
 15 established in tandem with the Royal. The Royal was
 16 a Comprehensive Care Centre -- the adult centre was a
 17 Comprehensive Care Centre, and we would look to the
 18 facilities in the Royal to support our care of the
 19 haemophilia patients in the Children's Hospital. So
 20 we were linked to the adult haemophilia unit.

21 I don't think we were ever recognised as being
 22 separate in any way although, from a *de facto* point of
 23 view, we were separate, from a patient management
 24 point of view, we were separate. But, as I say, we
 25 looked to the adult unit for support around

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1 coagulation, especially the coagulation laboratory was
 2 basically the Royal.

3 Q. Does it follow, then, that in terms of the information
 4 about how many products were being used and what type
 5 of products were being used in any given year, data
 6 relating to the Royal Belfast Children's Hospital
 7 would be included in the annual returns that were
 8 submitted by Dr Mayne to UKHCDO? You didn't submit
 9 separate returns?

10 A. No, I didn't submit separate returns, that's right.
 11 She amalgamated the returns in the Children's Hospital
 12 and sent them to Oxford as a unified whole.

13 Q. In terms of attendance at annual meetings of UKHCDO,
 14 the minutes which the Inquiry has seen suggest that
 15 you may have started attending regularly from around
 16 1988. Does that accord with your recollection?

17 A. I would have thought that I attended earlier. I would
 18 have -- from memory, I would have thought that I had
 19 gone to some of the meetings earlier. That's my
 20 recollection, yes.

21 Q. Whether or not you attended at the annual meetings in
 22 person in any particular year, did you receive
 23 the minutes of the -- (overspeaking) --

24 A. Yes, I think I did, yes.

25 Q. And you said in your statement that Dr Mayne would

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1 from volunteer donors sufficient plasma to provide
 2 the blood products required by patients living in
 3 that state, I think that would summarise the
 4 philosophy. And it seemed to me a perfectly sensible
 5 one, rather than relying on other nation states for
 6 plasma products.

7 Q. Do you have any knowledge as to why the arrangement
 8 with the Protein Fractionation Centre wasn't
 9 established earlier than it was?

10 A. I don't know why. I think we had a relationship
 11 with Elstree and -- the English fractionation centre
 12 prior to 1982. I don't know how that particularly
 13 arose. I think Elstree decided that they were going
 14 to distribute their products on a pro rata basis
 15 dependent on collection of plasma from the various
 16 regions of the UK, including Northern Ireland.
 17 Northern Ireland had difficulty initially in shipping
 18 fresh frozen plasma to the fractionation centre in
 19 England, and eventually, I think the arrangement with
 20 Scotland was arrived at because Scotland had the
 21 capacity to deal with the plasma that Northern Ireland
 22 was prepared to send -- or could eventually send, once
 23 the actual arrangements were established for sending
 24 it.

25 Q. Now I'm going to ask you shortly about your own use of

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1 also keep you up to date with what was being
 2 considered at UKHCDO level?

3 A. Yes, if there were matters of general interest, they
 4 would be discussed and she would discuss them with me.

5 Q. Now the Inquiry understands from evidence it's
 6 received and heard, that in the early 1980s, a link
 7 was established with the Protein Fractionation Centre
 8 in Edinburgh so that plasma collected in Northern
 9 Ireland previously possibly sent to BPL would be sent
 10 to Edinburgh for fractionation, and in return in
 11 Northern Ireland you'd receive the SNBTS factor
 12 concentrates.

13 Did you have any involvement with the
 14 discussions that led to the establishment of that
 15 arrangement?

16 A. No, not at all. I was aware that it happened in 1982
 17 but I wasn't involved in any discussions around it.

18 Q. And do you recall involvement in any discussions in
 19 Northern Ireland in the early 1980s about
 20 self-sufficiency and trying to achieve
 21 self-sufficiency?

22 A. Well, not particularly in Northern Ireland, but the
 23 philosophy of self-sufficiency I do recognise from an
 24 early date. It was a -- very much on people's agenda,
 25 yes. I mean, the idea that the state should collect

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1 SNBTS concentrates. But before we look at your own
 2 approach to treatment, the information the Inquiry has
 3 in relation to treatment at the adult Haemophilia
 4 Centre at the Royal Victoria Hospital suggests that
 5 commercial concentrates continued to be used to a very
 6 substantial extent from 1982 onwards in the first half
 7 of the 1980s. Do you recall whether you were aware of
 8 that or ever had any discussions with Dr Mayne about
 9 her use of commercial concentrates?

10 A. Well, I was aware when I was a senior registrar in
 11 the adult haemophilia unit in 1979, I was aware that
 12 commercial concentrates were used fairly extensively.
 13 After that, I lost contact with the arrangements that
 14 pertained in ward 22, so I didn't really have any
 15 clear impression about how extensive commercial
 16 products were being used in the adult centre after
 17 I left as a senior registrar and ultimately became
 18 a consultant. As to whether she spoke to me about it,
 19 no, she didn't. She didn't speak to me about it.

20 My arrangement with the blood bank was that I
 21 used the products that came into the blood bank,
 22 Dr Mayne negotiated for the products that came into
 23 the blood bank, be they blood products from SNBTS or
 24 elsewhere, be they commercial blood products.
 25 I selected from the products that were in the blood

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1 bank and used them to treat the patients under my
2 care. But I wasn't responsible for bringing product
3 into the blood bank in the Royal Victoria Hospital.
4 That wasn't one of my responsibilities. That was very
5 much her responsibility.

6 Q. So you had no involvement in the ordering arrangements
7 in the 1980s?

8 A. Oh, I had no arrangement, no part to play in the
9 ordering.

10 Q. And was that because that's just how it was, and that
11 was the situation you inherited? Did it strike you as
12 odd or concerning that as a consultant haematologist
13 caring for children, you weren't having a role in
14 those arrangements?

15 A. Well, no, it didn't bother me particularly. I didn't
16 aim to have a role. After all in the 1980s the amount
17 of product I was using for the children under my care
18 was pretty limited, pretty small. As we said, this
19 was a cohort of mildly to moderately affected children
20 who came irregularly for treatment, and their usage
21 was not great so the bulk of the material that was
22 brought in to the blood bank would have been used in
23 the adult centre, and it would always have been
24 appropriate that Dr Mayne did the ordering around
25 that.

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1 Centre Directors would still have a say in which
2 materials were purchased and this system would enable
3 the Department of Health and the Blood Transfusion
4 Service to have monthly returns on the amounts of
5 materials which were purchased and used. The
6 Reference Centre Directors were most concerned about
7 the effects of the DHSS's proposals on the day to day
8 running of their clinical practice and it was felt
9 that the scheme would result in a loss of
10 flexibility ..."

11 Then there is a worry about budgetary issues.
12 Then if we go to the last sentence of that paragraph:
13 "After much discussion it was agreed that the
14 Haemophilia Centre Directors would resist strongly the
15 transfer of factor VIII stock control to the Blood
16 Transfusion Service."

17 Dr Dempsey, recognising as I do that that was
18 not a meeting that you were present at and you
19 probably would not have seen the minutes, was that
20 issue the issue of whether Factor VIII stock control
21 should be transferred to the Blood Transfusion Service
22 and the resistance of the Haemophilia Centre Directors
23 to it, was that something that you were aware of or
24 that Dr Mayne ever discussed with you?

25 A. No, I wasn't -- I wasn't aware of that, no. Dr Mayne

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1 Q. I'm going to ask you to look at a set of minutes.
2 It's a meeting you were not present at. I just want
3 to ask you whether a particular issue was something
4 Dr Mayne discussed with you.
5 It's LOTH0000012_122.
6 You'll see, Dr Dempsey, that this is a meeting
7 of Haemophilia Reference Centre Directors,
8 September 1981, and the list of Reference Centre
9 Directors are there set out and we can see that
10 Dr Mayne was at the meeting.
11 If we go, please, to page 5. I just want to
12 pick up a discussion at the bottom of the page and
13 over the page, Dr Dempsey, so under the heading
14 "Distribution of Factor VIII and other Blood
15 Products", the minutes record this:
16 "Professor Bloom referred to a meeting in April
17 which the [DH] had called and to which representatives
18 of the Plasma Fractionation Laboratories, Haemophilia
19 Reference Centre Directors and Blood Transfusion
20 Services were invited. The main problems for the
21 Haemophilia Centre Directors was a recommendation from
22 the Department of Health that Blood Transfusion
23 Centres should purchase, hold, distribute and control
24 the stock of all blood products, including factor VIII
25 supplies. The [DoH] claimed that the Haemophilia

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1 appears to have held a budget for the -- at least
2 initially held a budget for the purchasing of
3 commercial Factor VIII, as far as I was aware. And
4 she did the negotiating, I presume she had the budget
5 for those purchases, at least initially.
6 I think I remember that, eventually, the
7 invoices went to the Blood Transfusion Centre and
8 Dr McClelland, when the product, the commercial
9 product came to the blood bank at the Royal. I think
10 that was ultimately the decision that was arrived at
11 somewhere along the line but, back in 1981, I think
12 she probably held the funds for the purchase of
13 commercial product.

14 Q. I'm going to ask you now to assist us with
15 understanding the approach to treatment that you
16 adopted from 1980, at the Royal Belfast Hospital for
17 Sick Children. So your witness statement tells us
18 that, from August 1980 when you took up your post, to
19 December 1982, you used some commercial concentrates,
20 Armour and Hemofil, also NHS Factor VIII and
21 cryoprecipitate, is that right?

22 A. Well, when I took up my post, I think cryoprecipitate
23 was used fairly exclusively in the unit. We had
24 a difficulty with a patient in 1981, a child was
25 admitted following an accident. There was no evidence

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1 of bleeding -- moderately affected child, no evidence
 2 of bleeding, but I think -- and I don't recollect the
 3 full details of the accident -- I felt that it was
 4 important to admit the child and cover the accident
 5 with Factor VIII.

6 So cryoprecipitate was given to get the factor
 7 level above 100 per cent, keep it above a trough level
 8 of 50 per cent, and see that it was given
 9 eight-hourly. The child had no evidence of bleeding
 10 in the late afternoon/evening but, despite the regime
 11 being closely followed, the following morning there
 12 was evidence of an intra-abdominal bleed,
 13 an intraperitoneal bleed, which was verified on
 14 ultrasound and which was a very worrying development.

15 The surgeons weren't keen to intervene,
 16 naturally enough. So, at that stage, I turned to the
 17 use of concentrate, and concentrate controlled the
 18 bleeding, and the child began to pick up. The
 19 bleeding was extensive enough for the child to require
 20 a blood transfusion. A factor level was done and the
 21 factor level was less than 10 per cent, whereas it
 22 should have been above a trough level of 50 per cent,
 23 and there was no evidence of an inhibitor. So that,
 24 to me, suggested that the cryoprecipitate had failed
 25 to do the job that was asked of it on that occasion,

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1 A. That's right.

2 Q. -- moderately affected children. It was the incident
 3 you've described, in 1981, that led you to switch from
 4 cryoprecipitate to concentrates, commercial
 5 concentrates, for moderately affected children, and
 6 then --

7 A. Right.

8 Q. -- you switched again in June 1983 -- we'll look at
 9 the letter in due course -- but -- the letter from
 10 UKHCDO -- you then stopped using commercial
 11 concentrates. And at that point did you then use the
 12 SNBTS concentrates?

13 A. Yes, SNBTS concentrate, yeah, from that point on.

14 Yeah.

15 Q. In terms of the type of commercial concentrates used
 16 during that intervening period, your statement
 17 suggests it was Armour and Hemofil. Was that simply
 18 a reflection of what was in stock at the blood bank or
 19 was that a conscious decision on your part to choose
 20 those products rather than any other product?

21 A. No, that was what was in the blood bank at that time.

22 Q. In terms of --

23 A. Hemofil in 1982, I think was being -- purchases were
 24 being reduced, and Armour Factorate was being
 25 increased. I think that was the pattern that was

27

1 and it definitely shook my confidence in
 2 cryoprecipitate, because we were looking at a very
 3 serious clinical situation that may have deteriorated
 4 with fatal consequences if it hadn't been picked up on
 5 the ward round.

6 At that point I introduced commercial treatment
 7 for this small group of moderately affected
 8 haemophilia A patients, after discussion with the
 9 parents and after due consideration of safety
 10 concerns, and that's the situation that remained in
 11 position for this small group of patients.

12 Cryoprecipitate remained as a treatment for mildly
 13 affected haemophilia A patients and von Willebrand's
 14 patients. But as I say, the commercial product was
 15 used for two years, from 1981 to 1983, and in
 16 June 1983, in consequence of the letter that came from
 17 UKHCDO, those children were transferred to SNBTS
 18 concentrate at that point and stopped using commercial
 19 material. And of course -- (overspeaking) --
 20 the AIDS -- the developing AIDS problem.

21 Q. So just to understand the chronology, is it right,
 22 then, that in 1980, joining the hospital as
 23 a consultant in August, you continued your
 24 predecessor's policy initially of using
 25 cryoprecipitate, including for the --

26

1 established in 1982, but yes, Hemofil and Armour were
 2 the two products that I used in that small group of
 3 moderately affected haemophilia A patients.

4 Q. In terms, then, of the choice between commercial
 5 concentrates and NHS concentrates in this period
 6 from 1981 to June 1983, why did you not choose to use
 7 SNBTS concentrate in preference to the commercial
 8 concentrate?

9 A. Well, I suppose SNBTS wasn't available in 1981. But
 10 they only established the link in 1982. But Elstree
 11 would have been available.

12 In 1981, the AIDS scare -- the AIDS crisis
 13 hadn't begun to emerge. The main safety question was
 14 around non-A, non-B hepatitis.

15 Hepatitis had been associated with commercial
 16 concentrates in the mid-70s, but a lot of those cases
 17 had been hepatitis B, and the firms were keen to
 18 advise us that that problem had been tackled with
 19 adequate testing of their donor population. They were
 20 also keen to emphasise the fact that they'd tightened
 21 up on the type of donor they looked to for their
 22 plasma source. So given that reassurance, I was
 23 disposed to look favourably on commercial products at
 24 that point in time.

25 I chose a commercial product because it was --

28

1 the commercial product was easier to reconstitute.
 2 But that's not an essential feature. What was more
 3 important was that you could make the commercial
 4 concentrate up in a much smaller volume and it was
 5 less viscous. And that meant that it was easier to
 6 administer to -- into the veins of the paediatric
 7 patient. And I found that the volume of
 8 reconstitution was quite helpful, and that's what
 9 tipped me over into favouring commercial concentrate
 10 at that time.

11 I wasn't persuaded at that time that the
 12 incidence of non-A, non-B hepatitis was greater in
 13 commercial product by comparison with those who
 14 received NHS concentrate.

15 Q. I want to come back in a little while to the issues
 16 relating to the hepatitis risks and relative risks of
 17 hepatitis but can I just ask this, you refer to a
 18 degree of reassurance -- I'm not sure if that's the
 19 word you use, but that's my summary -- from
 20 pharmaceutical companies about their products from
 21 a hepatitis perspective and in terms of donor
 22 selection and testing. What information did you have
 23 and from whom about what pharmaceutical companies were
 24 saying.

25 A. Well, I had it from representatives and it was verbal.

29

1 concentrates, I was anxious and apprehensive about
 2 repeatedly injecting patients with any material,
 3 particularly over periods of weeks and months via the
 4 intravenous route. Therefore, I decided that all
 5 children should remain on treatment with
 6 cryoprecipitate. This was early in the 1970s and
 7 Dr John Bridges, the paediatric haematologist, was
 8 happy with the decision. Later in 1982, his newly
 9 appointed successor, Dr Dempsey, was even more
 10 enthusiastic about using cryo in this way than myself.
 11 However, we agreed an exception should be made in
 12 respect of a very limited category of patient.

13 "14.4 In addition to the two severely affected
 14 paediatric patients already on home treatment, it was
 15 decided that patients with brain injuries or those who
 16 required major surgery should have definitive amounts
 17 of Factor VIII concentrate to guarantee the
 18 achievement of 100% VIII C levels. Fortunately, the
 19 situation never arose and concentrates were never used
 20 in those circumstances during my time."

21 Now, before we look at 14.5, I just want to ask
 22 you about a couple of matters there. Firstly, this
 23 indicates, it would appear, a decision in the '70s by
 24 Dr Mayne that children should be treated with
 25 cryoprecipitate, and then suggests that you were

31

1 But they were questioned fairly intensively because
 2 the products had a bad reputation in the '70s, and
 3 they were conscious that they would be asked these
 4 questions and that they would have to give
 5 a convincing answer.

6 I mean, I had to rely on the fact that they were
 7 telling me the truth. They were no more likely to
 8 have the truth in any documentation or literature they
 9 produced, and they did produce literature, actually,
 10 to go with their product. And, again, that told the
 11 same story.

12 These were licensed products. It's very hard to
 13 interrogate what commercial companies are doing if
 14 they choose to tell you untruths but, ultimately,
 15 I had to accept that these were ethical companies and
 16 that the information they provided was true, and that
 17 was my position.

18 Q. Can I ask you to look at one passage in Dr Mayne's
 19 statement, WITN0736009, please, Sully, and if we could
 20 go to page 15. Yes, so it's the first three
 21 paragraphs I just wanted to read out and invite your
 22 observations on, Dr Dempsey.

23 This was Dr Mayne talking about cryoprecipitate.
 24 She says:

25 "When planning for home treatment with

30

1 an enthusiast for cryoprecipitate. That would appear
 2 to be incorrect, based upon the evidence you've
 3 provided to the Inquiry.

4 A. I think that would be putting it a little strongly,
 5 saying that I was "even more enthusiastic".
 6 I accepted what the treatment arrangements were when
 7 I came initially and I proceeded to treat patients as
 8 they had been treated prior to my appointment. So
 9 that was my approach to cryoprecipitate at that time.
 10 I wouldn't say I was "even more enthusiastic", but --
 11 that would be my position.

12 Q. When you decided to change the approach from
 13 cryoprecipitate for your moderately affected patients
 14 to commercial concentrates, did you discuss that with
 15 Dr Mayne, as far as you can recall?

16 A. Well, I think -- oh, yes, at some stage she would have
 17 been aware of what I had decided and what I did. But
 18 I made the decision and I took the action I did, and
 19 I didn't look to her for approval of the action
 20 I took. So it was my responsibility, my decision and
 21 my action, to change the treatment and do what I did.

22 I definitely -- she was definitely aware of it
 23 at some later stage because I remember talking to her
 24 about it. She didn't register any particular comment
 25 in relation to the information, as far as I can

32

1 remember.

2 **Q.** Then you'll see the reference in 14.4 to the two

3 severely affected paediatric patients who were on home

4 treatment. Now, that may be patients who'd been

5 established as paediatric patients in the 1970s, but

6 did you have any awareness of Dr Mayne having

7 paediatric patients under her care?

8 **A.** No. I know that Dr Bridges, Professor Bridges had

9 a close link with Dr Mayne, and any decisions to put

10 paediatric patients on concentrates in the 70s were

11 arrived at jointly. There may have been one boy on --

12 a severely affected boy on concentrate at around the

13 time I was appointed, or before the time I was

14 appointed, and I think he was referred to the adult

15 unit having reached the age of 14, before I was

16 appointed, and he wasn't there when I came back to the

17 unit in August 1980, having worked in -- in the unit

18 up to December 1979. He was there in September or

19 December 1979, he wasn't there in 1980, and I think

20 he'd been referred to the Royal in the interim.

21 But there were no other children on concentrate

22 that I can recall when I took up post in August 1980,

23 and there were certainly none on home treatment, and

24 I don't remember any on home treatment when I worked

25 in the Children's Hospital as a senior registrar in

33

1 have to needle the child again. So we're back to the

2 situation where the size of the injection or the

3 volume of the injection is quite important.

4 So cryoprecipitate was fairly bulky, and for

5 older children, the amount would probably necessitate

6 erecting a drip and putting intravenous cannulae in.

7 And I never liked doing that, because intravenous

8 cannulae could lead to thrombosis of a vein and the

9 haemophilia patient is critically reliant on

10 intravenous access over a lifetime and their veins

11 needed to be protected and looked after from an early

12 age, and erecting an intravenous drip, putting in an

13 intravenous cannula was to be avoided if possible. So

14 that was a side effect, or a disagreeable attribute of

15 having to use cryoprecipitate in anything in a child

16 over maybe about 15 kilograms, aged five plus. So it

17 wasn't all that convenient to employ it in routine

18 care.

19 **Q.** Again, I want to pick up some issues relating to

20 cryoprecipitate in a while but just sticking with what

21 product choices were made first of all, you have

22 referred to June 1983 and advice from UKHCDO.

23 Can we look at HCDO000270_004.

24 This is a letter from Professor Bloom and

25 Dr Rizza dated 24 June 1983, headed "[AIDS]". It

35

1 1979.

2 **Q.** Then you'll see paragraph 14.5 Dr Mayne continues:

3 "Due to their diminutive size, children did not

4 require large doses of cryoprecipitate to be

5 effective. This reduced the likelihood of allergic

6 reactions which were common in adult patients who did

7 require larger doses. There are a number of problems

8 associated with cryoprecipitate in large doses."

9 Then I'm not going to go through what she says

10 in relation to that.

11 You'll see there Dr Mayne's view about

12 cryoprecipitate being suitable for children. Do you

13 recall discussions about that? Was that something you

14 disagreed with?

15 **A.** No, I agreed with it up to a point. Again, there's

16 a volume problem with children of any size. I mean,

17 a 15-kilogram child aged five, if you're dealing with

18 a bleed here, you're going to have a fair amount of

19 cryoprecipitate to syringe in through a vein if you're

20 going to level up to 30 per cent, 40 per cent, and

21 control the bleed. And cryoprecipitate was fairly

22 bulky, and it was fairly viscous stuff try to give

23 intravenously. And obviously you wanted to effect

24 a venepuncture on one occasion when you're giving an

25 injection and not have it fail halfway through and

34

1 refers in the first paragraph to:

2 "A Meeting of Regional Transfusion Directors ...

3 [in] May ... to discuss this problem [of AIDS] in

4 haemophilia, its implications and our

5 recommendations."

6 Then the second paragraph says this:

7 "At the above mentioned meeting on May 13th the

8 following general recommendations were agreed.

9 "1. For mildly affected patients with

10 haemophilia A or von Willebrand's disease and minor

11 lesions, treatment with DDAVP should be considered.

12 Because of the increased risk of transmitting

13 hepatitis by means of large pool concentrates in such

14 patients, this is in any case the usual practice of

15 many Directors.

16 "2. For treatment of children and mildly

17 affected patients or patients unexposed to imported

18 concentrates many Directors already reserve supplies

19 of NHS concentrates (cryoprecipitate or freeze-dried)

20 and it would be circumspect to continue this policy."

21 So was it this document that led to your change

22 of approach on the treatment of your moderately

23 affected patients, Dr Dempsey?

24 **A.** Yes, that's right. It was. Yes.

25 **Q.** So in relation to the moderate patients, you stopped

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1 using the commercial concentrates and started using
 2 the SNBTS concentrates; is that correct?
 3 **A.** Yes, that's right. Yes.
 4 **Q.** Did you have any particular problems or difficulties
 5 with the SNBTS product?
 6 **A.** Well, no. I mean, I felt that it was a question of
 7 having to change product. And when I started to use
 8 it, I didn't have any particular problems with it. It
 9 seemed perfectly acceptable. Probably the volume of
 10 reconstitution was larger and it's probably more
 11 difficult to reconstitute, in other words you have to
 12 agitate the vial for longer period of time to get
 13 the product into solution, but those were acceptable
 14 in the circumstances that we were dealing with then.
 15 So yes, it was an acceptable substitute for the
 16 commercial product.
 17 **Q.** Once you switched to the SNBTS product in 1983, did
 18 you then have to, in 1983, through 1984 and until
 19 heat-treated concentrates came along, which I'll come
 20 to later, did you have to use commercial concentrates
 21 at all or was there an adequate supply of SNBTS
 22 product to enable you to treat all your moderately
 23 affected patients with it?
 24 **A.** Oh, there was an adequate supply. But we've got to
 25 remember that I was using fairly limited quantities of

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1 with parental consent, of course. I mean, nothing was
 2 ever done without talking to the parents and
 3 explaining what we were doing or what we hoped to do,
 4 and why. So there were lengthy discussions with the
 5 parents at that time about what we suggested was the
 6 best way forward.
 7 **Q.** I'll come on later to ask you about the information
 8 provided to parents but, just in relation to the
 9 specific question, is it the case, then, that from
 10 a date in 1981, all moderately affected children,
 11 whatever their age, would be treated with the
 12 commercial concentrates and then from June with the
 13 SNBTS concentrates?
 14 **A.** That was the plan. I don't think -- I can't remember
 15 any new patients who I would categorise as moderate
 16 turned up and got initiated on concentrate. I can't
 17 remember any new patient appearing who'd have fallen
 18 into that category. Because new patients back then
 19 were very few and far between, for whatever reason.
 20 So the cohort that we had were started on commercial
 21 product and then that cohort was moved to SNBTS
 22 Factor VIII.
 23 **Q.** Did you have, in this period, the first half of the
 24 1980s, any patients with inhibitors?
 25 **A.** I thought not but, on reflection, I think there may

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1 material at that time because the cohort of patients
 2 were as they were, mildly, moderately affected. And
 3 they came infrequently and the amount of product that
 4 was used was limited. So there was sufficient for my
 5 needs, yes, certainly.
 6 **Q.** And did you ask Dr Mayne or ask the blood bank to
 7 ensure that there was always a sufficient supply of
 8 SNBTS product put aside for your patients, in other
 9 words a system of prioritisation, or did you not need
 10 to do that because you were using it in such low
 11 quantities?
 12 **A.** I didn't really need to ask them to prioritise my
 13 requirement, no. They knew I'd switched over.
 14 I spoke to Mr Carville in the blood bank, and he was
 15 aware of that.
 16 **Q.** Now, the approach you've taken up until this point
 17 June 1983 in relation to the moderately affected
 18 patients, did that apply to all your moderately
 19 affected patients? I know the numbers are not huge,
 20 but all of them, irrespective of age?
 21 **A.** Well, I --
 22 **Q.** And do you recall what the age range was?
 23 **A.** I can't remember what the age range was. I mean, we
 24 dealt with all age ranges. I can't remember what the
 25 age range was. I mean, these changes were effected

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1 have been one boy with a low responding inhibitor,
 2 that was easy enough to manage by increasing the
 3 quantity of Factor VIII to give on each occasion, so
 4 you could neutralise the inhibitor fairly effectively.
 5 So it wasn't in any way a major problem. Other than
 6 that, we had no inhibitor patients.
 7 **Q.** Was there any policy of what some others have referred
 8 to as "batch dedication", in other words trying to
 9 keep a patient, whether receiving of a commercial
 10 concentrate or an SNBTS product, as much as possible
 11 on the same batch rather than different types of
 12 product or different batches?
 13 **A.** Well, we tried to keep the product the same, if
 14 possible. Keeping batches was extremely difficult and
 15 I don't think we were ever able to get that to work.
 16 So we tried to keep the same product going, insofar as
 17 possible, but dedicated batches, no.
 18 **Q.** Can I then turn to the treatment of patients with mild
 19 haemophilia in the first half of the 1980s. Your
 20 statement suggests that patients with mild haemophilia
 21 were treated with cryoprecipitate or DDAVP. Do you
 22 recall whether you ever treated a mild haemophiliac in
 23 the first half of the '80s with a concentrate?
 24 **A.** I can't think that I did. DDAVP was used in the first
 25 instance and then, if we felt it necessary,

40

1 cryoprecipitate. DDAVP and Cyklokapron -- tranexamic
 2 acid -- and then cryoprecipitate. So I don't remember
 3 using the concentrate.
 4 **Q.** Now, I don't think we see DDAVP itemised on the annual
 5 returns during this period. Are you confident it was
 6 used at the Royal Belfast Hospital in 1980 onwards?
 7 **A.** Yes, it was, because I prescribed it. Collecting data
 8 on DDAVP was never very comprehensive. The patients
 9 were written up for the DDAVP, it was treated as
 10 a pharmaceutical product and given as a drug and
 11 treated as a drug, and data capture was never as well
 12 done as it should have been. So the fact that it
 13 didn't appear on returns to any extent doesn't
 14 necessarily mean that it wasn't being used. That's my
 15 feeling about DDAVP.
 16 **Q.** During that period in, I think, 1979 or so where you
 17 were a senior registrar at the Royal Victoria
 18 Hospital, and working for some part of your time under
 19 Dr Mayne in the haemophilia centre, was DDAVP in use
 20 there, do you recall?
 21 **A.** Yes, I think it was, yeah. I think I remember it
 22 being used. Occasionally, yeah.
 23 **Q.** Did you ever use a porcine product?
 24 **A.** No, because that was really for patients with high
 25 responding inhibitors, and I never had -- in the early

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1 a well established fact. Thereafter in the '70s, the
 2 mid-'70s, I was aware that hepatitis B had been
 3 a problem, was a problem, especially around
 4 transfusion of blood products. And that was a problem
 5 that remained ever present until effective screening
 6 procedures were introduced.
 7 But there was still a cohort of patients who
 8 were not hepatitis A sufferers, who were not
 9 hepatitis B sufferers, who had experienced jaundice
 10 following transfusion, and they were referred to as
 11 non-A, non-B hepatitis sufferers, because there was no
 12 agent that had been identified to account for it, and
 13 yet it seemed highly likely that a viral agent might
 14 be responsible. So that was the initial impression
 15 I had around hepatitis in the '70s.
 16 **Q.** By the --
 17 **A.** As for the severity of non-A, non-B hepatitis, well,
 18 I suppose in relation to haemophilia, we knew that
 19 there were a small number of patients who had serious
 20 liver disease, and that might have been related to
 21 preceding infection, it might have been related to
 22 preceding jaundice. But, for the most part, we
 23 thought that patients who had jaundice following blood
 24 products made a fairly full recovery, and those who
 25 did show minor abnormalities in transaminase levels we

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1 '80s certainly, and in the '80s, I didn't have
 2 patients with inhibitors. Later on, when I did have
 3 patients with inhibitors in the '90s, I never used
 4 porcine Factor VIII. I never had to use it.
 5 **Q.** Do you recall using the BPL concentrate at all in the
 6 early 1980s?
 7 **A.** That was the Elstree Factor VIII. Yes, it's difficult
 8 to recall. I don't think -- because it doesn't fit
 9 into my treatment regime, I don't think I probably
 10 used it. I don't think I used it. By the time I'd
 11 gone to NHS concentrate, it was SNBTS that I was
 12 using. But I think -- when I remember using it,
 13 I think, in ward 22 on occasion, in 1979.
 14 **Q.** Now, I want to move to ask you some questions about
 15 hepatitis and then AIDS knowledge and then I want to
 16 come back to some of the issues relating to product
 17 choices, once we've explored that.
 18 First of all, in general terms, can you recall
 19 what you learnt in your general medical training and
 20 then in your specific haematology training about the
 21 risks of viral transmission from blood or blood
 22 products.
 23 **A.** Well, I think way back when I was a medical SHO doing
 24 membership exams, I think I appreciated that jaundice
 25 could follow blood transfusion. I think that was

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1 didn't think would progress to any serious state of
 2 ill health.
 3 **Q.** The Inquiry has heard evidence about a World in Action
 4 documentary broadcast at the end of 1975 which looked
 5 at donor practices in the States, and the
 6 contamination with hepatitis of concentrates being
 7 used in the United States and in the United Kingdom.
 8 Do you recall whether you saw or heard about that
 9 documentary at the time? I think this was during your
 10 time in haematology training?
 11 **A.** Yes, haematology training at the City Hospital. I may
 12 have seen it. I can't remember if I saw it at the
 13 time, certainly heard plenty about it later on, but
 14 I would doubt that perhaps I hadn't seen it at the
 15 time. It was very relevant, of course, to patients
 16 with haemophilia, but no patients with haemophilia
 17 were seen in the City Hospital at that time. So I may
 18 not have seen it.
 19 **Q.** The Inquiry has also --
 20 **A.** Sorry, it would have had general relevance in terms of
 21 blood products. After all, every haematologist used
 22 blood transfusion and platelet transfusions, and
 23 anything that related to the transmission of infection
 24 from blood products would have been of interest.
 25 Whether I saw it, as I say, I can't remember at the

44

1 time.

2 **Q.** You were the senior registrar '78 to '79 under

3 Dr Mayne and Dr Bridges. Can you recall any

4 discussions with them or any training from them about

5 risks of hepatitis and the implications of hepatitis

6 for decision making on treatment of haemophilia

7 patients? Because this was your first experience,

8 I think, of haemophilia in '78/79?

9 **A.** Yes, that's right. Oh gosh, it was -- I think it

10 would be fair to say they were well aware of it as

11 a feature, and as a potential problem. Yeah, it was

12 discussed, and -- yeah. There was an awareness.

13 There was nothing novel about it when I came to be

14 a consultant. There was an awareness of the

15 condition.

16 And, as I say, there were patients, I think, who

17 were known to the unit and -- with haemophilia, who

18 had severe liver disease. So it was very much a topic

19 that was comprehended.

20 **Q.** The Inquiry has heard evidence about a paper published

21 in 1978, work from Sheffield under Professor Preston

22 involving liver biopsy analysis and looking at the

23 consequences of chronic liver disease in relation to

24 haemophilia patients. Is that a piece of work or

25 a publication that you recall being aware of at the

45

1 time?

2 **A.** Um, I can't aware -- I can't say that I was aware

3 of it being discussed. It may well have been

4 discussed, just -- I mean, I've heard of it since very

5 many times. It's very hard to know when you first

6 hear about a bit of information like that, or first

7 hear of a paper, when you've heard about it at length

8 subsequently. So it may have been discussed, and it

9 probably was, but I can't say for certain that I

10 remember it being discussed in 1978.

11 **MS RICHARDS:** Sir, I note the time. I've got a number

12 more questions on this topic, so perhaps we could take

13 a break now and then pick them up afterwards.

14 **SIR BRIAN LANGSTAFF:** Yes, very well.

15 Well, we'll take a break until 11.45.

16 Now, Dr Dempsey, this is the first break in your

17 evidence. Let me say what I say to all witnesses at

18 this stage, if I haven't already said it, and that is:

19 you're giving evidence, you must not talk to anyone

20 about the evidence you have given or the evidence you

21 think you may yet be asked to give, but you can talk

22 about anything else you like.

23 I look forward to seeing you back at 11.45.

(11.16 am)

(A short break)

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1 (11.44 am)

2 **SIR BRIAN LANGSTAFF:** Yes?

3 **MS RICHARDS:** Dr Dempsey, I just want to ask you a little

4 more about hepatitis. Sully, could we have

5 Dr Dempsey's statement on screen, WITN5560001 and go

6 to page 15, first of all.

7 Now at the bottom of the page you say this, in

8 paragraph 21.1:

9 "Commercial factor concentrates had been

10 associated with an outbreak of Hepatitis B in the

11 early/mid 1970s. By 1980 Hepatitis B testing of

12 donors and more careful donor selection had improved

13 the safety profile of commercial concentrates."

14 Then you say:

15 "[You] were not aware of any difference between

16 commercial concentrate and NHS concentrate with regard

17 to the background concerns about the transmission of

18 Non-A Non-B Hepatitis ..."

19 Just sticking first of all with hepatitis B,

20 would it be right to understand that, as at 1980, you

21 were aware that hepatitis B could be a very serious

22 condition?

23 **A.** Oh, yes, very much so.

24 **Q.** Then, as I understand your evidence, before the break,

25 the basis for your view that there was an improved

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1 safety profile of commercial concentrates in relation

2 hepatitis B were the assurances or information you'd

3 been provided with by pharmaceutical reps?

4 **A.** Well, in large measure, but I think there was feed

5 through also from the UKHCDO about this, and I got the

6 impression from reading minutes that, as far as they

7 were concerned, things had improved considerably.

8 **Q.** Do you recall what your understanding was of the

9 sensitivity of the hepatitis B tests and the different

10 types of hepatitis B tests that were available by

11 1980?

12 **A.** Well, I think there had been general -- I can't

13 remember exactly but I think there had been a growing

14 improvement, but I wasn't conscious that there was

15 a major problem with the residuum of hepatitis B

16 infection by 1980. I mean, obviously, the patients

17 who'd been infected in the past were still there but

18 I wasn't conscious that there was a still

19 a significant number of new cases coming through.

20 I mean, I was conscious that screening might not be

21 100 per cent effective at screening out hepatitis B,

22 but I wasn't aware that there were a continuing stream

23 of new cases --

24 **Q.** Now --

25 **A.** -- rather the opposite.

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1 Q. Now, there obviously wasn't testing for non-A, non-B
2 hepatitis at this point in time but did the assurance
3 you've received about more careful donor selection
4 procedures also reassure you that there was a reduced
5 risk of non-A, non-B hepatitis from the use of
6 concentrates?

7 A. I would have thought that there was still a risk of
8 non-A, non-B hepatitis with commercial concentrates.
9 But then I was aware there was a risk of non-A, non-B
10 hepatitis with NHS concentrates as well. Obviously,
11 as you say, there was no testing for non-A, non-B
12 hepatitis, and it's -- I mean, what more can one do
13 except screen the donors and exclude certain groups
14 and hope that that improves the profile of your panel
15 of donors and the plasma that comes to be fractionated
16 as a result? Excluding non-A, non-B would have been
17 a difficult task without having any criteria that you
18 could go by.

19 Q. Now, if one leaves aside the relative risks of
20 transmission of non-A, non-B hepatitis from commercial
21 or NHS concentrates, if one takes the class of
22 concentrates as a whole, and compares that to
23 cryoprecipitate, did you understand that there was
24 a greater risk of transmission of non-A, non-B
25 hepatitis through the use of concentrates than

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1 WITN5560001, and could we go to the bottom of page 16
2 to start with. You say there in paragraph 23.2:

3 "In relation to Non-A Non-B Hepatitis
4 I understood that occasional cases of jaundice had
5 been noted in relation to the administration of factor
6 concentrate."

7 Then if we go to the top of the next page, 23.3:

8 "A small number of cases of cirrhosis had been
9 documented. Subtle variations in liver function tests
10 were also noted in some patients. The problem was of
11 concern and was actively monitored but not thought
12 sufficiently serious to merit withdrawal of the only
13 really effective treatment for severe/moderate
14 haemophilia which carried a high risk of death and
15 crippling from uncontrolled haemorrhage."

16 Then, if we could just also go down a little
17 further, so we can see paragraph 23.5, you say there:

18 "Non-A Non-B Hepatitis, I appreciated, could
19 cause chronic liver disease and was transmissible by
20 blood products but in most cases was a self-limiting
21 condition without long term ill-effects."

22 Can you keep that up on the screen as it is,
23 please, Sully.

24 Can I ask you, first of all, about what you say
25 in paragraph 23.3 where you say the problem was of

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1 cryoprecipitate, because the recipient would be
2 exposed to vastly more donations?

3 A. Oh, yes, I realised that, at least in the short-term,
4 the risks with cryoprecipitate were very much less.
5 But, obviously, the more cryoprecipitate you got, over
6 a number of months, years, the greater exposure to
7 an increasing number of donations that went into that
8 cryoprecipitate. Your risk of developing or
9 contracting non-A, non-B hepatitis would increase over
10 time. So cryoprecipitate wasn't without risk also,
11 but reduced risk, certainly in the short-term, very
12 much reduced risk.

13 Q. For the cohort of patients, whom you were treating
14 with concentrates, the moderately affected patients,
15 those were, as I understand your evidence, relatively
16 infrequent attenders, you were not dealing with the
17 severely affected patients who, if they had been
18 treated with cryoprecipitate, would, as you say, be
19 receiving it on a regular basis?

20 A. They weren't coming very regularly, no. Yes --

21 Q. Then can we go back -- sorry.

22 A. Sorry, I keep adding to the sentences.

23 Sorry, this group of moderate haemophilia
24 patients, yes.

25 Q. Then can we go back to your statement, please,

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1 concern and was actively monitored. What kind of
2 active monitoring was undertaken for your cohort of
3 patients?

4 A. Well, just regular liver function tests, repeated when
5 the patients were routinely reviewed. I'm not saying
6 that I had any cases that I could definitely say were
7 non-A, non-B hepatitis but it was the case that
8 patients with haemophilia were monitored as a routine
9 with the repeat liver function tests, and people
10 looked at them and wondered about them, but provided
11 they weren't very elevated, then people didn't, at
12 times, know what to make of them.

13 Q. Then -- sorry.

14 A. Sorry.

15 Q. Carry on.

16 A. No, no, it was just an add-on to the sentence. There
17 wasn't anything major in it.

18 Q. Then paragraph 23.5, you talk about non-A, non-B
19 hepatitis in most cases being "a self-limiting
20 condition without long-term ill effects". What was
21 the evidential, factual basis for that, your
22 understanding of non-A, non-B hepatitis in those
23 terms?

24 A. Well, that was really around 1980, and we were on
25 a learning curve from 1980 on. The feeling that it

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1 wasn't a major concern was the general feeling among,
2 I think, haemophilia specialists and liver
3 specialists, generally. I can't quote chapter and
4 verse on it but I think that was the general feeling
5 at that time. But that's not to say that some
6 patients didn't have, at that time, evidence of
7 chronic liver disease, and certainly there were
8 patients like that in the adult haemophilia service in
9 the Royal Victoria Hospital.

10 **Q.** Wasn't the risk of chronic liver disease, albeit that
11 that might not be in most cases, but wasn't that risk
12 in itself a sufficient justification for preferring
13 cryoprecipitate to concentrates for the bulk of
14 moderately affected children?

15 **A.** Well, it would be if you had complete faith in
16 cryoprecipitate, but my faith in cryoprecipitate had
17 been severely damaged by the case I explained to you
18 earlier. I mean, when we come to look at joint
19 bleeds, a moderate patient may not bleed as frequently
20 as a severe patient, but the bleed, when it happens,
21 can be just as severe as any bleed in a severe
22 patient, and it must be adequately controlled.

23 If you lose control of joint bleeds, the risk is
24 that a joint will start deteriorating in as short
25 a space of time as a couple of months, if you get

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1 concentrates were the only really effective treatment
2 for moderate haemophilia, whatever the nature of the
3 bleed, whatever the frequency of the bleeding?
4 **A.** Well, I suppose that sentence would apply especially
5 to severe haemophilia patients who were rebleeding on
6 a regular basis. Moderate haemophilia patients with
7 factor levels of 2 to 5 per cent, it depends really
8 how frequently they'd bleed and I suppose, within that
9 category, you could get a degree of variation.

10 Internal bleeding is always a problem, and
11 internal bleeding especially can lead to pretty rapid
12 death in the haemophilia patient, and to rely on
13 cryoprecipitate in a situation like that, especially
14 in a moderate patient, or indeed a severe patient, is
15 taking a major risk.

16 As for joints, well, I suppose if you're happy
17 to try the cryoprecipitate -- but, you know, you look
18 at the joint, if you're not happy with
19 cryoprecipitate, you look at the joint you're managing
20 and you worry that it's not settling quickly enough
21 and you worry, is it really the cryoprecipitate is not
22 controlling this haemorrhage and maybe I should use
23 concentrate here in case there's going to be damage,
24 and maybe this joint has re-bled very quickly, and
25 maybe the cryoprecipitate that I was using hasn't

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1 bleeding and rebleeding and a cycle of rebleeding.
2 You're looking at degeneration starting inside the
3 space of two to three months, and it's absolutely
4 critical that effective control of joint bleeds is
5 affected because, otherwise, you're going to end up
6 with the patient with the crippling arthritis, the
7 crippling arthritis that was so typical of haemophilia
8 patients in the past.

9 So if one has faith in cryoprecipitate then, by
10 all means, it's the treatment of choice but I think,
11 if you feel that it's probably not or if you're
12 worried that it's not going to achieve what you set
13 out to achieve, then you've got to think again and
14 you've got to look at the possibility of
15 cryoprecipitate treatment as an alternative. So
16 I think that summarises what I was going to say.

17 **Q.** If we then just look back up on the screen,
18 paragraph 23.3, you say non-A, non-B hepatitis:
19 "... not thought sufficiently serious to merit
20 withdrawal of the only really effective treatment for
21 severe/moderate haemophilia which carried a high risk
22 of death and crippling from uncontrolled haemorrhage."

23 Now, we leave aside severe haemophilia because
24 you weren't treating patients with severe haemophilia
25 at that time; was it really your view that

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1 sufficiently controlled this joint, and do I keep on
2 with cryoprecipitate or should I go on to concentrate?

3 You're always going to have this conversation
4 with yourself, if you've any degree of worry about the
5 effectiveness of cryoprecipitate. If you're totally
6 convinced that cryoprecipitate is the treatment of
7 choice, then you're going to have faith in it and
8 you're going to be more reliant on it and less likely
9 to worry about having to intervene with concentrate.

10 **Q.** As I understand it, Dr Dempsey, you essentially
11 switched from what had been a policy of
12 cryoprecipitate for all moderately affected patients,
13 your predecessor's policy which you inherited and
14 continued for a while, to a policy of commercial
15 concentrates for all moderately affected patients.
16 Having regard to the risks of non-A, non-B hepatitis,
17 do you think, looking back now, that a more nuanced
18 approach might have been more appropriate whereby you
19 looked at each individual moderate patient and asked
20 yourself whether in the first instance, given the
21 reduced risk of non-A, non-B, cryoprecipitate was
22 right for that child on that occasion?

23 **A.** Well, possibly. But you might have ended up in
24 a situation where you were using cryoprecipitate
25 sometimes and you were using concentrate sometimes.

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1 And if you're using concentrate at all, you'd be
 2 subjecting the child to the increased risk of the
 3 non-A, non-B hepatitis if you introduced the
 4 concentrate at all. So it would either have to be
 5 totally cryoprecipitate, I think. You couldn't have
 6 a mixture of cryoprecipitate and concentrate every
 7 time you worried about it. But I suppose a nuanced
 8 approach might be -- have been more appropriate.
 9 In retrospect, I wouldn't have used the
 10 concentrates at all, given what was likely -- or what
 11 was going to happen further down the road. And when
 12 I look back on it, I feel that the NHS product might
 13 have been a better modality of treatment to have
 14 employed back in 1981. But there was still, as I say,
 15 a risk of non-A, non-B hepatitis from NHS products.
 16 So we -- I wouldn't have escaped that, the possibility
 17 of inducing or seeing non-A, non-B hepatitis arise in
 18 patients if I used only NHS material.
 19 **Q.** Can I move to the awareness of AIDS. We've touched on
 20 it obviously because of your change of approach on
 21 seeing the advice from UKHCDO in June 1983. Do you
 22 recall how and when you began to understand that there
 23 were cases of AIDS being reported in haemophiliacs in
 24 the States and cases of blood transfusion-transmitted
 25 AIDS?

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1 various stages, but more broadly, from late 1982
 2 onwards, were you ever under any real doubt that AIDS
 3 was transmissible by blood or blood products?
 4 **A.** Um, well, I was in no major doubt. I was in no major
 5 doubt, because any alternative theory didn't really
 6 seem to hold water. So I suppose I was in no real
 7 doubt, but the haemophilia community were not prepared
 8 to commit themselves totally and utterly to AIDS
 9 being -- the idea of AIDS being related to
 10 transmission by blood products. And when I've
 11 referred to the possibility of the relationship, I'm
 12 really echoing the feelings of the UKHCDO of which
 13 I was aware.
 14 **Q.** Now, you made the change from the commercial
 15 concentrates to the SNBTS product after seeing that
 16 advice from UKHCDO in June 1983. As I understand your
 17 statement, you then continued using the SNBTS product
 18 and then, in the autumn of 1984, you became aware that
 19 there were reports from Edinburgh of the SNBTS product
 20 having -- or patients in Edinburgh treated with the
 21 SNBTS product having been infected with HTLV-III. Can
 22 you remember how or from whom you heard about what had
 23 happened in Edinburgh?
 24 **A.** I'm not quite sure. It either came through Dr Mayne
 25 or perhaps through the blood bank. That information

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1 **A.** Well, I think I -- well, that was in 1982 or the
 2 latter part of 1982, I think I would have been aware
 3 of that then, yes.
 4 **Q.** We know that in January 1983, Dr Mayne, along with
 5 a number of others, not you, attended a meeting at the
 6 Excelsior Hotel at London Heathrow Airport with reps
 7 from Immuno but also other Reference Centre Directors
 8 and Professor Zuckerman and others. Was that -- do
 9 you recall her ever discussing that with you or
 10 telling you anything about that meeting?
 11 **A.** No, I can't say that I do. That's not to say that she
 12 didn't but I can't recall that.
 13 **Q.** And do you recall having discussions with Dr Mayne as
 14 this awareness of the risk of AIDS developed in the
 15 latter half of 1982 and through 1983?
 16 **A.** Well, yes, I think there was a general discussion
 17 about AIDS in every gathering in the hospital, it was
 18 discussed at the physicians meetings at the Royal, it
 19 would have been discussed at the Children's Hospital
 20 amongst paediatricians. It was a general source of
 21 interest and discussion. It would have been discussed
 22 by my haematology colleges, Professor Bridges and
 23 Elizabeth Mayne, yes, it would have been.
 24 **Q.** You've referred in your statement from time to time to
 25 there not being, I think, evidence of a firm link at

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1 would have come through from the PFC, who would have
 2 been -- who would have been aware that there was
 3 a contaminated batch of SNBTS Factor VIII, and they
 4 would have been alerting users and withdrawing
 5 batches, yeah.
 6 No, it would probably have come through from the
 7 PFC to the blood bank and I would probably have
 8 acquired the information there, in late October,
 9 probably the beginning of November.
 10 **Q.** Your statement suggests that you then contemplated
 11 stopping SNBTS product and reverting to the earlier
 12 policy of cryoprecipitate; is that right?
 13 **A.** That's right, I wouldn't have given the SNBTS product
 14 after the beginning of November, when I found out that
 15 the Edinburgh cohort had been discerned.
 16 **Q.** Then your statement says, in fact, the heat treated
 17 SNBTS product then became available to you in early
 18 December 1984; that's your recollection?
 19 **A.** Yes, oh yes, that's right definitely.
 20 **Q.** Did you, in 1983 or 1984, prior to the availability of
 21 the heat-treated product, did you ever offer your
 22 patients or their parents a return to cryoprecipitate
 23 as an option for them to consider?
 24 **A.** Well, my attitude to the SNBTS Factor VIII, over that
 25 period you've described, I retained faith in the

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1 safety of the blood supply from Northern Ireland and
 2 Scotland, which went into the concentrate. I very
 3 much regarded the problem with AIDS and its
 4 transmission as a problem around imported commercial
 5 concentrate and, at that time, I was very much --
 6 I had great faith in the Scottish product, until
 7 I found that that faith had been misplaced.

8 Now, of course, whenever I changed treatment, it
 9 was discussed with the parents at that time. The
 10 various changes that I've enumerated to you today in
 11 the Factor VIII that was utilised was always
 12 introduced after discussion with the parents and after
 13 discussion around the alternatives with them. So
 14 I think they were on board with the use of SNBTS.
 15 But, of course, the information you can provide
 16 patients with is the information you have and you
 17 can't do any better than that.

18 **Q.** After the end of 1984, as I understand your statement,
 19 you continued using the SNBTS heat-treated
 20 concentrates, which was, I think, NY --

21 **A.** *(Unclear)*

22 **Q.** -- until July 1987 when the next generation Scottish
 23 product, Z8, became available to you; is that right?

24 **A.** That's right.

25 **Q.** If we just look at your statement, WITN5560001, and we

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1 from the very beginning we knew that the heat
 2 treatment wouldn't necessarily render the product
 3 sterile from a non-A, non-B hepatitis point of view.
 4 **Q.** Now, BPL, at this time, was producing a product, 8Y,
 5 which was more effective than NY in terms of
 6 inactivation of non-A, non-B hepatitis. Do you recall
 7 being aware of that?

8 **A.** No, I was never aware of that. I was never aware of
 9 that, it wasn't available to me, and I didn't use it.
 10 If it had been available and I'd realised that it held
 11 out the prospect of not transmitting non-A, non-B
 12 hepatitis, I would have used it, of course. But
 13 I didn't realise it existed. I wasn't aware of it.

14 **Q.** I don't know whether you'll be able to answer this,
 15 Dr Dempsey, but do you know from any subsequent
 16 conversations you may have had with her whether
 17 Dr Mayne was aware of 8Y and its improved safety
 18 profile?

19 **A.** No, I don't know. I don't know if she was aware, no.
 20 I mean, it wasn't on general release throughout the
 21 UK. It was restricted, as far as I know, to England
 22 and Wales, the catchment area for Elstree and BPL.
 23 I didn't think it was available through the Scottish
 24 link.

25 **SIR BRIAN LANGSTAFF:** I wonder if you could just help me

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1 go to page 21, please -- so bottom of page 20, first
 2 of all.

3 Just picking it up at the bottom of page 20, you
 4 say -- it's paragraph 32.1 of your statement:

5 "Z8 treatment commenced in this Centre in
 6 July 1987. This product appeared to have an improved
 7 safety profile and was substituted for NY. The Centre
 8 stopped using NY after July 1987."

9 You then explain that NY was then withdrawn from
 10 use and then you refer in paragraphs 32.3 to 32.5 to
 11 an instance in which a parent was treated mistakenly
 12 with NY after that date because those vials had
 13 remained in stock when they should have been returned.

14 Leaving aside the circumstance of that patient,
 15 who you have said did not seroconvert to hepatitis C,
 16 it would be right then to understand that up until
 17 July 1987, your patients were being treated with the
 18 a Scottish product which was effective, in terms of
 19 preventing the transmission of AIDS, but which, it
 20 became known, was not effective at preventing the
 21 transmission of non-A, non-B hepatitis. Do you recall
 22 when you became aware that NY could still transmit
 23 non-A, non-B hepatitis? Was that always your
 24 understanding?

25 **A.** Oh, that was always my understanding, yeah. I think

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1 with one thing. As I understood your earlier
 2 evidence, what was stocking the blood bank for the
 3 treatment of those who had haemophilia was the
 4 responsibility of Dr Mayne to choose. And you chose
 5 your product from what was in the blood bank. So
 6 how -- in your last answer or last set of answers, you
 7 said that if you'd been aware that 8Y held out the
 8 prospect of not transmitting hepatitis, you would have
 9 used it. How would you have got hold of it if it
 10 hadn't been in the blood bank?

11 **A.** Well, if I knew it existed and they were making it
 12 in BPL, I'd have phoned BPL and asked for it.

13 **SIR BRIAN LANGSTAFF:** And you'd have been able to do that?

14 **A.** Well, I would have -- I would have phoned them and
 15 I would have spoken to them, and I would have found
 16 out if there was a possibility that I could have it,
 17 and if I could have it, I'd have liaised with the
 18 blood bank and Dr Mayne.

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

20 **MS RICHARDS:** I want to move to ask you now, Dr Dempsey,
 21 about the kind of information that was given by you to
 22 patients or their parents about the risks of viral
 23 transmission in the 1980s.

24 If we go to your statement again WITN5560001.
 25 Page 19, please, Sully.

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1 If you look at the bottom of the page,
2 paragraph 29.1, you say:

3 "Initially advice about infective risk and blood
4 products in the early 1980s centred around the
5 possibility of jaundice which in most individuals was
6 thought to be self-limiting although occasional
7 patients were noted to have developed cirrhosis."

8 Now in the early 80s, what -- in the early 80s,
9 what information do you think you gave patients and
10 their parents about risks of hepatitis?

11 A. Well, any patient starting treatment for haemophilia
12 had a very lengthy conversation about the disease
13 leading on to a very lengthy conversation about the
14 available treatments and the side effects of those
15 various treatments. And hepatitis would have featured
16 very strongly or very majorly in that discussion, very
17 prominently in that discussion. And I would have said
18 that there was a risk of jaundice: a minority of
19 patients became jaundiced, a minority of patients
20 could develop evidence of liver disease which could be
21 serious and progressive, but most patients didn't
22 experience these side effects. That would have
23 applied to cryoprecipitate, in my discussions about
24 cryoprecipitate, as it did in my discussions about
25 concentrate, if I was employing concentrate.

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1 patients the significance of pool sizes, or different
2 donor profiles or the fact that there was
3 a significantly greater risk of transmission of non-A,
4 non-B hepatitis with concentrates than there was with
5 cryoprecipitate?

6 A. Oh, yes. I mean, I spoke to them about the potential
7 risks associated with concentrate as opposed to
8 cryoprecipitate. I don't think I went into detail or
9 touched on pool sizes when I was talking to them, or
10 about donor panels. I don't discuss that level or go
11 to that level of discussion with them. But
12 I certainly discussed the relative risks of
13 cryoprecipitate and concentrate.

14 Q. And as well as referring jaundice, would you have, do
15 you think, mentioned cirrhosis or the possibility of
16 further significant liver disease or even cancer?

17 A. I spoke to them about severe liver disease, yes.
18 I did say that a proportion of people had severe liver
19 disease, that would mean cirrhosis, basically, which
20 could be progressive. I don't know whether
21 I mentioned cancer to them as such.

22 Q. And would these conversations, or at least the fact
23 that they'd taken place and that there'd been
24 a discussion about the risks and benefits of
25 treatment, would those be recorded in the patient's

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1 So that was what I said to patients in the
2 early 80s, in terms what was possibly -- what could
3 possibly happen around treatment with cryoprecipitate
4 or concentrate.

5 Q. And would those conversations have taken place only --
6 in terms of that level of discussion -- with a new
7 patient, or was that a conversation you had every time
8 parents brought a boy to the ward?

9 A. Oh, I wouldn't have had it every time. I would
10 probably -- I would have picked up on the patients
11 I took responsibility for back in 1980 when I came
12 into post, and I would have talked to each of the
13 parents then about the problems that might be
14 associated with the treatment they were having. But
15 I wouldn't have had a conversation with them every
16 time they came. I would assume that once I had the
17 conversation with them, I wouldn't necessarily have
18 a lengthy conversation again with them unless I was
19 changing the treatment or I proposed to change the
20 treatment, or I gave them the option of changing the
21 treatment.

22 Q. When you were changing your moderately affected
23 patients from cryoprecipitate to commercial
24 concentrates in that period 1981 through to the middle
25 of 1983, did you, as far as you can recall, explain to

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1 notes?

2 A. I think they would have been recorded in the patient's
3 notes, that I had spoken to them about concentrate,
4 about the side effects of treatment. Maybe I wouldn't
5 have enumerated each side effect that I'd gone over
6 with them, but I would have made a note that I had
7 discussed the situation with them.

8 Q. And then from late '82/early '83, with AIDS on the
9 horizon but you continuing to use commercial
10 concentrates until the middle of 1983, what, as far as
11 you can recall, did you say to patients about the
12 risk of AIDS, if anything?

13 A. Well, I first started to talk to them about it,
14 I suppose, in mid-'83, when I took the firm decision
15 that I would have to change from the commercial
16 concentrate to the NHS concentrate. And I would have
17 said to them then that there were concerns, there were
18 worries about the commercial concentrate and
19 a possible link to AIDS. I didn't say that there was
20 a definite link and "You're likely to get it".
21 I didn't want to cause that much fear and concern.

22 AIDS was being talked about more and more in the
23 press and whether I had raised the subject in
24 June 1983, it was going to be raised with me by
25 parents undoubtedly in the coming months. And when

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1 I say I spoke to them in June '83 and talked to them
 2 about the risks of what I regarded as the causative
 3 factor, commercial concentrate, and suggested that we
 4 should move to a safer product, I went into the detail
 5 about AIDS. And from there on, there was continuing
 6 conversation about AIDS, through to the end of 1984.
 7 But as I say, I continued to retain confidence in the
 8 Scottish product with relation to AIDS. Confidence
 9 that was ultimately misplaced, but nonetheless, that's
 10 the position that I did take with the parents.
 11 **Q.** As you say in your statement, by mid-1983, you saw the
 12 possible risk of HIV infection as minimal at that time
 13 because you were no longer using the commercial
 14 concentrates, and parents were advised accordingly.
 15 So it would be right to understand, would it, that the
 16 parents of children being treated with the SNBTS
 17 concentrate would understand that was safe in relation
 18 to AIDS because that was your view?
 19 **A.** Well, yes, it would be, unless they got an alternative
 20 view from someone else. That would be the view that
 21 I gave them, at that time, because, as I said before,
 22 I very much regarded the AIDS problem as being related
 23 to commercial concentrate.
 24 **Q.** I want to ask you a little bit about the arrangements
 25 that were made for testing your patients for

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1 **Q.** The Inquiry has seen evidence referring to a patient
 2 aged 14 in 1985 testing positive, the documentation
 3 refers to Dr Mayne not you. Do you recall Dr Mayne
 4 telling you about any patients -- teenage patients,
 5 testing positive for HTLV-III?
 6 **A.** No, she never mentioned that patient to me and I have
 7 no -- I had no details about that patient. I didn't
 8 previously know about that patient until the patient
 9 was mentioned during the Inquiry sessions.
 10 **Q.** If we just look at BHCT0000861_003. This is a letter
 11 from December 1986 from Dr Rizza addressed to
 12 Dr Mayne, Dr Bridges and to you, and it refers to
 13 an apparent case of a patient seroconverting in 1986,
 14 potentially. Do you have any knowledge of that
 15 patient or of what's referred to here?
 16 **A.** No, I don't know about that patient. No, I've no idea
 17 about that patient. I just wonder, was it the patient
 18 you just referred to a moment?
 19 **Q.** I don't know, is the answer, I'm afraid.
 20 **A.** I just wondered if that was the patient. But, no,
 21 I have no knowledge about the matter.
 22 **Q.** We can take that down, thank you.
 23 Turn, then, to non-A, non-B hepatitis. Now,
 24 obviously, there was no ability to test for non-A,
 25 non-B hepatitis during the 1980s. Do you recall,

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1 HTLV-III/HIV. Your statement says that testing began
 2 in March 1985. Can you recall whether all the
 3 patients, 12, 14, however many of them there were
 4 approximately, whether they were all asked to come in,
 5 in the spring of 1985, for testing or whether they
 6 were tested the next time they came in?
 7 **A.** No, they were all asked to come up individually over
 8 a short period of time, see me, talk to me, have
 9 a blood sample taken for testing.
 10 **Q.** Did you explain what the purpose of the test was?
 11 **A.** Very much so, yes, I did explain what we were doing.
 12 Yeah, why we had to do it, yes.
 13 **Q.** Now, as I understand your evidence, your written
 14 statement, none of the patients tested through these
 15 arrangements in 1985 were positive for HTLV-III; is
 16 that right?
 17 **A.** That is right.
 18 **Q.** Do you know whether there were patients who, by that
 19 time, had transferred to the adult centre, who were
 20 positive for HTLV-III and for whom the cause of their
 21 infection might have been the treatment that they
 22 received at the Children's Hospital?
 23 **A.** I think it's very unlikely because, if there were
 24 patients in that category, Dr Mayne would have been
 25 sure to advise me of the fact.

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1 however, having cases of patients who you suspected
 2 might have non-A, non-B hepatitis because of raised
 3 bilirubin or jaundice or ALT results.
 4 **A.** No, there were no patients with jaundice apart from
 5 the patient you've mentioned a moment ago, who
 6 received the NY treatment, two vials of it. That's
 7 the only patient who was jaundiced, in my experience,
 8 in my years in the Children's Hospital. There may
 9 have been patients with minor abnormalities of liver
 10 enzymes. There were never any major abnormalities of
 11 liver enzymes that I recall. So I was never very
 12 happy to label a person as non-A, non-B hepatitis
 13 during my time in the '80s, other than the patient
 14 we've referred to a moment ago, who had the jaundice,
 15 raised liver function tests, and who'd had the NY, as
 16 opposed to the Z8.
 17 **Q.** In terms, then, of testing for hepatitis C, once the
 18 test became available, your recollection in your
 19 statement was that that began in 1992. How was it
 20 arranged? Was it a question of calling all the
 21 patients in, as you did with HTLV-III, or was it
 22 a question of waiting until the patient presented and
 23 then on that next occasion testing for hepatitis C?
 24 **A.** No, they were called up individually. They were asked
 25 to come, matters were discussed with them, a blood

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1 sample was taken with their permission, and the tests
2 were batched and I think referred through Dr Mayne,
3 possibly to London initially, for the antibody
4 testing.

5 And I think it was possibly in 1991, as opposed
6 to 1992. I said 1992 in the statement, I think it may
7 have been 1991. But I think that the tests were
8 batched and I think they were referred with some of
9 hers, and I think it was possibly to London they were
10 sent, initially, if my memory serves me right.

11 Q. What's your recollection of how you communicated
12 a positive test result to your patients or their
13 parents?

14 A. I had counselled them on the matter, told them that
15 I would write and give them the result, and when I got
16 the result, if it was negative, I wrote to them and
17 told them it was negative. And if I got a positive
18 result, I wrote to them and I told them the result was
19 positive and I gave them an appointment to come up and
20 see me within the next few days to talk about the
21 situation.

22 Q. There's an example of a case I wanted to ask you about
23 which is in the materials that were provided to you,
24 Dr Dempsey. If we can -- and I'm -- this relates to
25 a patient who is anonymous, so I'm not going to be

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1 I just don't understand that.

2 Q. In any event, we -- sorry.

3 A. Unless the results were -- unless the test was done in
4 the local virology lab, the results were given to
5 Dr Mayne verbally and then communicated to me verbally
6 for transmission to the parents. And this is a late
7 report coming through that's been typed up.

8 I just find it very difficult to explain that.
9 It doesn't link in with my memories of what happened.

10 Q. In any event, we can see that the date of the test
11 result there is said to be January 1992.

12 If we could then look in relation to the same
13 anonymous patient at WITN0007005.

14 This is a letter from you in relation to the
15 patient dated May 1995, 29 May. It says:

16 "As you know we are now routinely testing
17 patients' blood for evidence of exposure to
18 hepatitis C and we did mention to you some months ago
19 we were taking a sample from [the patient] to test.

20 "Unfortunately the results do show that
21 [the patient] has been exposed to hepatitis C virus in
22 the past and carries antibodies to this virus. This
23 means that [he] is likely to be a carrier of the
24 virus.

25 "Many patients who are treated with Factor VIII

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1 referring to any identifying details, and it's really
2 a general issue I want to explore with you.

3 WITN0007003, we can see here -- we can see it's
4 addressed to you, Children's Hospital Laboratory,
5 Dr Dempsey. We can see there there's reference to
6 Anti-HIV 1 & 2, hepatitis B surface antigen, and then
7 "Anti-hepatitis C virus POSITIVE", and then we've got
8 the date in the bottom left-hand corner,
9 23 January 1992. So -- and then it appears the date
10 of the specimen is 14 March 1991.

11 First of all, are you able to assist us in
12 understanding what appears to be the time period
13 between the date of the specimen and the date of this
14 test result?

15 A. Actually, I have difficulty with that. As I say,
16 I thought they'd been batched together, sent as
17 a batch through Dr Mayne, and we got the results back
18 relatively quickly. Subsequently, when the testing
19 was set up in the Children's Hospital -- sorry, set up
20 in the virology lab, repeat testing would have been
21 done. That result, I would have thought, came about
22 from repeat testing, over and above the tests that
23 I've referred to and that was batched and, I thought,
24 sent away. I can't explain why the date of this
25 specimen here has been record, as the 14/03/91.

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1 in 1987 and prior to 1987 have been exposed to this
2 particular virus and are positive for antibodies to
3 it. Many patients who carry the virus are perfectly
4 well and are totally unaware. In some patients,
5 however, over a lengthy period of time, the virus can
6 cause some evidence of liver damage. I appreciate
7 this finding may be a shock to you and I would be
8 happy to talk to you both about [the patient] and the
9 implications of this for him."

10 Then you suggest a date. You say:

11 "[You] do not think that [the patient] needs to
12 be involved directly at this stage ... no evidence of
13 any problem with HIV or AIDS ... and immunised against
14 hepatitis B in the past."

15 Are you able to assist us in understanding why,
16 given there was the initial test result in
17 January 1992, a communication is being sent to the
18 patient's parents only in May 1995?

19 A. Yes, I remember looking at this in 1995. The patient
20 was 15 and, at that time, coming up to time for
21 referral to the adult unit.

22 On checking through the chart, I couldn't find
23 any reference to having seen or spoken to the parents
24 about the positive test result that you've alluded to
25 from 1992.

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1 I felt very strongly at the time, 1995, that I
2 had spoken to the parents, but I could find no
3 documentation relating to that. And because I could
4 find no documentation, I was forced to conclude that
5 perhaps I hadn't, despite my strong feeling that I had
6 communicated the result.

7 So I set about going through the motions of
8 contacting them again, talking to them again, and
9 talking to them about test results again.

10 But it was thoroughly documented, and that I was
11 I convinced in my own mind that eventually I had done
12 what I thought I'd done in 1992, what I felt strongly
13 I'd done in 1992, but could find no evidence of that
14 in the chart.

15 **Q.** So would you accept, as a matter of principle, and
16 general good practice, that if you got the test result
17 of the kind we looked at in 1992, that should have
18 been communicated to the patient or their parents at
19 that time?

20 **A.** Oh, absolutely. And I did look at the other charts
21 around this issue back in 1995, when I found this
22 chart and I was able to convince myself that I had
23 written to all the other patients' parents and I had
24 talked to them, and I continued to wonder why on earth
25 this patient apparently weren't -- his parents weren't

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1 unable to determine whether a patient is currently
2 infected or not.

3 "PCR confirmatory assays to detect viraemia
4 (active infection) were not routinely available in the
5 early 1990s and were then only used in a research
6 context. At this time, samples were sent to
7 Edinburgh University or to Birmingham Public Health
8 Laboratory for HCV PCR testing. The team advise that
9 from the mid-90s some HCV PCR tests were performed in
10 the RVL Belfast. However, none of the assays at this
11 time were commercial assays and all these assays had
12 intermittent sensitivity and specificity problems."

13 Then she says:
14 "Until the mid-00s, HCV PCR testing in the RVL
15 was done in a variable way (either locally or sent
16 away or both)" --

17 **SIR BRIAN LANGSTAFF:** I think we're missing that on the
18 screen.

19 **MS RICHARDS:** Oh, I'm sorry.

20 Can we go to the bottom of the page, please,
21 Sully.

22 "... and given issues with sensitivity and
23 specificity, the clinical advice from the virology
24 team was to look at the pattern of PCR results over
25 a period of time rather than absolutely rely on any

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1 in contact, didn't talk to them. I felt strongly at
2 the time I had done it but there was no evidence I had
3 done it. I had to assume I hadn't done it. And --

4 **Q.** Can I ask you to look at a statement from Caroline
5 Leonard of the Health and Social Care Trust because
6 she gives us -- although she was obviously not the
7 person involved and you were, she gives a slightly
8 what might be said a slightly different explanation.
9 It's WITN3449028.

10 And if we go to page 3, we'll see she is talking
11 about the patient that we've been discussing, but
12 again, I'm looking at this as a broader issue. So she
13 says in paragraph 2.5:

14 "In addressing Witness W0007's concerns relating
15 to a time delay between having a positive antibody
16 test for HCV in 1992, and not being informed about
17 a result until 1995, it may be helpful to explain the
18 development of antibody testing and ... (PCR) testing
19 in that period.

20 "Staff from the Regional Virology Laboratories
21 ... within the Trust have advised that with respect to
22 testing for HCV, the first antibody assays were
23 available from 1992. However, a HCV antibody positive
24 result only identifies that a patient has had exposure
25 to HCV (either via a past or current infection) and is

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1 one result."

2 Then she says:
3 "The Trust, having reviewed the medical records
4 of Witness W00007, can confirm that a sample was taken
5 from Witness W00007 in 1991 for HCV antibody testing
6 and the result was issued to the Trust in 1992
7 indicating that Witness W0007 was Hepatitis C Virus
8 (HCV) antibody positive."

9 Then she says:
10 "Those results are contained in the clinical
11 notes."

12 At 2.10 she says:
13 "The first [PCR] test results from the RVL ...
14 in the medical records is from December 1995 ... The
15 receipt of this first positive PCR result is the first
16 point where it can be said that Witness ... had an HCV
17 infection. This is because the previous antibody ...
18 test results could only identify exposure to HCV ..."

19 Then she refers to a letter, I don't think we
20 need to refer to it, a letter written by you to the
21 GP, and then says:
22 "However, once the PCR positive result from the
23 RVL became available confirming that Witness W0007 had
24 a current HCV infection, his parents were informed
25 accordingly."

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1 Now, it might be said that the explanation there
2 being given for this delay in informing the patient
3 and his parents there is different from the
4 explanation you've given, Dr Dempsey. You say you've
5 accepted he should have been told in 1992, you thought
6 you had but you couldn't find proof of it, and so you
7 did it again in 1995. Ms Leonard appears to be
8 suggesting that it's something to do with the
9 difference between the testing available in 1992 and
10 the PCR test reliability.

11 **SIR BRIAN LANGSTAFF:** Well, just -- this to you,
12 Ms Richards. At the moment I have difficulty in
13 seeing how Ms Leonard can be right about that because
14 she gives the date of the first PCR test, assuming
15 she's accurate, as being December 1995. The letter to
16 the GP is May 1995.

17 **MS RICHARDS:** The letter to the parents is May 1995.

18 **SIR BRIAN LANGSTAFF:** Sorry, parents is May 1995.

19 **MS RICHARDS:** Yes.

20 **SIR BRIAN LANGSTAFF:** So that's at a time when there
21 wasn't a PCR test, and it would appear that the letter
22 to the GP is June 1995, so there are letters written
23 without the need for there to be a PCR test first.

24 **MS RICHARDS:** Yes. I entirely see that, sir. It's really
25 because Dr Dempsey, who was the clinician involved,

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1 right, proper and reasonable to speak to the parents
2 on the basis of an antibody test, and that's what
3 I did.

4 It's interesting you say that the Trust
5 really -- or the virology lab only introduced antibody
6 testing in 1992 and from Ms Leonard's letter. So that
7 sample that was dated some time in 1991 and was
8 untested, and the result only reported back in 1992,
9 may have been submitted and retained, and done when
10 the tests became available. It remains my memory,
11 however, that I think tests were batched and sent,
12 I think, to London, and earlier results returned from
13 London, and the test from the virology is merely
14 repeating a test that was done in London. And that's
15 how my memory serves me on this.

16 **Q.** So would it be right to understand then -- we can take
17 that down, thank you -- that, as a matter of
18 principle, your approach would be those test results,
19 whether it's 1991 or 1992, if they're positive, you
20 should be telling the parents or the patients in
21 relation to that and your recollection is that is what
22 was done, not necessarily in the case we've been
23 looking at?

24 **A.** That's right. Yes, that's right.

25 **Q.** Can I then just ask you a handful of questions about

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1 has given us his own recollection of what the position
2 was, I wanted to just explore with him whether he had
3 any observations to make upon what Ms Leonard appears
4 to be suggesting.

5 **SIR BRIAN LANGSTAFF:** Yes, well at the moment, as I say,
6 I can't see how she's giving an explanation for what
7 happened, which is -- the explanation, at the moment,
8 that I have is from Dr Dempsey.

9 **MS RICHARDS:** So any observations upon what Ms Leonard
10 says, Dr Dempsey?

11 **A.** Well, I think, you know, an antibody test is
12 sufficient, points strongly to active infection and
13 I think, on the basis of a positive antibody, test
14 you'd see -- talk to parents and explain the situation
15 to them and, indeed, that's what I did with the
16 majority of these parents in 1991. I spoke to them on
17 the results of the antibody test.

18 Confirmatory test, or PCR was developed and
19 introduced later on as confirmation of the antibody
20 test. The antibody test strongly points to
21 a presumptive diagnosis of active infection and that
22 was borne out in most cases when the PCR tests were
23 subsequently done, when the PCR tests subsequently
24 became available.

25 So I would have thought that it was perfectly

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1 the arrangements for the care and treatment of the
2 patients who had tested positive for hepatitis C. As
3 I understand your statement, there was no paediatric
4 hepatologist to whom you could make a local referral;
5 is that right?

6 **A.** No paediatric hepatologist in Belfast no.

7 **Q.** Do you know whether funding had been sought for one by
8 the board or application made to the board?

9 **A.** I suspect they were looking for paediatric
10 gastroenterologists who would have overseen paediatric
11 hepatology. I expect a request had been made because
12 I think, certainly by 2000 one had been appointed. So
13 in the later '90s, I think there was a paediatric
14 gastroenterologist who had provided that sort of
15 advice and help.

16 **Q.** Did you give consideration to referring the patients
17 who tested want to hepatologists elsewhere in the
18 United Kingdom?

19 **A.** No, because I didn't think their liver function was
20 sufficiently abnormal or the general findings were
21 sufficient abnormal to warrant it, although certainly
22 referral to a hepatologist in England would have
23 allowed the hepatologist to talk at length to the
24 parents about the problem. So, from a counselling
25 point of view it might have been helpful but I didn't

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1 think there were a need of urgent medical intervention
 2 in my estimation.

3 **Q.** Was there any form of support or counselling that was
 4 available to parents at this time in the 1990s?

5 **A.** Well, we did have a social worker who -- and we may
 6 have had two social workers at that time, so there
 7 would have been some time available to assist with
 8 counselling. But not a psychologist, no.

9 **Q.** You, I think, didn't arrange for the treatment of your
 10 patients with interferon, or interferon-ribavirin, but
 11 took a decision that treatment should await their
 12 transfer to the adult centre. Why was that and was
 13 there not a risk of ongoing liver damage in the
 14 intervening period?

15 **A.** Well, to my -- as far as I could see, they were well
 16 when I was counselling them. The liver disease
 17 associated with non-A, non-B hepatitis generally
 18 developed over a period of roughly two decades. There
 19 was interferon treatment -- which was licensed,
 20 actually, in November 1994 -- it was toxic,
 21 unpleasant, and not very effective.

22 Results -- permanent elimination of virus
 23 test -- results of studies were as low as 12 per cent,
 24 of the patient population treated with interferon
 25 alone, sustained continuing response.

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1 their liver function tests, check their physical
 2 health and do physical examination. We didn't do
 3 scans.

4 **Q.** And why was that? Why no scans?

5 **A.** Well, I -- a progression to cirrhosis would be a focal
 6 problem and I thought at this stage in the disease it
 7 was unlikely they were going to pick up focal
 8 abnormalities. It was more a diffuse problem.

9 **Q.** And can you recall what kind of advice and information
 10 was given to the patients or their parents about the
 11 condition and what they should expect?

12 **A.** Well, I was fairly forthright at the beginning and
 13 I said that this was probably a progressive disease
 14 over around -- over roughly two decades. There was no
 15 treatment initially. There was hope that treatment
 16 might become available. They understood it was
 17 serious and quite probably progressive and that over
 18 time quite serious liver disease might result in
 19 consequence of their infection. So that was the
 20 advice I gave.

21 **Q.** The Inquiry has seen evidence, in relation to patients
 22 at the adult centre, of hepatitis C tests being done
 23 in 1990, 1991, but not being communicated to the --
 24 the results not being communicated to the patients
 25 potentially for a number of years, until perhaps two

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1 So there were prospects at that time that the
 2 interferon-ribavirin combination would provide better
 3 results. There were clinical trials ongoing at that
 4 time, and I felt it was best to await the results of
 5 those clinical trials which held out the hope for
 6 better results. And that's what I explained to the
 7 parents.

8 By the time those results came through, we'd got
 9 to 1996, and most of the patients were ready for
 10 referral, or had reached the age for referral to the
 11 adult unit, who had more experience in treating
 12 hepatitis C than I had, and I thought it was probably
 13 preferable that the experienced team should undertake
 14 the work of delivering what was a fairly complex
 15 treatment with a lot of side effects and a lot of
 16 unpleasantness associated with it. So that was my
 17 advice at the time.

18 **Q.** And your statement suggests that by 1998, the last of
 19 your paediatric patients with hepatitis C transferred
 20 to the adult centre?

21 **A.** Yes, I think 1997, they'd all have gone.

22 **Q.** In the intervening period, prior to transfer to the
 23 adult centre, what form of ongoing monitoring or
 24 review was there of the hepatitis C patients?

25 **A.** Well, we'd see them about every four months and do

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1 or three years later. Did you ever have any
 2 discussions with Dr Mayne about that, or did she ever
 3 say to you anything about a policy or practice of not
 4 communicating the early hepatitis C results to her
 5 patients?

6 **A.** No, she never communicated any such feeling. In fact,
 7 when she let me know the results of the batch tests
 8 that were sent away in 1991, she suggested that I
 9 should get on with approaching the parents and letting
 10 them know the result. That's my memory of the
 11 discussion I had with her way back in 1991.

12 **Q.** Can I then just ask you briefly about the vCJD
 13 notification exercises with which you were involved.
 14 You described in your statement, I think, involvement
 15 with two such exercises, one in 2001, one in 2004.
 16 We've got various documents relating to them and
 17 I think we've looked at some of them in earlier
 18 Inquiry hearings.

19 Could you just tell us -- and if you need to go
 20 to the documents to prompt your memory, we'll do so --
 21 but could you tell us your recollection of the
 22 discussions you and Dr Julia Anderson had about the
 23 approach that you should take to notifying patients
 24 and why you took the approach that you did?

25 **A.** The first notification in 2001, at that time we had

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lengthy discussions between ourselves. There was a suggestion from some quarters of the UKHCDO that we should write to patients' parents and give them the option of finding out if they had been exposed to an implicated batch or not. We chose in Belfast, in conjunction with a number of other centres in the UK, to directly approach those patients who had been exposed to an implicated batch, talk to their parents, and inform them of that result.

In 2004, the approach changed and we had -- I think most people at that time adopted the approach of writing to all the patients who had had plasma products between certain dates, and I've forgotten exactly the dates, notifying them on the risks that might accrue, or could possibly accrue, around the exposure to an implicated batch derived from someone who went on to develop vCJD. And we invited them to write back to us and choose to determine whether or not they wished to know whether they had been exposed.

I wrote to quite a number. I wrote, I think, to 19 patients. I think 17 replied and I think all of the 17 wanted to know if their children had been exposed to that batch, including one or two who had been exposed to a batch, and the many others who hadn't been exposed to a batch. So we wrote the

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measures would apply to all patients attending the Centre who had been exposed to treatment with blood products.

"The dental department was informed and a list of patients provided; the list to remain confidential. The dentists concerned had been provided with information around precautionary measures to be taken.

"Liaison was established with the surgery department in the Children's Hospital. They had been advised of appropriate measures to be taken ... Protocols for the care of operative instrumentation had been received."

Then:

"Arrangements for children requiring surgery were in place for the parents to liaise with the Centre prior to surgery and for surgery to be carried out exclusively in the Children's Hospital. Permanent medical staff covering the Centre were aware of the list of patients previously treated with blood products and patients on this list presenting for surgery and coagulation factor cover would be notified to the surgeon concerned."

Do you know whether the patients or their parents were told that their details were going to be provided to the dental department and to the surgery

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appropriate letters to each of them and we saw the patients who had been exposed to an implicated batch, and we talked to the parents and counselled them, and we invited any of the others who wished to come and talk to us to come up and talk to us. And I think that was a summary of how we approached the problem, both in 2001 and 2004.

Q. Do you recall anything about the response of patients, the impact upon them of this information, with all its inherent uncertainties?

A. Well, I think most of the parents seemed to be fairly phlegmatic about it? I mean, how people appeared to you in a counselling session doesn't necessarily reflect the turmoil which lies beneath but, from what I could see, most patients -- most parents took the information fairly phlegmatically and there weren't many major emotional outbursts, in a way, surprisingly. And that's what I found.

Q. I just want to ask you, lastly on vCJD, about the public health measures that were implemented. If I pick it up at your statement, Dr Dempsey, WITN5560001, and if we could go to page 54, please, Sully.

So you say in paragraph 109, onwards:

"It was decided advice around public health

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department, as described there?

A. Well, the details weren't referred to the surgery department. The plan was that, if a patient presented to the unit and required surgery -- to our unit, required surgery and was on the list, the member of staff covering the unit on the night in question or day in question would liaise with the surgeons.

In relation to the dentists, well, no, I don't think we said to the relatives, "We're going to go to the dental department and we're going to advise them". I suppose we were in the habit of advising the dental department anyway about patients who were hep C positive. Did we tell the patients about that? Um ... I think probably we did, in discussion.

When we talked to the parents, the parents who had the implicated batches in the vCJD scenario, I think we told them that precautions would have to be taken in the dental department, and they realised that there was -- precautions would necessitate telling the dentists.

So I think they realised that we would be liaising with surgeons and dentists if they came to rely on either specialty for help with a patient.

Q. Did you receive any reports, whether from the patients or their parents or from other sources, of the

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1 negative impact on children and their treatment of
 2 appointments being deferred or cancelled or
 3 a reluctance to treat or being pushed to the end of
 4 the day and made to feel like a pariah, did that get
 5 reported to --
 6 **A.** No, not at all, no, no. The dental department was
 7 right beside our outpatient then and we had close
 8 liaison with the dentists so all haemophilia patients
 9 came up to the review clinic, they were seen by myself
 10 or Dr Cairns, and then we would liaise with the
 11 dentist next door, the patients would go out, wait,
 12 and then go in to see the dentists. So we had a very
 13 close relationship with the dental department then,
 14 and that's how it worked and there was never any
 15 question that they were treated as pariahs or excluded
 16 or not treated as they ought to have been.
 17 **Q.** Then, finally, Dr Dempsey, more broadly, and thinking
 18 now as a haematologist more generally rather than
 19 focusing on the haemophilia patients about whose care
 20 I've been questioning you, do you recall in the '70s,
 21 '80s, '90s, consideration being given more generally
 22 to the importance of minimising the use of blood or
 23 blood components, avoiding transfusions where
 24 unnecessary, not over-transfusing, avoiding single
 25 unit top-ups? Do you recall those kind of

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1 back with any further questions after lunch?
 2 **SIR BRIAN LANGSTAFF:** Yes, well, we'll do that.
 3 We'll come back at 2.00. Would that suit --
 4 **MS RICHARDS:** Yes, that would be fine.
 5 **SIR BRIAN LANGSTAFF:** -- your timetable?
 6 2.00, if you please, Dr Dempsey. There will be
 7 some further questions. What counsel has to do is to
 8 liaise with those who are Core Participants. They
 9 aren't, of course, here in the room. And they may
 10 have further questions which they would like her to
 11 put to you.
 12 So that will happen at 2.00.
 13 **A.** Thank you.
 14 **(1.04 pm)**
 15 **(Luncheon Adjournment)**
 16 **(2.00 pm)**
 17 **(Proceedings delayed)**
 18 **(2.05 pm)**
 19 **SIR BRIAN LANGSTAFF:** Yes.
 20 **MS RICHARDS:** Dr Dempsey, just a handful of further
 21 matters. If we could start by going back to your
 22 witness statement. So, Sully, could we have
 23 WITN5560001, and go to page 37.
 24 You say, at the top of the page, paragraph 74.1,
 25 in response to a question about the treatment of

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1 conversations taking place?
 2 **A.** Oh yes, they did, yes. There was a transfusion
 3 committee in the Children's Hospital, or in the Royal
 4 group, which came into existence, I'm not sure if it
 5 was the late '90s or 2000s, took on board that remit.
 6 So I think very much that was a topic of conversation.
 7 **Q.** And prior to the establishment of the transfusion
 8 committee, do you remember it being a focus of
 9 education or training more generally?
 10 **A.** Well, I think from way back, I mean -- when I was
 11 a junior doctor, blood was -- tended to be transfused,
 12 I wouldn't say on a whim, but fairly liberally. And
 13 then we come to an age when we were told if a patient
 14 needed -- and this is an adult practice -- if
 15 a patient only needed one unit of blood, they didn't
 16 need the blood at all. So there was a developing --
 17 people were developing an idea that blood had to be
 18 treated with certain respect, and patients who were
 19 exposed to blood had to be exposed in a very good
 20 pretext.
 21 **MS RICHARDS:** Sir, those are the questions I have for
 22 Dr Dempsey. Bearing in mind it's gone past 1 and we
 23 need to afford the opportunity to Core Participants
 24 and their legal representatives to suggest any further
 25 questions, could we break for lunch now and then come

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1 previously untreated patients, you refer to the use of
 2 DDAVP or cryo for those with mild haemophilia or
 3 von Willebrand's, factor concentrate for moderate or
 4 severe, then you say this:
 5 "To limit donor exposure we would aim to set
 6 aside one batch of factor for their regular use."
 7 I think you told us this morning, Dr Dempsey,
 8 that, in practice, batch dedication wasn't a very
 9 useful option, but I thought should remind you of that
 10 sentence and just ask you to recall what was or wasn't
 11 done in that regard.
 12 **A.** Well, it didn't really happen. There were times when
 13 we thought we might get it established for a patient,
 14 but it didn't work out. One way or another, the batch
 15 got mislaid and used, and it didn't seem to work.
 16 And I'd limited -- I'd limited confidence in its
 17 ability to make a major contribution to keeping people
 18 infection free; depend on the batch you chose,
 19 I suppose.
 20 **Q.** Then still on the statement but on a different topic,
 21 if we could go to page 9, please, Sully.
 22 At the bottom of the page in response to a
 23 question posed about the relationship with
 24 pharmaceutical companies and their influence, you say:
 25 "I had occasional visits from sales

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1 representatives of commercial companies, but these
 2 visits did not influence my decisions on which product
 3 to use."

4 First of all, can you assist us in understanding
 5 why -- and you've told us this morning already you had
 6 conversations with pharmaceutical representatives
 7 about hepatitis risks in relation to their products.
 8 Can you assist us in understanding why you were
 9 receiving visits and having these discussions with
 10 pharma reps when it was Dr Mayne who did the ordering?

11 A. Well, I suppose the reps liked to say they'd visited
 12 so many people, and it looks good when they go back to
 13 base and they've covered all the options. I didn't do
 14 the ordering and I had a very limited patient group to
 15 utilise their products, but they still came to visit
 16 me, and I felt that, you know, I was keen to hear what
 17 they had to say, and I was keen to be civil to them
 18 when they came round the door looking for a short
 19 talk.

20 That really underlies what was going on. They
 21 didn't come too often and, as I say, I wasn't the one
 22 who did the ordering. And I guess they knew that, or
 23 I made it fairly plain to them. So I was happy to sit
 24 and listen to what they had to say but I didn't feel
 25 that I was being placed in a compromising position at

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1 your treatment choice because they reassured you that
 2 concentrates, commercial concentrates, were, from
 3 a hepatitis perspective, safer than they previously
 4 had been?

5 A. Yes, they influenced me in that respect. But I had
 6 that opinion anyway, become -- before they came to
 7 visit me, I think I had established the idea that
 8 commercial concentrates were safer than they had been
 9 in the mid-70s.

10 Q. You can take the statement down. Thank you.

11 Is it right to understand, in terms of the
 12 treatment decisions you took in the early '80s, that
 13 as a result of the one patient you described with an
 14 internal bleed in 1991 who did not respond well to
 15 cryoprecipitate, you decided to transfer your entire
 16 cohort of moderate patients to commercial concentrates
 17 notwithstanding that they'd not previously been
 18 treated with those concentrates?

19 A. That's right. But, you know, I always had doubts
 20 about cryoprecipitate, and I think my feeling was that
 21 many people did, and I think that experience shook me
 22 to the core, tipped me over the edge, as far as
 23 cryoprecipitate was concerned, and I decided I really
 24 ought to be more circumspect before a similar episode
 25 occurred and then there was a more unwelcome outcome.

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1 any time.

2 Q. Can you recall which companies -- of the companies
 3 producing Factor VIII concentrates, which companies
 4 you had these occasional visits from?

5 A. Well, I think it was mostly Armour, as I recall. It
 6 was mostly Armour.

7 Q. Do you recall the names of any of the individual reps?

8 A. Well, I can visualise them but I can't remember his
 9 name now.

10 Q. Do you recall a visit from a Christopher Bishop for
 11 Armour?

12 A. Not really, no. No.

13 Q. And were these ever joint visits with Dr Mayne? In
 14 other words, was she present on some of these
 15 occasions?

16 A. Oh no, never. Never. She never came with them to
 17 visit me. They would always visit her on their own,
 18 yeah.

19 Q. And you say in the statement that visits didn't
 20 influence your decisions on which product to choose,
 21 and in terms of choosing between different commercial
 22 products I understand you've said you took whatever
 23 was in stock. But --

24 A. Yes.

25 Q. -- it would right to say that the visits did influence

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1 Q. Looking back now, was that, in retrospect, the wrong
 2 decision to take?

3 A. Well, looking back now, I would think that perhaps the
 4 best decision should have taken was to go onto the NHS
 5 material, given what was going to develop. So if
 6 I had to do it again, I'd have gone to the NHS
 7 material. The thrust among the haemophilia treaters,
 8 among the haemophilia treaters, was to maximise and
 9 intensify treatment of bleeding episodes into joints.
 10 The aim and object was to preserve the joint function,
 11 and you really have to work at it to do that. And
 12 failure around a joint was a tragedy because the
 13 patient was going to have that joint with them for the
 14 rest of their lives, and the feeling was that to
 15 intensify and maximise treatment on joints that were
 16 causing trouble, the feeling was that really
 17 concentrate was the best way to do it.

18 So the pressures were on to look after the
 19 joints and the best way to do that was with
 20 cryoprecipitate -- I'm sorry, with concentrate. And
 21 that was the feeling I took from many meetings among
 22 the leaders in the field.

23 Q. Once the arrangements with the PFC was under way in
 24 1982, why did you not then switch immediately to SNBTS
 25 product? Why did you continue using commercial

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1 products until June 1983?

2 **A.** Um ... because the haemophilia community was still --

3 or sorry, the haemophilia organisation, the UKHCDO,

4 still hadn't come round fully to the idea that

5 concentrates, commercial concentrates, were

6 responsible for the emerging AIDS problem. There was

7 still resistance among the haemophilia treaters about

8 the significance of concentrate and the emerging AIDS

9 problem. And I suppose I absorbed some of that,

10 probably that delayed the conviction that the

11 concentrates were responsible, and that really action

12 should be taken to stop using them and switch over to

13 the Scottish product.

14 **Q.** On the issue of hepatitis C testing, were you aware

15 that Dr Mayne was sending samples to London for

16 testing for hepatitis C as early as 1990?

17 **A.** No, I don't think I was. I think she contacted me

18 when she thought that I should slot into the

19 arrangements she had made with London. I don't think

20 it was 1990 she got me to send the samples over.

21 I think it was more likely to have been 1991 but

22 I couldn't honestly be awfully sure about the dates.

23 That's as much as I can recall.

24 **Q.** I asked you this morning about whether it might have

25 been more appropriate to have a more nuanced approach

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1 them any good from the safety point of view, and you

2 would deprive them of the benefit of concentrate if

3 you perceived concentrate to have special benefits

4 when it came to treating bleeding episodes.

5 So you were probably getting the worst of both

6 worlds by mixing them together.

7 **Q.** In terms of the conversations you had with patients or

8 with their parents pre-AIDS, so when you were

9 discussing the change to cryoprecipitate -- from

10 cryoprecipitate to concentrate in '81, '82, did you,

11 as far as you can recall, tell the parents in terms

12 that concentrate was riskier in terms of liver

13 disease?

14 **A.** Oh, yes, I would have. Yeah.

15 **SIR BRIAN LANGSTAFF:** Did you tell them what you've just

16 told us: that once you've given concentrate, you have

17 to assume that the patient has been exposed and may

18 well have contracted hepatitis? In other words,

19 giving them concentrate was giving them hepatitis.

20 **A.** I don't know that I said that to them. I've said

21 a moment ago that what I think about concentrate now

22 may be coloured by what we subsequently learnt about

23 it. At the time, I may not have appreciated that

24 every time they got concentrate they were exposed to

25 hepatitis.

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1 in relation to concentrates and cryoprecipitate,

2 rather than swapping all the children onto

3 concentrates, the moderate children, and you indicated

4 that using both concentrate and cryoprecipitate for

5 a patient would be something to be avoided.

6 Why would that be the case? If there's a risk

7 from concentrates that's greater than the risk from

8 cryoprecipitate, in terms of hepatitis, why not with

9 an individual patient, treat them with the safer

10 product, cryoprecipitate, if that's effective for the

11 individual presentation on that day, and if, in four

12 months' time, there is an internal bleed which

13 requires concentrate, then use concentrate on that

14 occasion?

15 **A.** Well, I think the feeling was that once you'd used

16 concentrate, you probably had compromised the patient

17 with regard to non-A, non-B hepatitis anyway. So my

18 feeling, and it may be coloured by subsequent

19 knowledge about non-A, non-B hepatitis, or hep C,

20 actually, was that most of these concentrates were

21 probably contaminated and that once you'd used them

22 you'd probably have exposed the patient to hep C and

23 they'd probably been exposed to the virus at that

24 stage.

25 So going back to cryoprecipitate wouldn't do

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1 **SIR BRIAN LANGSTAFF:** I see, so you're answering the

2 nuanced approach, not because of what you thought at

3 the time, but because of what you think you know,

4 having looked back?

5 **A.** Yes, that's what I think I know now, yes. No, what

6 I knew then was different. I don't think we knew that

7 every batch was contaminated then, no. I don't think

8 that, no.

9 **SIR BRIAN LANGSTAFF:** Well, can you help me with this: of

10 the moderate haemophiliacs that you actually had, were

11 there any who did not contract hepatitis C?

12 **A.** I can't honestly remember. There were a small number

13 of people who didn't contract it, but they would have

14 been primarily in the von Willebrand's/mild

15 haemophilia category.

16 **SIR BRIAN LANGSTAFF:** I see.

17 **A.** I can't think of anybody in the moderate who didn't

18 contract it.

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

20 **MS RICHARDS:** In terms of the conversations you were

21 having with parents, given that, as you've told us,

22 you thought that concentrate was the more effective

23 treatment, would it be right or fair to assume that

24 you would have been telling parents of your strong

25 view that they -- that concentrate was a better

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1 treatment for their child than cryoprecipitate?
 2 **A.** Well, I would have told them my experience and what
 3 I thought was the general experience of the
 4 haemophilia treating community, *vis à vis* concentrate
 5 versus cryoprecipitate.
 6 I mean, what I would -- I would have emphasised
 7 that the cryoprecipitate could work, maybe not as
 8 effectively, but I did say that it was going to be
 9 less -- there was going to be less risk of infection
 10 in the short-term with the cryoprecipitate.
 11 **Q.** In terms, then, of your discussions with parents about
 12 AIDS, why -- as I understand your evidence this
 13 morning, you indicated that was a conversation you
 14 really started having in mid-1983, following the
 15 UKHCDO advice and the switch from commercial to SNBTS
 16 product. Do you think you should have been telling
 17 patients or their parents about the risk of AIDS
 18 really from 1982, when you had no real doubt yourself
 19 that there was the possibility of transmission?
 20 **A.** Well, I suppose, in retrospect, maybe I should have
 21 told them earlier. In retrospect, of course.
 22 There was a cloud of unknowing then that covered
 23 the haemophilia treating community. Things were not
 24 as clear-cut then as they appear now. With the
 25 knowledge we have now, yes, probably we should have

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1 No, none from Dr Dempsey's own representatives.
 2 Do you have any questions for Dr Dempsey?
 3 **SIR BRIAN LANGSTAFF:** No, those I've had I've asked along
 4 the way.
 5 **MS RICHARDS:** Dr Dempsey, is there anything you would wish
 6 to add?
 7 **A.** I only want to say that I appreciate the pain and
 8 suffering that these conditions have caused to the
 9 haemophilia community in Britain and Northern Ireland,
 10 and I realise it's a pain that continues to this very
 11 day, and certainly I regret that any of it ever
 12 happened.
 13 **MS RICHARDS:** Sir.
 14 **SIR BRIAN LANGSTAFF:** Well, can I thank you for evidence
 15 which, in many ways, has been really quite informative
 16 and enlightening. Thank you for your time, and for
 17 being here with the us today.
 18 **A.** Thank you.
 19 **MS RICHARDS:** Sir, that concludes the evidence for this
 20 week, sir. We're not sitting next week and then we
 21 resume --
 22 **SIR BRIAN LANGSTAFF:** On the Monday?
 23 **MS RICHARDS:** On the Monday.
 24 **SIR BRIAN LANGSTAFF:** We need to make a note of that
 25 because people will be used to us starting on

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1 been more -- maybe held these conversations earlier,
 2 maybe. That's me, me. I'm not speaking for anybody
 3 else in this context: me, me alone.
 4 **Q.** Then, in relation to the SNBTS concentrate, you said
 5 you had confidence in it in terms of the risk of
 6 transmitting AIDS when you made the switch in or
 7 around June 1983, a confidence which ultimately turned
 8 out to be misplaced. Was that confidence based upon
 9 an assumption that it was safe because it was made
 10 from volunteer donors in the United Kingdom or did you
 11 have any particular information about the measures
 12 being taken in Scotland or any particular assurances
 13 about the PFC concentrate that you relied upon?
 14 **A.** No, no, I had no information from PFC about it. It
 15 was related mainly to the fact that the cases of AIDS
 16 that occurred in relation to blood products had
 17 occurred in relation to commercial concentrate, and
 18 I saw the AIDS problem as being related to commercial
 19 concentrate. And that is primarily why I probably
 20 thought that the SNBTS material was safe -- in common,
 21 of course, with a lot of other people who also felt
 22 the same.
 23 **MS RICHARDS:** Sir, those are the questions I'm proposing
 24 to ask from the suggestions from Core Participants.
 25 I'm just going to check whether there are any from --

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1 a Tuesday. That week we're doing Monday to Thursday.
 2 **MS RICHARDS:** We are, and that week and the following week
 3 the precise dates and details are on the Inquiry
 4 website, but the focus is on transfusion practice from
 5 the perspective very much of what was happening in the
 6 hospitals, having heard the evidence we have over the
 7 last few weeks about the Transfusion Centres
 8 themselves.
 9 **SIR BRIAN LANGSTAFF:** Yes, well, we heard quite a lot
 10 about some of the aspects of transfusion practice, and
 11 now we're going to hear it from those who were
 12 actually doing the job at a clinical level.
 13 **MS RICHARDS:** Exactly.
 14 **SIR BRIAN LANGSTAFF:** Yes. Well, thank you very much, and
 15 thank you again, and that's it for this week.

(2.26 pm)

(Adjourned until 10.00 am on Monday, 21 February 2022)

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(31) because... - cirrhosis

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