

1 Tuesday, 1 February 2002

2 (10.00 am)

3 **SIR BRIAN LANGSTAFF:** Good morning, Dr McClelland, can you
4 hear me?

5 **THE WITNESS:** Yes.

6 **SIR BRIAN LANGSTAFF:** Ah, good. And you can see me?

7 **THE WITNESS:** Yes, I can.

8 **SIR BRIAN LANGSTAFF:** Good.

9 Now you are in the Belfast City Hospital, are
10 you?

11 **THE WITNESS:** Well, I'm actually in the blood transfusion
12 centre headquarters, which is in the Belfast City
13 Hospital.

14 **SIR BRIAN LANGSTAFF:** And are you there on your own?

15 **THE WITNESS:** Just with legal representatives next door.

16 **SIR BRIAN LANGSTAFF:** I think there is a technician on
17 hand in case the IT has problems.

18 **THE WITNESS:** In this -- yes, in this room as well.

19 **SIR BRIAN LANGSTAFF:** Good.

20 You're talking to Aldwych House in London. We
21 have a select and small group of people in this room,
22 but you're talking more particularly to the public who
23 are watching online. There will be at any one time
24 around 100 or so people listening. So that is the
25 audience which will be listening to your answers once

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1 aspect of haematology.

2 So I worked for a considerable amount of the
3 time in the ward, in the inpatient, also the day
4 patient centre. That involved treatment of patients
5 with leukaemia and indeed haemophilia. But there was
6 also a laboratory component, including blood
7 transfusion, hospital blood transfusion practice.

8 **Q.** When you moved to the Blood Transfusion Service in
9 August 1978, I think the director at that time was
10 Colonel Field; is that correct?

11 **A.** That's correct.

12 **Q.** And you were deputy director until May of 1980.
13 During that time you've told us in your statement you
14 had a range of one to two-month placements in regional
15 transfusion centres in Edinburgh, Bristol, and London.
16 What was the purpose of those placements?

17 **A.** To learn as much as I could about running a blood
18 transfusion centre. My experience until my
19 appointment had been entirely hospital-based. I had
20 spent occasional one-week periods in the Northern
21 Ireland blood transfusion centre, but it was very much
22 a requirement for me to broaden my experience in other
23 blood transfusion centres to learn how other people,
24 other centres carried on their work to gather up ideas
25 about developments. Now I think we were very -- when

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1 you have been sworn. Mary will ask you to affirm in
2 a moment. Then Ms Richards will ask you the
3 questions.

4 Mary, please.

5 **WILLIAM MORRIS McCLELLAND (affirmed)**

6 **Questioned by MS RICHARDS**

7 **MS RICHARDS:** Dr McClelland, can you see and hear me? You
8 can?

9 **A.** Yes.

10 **Q.** Good. You took up your post as consultant and deputy
11 director of the Northern Ireland Blood Transfusion
12 Service in August 1978; is that right?

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

14 **Q.** Before you joined the Northern Ireland Blood
15 Transfusion Service, what was your clinical experience
16 and practice?

17 **A.** It was after my houseman year in '71 to '72,
18 I trained -- went through a training programme in
19 haematology and laboratory medicine. From '72 to '75
20 I was based in the laboratories at the Belfast City
21 Hospital, so that involved not just haematology but
22 also histopathology, biochemistry and bacteriology.
23 I then moved to the Royal Hospital in '75 until '78,
24 and that was based in haematology, with greater
25 emphasis there, when I was there, on the clinical

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1 I say "we" I mean Colonel Field and myself -- we were
2 very conscious of the relatively isolated position,
3 being in Northern Ireland, and it was essential for me
4 to spend periods of time like that in other centres.

5 **Q.** Then in June 1980, you became the director of the
6 Blood Transfusion Service in Northern Ireland when
7 Colonel Field retired?

8 **A.** Yes.

9 **Q.** And you remained in that post with that title until
10 May 1994, and then with effect from June 1994 to
11 July 2009 you were chief executive and medical
12 director of the Northern Ireland Blood Transfusion
13 Service Agency; is that correct?

14 **A.** That's correct.

15 **Q.** As I understand it from your witness statement,
16 Dr McClelland, the main difference with the latter
17 role, the agency role, was that you had a greater
18 degree of budgetary responsibility in that role and
19 a greater degree of monitoring by the agency board; is
20 that correct?

21 **A.** That's correct.

22 **Q.** But essentially from June 1980 to July 2009 you were
23 in charge of the Northern Ireland Blood Transfusion
24 Service?

25 **A.** That's correct. I was responsible to the board,

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1 the agency board, for the general management of the
2 Blood Transfusion Service.

3 Q. I want to ask you a little first of all about the
4 facilities that were available to you when you joined
5 the service in 1978 and then became director in 1980.
6 The headquarters of the Blood Transfusion Service,
7 were they in Durham Street in Belfast?

8 A. That is right. Yes.

9 Q. And is it right to understand that they were not part
10 of a hospital, the physical site of a hospital?

11 A. No, it was -- the Durham -- I can explain, if you
12 would like me to, a little bit of the background.
13 This was an old chest clinic -- it was an old building
14 and had been used as the main chest clinic in Belfast.
15 It was -- I maybe should explain. My --
16 Colonel Field, when he took over in '69, actually the
17 service was not only physically but administratively
18 separate, in other words the laboratories and the
19 donor administration were separate organisations and
20 physically separate. When Colonel Field took over, he
21 did two things: one, he merged those two aspects of
22 the service, which is very much in keeping with every
23 other blood transfusion centre in the UK; and he also
24 located this centre in Durham Street, this chest
25 clinic, and it was refurbished for the purpose. It

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1 responsibility for the laboratory side and one with
2 responsibility for the donor programme; is that
3 correct?
4 A. That's correct, yes. I probably should have added in
5 my statement: in addition, at that time, the head
6 nurse, who was responsible for the blood donor
7 attendance, actually reported directly to me for
8 a number of years. Then, in 1992, a new -- a donor
9 services manager was appointed who was responsible for
10 the donor attendants as well as the other staff.

11 Q. And there were a range of medical staff and blood
12 donor attendants, but I'll come on to ask you about
13 those in a while when we look at the donor collection
14 arrangements?

15 I want to start next, then, by asking you to
16 look with me at some annual reports of the Eastern
17 Health and Social Services Board, Dr McClelland, which
18 I hope made their way to you overnight.

19 A. Yes, yes. I just got a chance to look at them about
20 half an hour ago.

21 Q. Good, good.

22 A. Yes.

23 Q. Although they're long documents, I'm only going to
24 take you to the sections relating to the Blood
25 Transfusion Service.

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1 was only ever intended to be a temporary arrangement,
2 that's what Colonel Field always said to me, that it
3 was intended to suffice for perhaps ten to 15 years,
4 and then the plan at that time was that there would --
5 should be provided a new purposed designed centre.

6 That took rather longer to achieve.

7 Q. You told us in your statement that the building was
8 increasingly unsatisfactory for a blood transfusion
9 service, and it was accepted, really from the time you
10 were a director in 1980, that there was a need for
11 a new building, but that didn't happen, I think, until
12 1995?

13 A. That's right. That's right. It was increasingly --
14 as more development took place, it was increasingly
15 short of space to start with. And just the general
16 environment for transfusion operation, it did not meet
17 what would have been considered the requirements of
18 a transfusion centre.

19 Q. Now in terms of staffing, you've told us in your
20 statement that Colonel Field operated largely
21 single-handedly for much of his tenure, but when you
22 became director you recruited a deputy director and
23 consultant, and that was Dr Bharucha, was it?

24 A. Yes, that is correct. Yes, in 1981.

25 Q. You had two operational managers, one with the

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1 Sully, could we have RHSC0000078, please.

2 You'll see, Dr McClelland, this is the annual
3 report of the Eastern Health and Social Services Board
4 for the year 1980.

5 Sully, could we go to, I think it should be,
6 page 41.

7 So at the bottom of the page, there's a heading
8 "Northern Ireland Blood Transfusion Service and Blood
9 Transfusion Service Laboratories". And I'm just going
10 to read those paragraphs:

11 "This was a difficult year for the Northern
12 Ireland Blood Transfusion Service and for the first
13 time in recent years the number of units of blood
14 collected was actually less than in the previous year.
15 This was the case in spite of the fact that the total
16 number of donation sessions was increased. The
17 reduction was undoubtedly due to the effects of the
18 recession with resulting factory closures and
19 pay-offs. In spite of this the needs of all hospitals
20 in Northern Ireland for blood and blood products were
21 met.

22 "During the year a total of 66,401 donations
23 were made to the service. This again included
24 emergencies when donors attended at all hours of the
25 day and night. Good cooperation is still being

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received from employers who continue to permit sessions to be held on their premises and in many cases permit employees to attend nearby sessions during working hours."

If we can just keep that on the screen, Sully, before we go to the next page.

What was it that made this a difficult year?

There's a reference to the recession and factory closures --

A. Yes.

Q. -- where did that have an impact upon the Blood Transfusion Service?

A. Factories and other places of work were a very important source of donors in those days, certainly. If you compare factories and workplaces with public sessions, the percentage of members of the public -- of people donating -- was much higher with -- in those facilities, perhaps for fairly obvious reasons, that people were -- it was much more convenient with the service visiting their place of work.

Whatever the reason, that was -- these were a very, very important source of blood donors and, of course, when one -- if a factory closed down or -- I mean, to give the example of perhaps best known in Northern Ireland, the shipyards at Harland & Wolff, we

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out to be not a very suitable location. It was rather close to areas of civil strife and it was directly affected, certainly during the '70s and into the '80s and beyond by bombings with -- there were times when the centre actually had to be evacuated during such episodes.

So that was the headquarters. Yes, throughout the province, there were areas where one had to take account of the impact of the Troubles in terms of arranging sessions. I must say, in terms of cross-community support, that was often extremely good. But, you know, nevertheless, there could have been fears among donors about, in mixed communities, crossing to a particular venue. So there were issues there that would have had an effect.

Q. If we go to the next page, please, of this report, you can see at the top of the page it says, "New centres open during the year were as follows", and we can see reference there to a Young Offenders Centre and Ebrington Barracks. I'll come back to the issues raised by donor sessions in locations such as those a little later, Dr McClelland.

If we skip the next paragraph the paragraph after that records:

"During the year recruitment was commenced for

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used to go there for a full week. There were enough staff to enable us to collect blood for a full week.

Some years later that was down to one day, and there were numerous examples like that. And, of course, when those places of work closed down, they had to be replaced. We had to find alternatives and that took a lot of effort and time to do.

Q. You also, in your witness statement, Dr McClelland, as well as referring to the impact of factory closures, also refer to the impact of the Troubles --

A. Yes.

Q. -- on the work of the Blood Transfusion Service.

A. (Witness nodded)

Q. In broad terms, how did that make the Blood Transfusion Service's role more problematic? What difficulties did it cause?

A. From two points of view. First of all, of course, demand for blood, as you can imagine, especially during major trauma episodes like bombings, and so on, there would be a very sudden increase in the demand for blood at short notice. So that was one aspect. The other, of course, is just the security situation itself.

You start with the headquarters at Durham Street. It turned out -- Durham Street turned

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a special panel of blood donors who were prepared to undergo pheresis on the cell separator machine which is cited in the Royal Victoria Hospital. This procedure is used to collect white cells which are of value, mainly in the treatment of patients with acute leukaemia."

I'll come back to the question of plasmapheresis again later. Then it continues:

"The increasing need for blood components resulted in a larger proportion of the blood collected being fractionated. This is reflected in the increased number of concentrated red cells prepared and also the increased production of platelet concentrates and fresh frozen plasma. The laboratory continued to send plasma for fractionation to the Blood Products Laboratory ... Elstree and in return received plasma protein fraction and other blood components. Some of these components were sent from BPL directly to hospital units, eg Factor IX and certain immunoglobulins and these are not included in the statistics. Other blood components supplied by the Blood Bank were cryoprecipitate, dried plasma and anti-D immunoglobulin."

Again, Dr McClelland, I'm going to come back to the question of arrangements with BPL in a little

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1 while.

2 Then if we go a little further down, we can see
3 a paragraph beginning:

4 "The hepatitis laboratory continues to test all
5 blood donors and ante-natal patients with the presence
6 of hepatitis B antigen."

7 I'll come back to that again later.

8 Then the final paragraph:

9 "During the year doctors, medical laboratory
10 scientific officers and for the first time medical
11 students, were given tuition on various aspects of
12 blood transfusion."

13 Just pausing there, Dr McClelland, at that time,
14 so 1980, what kind of tuition were you providing to
15 doctors MLSOs and medical students, on blood
16 transfusion?

17 A. Yes, well, on my appointment I was asked by Professor
18 Bridges, the professor of haematology, to take on the
19 teaching of medical students in all aspects of blood
20 transfusion. So that would have involved two lectures
21 to the whole year, and then we divided the year
22 into -- I think there were eight different -- eight
23 small groups who came to the transfusion centre for
24 the more detailed instruction provided, and actually,
25 at that time, were able to visit particular parts of

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1 Sully. Thank you.

2 So we've got there some statistics. Again,
3 I won't go through all of them but it gives us a sense
4 of what was happening: whole blood issued, 57,462
5 units; red cell concentrates prepared, 23,630 units.

6 Then we can see, a few lines further down:
7 plasma collected for albumin production for BPL,
8 6,000; and albumin production for Dublin, 1,210; fresh
9 frozen plasma prepared, 1,574; then cryoprecipitate
10 prepared, 5,080 packs prepared, and then 3,531 packs
11 issued.

12 Then there are various other statistics in
13 relation to other products and components.

14 In relation to the cryoprecipitate, are you able
15 to assist us, Dr McClelland, in understanding the
16 reason for the shortfall between the volume prepared
17 and the volume issued?

18 A. Um, no, other than it would have been really a case of
19 demand. It does seem quite a low figure for issues,
20 but that must be correct.

21 But cryoprecipitate, like most blood components,
22 were -- production was very much demand led. The
23 difference there would suggest that we would have been
24 holding quite a large stock. Of course the shelf life
25 of cryoprecipitate was, I think, in the region of

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1 the laboratories. So it was really all aspects of
2 blood transfusion, laboratory aspects and clinical
3 aspects.

4 Q. Then if we can turn to page 108, please, of this
5 document, Sully.

6 This is an appendix which gives various
7 statistics for the Transfusion Service so we can see
8 we have the numbers on the civilian donor panel, as at
9 the end of 1980, the figure being 96,309. Places
10 outside Belfast visited, 125. Then it sets out
11 centres at which donations were received.

12 Sessions held: 230 in Belfast; 502 outside
13 Belfast. Then donors attending sessions: 20,425 in
14 Belfast; 52,866 outside of Belfast.

15 Then if we just look at the table at the bottom
16 of the page, it gives an idea of the statistics. I'll
17 just, for present purposes, look at the figure for
18 donations. So we can see 1974 it's 54,000-odd, and
19 then there seems to be a small annual increase in most
20 years, and then in 1980 a slight decrease.

21 Then if we could go over the page, there's
22 a heading "Statistical Report 1980", I don't need to
23 ask you about this page but, if we can go to the next
24 page, please, could we just go closer so we can see
25 the figures under the heading "Blood Bank", please,

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1 six months. At least six months. So I can't give an
2 exact explanation as to why there's quite a -- such
3 a large discrepancy there, or apparent discrepancy.

4 Q. I'm going to ask you to look next at the report for
5 the following year, for 1981.

6 Sully, could we have RHSC0000073.

7 So this is the eighth annual report, year ended
8 31 December 1981.

9 Could we go to page 38, please.

10 We can see there the heading:

11 "Northern Ireland Blood Transfusion Service and
12 Blood Transfusion Service Laboratories

13 "The effects of the recession continued to
14 create difficulties for the Northern Ireland Blood
15 Transfusion Service with the resulting factory
16 closures and redundancies: 26 sessions were lost
17 during the year and many of the existing factory
18 sessions produced fewer donors. Strenuous efforts
19 were made to compensate for this loss by opening new
20 sessions and increasing the level of publicity.
21 Twenty new centres were opened including a regular
22 weekly session at the YMCA, Wellington Place. The
23 total number of sessions was increased from 732 to 758
24 and the needs of all the hospitals for blood and blood
25 components were met despite many problems.

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"During the year a total of 64,135 donations were collected. This represented a slight decrease on the previous year's total but there was evidence of a significant improvement during the latter months of the year as the new strategies for recruiting donors became effective."

And then if we go further down the page -- thank you. So about three paragraphs up from the bottom of your screen, Dr McClelland, there's a paragraph beginning:

"The laboratory continued to send plasma for fractionation to the Blood Products Laboratory ... [at] Elstree and in return received plasma protein fraction and other blood components."

And it continues by explaining:

"Blood components supplied by the Northern Ireland Blood Transfusion Service were: cryoprecipitate, dried plasma, salt-free albumin and anti-D immunoglobulin."

So right to understand, a similar picture, broadly speaking, to the previous year?

A. Yes.

Q. Then if we could go, please, Sully to page 102, we've got the donor panel figures there. They're not easy to read in full because the right-hand side of the

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Transfusion Service.

"Five factory sessions were lost but to compensate for this eleven new centres were opened during the year. The total number of donations collected was 63,310, which represents a slight reduction on the previous year. In spite of the difficulties the needs of all hospitals in Northern Ireland for blood and blood components were met."

Then if we go -- if we have the whole document, thank you. If we go to fourth paragraph further down:

"In the laboratories an important development during the year was the establishment of a link-up with the Protein Fractionation Centre, Edinburgh ... which produces purified proteins made from blood plasma which it receives from Transfusion Centres. All plasma previously sent to the Blood Products Laboratory, Elstree, is now sent to the PFC for fractionation. The easier access to the Edinburgh Centre allows the transport of fresh deep frozen plasma which is necessary for the production of Factor VIII concentrate. This protein is necessary for the treatment of haemophilia and its usage had been increasing rapidly. Previously Factor VIII has been purchased from commercial sources but it is hoped to become self-sufficient in the not too distant

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page is cut off. But if we could go two further pages on, again we've got similar statistics, and I just wanted to pick up upon the figures for cryoprecipitate. That's just over halfway down the page.

"Cryoprecipitate prepared ... 2,918 Packs ...

"Cryoprecipitate issued ... 3,473 Packs ..."

So it looks as though in that year you were producing less cryoprecipitate although the amount actually issued was roughly the same as the previous year?

A. Yes. Yes, it looks like we were -- it looks like we had built up a fairly healthy stock from the previous year and presumably had run down that -- allowed that to run down a little bit, and hence the smaller figure for number of packs prepared.

Q. Then we can pick up the picture for 1982 at RHSC0000076.

So we've got there the 1982 annual report. If we could go, please, to page 34. Under the heading "Northern Ireland Blood Transfusion Service and Blood Transfusion Service Laboratories", the report reads: "The effects of the recession with resulting factory closures and redundancies continue to create difficulties for the Northern Ireland Blood

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future."

Then there's a reference to some additional laboratory tests.

Again, I'm going to come back, Dr McClelland, to the arrangements with the PFC. These documents are just by way of overview.

If we can go to page 106, please, the statistical report.

Again, we've got the donor panel figures there.

Can you just assist me with understanding, "Donors removed from panel during year" -- we saw this in the earlier reports as well -- so the third figure down on the page gives a figure there of 9,338. Was that mainly because of donors reaching an age whereby donations were no longer taken from them or was that due to assessment for unsuitability, or what, in general terms, would lead to removal from the panel?

A. Yes, a mixture of reasons. You've mentioned exceeding the age limit for donation. We would have had a practice that if, after -- obviously donors were called by letter to invite them to donate. If there was no response after a certain length of time, typically that would be two years but it would vary according to the frequency of visits, I think, to that venue, but in the absence of response after a certain

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1 length of time, donors -- a donor would be no longer
 2 called, no longer invited by letter and would
 3 therefore be removed from the panel.
 4 **Q.** Then if we go two pages further on, please, Sully,
 5 page 108.
 6 The bottom half of the page, under the heading
 7 "Blood Bank" again gives similar information to that
 8 which we've seen previously.
 9 Towards the bottom of the page we can see the
 10 figures for cryoprecipitate packs: 3,086 issued --
 11 sorry, prepared; 3,253 packs issued.
 12 Then if we go over the page we can see the first
 13 two entries refer to the plasma being sent to
 14 Edinburgh, "Outdated plasma". Is that what we see
 15 referred to elsewhere as "time-expired plasma",
 16 Dr McClelland?
 17 **A.** That's correct, yes. It's really the same as
 18 time-expired.
 19 **Q.** Then -- sorry. And then fresh frozen plasma for
 20 Edinburgh, plasma collected for fractionation for
 21 Dublin. Again, I'll come back to those.
 22 If we can just then move to the report for 1983,
 23 RHSC0000081, please. So the tenth annual report, year
 24 ended 31 December 1983.
 25 If we go to page 25, please, Sully, bottom half

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1 particularly Factor VIII and albuminoid products, the
 2 demand for both of which is increasing rapidly."
 3 Then if we can go to page 95.
 4 We've got the figures there for the donor panel.
 5 We can see from the fifth line the number of
 6 donations: 62,283. So that, again, is a slight
 7 reduction on the previous years. Then we have the
 8 figures there for plasmapheresis and cell separator
 9 donors.
 10 If we go on a further two pages, we've got the
 11 "Blood Bank" figures at the bottom of the page.
 12 And if we can go over the page, top of the next
 13 page, we've got the cryoprecipitate figures: 2,432
 14 packs prepared, 2,516 packs issued.
 15 So we can see, I think, Dr McClelland, overall
 16 between 1980 and 1983, a reduction in the amount of
 17 cryoprecipitate being prepared and being issued.
 18 **A.** Yes.
 19 **Q.** And then we've got the figures in terms of plasma for
 20 Edinburgh, and we can see there, in relation to the
 21 fresh frozen plasma for Edinburgh, a significant
 22 increase. So over 5,500 kilograms there recorded.
 23 The last report I want to ask you to look at is
 24 the following year, 1984. RHSC0000069, please.
 25 This is the annual report for 1984.

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1 of the page.
 2 We've got the now-familiar heading, and then it
 3 explains:
 4 "As in the previous two years, the effects of
 5 the recession with resulting factory closures and
 6 redundancies, led to the loss of further donation
 7 sessions. Altogether 15 sessions had to be closed
 8 down of which the majority were in factories, but 13
 9 new centres were opened.
 10 "An important development was the opening of
 11 a new Blood Donor Centre at College Street, Belfast
 12 towards the end of the year. This is open every
 13 Tuesday and Thursday while a session continues to be
 14 held in Durham Street on Mondays. It is hoped that
 15 this arrangement will lead to a steady increase in the
 16 number of donations collected at Headquarters."
 17 And then if we go two paragraphs further down,
 18 it refers to:
 19 "A link-up between the Northern Ireland Blood
 20 Transfusion Service and the Protein Fractionation
 21 Centre, Edinburgh was established in 1982 and during
 22 1983 a steadily increasing supply of plasma was
 23 transported to this centre and purified blood products
 24 received back on a pro-rata basis. The aim is to
 25 achieve self-sufficiency in all blood products,

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1 If we go to page 21, please. Bottom half of the
 2 page, it records:
 3 "The graph illustrates the decline in the number
 4 of donors during the period 1979-1983. A great deal
 5 of effort has been required to compensate for this
 6 loss by opening new 'public' sessions which ensure
 7 that the needs of all hospitals for blood products
 8 were met.
 9 "There was a slight increase in the number of
 10 donors during the year -- at 64,766 as against 62,283
 11 in 1983."
 12 Then there's reference to a garden party at
 13 Hillsborough Castle.
 14 Then:
 15 "During the year the acquired immunodeficiency
 16 syndrome (AIDS) became a very public issue, not least
 17 because of the implications for blood transfusion
 18 services. Number of important measures are being
 19 taken to prevent the transmission of AIDS to
 20 recipients of blood and blood products. The virus has
 21 now been identified and it is likely that a screening
 22 test will soon be available for detecting any blood
 23 donors who are carrying the virus.
 24 "A continuing trend in blood transfusion
 25 practice has been the increase in demand for blood

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components (platelets, plasma products, etc), while the requirement for 'ordinary' blood transfusion (red cells) remained fairly steady. To meet this demand 1984 saw a further substantial increase in component production and in the supplies of plasma to the Protein Fractionation Centre, Edinburgh."

Then we don't have, I'm afraid, a similar statistical report to the reports in the previous years.

Does what's set out there, in terms of in particular issues relating to numbers of donors, accord with your recollection of the difficulties that were experienced in the early 1980s?

A. Yes, I think so. I have not seen these reports for a very, very long time, and -- but yes, it does accord with what I -- my memories of the particular difficulties in those -- the 80s, with factory closures and so on. Certainly we -- we did have to work very hard in order to maintain supplies and had to look at various methods. Very -- often, increasing just the number of opportunities to donate, in other words increasing the number of venues, but there were also recruitment initiatives which maybe are not mentioned there, but that was also important.

Q. Now, those were reports published by the Eastern

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of money covering all laboratories in the province -- hospital diagnostic laboratories and the blood transfusion laboratories, and so each of those put in their bid each year for additional staff or major items of equipment, and how that money was allocated was decided by a committee of pathologists, of senior doctors, and fed down through the boards. So there were those special arrangements in respect of laboratory services, which is obviously -- obviously an important part of our business.

Q. Do you know why it took so long to get a new headquarters, a new location and proper building?

A. A number of reasons. When -- although I was told that it had been decided that this was a temporary -- the building in Durham Street was temporary, certainly when I joined the service there was no actual earmarking of funds or site for a new centre. So it was there as a kind of aspiration, but nothing was actually there to make it happen at that point. I obviously lobbied -- it was one of my major objectives, obviously, to get a new centre. I lobbied anyone who seemed relevant to do so at the Eastern Board and at the Department of Health.

One of the problems we ran into was major capital development, major building works. These were

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Health and Social Services Board. Is it right to understand that it was that Board which provided the funding for the Blood Transfusion Service until around 1993/1994?

A. Yes, the NIBTS was responsible to the Eastern Board and, in fact, the Eastern Board held the budget. NIBTS -- I was not in those days the budget holder, which was probably unusual. I think, in those parts of the UK the director was the budget holder. That's not what I inherited. So the budget was held at the Eastern Board and management support was provided by the Eastern Board. There was a section within the Eastern Board called management services, which provided a range of support services.

Really, in terms of funding, I suppose control was exercised by -- as I say, I was not the budget holder but control was exercised by limiting the appointment of new staff. I think that was the -- any small change in staff, any increase, no matter how small, required the approval of the Eastern Board.

There were also special arrangements for laboratory staff which was a regional -- was a special regional arrangement for funding laboratory staff and laboratory equipment. So that was considered on a regional basis but -- in that there was a fixed pot

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operated on five-year cycles. I remember -- certainly I can't remember the first time this happened but we ran into a situation where there was a complete -- within the Health Service in Northern Ireland, there was a complete embargo on any capital development. So you had, therefore, one of these five-year periods where there was absolutely no new money for capital development of any kind.

So that was a major cause of hold-up. Then, when money -- some money started to become available, there was an issue around a site -- selecting an appropriate site. I certainly was keen that the centre moved to a hospital site, preferably a teaching hospital site, and that eventually happened but there were difficulties there in achieving that.

Q. Now, other than issues relating to funding, which obviously had an important role to play, but leaving those aside, did the Eastern Health and Social Services Board become involved in decision making regarding the policies and practices of the Blood Transfusion Service or was that left largely to you?

A. Well, yes, they did become involved on major issues. Obviously, I would -- the first big issue, the first big issue which was brought to them, and when they became very involved and had to involved in, was the

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1 old question of self-sufficiency and plasma products.
 2 I had put forward a proposal of this, of various
 3 advantages of the move to Edinburgh, and so on, that
 4 led to that. And, yes, in the -- they were -- became
 5 very much involved in that.
 6 And obviously some -- major policy decisions
 7 linked -- related to AIDS later, and so on, they would
 8 have been involved. Not really so much in the
 9 day-to-day running on the service, although I have
 10 to -- as I think I alluded to earlier, any new
 11 member -- any new additional staffing did have -- did
 12 require the approval of the Eastern Board and it was
 13 this department, management services, which one had to
 14 apply to get approval for anything of that nature.
 15 **Q.** Then what about the Department of Health and Social
 16 Services in Northern Ireland? What kind of
 17 relationship did you have with that Department and
 18 what role did they have *vis à vis* the Blood
 19 Transfusion Service?
 20 **A.** Yes, I certainly had a relationship with the
 21 Department of Health. I should say, as far as my job
 22 description was concerned, these sort of reporting
 23 relationships were never -- weren't really spelt out.
 24 There was a sort of ultimate responsible to the head
 25 of the Eastern Board, the chief administrative

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1 London?
 2 **A.** Just that, as it is stated here, that policies adopted
 3 in London, almost invariably, I would say, certainly
 4 anything that affected NIBTS followed the policy in
 5 London. If you contrast that with post-direct rule
 6 when the Assembly was started, which I think was 1999,
 7 I think one would still have found that their policies
 8 tend to follow the DoH London. But, on some issues,
 9 there might have been begun -- there might have
 10 started to be some divergence.
 11 **Q.** Did you, yourself, have any direct dealings with the
 12 Department of Health and Social Security in London?
 13 **A.** No, no. That would have been via the Department in
 14 Northern Ireland. So I can think of some committees,
 15 advisory committees, in London. Concerning blood
 16 transfusion, I can think of one that the Inquiry
 17 provided me with, it's an example advisory committee
 18 on blood transfusion, but the representative from
 19 Northern Ireland on that was one of the medical people
 20 from our own Department of Health --
 21 **Q.** Then --
 22 **A.** -- not myself.
 23 **Q.** -- did you have any significant dealings with Health
 24 Authorities or Department of Health in the Republic of
 25 Ireland in the '80s or '90s?

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1 officer, I think that was the only thing. In
 2 practice, I had a relationship -- working relationship
 3 with the chief officer -- the Chief Medical Officer of
 4 the Eastern Board and with the Chief Medical Officer
 5 of Northern Ireland -- of the Department of Health.
 6 Yes. Yes.
 7 And I did, in practice, have pretty regular
 8 communication on medical matters, again certainly with
 9 regard to the self-sufficiency issue, important issues
 10 like that, and the HIV.
 11 **Q.** In your witness statement -- we'll just put it up on
 12 screen, it's WITN0892001, please, Sully. Yes, page 5.
 13 So it's the top of page 5. You've said:
 14 "There were no formal relationships with other
 15 blood services in the UK but policies and procedures
 16 were often shared with other RTCs in GB and adopted by
 17 NIBTS."
 18 Then this:
 19 "This was particularly appropriate because
 20 policies adopted by [Department of Health and Social
 21 Services Northern Ireland] typically followed those of
 22 DoH (London) since [Northern Ireland] was under direct
 23 rule from London."
 24 What, in practice, was your understanding of the
 25 impact of, as you described there, direct rule from

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1 **A.** Not -- I wouldn't have had any dealings with the DoH
 2 in the Republic of Ireland. But, obviously, our own
 3 Department would have that. We had -- quite a lot of
 4 informal communication with the -- at the blood
 5 transfusion level. Mainly at a professional level
 6 there were a lot of cross-fertilisation of ideas in
 7 various ways, at the medical level, those in the Irish
 8 blood -- so mainly medical.
 9 There was a very active laboratory MLSO group
 10 that met on an annual basis between the Dublin service
 11 and themselves and also at the donor organisation
 12 level, there were regular communications there and
 13 there were even invitations to donor award events in
 14 both directions that I can recall, particularly in the
 15 early '80s, or during the '80s.
 16 **Q.** Now, I just want to ask you a little next about the
 17 process of inspection by external agencies or
 18 organisations. Is it right to understand that your
 19 first recollection of an external inspection of the
 20 Transfusion Service was the 1981 visit by the Protein
 21 Fractionation Centre?
 22 **A.** That's right, yes. Yes.
 23 **Q.** We'll look at that in a little while. But I -- as
 24 I understand it from your statement, personnel from
 25 the Protein Fractionation Centre would then

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1 subsequently carry out, from time to time, inspections
 2 of the processes and procedures at the Northern
 3 Ireland Blood Transfusion Service; is that right?
 4 **A.** That's correct.
 5 **Q.** Then your statement explains also that there was
 6 inspection by the Medicines Inspectorate of the
 7 Northern Ireland Blood Transfusion Service. Your
 8 recollection is that the first one was December 1982,
 9 and then it was roughly every two years; is that
 10 correct?
 11 **A.** That's my recollection, yes.
 12 **Q.** Then if we can go back to your statement, WITN0892001,
 13 and go to page 10, please.
 14 We pick it up at the bottom of this page. This
 15 is where you refer to the inspection by the Medicines
 16 Control Agency. The last three lines of that page you
 17 say:
 18 "The granting of a manufacturing licence ... to
 19 NIBTS was delayed due to the inadequate premises.
 20 Indeed, this was a crucial factor in securing the
 21 eventual funding for a new NIBTS [then we go to the
 22 top of the next page] Headquarters unit. The service
 23 relocated to the new (current) centre in 1995, and was
 24 granted a manufacturing licence after the first
 25 subsequent inspection."

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1 Blood Transfusion Service in England and Wales
 2 operated?
 3 **A.** Um ... well, I suppose the most obvious difference
 4 would have been the fact that it was -- Scotland had
 5 a national service, a nationally coordinated service,
 6 whereas in England that service was delivered by,
 7 whatever, 14 Regional Health Authorities. So there
 8 was that attempt, certainly, to run a nationally
 9 coordinated service, albeit each regional centre
 10 seemed to have quite a lot of autonomy in their
 11 operations. There wasn't an absolute requirement to
 12 follow a national line. So I suppose national
 13 decisions were taken more by consensus than by diktat.
 14 So, let's see, differences. I mean, there are
 15 certainly a lot of similarities. I think that's --
 16 perhaps that's the most -- high-level -- at a high
 17 level, that was the most important difference.
 18 There was obviously an earlier approach in
 19 Scotland towards self-sufficiency, which had quite a
 20 lot of influence in my own thinking, because Edinburgh
 21 was the first -- going back to those placements, it
 22 was the first centre I had spent some time in. And
 23 I became very conscious of the importance of that.
 24 **Q.** Now you've told us in your statement that you also
 25 attended an annual forum with Dr Elizabeth Mayne, the

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1 If we can just go back to the bottom of that
 2 previous page, Sully.
 3 Can you recall what it was about the premises
 4 that held up the grant of the licence or what it was
 5 that the MCA was particularly concerned about?
 6 **A.** I don't recall that the MCA identified any specific
 7 issue. I think it was just the general environment
 8 and the -- a lack of -- the insufficient space for
 9 a blood transfusion facility. I can't recall there
 10 was anything -- any specific issue on the premises.
 11 **Q.** You can take that down. Thank you.
 12 I just wanted to ask you next a little about the
 13 kind of meetings that you held with others working in
 14 the transfusion service across the United Kingdom.
 15 You attended the meetings of the Regional
 16 Transfusion Directors of England and Wales,
 17 I understand.
 18 **A.** That's correct.
 19 **Q.** You also, following the establishment of the
 20 arrangements with the Protein Fractionation Centre,
 21 attended the directors' meetings of the SNBTS in
 22 Scotland?
 23 **A.** That's correct.
 24 **Q.** Did you observe any particular differences between the
 25 way in which SNBTS operated and the way in which the

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1 Haemophilia Centre Director in Belfast,
 2 representatives of the Eastern Health Board. I don't
 3 think we have any minutes of those meetings but can
 4 you recall broadly what their format and purpose were?
 5 **A.** Yes, I can't remember what year those started.
 6 I suspect it was probably the middle '80s before those
 7 got under way. The purpose was really to try to
 8 coordinate supplies with usage and demand for
 9 Factor VIII and other coagulation concentrates. There
 10 was a great deal of concern at the management level of
 11 the Eastern Board level of the rapidly rising costs,
 12 but obviously the board wanted to understand how the
 13 system worked. Perhaps how costs might be contained.
 14 So it was really a coordinating role with respect to
 15 supply and demand for those products.
 16 **Q.** You've referred to self-sufficiency, and indeed we saw
 17 that as an objective identified in the annual reports
 18 that we looked at. Was attaining self-sufficiency
 19 a policy that was adopted really after you took up
 20 your job as director? Or had it always been, in
 21 principle at least, the policy of the Blood
 22 Transfusion Service?
 23 **A.** I can't really speak about what was pre -- certainly
 24 pre-1978, or even pre-1980. I think during most of
 25 the '70s, self-sufficiency would have meant

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1 maintaining supplies of blood and blood components at
 2 an extremely difficult time. I really do not know
 3 what kind of -- I'm not aware of what kind of
 4 decision-making approach was taken during the '70s
 5 with respect to self-sufficiency and Factor VIII.
 6 I presume there would have been meetings involving the
 7 Department of Health's Blood Transfusion Service and
 8 the Haemophilia Centre on these matters, but I'm not
 9 sure. I really do not know what kind of policy was
 10 adopted.

11 I wasn't conscious on joining the service that
 12 self-sufficiency in Factor VIII, for example, which
 13 was what it really came to mean, in practice --
 14 I wasn't conscious that that was a major strategic
 15 decision -- or objective at that point.

16 **Q.** So would it be right to understand that it's something
 17 which, after you became director, you consciously
 18 formulated a policy, which may or may not have existed
 19 to some extent previously, but you consciously
 20 formulated a policy of wanting to achieve
 21 self-sufficiency in relation to factor concentrates
 22 for Northern Ireland?

23 **A.** Well, yes. I mean, as I mentioned, particularly when
 24 I spent time in Scotland, I became very conscious of
 25 this. I also, in discussion with Dr Mayne, the

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1 **Q.** Is it correct -- this is certainly what your statement
 2 suggests -- that the Northern Ireland Blood
 3 Transfusion Service was receiving what you've
 4 described in your statement as a very small amount of
 5 Elstree Factor VIII from BPL?

6 **A.** Yes, yes. I think it was in the region of
 7 200,000 units of Factor VIII, which would only have
 8 represented somewhere between 10 and 20 per cent of
 9 the total. Again, I have no idea how that arrangement
 10 or when that arrangement was made. But obviously,
 11 it -- by I think it was '80, '81 we ceased receiving
 12 that small allocation.

13 **Q.** And your statement suggests that you were aware of
 14 there being capacity issues at BPL. So you've
 15 identified one problem, which was the transportation
 16 problem in relation to shipping fresh frozen plasma
 17 from Belfast to Elstree. But were there also -- was
 18 it also your understanding that BPL might not have the
 19 capacity to fractionate fresh frozen plasma supplied
 20 by you?

21 **A.** Yes, it was my original assumption that we would start
 22 investigating sending some fresh frozen plasma to BPL,
 23 as I think letters to Dr Lane illustrate.
 24 And I remember doing meeting -- I remember meeting
 25 with Dr Lane to discuss aspects of this.

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1 Haemophilia Director, I was conscious that she was
 2 certainly also very supportive of going down this
 3 route, and when I put to her the notion of changing
 4 fractionators so we could start providing our own
 5 Factor VIII, she was supportive of that, very
 6 supportive.

7 **Q.** At the time you took over as director, in relation
 8 to BPL, is it right to understand that it was only
 9 time-expired plasma that you were supplying to BPL?

10 **A.** That's right. That's right. It was only liquid
 11 plasma, which could not be used to make Factor VIII.
 12 And that seemed to be entirely because of logistical
 13 difficulties of shipping plasma in the -- it had to be
 14 maintained at a very low temperature. I'm not sure if
 15 any -- how much effort was made to try to get around
 16 that problem. It certainly would have been difficult.
 17 So I don't know. But that was -- yes, sorry, to
 18 answer your question, that's correct. It was only
 19 liquid plasma, time-expired plasma, if you like.

20 **Q.** And the fresh --

21 **A.** -- (overspeaking) --

22 **Q.** Sorry, the fresh frozen plasma that was produced in
 23 Northern Ireland was not being produced at that stage
 24 for fractionation?

25 **A.** No, that was purely for hospital use.

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1 But then I did become aware that there seemed to
 2 be capacity issues. In fact there was something in
 3 the BMJ, published, which suggested that. And then
 4 I became aware that PFC may have spare capacity. So
 5 it made sense to investigate that.

6 At the same time, this issue seemed to have been
 7 discussed at the department level at one of those
 8 advisory committees in which that -- I'm not sure
 9 which came first, but this possibility of transferring
 10 was discussed quite early on at the department level
 11 as well as something that might -- transferring
 12 Northern Ireland's requirements from BPL to PFC.

13 **Q.** If we just look at one document before we break,
 14 Dr McClelland, and it's one of your letters to Dr Lane
 15 on this issue, CBLA0005101. So this is a letter from
 16 you, 25 September 1980, so it's not long after you
 17 were taken had taken over as director in June 1980:

18 "Dear Dr Lane,

19 "I am writing to inform you of my plans for the
 20 supply of plasma to BPL in the near future.

21 "As you will be aware we have been sending you
 22 approximately 7,000 litres of liquid plasma per year.
 23 We have not provided any fresh frozen plasma for
 24 Factor VIII production, but, in view of our special
 25 difficulties in Northern Ireland we have been

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receiving some 240,000 iu Factor VIII per year.

"Following the recent proposals for the supply of Factor VIII and albumin to regions in amounts pro rata with their input of raw material, I have formulated plans for the transport of fresh frozen plasma to BPL. These plans were submitted for funding to our local Health Authority several months ago, but I am still awaiting final approval. Basically, I am planning to introduce RIA for hepatitis testing and to purchase a liquid nitrogen refrigerator for the transport of FFP. We could then commence supply of FFP as soon as the new single transport pack becomes available to us. I would estimate that initially we can send about two thirds of our present plasma supply in this form.

"I would welcome any comments, and in particular, it would be helpful if you could clarify a few points as follows:

"1. Is it envisaged that the special position of Northern Ireland with regard to the supply of Factor VIII concentrates would cease after 1st April, 1981?

"2. I was disturbed to read a recent letter in BMJ ... in which it is stated that BPL had not the capacity to handle extra plasma. Can you provide any

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reassurance on this point?"

Then over the page, the third point was about the availability of BPL's RIA reagents for hepatitis testing. I'll come back to hepatitis testing later, Dr McClelland.

If we go back to the first page, if we look at that second paragraph, what did you mean by "our special difficulties in Northern Ireland" in this context?

A. I assumed there had been some recognition that there were -- I think it would probably have been referring to the Troubles. It could also have been referring partly to the difficulty of transport of fresh frozen plasma. But I suspect it was mainly our, sort of, recognition that special provision should be made for Northern Ireland, in view of the pressure that the Transfusion Service was under to maintain a supply of blood and blood components.

Q. If we look at the paragraph numbered 1, towards the bottom of the page, "the special position of Northern Ireland with regard to the supply of Factor VIII concentrates", does that refer to the fact that, although you sent no fresh frozen plasma to BPL for fractionation, you did receive some BPL Factor VIII, albeit only a modest amount?

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A. That's correct.

Q. We'll pick up after the break what then happened with PFC. I don't think we've got Dr Lane's reply to this but is it right to understand -- well, no. Can you recall, either -- whether it was through meeting or correspondence or some other format, what Dr Lane's response in broad terms was?

A. I can't. I don't know if there was a response to this letter and, certainly, I know the supply of Factor VIII did cease, certainly I can't remember exactly when that happened, but it must have been -- it says after 1 April 19 -- I think it probably did happen at that time that the Factor VIII supply from BPL did cease at that point.

MS RICHARDS: Sir, we can pick up the picture in relation to the PFC arrangements perhaps after the break.

SIR BRIAN LANGSTAFF: Yes. Well, we'll do that.

So we'll take a break now. We will come back at 11.50. Let me tell you what I say to all witnesses at this stage, if not before, in their evidence. When there's a break, you may not discuss with anyone anything that you have been asked about already, and anything you think you may yet be asked about in evidence. You can talk about anything else that you like.

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THE WITNESS: Thank you, sir.

SIR BRIAN LANGSTAFF: 11.50.

(11.19 am)

(A short break)

(11.50 am)

SIR BRIAN LANGSTAFF: Yes?

MS RICHARDS: Dr McClelland, you referred to the -- one of the advisory committees and the discussion of starting this arrangement with the PFC. For the sake of completeness we're just going to look at those minutes.

CBLA0001287.

These are the minutes of a meeting of the Advisory Committee on the National Blood Transfusion Service, 23 February 1981.

If we just go a little further down so we can see the full list of attendees. We'll see that, as you observed, Dr McClelland, you were not present at this meeting, but the observers included Dr Lawson from the Department of Health and Social Services in Northern Ireland.

If we go to the second page, if we pick it up in paragraph 6, halfway down the page, there's a heading "Pro rata supply of blood products", and then paragraph 6 explains:

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1 "The Chairman explained that the pro rata
2 distribution of certain blood products was due to
3 start from 1st April 1981 and Paper AC(81)3 set out
4 those issues on which the Department sought the
5 Committee's advice, particularly in relation to
6 supplies to special units."

7 Then there's a discussion of whether special
8 arrangements need to be made for various
9 organisations. But if we go to the next page,
10 paragraph 9, at the top of the page, it says:

11 "On the question of 'other users', members
12 agreed that ..."

13 Then (d):

14 "The pro rata screen should apply to Northern
15 Ireland. Dr Lawson explained that the Northern
16 Ireland Blood Transfusion Service intended to send
17 plasma (both time-expired and fresh-frozen) to the
18 Protein Fractionation Centre, Edinburgh. This had
19 been agreed by the Directors concerned."

20 So I think that's the -- those are the minutes
21 that you may have been referring to in your evidence
22 earlier this morning.

23 A. I think that's right.

24 Q. Now if we then just pick matters up with your own
25 communications with Scotland on this issue,

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1 instance, receive no anti-D immunoglobulin."
2 Did the relationship between the Northern
3 Ireland Blood Transfusion Service and SNBTS evolve in
4 the way in which Dr Cash was hoping for? With you
5 integrated into the organisation as an equal partner?

6 A. I think so. Broadly, yes. Obviously we, as he says,
7 with -- anything that had any policy that had an
8 impact on the relationship with PFC would have
9 required NIBTS to follow the policy in Scotland, but
10 regarding other matters, well, it was really up to
11 ourselves in Northern Ireland whether we would wish to
12 follow the Scottish approach, the English approach, or
13 our own approach.

14 Q. Paragraph 2 observes:

15 "Strenuous efforts have been made by the SNBTS
16 regions in the last 5 years to meet the concept of
17 self-sufficiency ..."

18 Then Dr Cash refers to a table which I don't
19 think I need trouble you with.

20 Then the bottom of the page says this,
21 paragraph 3:

22 "There is no doubt that the most immediate and
23 pressing problem is to get the NIBTS transferred to
24 HBsAg RIA testing of all donations. Such a move would
25 bring you into line with all plasma coming into PFC."

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1 NIBS0001680.

2 This is a letter from Dr Cash to you,
3 11 March 1981. Thanks you for a letter of 4 March.
4 Says:

5 "At least we've made a start.

6 "Now it seems to me that it might be helpful to
7 you, with regard to interactions with colleagues in
8 your Department of Health, if I made the following
9 comments ..."

10 Then paragraph 1:

11 "The SNBTS Directors would prefer to see an
12 evolution of the relationship with the NIBTS in which
13 you were integrated, as far as possible, into our
14 organisation as an equal partner. In terms of access
15 to blood products from PFC, and indeed on any
16 professional matters related to policy, etc. At this
17 point I believe we should assume that this is what you
18 wish to see emerge but we must all be aware that
19 contrary views may exist in our respective Department
20 of Healths, who may wish to operate a strict
21 contractual (pro rata) arrangement for all products.
22 Such an arrangement would have significant attractions
23 to our administrative colleagues who have to deal with
24 financial and political matters. Such an approach may
25 be of some concern to yourself - you would, for

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1 What it was the issue, Dr McClelland, in
2 relation to the hepatitis B surface antigen testing?

3 A. At that point the method used by NIBTS for
4 hepatitis B screening was the RPHA reverse passive
5 haemagglutination method, which had been operation,
6 I think, since about the mid-1970s, I think.
7 The sensitivity level was somewhat lower than RIA, and
8 I think advice was coming through from the -- I think
9 from the fractionation perspective that -- from
10 the expert advisers, that centres should be looking to
11 change to the more sensitive technique.

12 I must say I personally welcomed this move,
13 this -- if you like, call it a requirement by PFC,
14 because I was very keen for us to go onto RIA in any
15 case as our routine method. So we were able to take
16 steps to put that in place.

17 It was not easy, because the existing method of
18 hepatitis B screening was carried out in a very, very
19 cramped, very small, cramped facility, which would
20 have been totally inappropriate and impossible to use
21 for a radioisotope-based method. So we had to
22 identify -- fortunately, we did have one space --
23 which was used for staff -- which had that potential,
24 so ... but we did take a little bit of time to get
25 that work carried out, so that we were able to look at

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1 starting this RIA testing.

2 **Q.** Now some months after this, I think in around
3 September 1981, there was a visit from the PFC to
4 the premises of NIBTS. I'm not going to put up on
5 screen the report of that visit, but for the
6 transcript and if anyone wants to look at it, it's
7 SCGV0000104_117.

8 What I will ask you to look at, Dr McClelland,
9 is a letter that was written referring to that
10 inspection in September 1981.

11 It's NIBS0001698.

12 This is a letter of 3 September 1981. It's from
13 John Watt, scientific director of the PFC, to Dr Cash,
14 and it was copied to you, and that's apparent from the
15 end of the letter.

16 If we look at the first few paragraphs, it says:
17 "Dr Perry and I visited Belfast on 18 August to
18 see the working arrangements of the transfusion centre
19 and to discuss with Dr McClelland the detail necessary
20 to get plasma to Scotland in good order and to return
21 fractions to Northern Ireland.

22 "The actual mechanics of the transfer would be
23 best handled by sending the PFC truck to Belfast on
24 a routine monthly basis to collect plasma and deliver
25 product."

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1 Dr McClelland was any too well aware."

2 Just pausing there, was there anything in that
3 paragraph and those observations that you disagreed
4 with, Dr McClelland, or do you accept the accuracy of
5 what was set out there?

6 **A.** No, I would have agreed with that, I think.

7 **Q.** Then the next paragraph says:
8 "We would require a reasonable commitment from
9 Dr McClelland or his board that effort would be made
10 to bring the centre to a position that would meet the
11 need of PFC so far as the centre was a supplier of raw
12 material for fractionation. No doubt the Medicines
13 Inspectorate would hold the same view. However, it is
14 recognised that this could not happen over-night
15 whereas both Dr McClelland and the NIHD would wish
16 transfer of plasma to PFC to start before the end of
17 1981."

18 Then the next paragraph refers to the facilities
19 for hepatitis testing by RPHA and that equipment was
20 awaited for the RIA testing.

21 The next paragraph explains that you were
22 anxious to get a programme started with PFC. Then if
23 we could just go to the bottom of the page, the last
24 three paragraphs are a discussion about what
25 quantities might be provided. The last paragraph says

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1 Then the next paragraph says:
2 "The arrangements made in Belfast for collection
3 and handling of [fresh frozen plasma] are basically
4 sound but will require some modification in the area
5 of quality control and Dr Perry is already in
6 correspondence with Dr Bharucha (Deputy Director) on
7 the main QA topics and plans to return to Belfast
8 tomorrow, 4 September, to continue these discussions
9 ..."

10 Then there's a reference to the need for
11 microbiological monitoring which is said to "create
12 the greatest problems since there [was] no in-house
13 facilities".

14 Then if we go over the page, top of the next
15 page:
16 "Looking at the centre with an inspector's eye
17 it was clear that Dr McClelland had problems getting
18 access to adequate standard and sufficiently fast
19 response so far as building and equipment maintenance
20 was concerned, beyond those items in his own hand
21 where contract maintenance of centrifuges, LAF
22 cabinets etc were concerned. We were shown
23 a modification in course of progress, to refit an area
24 of the hepatitis testing but which would be only
25 barely adequate when finished, a deficiency of which

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1 this:
2 "The figures I have quoted are safe minima but
3 I would expect on a 'best efforts' basis the PFC could
4 do better than they suggest. Recent trends in
5 recovery of Factor VIII, for example, would yield
6 about 1.3 million IU or 6,000 dose units of 220 IU
7 average content. Such a return might persuade
8 Dr McClelland to move steadily away from cryo toward
9 concentrate in time."

10 What did you understand or what, looking at it
11 now, do you think was meant by that last sentence
12 about persuading you to move steadily from cryo toward
13 concentrate?

14 **A.** I can't actually remember. It seemed to be felt by
15 the Scots that we were producing a relatively large
16 amount of cryo, although I wouldn't have thought that
17 was all that apparent. So I'm not -- I don't fully
18 understand that there would have been much potential
19 to move any further away from cryo anyway. In any
20 case, the amount of cryo would be -- would have been
21 determined by clinical demand, by the hospitals, and
22 we would expect to have to respond to that.

23 **Q.** Then the letter continues over the page. I don't need
24 to ask you to look at the detail of it. If I can just
25 ask you to look at the last -- sorry, the previous

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page to that, Sully -- the last paragraph, the first sentence of the last paragraph:

"One area which concerns Northern Ireland is that of cost."

Is it right to understand, Dr McClelland, that that question of cost, what payments would be made, was dealt with at departmental level, so between the Department of Health and Social Services Northern Ireland and its Scottish counterparts, rather than being negotiated by you?

A. Well, um, I know the financial arrangement that was worked out. That was on the basis of a charge being applied to each individual product. And, as far as I can recall, those charges were really set by PFC, presumably, based on their costs, on the costs of manufacturing them. I don't recall that there were any great negotiation on the actual cost. I think the unit price for the products was basically set by PFC.

Q. If we then turn to one further document which is SCGV0000104_090, these are the notes of a meeting to discuss the supply of blood products to Northern Ireland and the date of the meeting is 26 August 1982. We can see that there are a number of representatives there from Scotland and Northern Ireland, including yourself. Then paragraph 1 explains that the:

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"There was already a good exchange of information between the PFC and the Belfast Centre, which in Mr Watt's, view did not have the resources to tackle the implications of the Medicines Inspectorate report alone. Dr Lawson [who, as we have already seen, was from the Department of Health and Social Services Northern Ireland] advised that the provision of a new BTS Centre in Belfast was in the very early stages of consideration, so clearly interim arrangements might well be required. It had been accepted, however, in Northern Ireland, as a matter of principle that steps would be required to improve the facilities of the Blood Transfusion Service, following the Medicines Inspectorate report."

Then paragraph 3 refers to the need for the Northern Ireland BTS to enter into a commitment in respect of certain professional matters. I'm not going to go through the detail of them but we can see subparagraph (d), "HBs-Ag Testing":

"It was noted that this matter had been resolved although the need for a UK reference lab for such testing was recognised."

So is it right to understand that by the date of this meeting, August 1982, you had changed from the RPHA method of testing to the RIA method of testing?

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"The purpose of the meeting was to discuss arrangements for the supply of blood products to Northern Ireland."

Paragraph 2 is headed "Progress Towards Resolution of Defects Noted in Report of Visit to Belfast in 1981", and it records:

"Mr Watts stated that it was clear that the Northern Ireland Blood Transfusion Service was also affected by the provisions of the Medicines Act, to which the Protein Fractionation Centre had already been heavily exposed. On his visits to Belfast, he had only been able to identify general defects although it was clear that much new building would be required. In addition, quality assurance procedures required to be formalised and validated although in this respect, the Belfast was in no worse a position than elsewhere in the UK. The PFC was already three years down this road."

Then there's a reference to anticipated visit to Belfast from the Medicines Inspector. Then it says:

"Dr Perry reported that problems which had earlier been identified in relation to hepatitis testing and testing of hyperimmune plasma had now been resolved."

If we go over the page, top of the next page:

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A. That's correct.

Q. Then top of the next page, paragraph 4 refers to "Transport":

"... preferred option with regard to transportation of plasma and products between Belfast and Edinburgh was for [NIBTS] to supply a suitable vehicle to make one round trip per month from Belfast, with air transport being used as a fallback in case of disruption-off ferry services, etc."

Then there's then a reference to the financial arrangements and a reference to there having been preliminary discussions on financial arrangements -- not proposing to go through the detail of those -- and then paragraph 7 records Dr Cash's proposal that you would be invited to all meetings of the Scottish Transfusion Directors and their coordinating group and would be issued with appropriate papers.

Is it right to understand, Dr McClelland, from the note of this meeting, August 1982, that the arrangement with the PFC had not yet actually started? It was obviously well advanced by the time of this meeting, in terms of planning, but you hadn't yet begun supplying fresh frozen plasma to the PFC?

A. I think that's right, yes, that probably would have -- this was August --

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1 Q. 1982.
 2 A. -- 1982. I think that would have commenced shortly,
 3 and with a -- perhaps a couple of months later. I'm
 4 not 100 per cent sure of that.
 5 Q. Bearing in mind that we saw that advisory committee
 6 meeting from February 1981, which showed that there
 7 was agreement in principle that this should be the
 8 arrangement, it appears to have taken around
 9 18 months, or so, to actually put the arrangement into
 10 practice. Why did it take that long?
 11 A. A mixture of issues. In some, I would say
 12 administrative at the -- given the fact that there
 13 were two levels or three levels of administration
 14 involved with the Departments of Health, the Common
 15 Services Agency in the Eastern Board at the next level
 16 and then the blood transfusion centres. I remember
 17 there was a bit of frustration around delays at that
 18 level with the necessary communications taking place
 19 or not taking place.
 20 And the other factor, of course, was at the
 21 operational level there was quite a lot of work. We
 22 talked about the radioimmunoassay and quite a lot of
 23 additional work, building work, to be carried out.
 24 That was certainly always going to take some time.
 25 Quite a lot of additional equipment. The snap

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1 a position of being self-sufficient)."
 2 Then you go on to say that the PFC position was
 3 a temporary problem, "plans to increase capacity are
 4 unlikely to materialise before early 1986".
 5 Now if we leave aside any issue relating to
 6 plasma protein fraction, my question is really about
 7 that bit in brackets, where it says, "we have now
 8 reached a position of being self-sufficient". So this
 9 is May 1984. How should we understand your suggestion
 10 that in relation to Factor VIII, Northern Ireland was
 11 now self-sufficient?
 12 A. Yes, um ... it often comes down to definition of what
 13 you mean by self-sufficiency. Certainly I think even
 14 by this stage we had reached the point where we were
 15 producing at least as much if not beyond the
 16 quantity -- sorry, when we set up the arrangement,
 17 there was a certain amount of Factor VIII usage,
 18 obviously, and I think we had certainly reached that
 19 level if not somewhat beyond that level. But I'm not
 20 sure, I'm a little bit -- in fact, a little bit
 21 surprised to see that, because I'm not sure that we --
 22 we certainly were not using 100 per cent PFC
 23 Factor VIII at that point, because the total demand
 24 was starting to increase really quite rapidly.
 25 Q. That leads to the next issue I wanted to explore with

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1 freezing equipment had to be purchased and
 2 commissioned. That would have taken -- you know, and
 3 deciding what was the appropriate type of equipment.
 4 Those are probability the main causes that come to
 5 mind.
 6 Q. Then in terms of the mechanics of the arrangement, was
 7 it your understanding that plasma collected in
 8 Northern Ireland would be kept separate from or pooled
 9 with Scottish plasma at the PFC?
 10 A. I think it -- my understanding was that it would be
 11 pooled with the Scottish plasma.
 12 Q. If we can then just look at NIBS0001719.
 13 This was a letter from you to Professor Bridges,
 14 22 May 1984. It appears the main topic of the letter
 15 was regarding plasma protein fraction, rather than
 16 the supply of fresh frozen plasma for the production
 17 of Factor VIII. But I just wanted to ask you about
 18 what's set out in the third paragraph. It says:
 19 "... the PFC, Edinburgh have recently reached
 20 the limit of their capacity and is no longer able to
 21 fractionate all plasma received from Transfusion
 22 Centres in Scotland and Northern Ireland. This
 23 applies only to outdated plasma (all fresh frozen
 24 plasma is being fractionated in order to meet the
 25 demand for Factor VIII for which we have now reached

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1 you, Dr McClelland, which is concerning the supply of
 2 concentrates to the Haemophilia Centre in Belfast.
 3 SIR BRIAN LANGSTAFF: If we just stop there for the
 4 moment, what you've just been asking Dr McClelland
 5 about is the meaning of self-sufficient. It may be
 6 that what you had meant to say was that --
 7 theoretically self-sufficient, because if you read the
 8 last two sentences of that paragraph, you say:
 9 "... for the next year or two we will be
 10 receiving no more than 85% of our full entitlement ...
 11 If all plasma supply from here was being fractionated
 12 we could in fact have met the demand in full."
 13 In other words, you can't meet the demand in
 14 full because you're not getting 100 per cent back. Is
 15 that how it should be read?
 16 A. Um, I think this is referring to protein -- plasma
 17 protein fraction, or albumin, if you like --
 18 SIR BRIAN LANGSTAFF: I see.
 19 A. -- where they have -- where there seemed to be
 20 a temporary pause in manufacture. Obviously priority
 21 was given to Factor VIII production, but ... Yes,
 22 I remember there was a pause. Also I think it may
 23 have been related to staffing issues at PFC but I
 24 can't remember exactly.
 25 SIR BRIAN LANGSTAFF: Yes. I had thought that perhaps the

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1 last paragraph of the -- or the next paragraph that
 2 follows, it was talking about PPF, whereas this
 3 particular couple of sentences followed on from the
 4 reference to Factor VIII and self-sufficiency. But
 5 I don't know, it's obviously some time since you've
 6 read this letter.

7 **A.** Yes.

8 **MS RICHARDS:** Dr McClelland, more broadly, can I then
 9 explore with you the arrangements for the supply of
 10 concentrates to the Haemophilia Centre in Belfast.

11 Before I ask you specifically about the
 12 arrangements with Dr Mayne, were there other hospitals
 13 in Northern Ireland that you supplied with either
 14 cryoprecipitate or factor concentrate?

15 **A.** As far as cryoprecipitate was concerned, we may
 16 have -- I think we supplied some hospitals with
 17 a small amount of cryoprecipitate. As far as
 18 I remember, I'm pretty sure that all Factor VIII
 19 concentrate would have been issued from the
 20 Haemophilia Centre to those other hospitals.

21 **Q.** So first of all in relation to the small amount of
 22 Elstree BPL factor concentrates that you -- or that
 23 the Service was receiving prior to the arrangement
 24 with PFC, that was, as I understand it, received by
 25 the Northern Ireland Blood Transfusion Service, was

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1 Centre rather than by you?

2 **A.** That's correct.

3 **Q.** Is it also right, however, that the cost of the
 4 commercial concentrates was a cost that essentially
 5 came out of the Blood Transfusion Service's budget?

6 **A.** Yes, I think, from 1985, new financial arrangements
 7 were established so that -- I mean, I was quite --
 8 I think it was myself who had proposed it actually,
 9 that in order -- it was becoming -- or it was becoming
 10 complicated to estimate the demand, because when we
 11 started off this arrangement with PFC, hospitals --
 12 this really applies to the products like albumin --
 13 purchased their own -- they received product from
 14 NIBTS but any shortfall was made up by purchasing from
 15 commercial providers. It was difficult for us to know
 16 what the demand was at any one time. And I had
 17 proposed that the arrangement be centralised at NIBTS,
 18 so that we knew what -- exactly what our targets were
 19 going to be. And that applied to Factor VIII and
 20 coagulation concentrates as well, in the sense that
 21 the budgets sat with NIBTS/Eastern Board, who really
 22 held the budget, but the actual arrangements for
 23 ordering, procuring the product, and decisions about
 24 which product, was made by the Haemophilia Centre, is
 25 it meant that we were -- because -- it was funded or

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1 it, and then supplied by you to Dr Mayne?

2 **A.** Yes.

3 **Q.** Or did BPL send -- that was the route?

4 **A.** Yes.

5 **Q.** Then once the arrangement with the Protein
 6 Fractionation Centre was up and running, was it the
 7 same position, that you received the Factor VIII
 8 concentrate from the PFC and you then supplied it to
 9 Dr Mayne?

10 **A.** Yes. That's correct.

11 **Q.** Now we know from other evidence the Inquiry has
 12 received but also from your own evidence, that
 13 a significant amount of commercial Factor VIII
 14 concentrates were used by the Haemophilia Centre in
 15 Belfast. Were those supplied via the Blood
 16 Transfusion Service or were they procured directly by
 17 the Haemophilia Centre, as far as you can recall?

18 **A.** The latter. They were procured by the Haemophilia
 19 Centre and supplied to the Haemophilia Centre direct.

20 **Q.** So you had no direct involvement in the arrangements
 21 to obtain commercial concentrates?

22 **A.** That's correct, no, we didn't. We had no involvement
 23 in that.

24 **Q.** Does it follow that the choice of which commercial
 25 concentrates was a choice made by the Haemophilia

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1 sat on the NIBTS but it had meant at any one time we
 2 were informed about actual usage of Factor VIII.

3 Commercial and NHS.

4 **Q.** The Inquiry has heard evidence that some Regional
 5 Transfusion Centres themselves held commercial
 6 concentrates and then supplied them to the relevant
 7 Haemophilia Centre. Did you ever discuss with
 8 Dr Mayne or anybody else changing to a system whereby
 9 the commercial concentrates were ordered by and held
 10 by you?

11 **A.** No, I don't think so. I don't recall doing that.
 12 I think I would have recognised that in this
 13 specialised area of blood product treatment, the
 14 Haemophilia Centres were the experts. They were in
 15 possession of all the information and, it would have
 16 seemed to me, were in the best position to make those
 17 decisions.

18 **Q.** If we have a look at NIBS0001714, this is a letter
 19 from Dr Cash to Dr Mayne dated 5 January 1984, and he
 20 says in the first paragraph:

21 "Through colleagues here at our Protein
 22 Fractionation Centre I have discovered that there has
 23 been a fairly substantial movement of commercial
 24 factor VIII purchased in Edinburgh (we think) and
 25 shipped to you in exchange for the PFC material you

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1 have received via Morris McClelland.

2 "Am I right? If so, could you illuminate? On
3 the face of it this development looks a little
4 worrying -- AIDS -- etc -- and I am anxious to help as
5 much as possible."

6 Then we can see this letter was copied to you.

7 Do you recall whether you had been, prior to
8 receiving this letter from Dr Cash, aware of this
9 arrangement?

10 A. No, I wasn't aware of the arrangement before it
11 happened. I'm not sure if this was the first time --
12 this letter was the first time I was aware, I think it
13 may well have been. No, I wasn't aware in advance of
14 the arrangement.

15 Q. Had you been aware of it, would you have been
16 concerned? Because it might be said to be undermining
17 the work that was being done to achieve
18 self-sufficiency for Northern Ireland in factor
19 concentrates?

20 A. Yes, somewhat concerned. I mean, I understood
21 the rationale, I think, behind the arrangement. But
22 I would have thought this was the kind of thing that
23 probably should have been approved at sort of higher
24 administrative level in advance, as the, I think the
25 Chief Medical Officer from Northern Ireland -- maybe

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1 example, if a major operative procedure, which might
2 require huge amounts of Factor VIII, the appropriate
3 product to use for that situation.

4 So in general, yes, I would have had discussions
5 in general terms, but I wouldn't have seen that it was
6 appropriate for -- that I could really influence such
7 change in prescribing patterns.

8 Q. If we just look at BHCT0000501, please. This is
9 a memorandum from the Eastern Health and Social
10 Services Board, 25 October 1984, supply of blood
11 products. It says:

12 "It has been agreed that with effect from
13 1st December 1984, all of the blood products as
14 identified on the attached schedule must be obtained
15 from the [Northern Ireland] Blood Transfusion Service
16 and none should be purchased or obtained by a UMG
17 directly. Local arrangements should be negotiated
18 with Dr McClelland, Director, Blood Transfusion
19 Service."

20 Now, unfortunately, we don't have the attached
21 schedule so we don't have the list of blood products
22 to which this arrangement was intended to apply. As
23 far as you can recall, in relation to the purchase of
24 commercial factor concentrates, did that fall within
25 this arrangement so that it was now to be obtained

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1 not, I can't remember if it was in relation to this

2 arrangement or a future one -- spelled that out. This
3 kind of arrangement should really have been approved
4 in advance at a higher level, a higher administrative
5 level.

6 Q. Now, the Inquiry knows from other material, including
7 documents authored by Dr Mayne at the time, that,
8 until the end of 1984, virtually all of the treatment
9 used at the Haemophilia Centre was commercial
10 concentrates. Those are her own words, the reference
11 for the transcript is BHCT0000503. Do you recall ever
12 having any discussions with Dr Mayne about her use of
13 commercial concentrates, trying to discourage the use
14 of them at all?

15 A. Yes, regular discussions. I mean, I had a session,
16 regular weekly session, in the Royal Hospital,
17 clinical haematology session. So I once -- in a way,
18 Dr Mayne was a colleague because I was visiting the
19 Royal on a weekly basis, sometimes twice weekly basis.
20 So I was in discussion with Dr Mayne on a very regular
21 basis. But I would have accepted that she was the
22 expert on this area for a number of factors that had
23 to be taken into account in -- at any one time in
24 deciding about which product to use at a certain
25 length -- at a certain point in time, and, for

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1 through you, or did it continue to be the position
2 that Dr Mayne obtained those directly herself?

3 A. Reading this letter, this memo, it's a very general --
4 it's a very general update on the new arrangements
5 from one manager to the managers of the -- of all
6 other hospitals in Northern Ireland. It doesn't
7 really get into the special arrangement in relation to
8 the Haemophilia Centre, that's not really dealt with
9 in this letter. It would be more relevant to
10 arrangements in respect of other products like albumin
11 and immunoglobulin, where this arrangement, this new
12 arrangement would apply as -- exactly as set out here.
13 Obviously, there is the special arrangement with
14 respect to the Haemophilia Centre which is not really
15 dealt with in this memo.

16 Q. If we look at HRSC0000066_024, this is a rather later
17 document, this is dated February 1989, from the
18 Board's Treasurer's department, and it's "Blood
19 Transfusion Service Financial Position on Baseline
20 Funding". If we go over the page there's a broad
21 description including of the arrangements with the
22 Protein Fractionation Centre.

23 Sorry, can we see the whole page, Sully?

24 You'll see there, we don't need to zoom in on
25 any particular paragraph, but we've got the heading

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"Blood Products", "From the Protein Fractionation Centre, Edinburgh" is paragraph 1. Paragraph 2: "Commercial blood products required in place of or as a supplement to PFCE supplies."

Then it says, this is the bottom of the page:

"These commercially produced blood products which were acquired either in preference to PFCE products or as a top up for limited PFCE supplies, were purchased centrally for the Northern Ireland Region by the Blood Transfusion Service with effect from 1 January 1985 and these too [and then the top of the next page] charged to other Boards on an actual cost basis."

Then before I ask you about it, if we just read paragraph 3:

"Supplies to the Haemophilia Centre, Royal Victoria Hospital", it says:

"All clotting agents (Factor VIII, Factor IX, etc), are managed exclusively in the Haemophilia Centre, Royal Victoria Hospital, under Dr Mayne the Centre Director. All supplies of clotting agents whether obtained from PFCE and through ed through the Northern Ireland Blood Transfusion Service or obtained directly from commercial sources, eg Profilate, Hyate, Feiba, Autoplex, must be delivered directly to the

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Haemophilia Centre.

"Mr Carville, the senior chief MLSO in the Blood Bank, [Royal Victoria Hospital], under the direction of Dr Mayne, is responsible for the ordering and control of all clotting agent supplies.

"As the Haemophilia Centre is solely responsible for the provision and management of all clotting agents, all supplies required either or EHSSB patients or for patients admitted to hospitals outside the Eastern Board are issued in respect only of named patients under Mr Carville's control."

Then if we skip over a paragraph, the paragraph in bold says:

"The Northern Ireland Blood Transfusion Service bears the cost of all clotting agents issued from the Haemophilia Centre in respect of supplies provided for patients in hospitals outside the Eastern Board and for home use at non EHSSB addresses."

So that paragraph would appear to suggest that the ordering of the commercial concentrates continued to be the responsibility of the Haemophilia Centre rather than the Blood Transfusion Service.

A. That's right.

Q. That's your understanding of the practical arrangement?

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A. That is correct, yeah.

Q. If we go to the bottom of the previous page, so where those last four lines say, "These commercially produced blood products" and we can see that they included albumin, immunoglobulin and clotting agencies, "were purchased centrally for the Northern Ireland region by the Blood Transfusion Service with effect from 1 January 1985", is that talking about it from a budgetary position then?

A. Yes. Yes, that's correct. The -- it is purely from a budget -- as far as clotting agents, certainly Factor VIII and all clotting agents is concerned, um, it is really only the financial arrangements that are referred to here, the funding being centralised at the NIBTS, but not the actual procurement.

It did have the effect that, as the cost of clotting agents, Factor VIII, et cetera, had climbed quite rapidly during the 1980s, and the cost escalating, that it was showing up as a major -- as an overspend on the NIBTS budget, which I found myself having to explain to various people within the bureaucracy, Department of Health, et cetera, who maybe didn't understand fully how the system worked. But yes, that was the ...

The finance people were keen to maintain this

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position. I had some reservations about having to account for something over which I had no control. But the finance people were keen to maintain this centralised arrangement. I think because they felt they were in a better position to understand exactly what was going on, rather than having to rely on getting information back from the hospital as well as BTS. You know, it's relying on different sources of information. At least they were -- in terms of planning, financial planning, they were in a position to know what was happening.

Q. Okay. We can take that down. Thank you.

A. I don't know if that answers your question.

Q. Do you recall any of the other bodies or agencies involved, whether it was the Eastern Board itself or the Northern Ireland Department of Health or the Chief Medical Officer, any of those bodies getting involved with this issue of whether too much was being used by way of commercial concentrate at the Haemophilia Centre?

A. Sorry, Ms Richards, I seemed to lose a bit of that. Would you mind repeating?

Q. Of course.

On the issue of whether too many commercial concentrates were being used by the Haemophilia

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1 Centre, do you recall whether the Eastern Board or the
 2 Northern Ireland Department of Health or the Chief
 3 Medical Officer for Northern Ireland became involved
 4 with that question? Or expressed any concern about
 5 it?
 6 A. Yes, as I recall, it was a continuing concern, which
 7 was -- you referred earlier to those coordinating
 8 meetings at the Eastern Board, annual meetings, at
 9 which this matter was discussed. That was a big
 10 concern.
 11 Having said that, I think my understanding
 12 always was in relation to the cost of these products,
 13 whereas the Department and the Eastern Board were very
 14 concerned about the cost and they wanted to have as
 15 much advance warning as possible about the likely
 16 future cost. I was never aware that any real form of
 17 cash limit was placed. I think in this area, in other
 18 words, it seemed to be accepted that this was an
 19 inevitable expenditure. I mean, I was aware that
 20 in -- as far as I understood Haemophilia Centres in
 21 England and Scotland, there probably was a budget for
 22 this to cover blood products, so there were cash
 23 limits applied, but I don't think that ever did apply
 24 in Northern Ireland.
 25 Q. And do you have any recollection of how Dr Mayne

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1 for special reagents, in other words either donors or
 2 antenatal patients who were identified as having
 3 a particularly valuable antibody, and were asked to
 4 donate their blood or their plasma, most efficient way
 5 was to donate the plasma. That -- it would really
 6 have been for the production of blood grouping,
 7 special blood grouping reagent, not standard ABO blood
 8 grouping reagents but particular antibodies.
 9 Then, when the arrangements with PFC started up,
 10 there was, as referred to in your correspondence
 11 there, the establishment of an anti-D programme. And
 12 that was set up at '82, '83. That involved the
 13 immunisation of -- the recruitment and immunisation of
 14 donors to produce this antibody. And the method used
 15 at that time -- this was relatively small number --
 16 there were relatively small numbers of people
 17 involved. Very -- quite a time consuming process
 18 involved and a number of -- many visits, different
 19 visits of the donor before they were even in
 20 a position to start donating. So it was a time
 21 consuming process for donor and staff. And the
 22 numbers going through actually donating plasma was
 23 quite small. So manual plasmapheresis was the method
 24 used.
 25 Then at that point in any case the machines

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1 responded when issues relating to the use of
 2 commercial concentrates were raised with her?
 3 A. Yes, I remember some very detailed letters responding,
 4 really, to requests from the Board and the Department,
 5 particularly the Eastern Board, regarding the causes
 6 of this major expenditure. And to the point of
 7 setting out in detail for individual patients -- not
 8 by name, maybe, but the reasons why so much material
 9 was being required for certain situations.
 10 There seemed to be quite a high level of
 11 inhibitor patients, and -- which used a huge amount of
 12 material, not just, of course, Factor VIII, but also
 13 other products which were not available, were not
 14 human derived, even, but were extremely costly.
 15 Q. Can I move, then, to ask you a little bit
 16 plasmapheresis.
 17 So as I understand your evidence in your
 18 statement and from the documents you've referred to,
 19 in the 1970s there was the occasional use of manual
 20 plasmapheresis. But the extent to which you could
 21 develop any broader program of plasmapheresis was
 22 limited by the Transfusion Service's facilities; is
 23 that right?
 24 A. Yes. I mean, I think the plasmapheresis in the '70s
 25 would only have applied to the collection of plasma

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1 available were not completely regarded as safe,
 2 I think it would be fair to say, to use outside of
 3 a hospital setting. But that changed with the --
 4 especially with the development of the Haemonetics
 5 machines, which were -- became available in the
 6 mid-eighties, and were designed to collect routine --
 7 sort of routine plasma collections, and led to many
 8 centres, including our own, starting to collect just
 9 routine plasma. So it was no longer -- in addition to
 10 these special plasmas, anti-D and other hyperimmune
 11 plasmas, we were now starting to use these new
 12 machines.
 13 That -- there was a -- sorry, there was
 14 a working party that set up a code of practice for the
 15 use of these, and this really meant that it -- the way
 16 was now clear for centres like ourselves, that were
 17 not in a hospital setting, to very safely use this
 18 process to collect more plasma.
 19 Q. So is it correct to understand, from your evidence,
 20 that one of the limiting factors which meant you
 21 couldn't use machine plasmapheresis more widely any
 22 earlier was the fact that you were not located as part
 23 of a hospital, but were this separate and discrete
 24 building in Durham Street?
 25 A. Well, no, I think from the point of view of quantity,

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once we were up and running, the main -- the major limiting factor was the size of the facility. We would not have been in a position at Durham Street to utilise more than three -- I think it was maximum of three machines. So that limited us in the amount of plasma that could be collected in that way.

Q. So if we pick it up from your statement, Dr McClelland, WITN0892001, page 23. Sorry, page 23.

So we can see you set out -- in the first main paragraph of your answer on that page, you refer to the specific anti-D programme established with PFC. And then towards the bottom of the page you say:

"With the early apheresis machines, it was a requirement that their use had to be restricted to a hospital setting where resuscitation facilities were available. This continued to be the case into the 1980s. The NIBTS centre (HQ) was not based in a hospital at that time. With the availability of a new generation of machines, this requirement no longer applied."

Then if we go over the page, if we pick it up at the bottom half of the page, you say under subparagraph d):

"The plasmapheresis programme augmented supplies of plasma (and later platelet concentrate). By the

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it was a better product and a safer product, to provide single donor apheresis platelets, as opposed to a pool of four to six units of platelets. But it had always been a mixture.

At this point we had actually come to rely on apheresis platelets to actually meet the demand. So that was encroaching -- that was a factor that came into play when looking at the "any further enhancement of plasmapheresis". Not only the facility, not only the space, even in the new facility now, but also the donor pool, because you were -- you were really tapping into the same very, very -- we're talking here about very enthusiastic donors who are prepared to give so much of their time to donate plasma or platelets. So we are looking at the -- a similar pool of donors.

So yes, in my opinion platelet pheresis is something that had to be considered alongside the plasmapheresis programme.

Q. Then a second strategy I wanted to ask you about briefly, in relation to working towards achieving self-sufficiency, was the use of red cell concentrates. We can pick that up I think, from your statement.

Can we go to page 27, please, Sully.

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early 1990s, NIBTS was collecting over 3000 plasma donations per annum. This was the maximum throughput that could have been achieved in the (old NIBTS) building and represented about 10% of total FFP being sent to PFC."

So, just pausing there, it's the limitations of the building that, essentially, imposed a cap, did it, on the amount that could be collected by way of plasmapheresis?

A. Sorry, I'm just -- yes, I'm just reading your -- yes, it was. That's correct.

Q. Then we see -- you continue that:

"When [the service] relocated to the new, purpose-designed centre (1995), donation facilities were enhanced allowing more apheresis procedures."

But you've explained that's the point at which priority had shifted to platelet concentrate.

A. Yes.

Q. So --

A. Yes, it had. Yes, indeed, the demand for platelet had increased very rapidly throughout the '80s, and continuing into the '90s, and it was also desirable that, if at all possible, to single donor platelets, we'd talked about limiting pool size. This also applied to platelet concentrates. If at all possible,

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So you were asked at question 32:

"What steps, if any, did the NIBTS take to persuade hospital clinicians to use less whole blood and more red cell concentrates ..."

You responded:

"Education of clinical users of blood/red cells and persuasion towards the use of red cell concentrates instead of whole blood was a key part of the strategy towards achieving self-sufficiency. Without this, the programme referred to above could not have been as successful. The most effective route of influence was via staff in charge of hospital blood banks (haematologists and laboratory staff). Dr Bharucha and I took every opportunity to influence these staff who, in turn, were in a position to influence the clinical users of blood in each speciality."

Now, what was the response to your efforts and the efforts of Dr Bharucha to try to persuade the staff in charge of the hospital blood banks to use more in terms of red cell concentrates?

A. I think the response was very positive in many ways. I would even go so far as to say it was more positive than I expected. One heard from experience of other parts of the country that resistance -- if there was

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1 resistance to the use of red cell concentrates in
 2 certain clinical situations. I think we found that,
 3 actually, in persuading clinicians that, for certain
 4 clinical situations, there was no benefit in using
 5 whole blood, as opposed to red cell concentrates.
 6 That seemed to be accepted quite well, and we were --
 7 I think the figures show, really, that we were able to
 8 move quite rapidly to a much higher proportion of red
 9 cell concentrates than we started with in the early
 10 '80s.

11 Obviously, a big help -- a big benefit was the
 12 available -- which became available, I think, at
 13 '86/87, the availability of optimal additive
 14 solutions, which we adopted quite quickly, I think.
 15 We were one of the early centres to adopt this method.
 16 I think it's been explained by other people to the
 17 Inquiry how that works, but it basically enabled us to
 18 harvest more plasma, I think about 60, 70ml more
 19 plasma than one could without optimal additive
 20 solutions.

21 This meant that because the problem of
 22 viscosity, which certainly did apply -- Dr McClelland
 23 in Edinburgh I think referred to this -- the problem
 24 of viscosity in certain clinical situations, which
 25 would have been a problem, no longer was a problem

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1 Sir, I note the time, and I'm going to move to
 2 a separate topic. So perhaps time for lunch.
 3 **SIR BRIAN LANGSTAFF:** Yes. Well, in which case we'll take
 4 a break now until 2.00, and come back then. 2.00.

(1.00 pm)

(The Luncheon Adjournment)

(2.00 pm)

8 **MS RICHARDS:** Dr McClelland, I'm going to ask you a little
 9 about hepatitis now. I'm going to start with an
 10 article at WITN3082021.

11 This is an article in the Ulster Medical
 12 Journal, "Hepatitis B Virus Infection in Northern
 13 Ireland 1970-1987", and we can see you are a co-author
 14 of this article. Then if we look at the summary:

15 "In the 18 years between 1970 and 1987,
 16 504 patients were found to have hepatitis B surface
 17 antigen ... in their blood. Acute hepatitis was
 18 present in 184 patients and six died ... The annual
 19 incidence of acute hepatitis B virus infection in
 20 Northern Ireland was about one quarter that of England
 21 and Wales. A decrease in acute infection occurred in
 22 1986-87, while in England and Wales acute infection
 23 has fallen by more than half since the peak in 1984.
 24 Hepatitis B virus infection in healthcare staff and
 25 patients in high risk groups were reviewed: 32% were

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1 because with optimal additive solutions the viscosity
 2 was equivalent to that of whole blood.

3 Q. And --

4 A. And -- sorry.

5 Q. -- the optimal additive solutions, that is the
 6 addition of SAG-M, as some other witnesses have
 7 referred to it?

8 A. That's correct.

9 Q. Prior to that becoming used in the Northern Ireland
 10 service in, as you say, around 1986, 1987, were
 11 your -- the clinical users still fairly resistant to
 12 the use or increasing use of red cell concentrates?
 13 Did the SAG-M availability represent a sea change in
 14 their attitude or was it more gradual?

15 A. Oh, I think it was already -- I think we had already
 16 got to something like 75-80 per cent concentrated red
 17 cells even before we introduced SAG-M. So that's why
 18 I say the -- the response was actually quite positive.
 19 I think by '86 we had gone from something like
 20 20 per cent to 75-80 per cent concentrated red cells,
 21 in the space of about three years, or three or
 22 four years. That may sound quite a lot, but there
 23 was -- compared to many -- I think, the experience of
 24 many centres, that was pretty quick.

25 **MS RICHARDS:** Thank you.

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1 in those of foreign origin who had known foreign
 2 contacts. In blood donors there was a marked fall in
 3 incidence of hepatitis B surface antigen carriage from
 4 1982 onwards ..."

5 Now, I'll come back to that 1982 date in
 6 a moment, but if we can go over the page and look at
 7 the third paragraph, this gives us the dates of the
 8 various tests that were in use in the Transfusion
 9 Service:

10 "The Northern Ireland Blood Transfusion Service
 11 began routine screening of all blood donors in 1972
 12 using the immunoelectro-osmophoresis test. The RPHA
 13 test was introduced in 1975 and the radioimmunoassay
 14 test (Blood Products Laboratory, Elstree) in 1982.
 15 An ELISA test ... used [since] July 1987."

16 And then we can see, if we go to page 4, please,
 17 halfway down the page there's a heading "Blood and
 18 blood products transmission", and then we have:

19 "Haemophiliacs: Acute infections occurred in
 20 11 patients between 1972 and 1982 after receiving
 21 blood transfusions, cryoprecipitate or factor VIII,
 22 and one patient died aged 51 years."

23 Then the next paragraph:

24 "Multiple transfusions: Acute infections took
 25 place in 1970 and 1980 in eight patients who had

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(21) Pages 81 - 84

1 received multiple transfusions after surgery."
 2 So looking at that overall, it's right, I think,
 3 to understand, as the Inquiry has seen elsewhere, that
 4 screening for hepatitis B surface antigen did not
 5 eliminate entirely the transmission of hepatitis B.
 6 **A.** Yes, yes. That would be right. The early tests, of
 7 course, were relatively insensitive, especially the
 8 first one that was used. There was quite a big leap
 9 in sensitivity with the RPHA test, and then a further
 10 improvement, although I'm not -- with the RIA test,
 11 I don't think in practice there was -- there were
 12 many, if any, detected. I don't think we detected any
 13 donors who would not have been detected by the RPHA,
 14 but I'm not completely sure of that.
 15 **Q.** Can you assist us with understanding why the RIA, the
 16 improved sensitivity test, was not introduced until
 17 sometime in 1982? Why not earlier?
 18 **A.** As I mentioned earlier about the facility, it was
 19 a very, very cramped, very small laboratory that was
 20 in use, and it would have been totally unsuitable for
 21 use of radioisotopes, so I don't know whether it was
 22 seriously considered by my predecessor. I --
 23 obviously with the -- I would have been -- I was keen
 24 to introduce it and the link with PFC gave us the
 25 opportunity to really -- it provided us with a bit of

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1 consequences?
 2 **A.** As far as I recall, the TTV study is the one I keep --
 3 would keep coming back to, because it was the most --
 4 I felt it was the most important study. As far as
 5 I recall, the follow-up, I think there were interim
 6 reports from time to time during that study, and
 7 I think, as I recall it, they were beginning to show
 8 evidence, some evidence of chronic liver disease
 9 appearing. And initially it looked like it was mostly
 10 mild chronic persistent hepatitis, but, as I recall
 11 it, it was beginning to -- those studies were
 12 beginning to show some evidence of more serious
 13 chronic liver disease.
 14 **Q.** Do you recall whether you read or were aware of work
 15 being undertaken by Professor Preston and others in
 16 Sheffield which looked at the position in relation to
 17 a number of haemophilia patients?
 18 **A.** Yes, I was very aware of that when it appeared, when
 19 it was published -- when that work was published, yes.
 20 Yes, obviously I didn't have any -- sorry,
 21 I did -- obviously I didn't provide any information
 22 about the real risk in the UK because that would have
 23 been reflecting the use of possibly imported products.
 24 **Q.** If we just go to your statement, WITN0892001. And go
 25 to page 67, please.

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1 leverage in order to get it up and running reasonably
 2 quickly.
 3 **Q.** Can I turn to non-A, non-B hepatitis.
 4 We can take that down. Thank you.
 5 When you took up your post as deputy director
 6 in 1978 and then as director in 1980, doing the best
 7 you can, what was your understanding of
 8 non-A, non-B hepatitis at that time?
 9 **A.** I was certainly well aware of it when I took up post
 10 in '78 just from reading and reading the literature.
 11 I had read about the -- particularly the TTV study in
 12 the United States, and in many ways I thought it
 13 was -- I looked upon it for many years throughout the
 14 80s as the biggest single issue or single biggest
 15 problem left for Blood Transfusion Services to solve.
 16 Obviously that changed with HIV, but, you know, I was
 17 very interested in it, and followed the literature
 18 very closely.
 19 **Q.** You've referred in your statement to there having been
 20 a dearth of good quality research in the UK as to the
 21 extent of non-A, non-B hepatitis in the UK.
 22 **A.** Yes.
 23 **Q.** What was your understanding of the potential
 24 seriousness of non-A, non-B hepatitis in 1978, 1980?
 25 Did you understand it could have serious long-term

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1 If we look at the second main paragraph on this
 2 page, and pick it up at the end of the second line --
 3 or, sorry, in the third line, you say:
 4 "... there was an educational issue among some
 5 clinicians about the importance of reporting, and in
 6 some cases even about the existence of [non-A, non-B]
 7 hepatitis. Hospital blood bank and haematology staff
 8 were well aware of this, but not necessarily other
 9 users of blood and blood components. Every
 10 opportunity was taken to educate clinical staff about
 11 this and also through publications ..."
 12 I'm going to come on shortly to the question of
 13 reporting and the publication, I think, that's
 14 referred to there. But the educational issue amongst
 15 some clinicians, even about the existence of non-A,
 16 non-B hepatitis, can you recall or can you tell us
 17 more about what the basis is for that statement?
 18 **A.** Just comments at meetings. I can recall speaking to
 19 groups, including senior clinicians, some of whom
 20 seemed to be -- sort of seemed to assume that the
 21 problem of post-transfusion hepatitis had gone, and
 22 seemed slightly, in some cases, a little bit sceptical
 23 about whether this was really an issue -- that this
 24 was really an issue for clinical practice at all.
 25 I do recall that in some cases.

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1 **Q.** I'm going to ask you to look next at a document which
2 set out the process for investigating Transfusion
3 Associated Hepatitis. It's WITN0892004. It's
4 a document authored by Dr Bharucha, November 1983, and
5 it's described as:

6 "A summary of present practices with respect of
7 recognition and investigation of Transfusion
8 Associated Hepatitis in Northern Ireland."

9 Then under the heading "Recognition of TAH":

10 "Jaundice in a patient who has previously
11 received blood and/or blood products is reported to
12 the NIBTS either by the clinical staff or the hospital
13 laboratory. District hospitals are actively
14 encouraged to report all [cases] of TAH/transaminitis.
15 However, we recognise that a significant number of
16 patients with milder clinical attacks are seen by the
17 General Practitioner. Reports from GPs are seldom
18 received."

19 Then the investigation process is then set out.
20 2.a, it says:

21 "A summary of PID, blood/blood products
22 transfused together with dates, serial numbers of
23 units and reason for transfusion, clinical and
24 laboratory data on patient are obtained.

25 "b. Clinical staff in-charge of the patient are

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1 **Q.** And what was it that had prompted you to decide to
2 start the practice of storage?

3 **A.** I can't remember exactly. I do remember it being
4 discussed in Scotland at one of their meetings, and
5 being impressed and -- by the reasons that -- you
6 know, well, obviously one of reasons is as set out
7 here, for the investigation of post-transfusion
8 hepatitis, to help you do that. Also -- and new tests
9 came along, to go back at the old -- and look at the
10 old -- repeat the samples done by the old test. There
11 were a number of potential advantages. So yes,
12 I think very quickly I think Edinburgh started to do
13 this around the same time, or if not before. And
14 I was very impressed by the, you know, potential
15 benefits of doing this.

16 **Q.** And so we can see from subparagraph c:

17 "Tests for anti-HBc and ALT [would be] performed
18 on the stored sample."

19 **A.** Yes.

20 **Q.** Then d tells us that next time the donor comes,
21 a sample is taken, and:

22 "In addition to routine HBsAg, tests for
23 anti-HBc and anti-HBs are performed on the sample
24 obtained on this occasion.

25 "e. The unit of blood collected from such a

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1 advised to send serum to the PHL for hepatitis A and B
2 markers, EBV and CMV.

3 "c. Since November 1982, donor serum samples
4 are stored at -20°C in the NIBTS for a period of 1
5 year. Tests for anti-HBc and ALT are performed on the
6 implicated stored samples."

7 Just pausing there, it would appear that the
8 decision to store serum samples was, at the date of
9 this document, a relatively recent one, November 1982.
10 What had led you to decide to start storing serum
11 samples from donors, and why for only a year?

12 **A.** Well, actually it says a year. I'm not sure when this
13 was -- when this document was written. But in fact we
14 ended up maintaining stored samples for much longer
15 than that. Many years. I mean, as far as I recall,
16 we were still storing samples that -- seven,
17 eight years down the line. In fact, the main problem
18 then we encountered was finding that in some cases the
19 oldest ones were no longer in proper condition, they'd
20 dried out and would no longer have been suitable for
21 testing, unfortunately.

22 But no, we definitely held sample -- it may be
23 that in the first instance, when we decided to do
24 this, that it was only going to be for a year but it
25 was much -- it was much longer than that.

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1 donor is not issued for transfusion until all of the
2 tests are completed."

3 What was the thinking behind the tests for
4 anti-HBc and ALT? Was that on the basis that they may
5 be an indication of non-A, non-B hepatitis?

6 **A.** Either non-A, non-B or B, indeed, hepatitis B.
7 Especially for anti-core, might have been an
8 indication of a very low level of hepatitis B, that
9 was missed by the existing screening tests. And the
10 anti-HBs would be done and -- with that, alongside
11 that to interpret the result. ALT, again, could be
12 non-A, non-B, or hepatitis B possibly, particularly
13 non-A, non-B.

14 **Q.** Then if we go to the bottom of the page, under the
15 heading 3, "Action taken", it says:

16 "If ALT levels in the donor are repeatedly
17 within the normal range and no Hepatitis B markers are
18 detected, the donor is retained on the panel and
19 treated as normal."

20 Just pausing there, what was -- the reference to
21 "repeatedly within the normal range", how many tests
22 would be regarded as being repeatedly within the
23 normal range? Is that a reference to testing the
24 stored sample and then --

25 **A.** Mm, I really can't remember how many times we would

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1 have repeated the test. It would probably be
 2 influenced -- dealt with, I imagine, on an individual
 3 basis, for example depending on how strongly the
 4 implication was. Some of these -- many of these
 5 cases, yeah, where there were, either the recipient --
 6 it may have been rather dubious as to whether it
 7 really was transfusion hepatitis or multiple donors
 8 were involved, perhaps -- you know, a very large
 9 number of donors were involved, that might influence
 10 the decision about reinstating the donor. In other
 11 words a judgment would be made on the basis of various
 12 factors, not just a fixed number of, as noted there.

13 Q. And then just to complete it, b says:

14 "If an 'implicated' donor is noted to have
 15 repeated elevation of ALT in the absence of
 16 Hepatitis B markers, his/her GP is notified for
 17 further follow-up. Blood and/or blood products from
 18 such donors are not used for transfusion."

19 So that was the procedure at the Northern
 20 Ireland Blood Transfusion Service.

21 If a possible case of transfusion-associated
 22 hepatitis was notified to you, would you be notifying
 23 the PFC or SNBTS in relation to that? If the donation
 24 was potentially -- or if the implicated donor was
 25 someone whose donations had been used as part of the

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1 Can you recall, Dr McClelland, whether that
 2 upward trajectory in reports, whether that continued?
 3 Did you continue to receive a greater number of cases?

4 A. I suspect perhaps not. I know my colleague
 5 Dr Bharucha did publish a report again, just in the
 6 Ulster Medical Journal, on the non-A, non-B in
 7 Northern Ireland. I don't think that showed very many
 8 cases at all. So I am not sure, but I suspect not.
 9 I don't think there was actually even as big an
 10 increase as I seem to be anticipating here.

11 Q. Well, if we just look at Dr Bharucha's 1985 article --
 12 sorry, it was accepted for publication 1985, published
 13 1986.

14 WITN0892005.

15 So, "Post-transfusion hepatitis: a problem in
 16 Northern Ireland?"

17 You'll see, Dr McClelland, it says:

18 "Accepted 8 October 1985.

19 "Summary

20 "A retrospective analysis of post-transfusion
 21 hepatitis reported to us from 1980 through 1984
 22 revealed 16 patients. We believe that this apparently
 23 low incidence is due to lack of notification and make
 24 a case for direct notification to us of any suspected
 25 cases. Disqualification of implicated blood donors is

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1 process of sending plasma for fractionation?

2 A. I really can't remember what the policy was. There
 3 probably was a PFC policy on that issue, but I really
 4 can't remember at what point one would -- the PFC
 5 would have liked to be informed. I imagine there
 6 would have been a policy in that.

7 Q. And then can I just ask you to look at two further
 8 documents on this issue.

9 The first is a letter from you to Dr Gunson,
 10 NHBT0094549_007.

11 So we can see it's dated 30 May 1984, and you
 12 are reporting cases of transfusion associated
 13 hepatitis to Dr Gunson. You say:

14 "I enclose summaries of the only 3 convincing
 15 cases of post-transfusion hepatitis which were
 16 reported to us during 1983 (1 hepatitis B and 2 Non
 17 A, Non Bs).

18 "I apologise that due to an oversight there has
 19 been such a long delay in sending you these reports.
 20 I should perhaps add that the number of reports in
 21 1984 so far has increased strikingly. This followed
 22 some publicity which we initiated regarding the need
 23 for reporting of such cases to the Transfusion Centre
 24 and tends to emphasise the degree of under reporting
 25 which has existed."

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1 of prime importance in prevention of
 2 transfusion-associated hepatitis."

3 And then if we go to -- well, perhaps we pick it
 4 up at the bottom of page 3. So in that last
 5 paragraph, it says:

6 "In this report, 11 of 16 patients developed
 7 post-transfusion hepatitis which was due to causes
 8 other than hepatitis B. If a diagnosis of non-A,
 9 non-B hepatitis is suspected it is important to
 10 identify the donors implicated, in order to prevent
 11 further transmission to other patients through future
 12 blood donations. In the absence of a screening test,
 13 our present policy is empirical exclusion of any donor
 14 implicated in two instances of post-transfusion
 15 hepatitis."

16 Can you just help us in understanding what that
 17 refers to, what that means? The "empirical exclusion
 18 of any donor implicated in two instances of
 19 post-transfusion hepatitis"?

20 A. I think that would have just referred to the scenario
 21 where the same donor was implicated in two cases of
 22 post-transfusion hepatitis. I suppose the other
 23 possibility would be if some of the tests on the
 24 donor, that were referred to earlier, were positive,
 25 but I think this probably refers to it being

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1 implicated on two occasions.
 2 **Q.** And on that reading it would mean that if there was
 3 a donor implicated in two occasions, then,
 4 irrespective of the testing on those donors' samples,
 5 they would be excluded?

6 **A.** Possibly, yes. Although I'm not -- I don't recall
 7 exactly. I mean, this is a scenario that would, in
 8 practice, I -- as far as I remember, rarely ever
 9 occurred, if it ever occurred. But I would say it was
 10 a very rare situation.

11 **Q.** If we just go over the page, I'm just going to draw
 12 attention to the last two paragraphs which may be of
 13 wider importance.

14 So:

15 "The reported incidence of post-transfusion
 16 hepatitis shows great variation, the lowest being 2%.
 17 There is little doubt that the apparently negligible
 18 incidence in Northern Ireland during the years
 19 1980-1983 must be due to lack of notification. It is
 20 still uncertain how many cases are missed, and even
 21 among a small population like that of Northern Ireland
 22 it is difficult to hazard a guess at the true
 23 incidence of the disease. Of the non-B infections,
 24 non-A, non-B hepatitis is a significant problem
 25 particularly in terms of chronic liver damage, despite

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1 indeed. I suppose as things turned out, when we were
 2 able to do hepatitis screening, it did actually turn
 3 out that our incidence of hepatitis C among donors was
 4 particularly low, but I don't think that changes the
 5 fact that, yes, I would agree with this, and
 6 I particularly agree with the message that is being --
 7 to some extent there's speculation here about
 8 suggesting that the reason must be due to
 9 non-notification, but I very much agree with the
 10 message which was being sent out to encourage doctors
 11 to look out for this condition and they issued it even
 12 saying report it direct to the Blood Transfusion
 13 Service.

14 **Q.** I'm going to turn now to ask you some more general
 15 questions about the donor collection sessions and
 16 donor selection. And you've told us, I think, in your
 17 statement, and we've seen elsewhere that there were
 18 donor collection sessions in a range of different
 19 venues as well as in some fixed locations. And in
 20 terms of the staffing arrangements at the donor
 21 sessions, you have mentioned in your witness statement
 22 that there would be a doctor overseeing the blood
 23 donation sessions who would receive appropriate
 24 training.

25 What particular kind of training, relevant to

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1 the mildness of the initial illness. In the absence
 2 of tests capable of detecting an infective donor, we
 3 must rely on notification of transfusion-acquired
 4 infection and retrospective investigation of blood
 5 donors for eventual disqualification of implicated
 6 donors.

7 "Lack of notification may be attributed to
 8 several factors. A significant proportion of
 9 non-A, non-B infection is sub-clinical and serum
 10 transaminase levels fluctuate independently of
 11 clinical illness. Vague symptoms after surgery or
 12 anaesthetic may be ignored by the patient and doctor.
 13 The prolonged incubation time of hepatitis B and
 14 moderate incubation time of non-A, non-B infection
 15 sometimes make the correlation between transfusion and
 16 clinical illness difficult. Patients are discharged
 17 from hospital and the present system of liaison
 18 between general practitioners, hospital doctor and the
 19 NI Blood Transfusion Service is unsatisfactory. There
 20 is a good case for direct notification to the NI Blood
 21 Transfusion Service of any cases of suspected
 22 transfusion-associated infection."

23 Do you agree with everything that Dr Bharucha
 24 and her colleague wrote there?

25 **A.** Yes, yes, I would have agreed at the time, yes,

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1 the donor collection -- sorry, donation collection
 2 exercise, would the doctor have received?
 3 **A.** Going back to the -- when I started with Blood
 4 Transfusion Service we had one full-time associate
 5 specialist who looked after various aspects of the
 6 donor programme including the rotation -- I mean
 7 making out the rota for doctors and liaising with
 8 session doctors as well. And certainly when a new
 9 doctor started would have gone out with this doctor
 10 who was an associate specialist and undergoing
 11 training on all the aspects with respect to the
 12 procedures, and the -- particularly the selection
 13 procedures.

14 As well as that, we did regular update meetings
 15 for all doctors about twice a year, I think, on
 16 a Saturday morning, we had a get-together, and talked
 17 through various -- all the sort of relevant issues at
 18 the time, and update any -- updated them with any
 19 changes.

20 **Q.** And then the donor attendants did they have any
 21 particular qualification or experience?

22 **A.** They didn't have any particular qualification. They
 23 underwent training again. They were overseen, when
 24 I started, with one head nurse who was a sort of
 25 sister-level nurse, to use the old grading parlance.

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1 And she would have been responsible for organising the
2 training of all donor attendants and assessing them
3 with respect to the roles that they were able to take
4 on. Some of the more senior and experienced ones, and
5 who were deemed to have passed the, sort of, training
6 assessment, would have been permitted to carry out the
7 interviews with donors, which, when -- the routine
8 oral interview which we had in place.

9 **Q.** Now in the kind of community settings that you've
10 described for some of the collections, village halls,
11 and the like, or indeed in the workplace sessions,
12 were there opportunities or facilities for donors to
13 talk in confidence to either the donor attendant or
14 the medical officer?

15 **A.** Well, this could be quite variable. Indeed, I mean
16 there was a curtained-off area in which these routine
17 interviews took place, and also in which the -- if
18 there was an issue for them, the medical officer, that
19 would take place in that same curtained-off area. But
20 inevitably, depending on the venue, that could have
21 been -- that was a bit problematic at times. I'm sure
22 confidentiality couldn't always be completely assured.

23 **Q.** And in terms of --

24 **A.** -- (overspeaking) --

25 **Q.** -- the workplace sessions, which you've explained were

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1 Dr McClelland. There are various versions of this
2 document at different dates. Do you think it's likely
3 that this is the guidance that you used?

4 **A.** Yes, yes. We did use these national guidance. Yes.
5 Yes. Certainly when I started. I think they were
6 by -- I can't remember exactly when, mid to late '80s,
7 I think we started producing our own questionnaires,
8 and I think we produced our own sort of alphabetic
9 guidelines for selection of donors as well, to put
10 them into sort of local context. But yes, we would
11 have been basically following these national
12 guidelines.

13 **Q.** If we just look briefly at the bottom of the page,
14 we can see, under the heading "Medical History":
15 "A donor is the best judge of whether he is in
16 normal health and truthful answers to simple questions
17 concerning his medical history and general health form
18 a main part of the examination.

19 "In practice the donor session clerk should
20 specifically question the donor about the conditions
21 listed on form NBTS 110A and request the donor's
22 signature on form NBTS 110."

23 Then, if we go over the page, we can see at the
24 top of the page it's said that there are three
25 categories of illnesses or conditions listed in the

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1 very important for the Northern Ireland service, in
2 order to be able to keep up with the level of donation
3 it required, did you ever consider whether employees
4 giving donations in workplaces were truly voluntary,
5 or whether there might be an expectation from their
6 employer that if a session has been arranged, they
7 would go along and donate?

8 **A.** I can't remember that being a very strong
9 consideration when I started off, or even until -- or
10 even for some time. I guess it might have crossed
11 one's mind a little bit with HIV, when you started to
12 think about all categories of donors as opposed to
13 individuals, individual donors. But no, I think
14 without workplace sessions, in those days, even with
15 all the closures and so on, we would still have
16 been -- felt we were very dependent on those.

17 **Q.** You've said in your statement that you think that you
18 used the national guidelines for the selection
19 examination of donors. Can we just have look at
20 those.

21 PRSE0004358 .

22 If we just zoom in on the top part of the page:

23 "[NBTS] memorandum on the selection, medical
24 examination and care of blood donors."

25 This is a version from November 1977,

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1 form:

2 "1. Those which disqualify a person from acting
3 as a donor ...

4 "2. Those which require referring to the
5 Medical Officer for decision as to acceptance,
6 deferral or rejection ...

7 "3. Those which necessitate temporary
8 deferment, eg pregnancy, contact with infectious
9 disease, inoculations."

10 You've described in your statement how the donor
11 attendant would undertake a health screening
12 interview. Is that essentially the process we see
13 described here?

14 **A.** I'm not absolutely sure whether it's quite equivalent.
15 It sounds -- what we would have -- obviously when
16 the donor arrives they are greeted by a clerical
17 officer, who would go over certain basic details such
18 as, you know, "When did you last give blood?" or --
19 a few basic details. This was -- I'm describing our
20 practice. And then at the next stage would have gone
21 through a more detailed interview with the
22 donor attendant.

23 This seems to imply that the interview is
24 conducted by the clerical officer but I'm not quite
25 sure -- I'm not sure. That may not be the case.

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1 Q. If we just go, then, to the bottom of the next page,
 2 we have the heading at the bottom of the page:
 3 "Jaundice or Hepatitis."
 4 "Individuals who give a history of jaundice or
 5 hepatitis or in whose blood anti-HBsAg is present may
 6 be accepted as donors providing that they have not
 7 suffered from jaundice or hepatitis in the previous
 8 twelve months, have not been in house contact with
 9 hepatitis or received a transfusion of blood or blood
 10 products in the previous six months, and providing
 11 their blood gives a negative reaction for the presence
 12 of HBsAg when tested by a sensitive method
 13 (RPH or RIA)."

14 Now, Dr McClelland, as currently understood by
 15 the Inquiry, this recommendation or this suggestion
 16 that individuals who give a history of jaundice or
 17 hepatitis may be accepted as donors provided they've
 18 not suffered from it in the previous 12 months was
 19 a change introduced in around 1977, following the
 20 report of an advisory group. But it was left open to
 21 Regional Transfusion Centres as to whether they
 22 adopted that or whether they continued with the
 23 previous practice of permanent exclusion of donors
 24 with a history of jaundice or hepatitis. What was the
 25 policy in the Northern Ireland Blood Transfusion

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1 And that was asked along with things like, "Have you
 2 ever had brucellosis? Have you ever had cancer?" In
 3 other words, it's asked along with issues or items
 4 that would result in permanent deferral. I have a
 5 feeling, though -- so we were picking up people who
 6 had a history of jaundice at any time. They would be
 7 referred to the medical officer, I think.

8 I have a feeling that we -- it was kind of
 9 assessed on an individual basis, possibly based on
 10 obtaining a GP letter. The vast majority of these
 11 cases we knew would have been caused by hepatitis A,
 12 infective hepatitis. And it may be that I think if
 13 the doctor was content that this was a typical case of
 14 infective hepatitis, perhaps as part of a local
 15 outbreak or something like that, you could be
 16 virtually certain that it was hepatitis A. But
 17 I can't be completely sure. I'd say the only little
 18 bit of evidence I can look at is that questionnaire
 19 which asks: "Have you ever had jaundice or hepatitis?"

20 Q. You've said in your witness statement that your donor
 21 selection criteria were very strict, and you recalled
 22 several doctors outside NIBTS expressing the view that
 23 the rules seemed unnecessarily strict. Can you recall
 24 anything further about that? What was it that led to
 25 that expression of opinion?

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1 Service?

2 A. I am struggling to remember exactly how we dealt with
 3 this area of history of jaundice, I'm afraid, and
 4 unfortunately there is no documentation available.
 5 I know when I retired there was a lot of guidelines
 6 and documents that would indicate what -- the exact
 7 policy of at particular points in time. I haven't so
 8 far been provided with anything that really indicates
 9 what our policy was. I mean obviously there are three
 10 possibilities: follow this and only accept people who
 11 are -- sorry, accept anyone who hasn't that jaundice
 12 in the last 12 months; or take the more rigorous view
 13 of this -- you can't exclude the possibility this was
 14 non-A, non-B hepatitis, totally, in which case maybe
 15 only accept people who are -- had the jaundice in
 16 childhood.

17 I have a feeling but I can't totally -- I have
 18 no -- I remember this was a frequent issue of
 19 discussion at our medical officer meetings. I have a
 20 feeling, although I can't -- have nothing to back it
 21 up, that it was a kind of halfway house, in that it
 22 was left -- this would have been -- I -- no, sorry.
 23 I do know that our questionnaire -- that when we
 24 introduced these questionnaires, it did ask the
 25 question, "Have you ever had jaundice or hepatitis?"

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1 A. I think it was just -- it would have been most
 2 commonly the occasional comment from GPs who were --
 3 sometimes donors would go to their GP and be told they
 4 were fit to give blood irrespective of the particular
 5 condition they were getting advice on. And the GPs
 6 would perhaps -- sometimes approach us, you know,
 7 "What is the logic for including a donor with this
 8 purpose?" It didn't seem to them very logical.

9 I'm really just making the point that,
 10 generally speaking, the guidelines took the line that
 11 if in doubt -- well, even if there was a theoretical
 12 doubt about a risk, that you err on the side of
 13 safety. I must confess the jaundice/hepatitis one
 14 perhaps doesn't fully abide by that approach.

15 Q. I want to ask you next about three categories of
 16 potentially high-risk donors. The first, inmates of
 17 prisons or young offender institutions. We saw when
 18 we looked at one of the annual reports this morning
 19 a reference to a session being established at a young
 20 offender institution, and you told us that sessions
 21 were held at HMP Belfast and HMP Magilligan, and
 22 indeed I think you've exhibited to your statement some
 23 sample donor forms from sessions in the latter
 24 institution.

25 So that was a practice you inherited. Your

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1 statement suggests that it ended in October 1983. Why
 2 did you not end the practice of prison collection
 3 earlier than that?
 4 A. I can -- would say I simply hadn't really considered
 5 it seriously up until that point. I was -- when I
 6 joined the Service I almost got the impression that it
 7 was seen as a positive thing, and I remember in one of
 8 my placements visiting -- I say, or had been brought
 9 to a session of -- virtually a prison session, and
 10 they'd shown to me with almost a certain amount of
 11 pride that this was a very good thing.

12 So I don't -- I think the short answer is
 13 I hadn't really seriously considered it until I began
 14 to -- well, certainly I think I would have been aware,
 15 even in our own -- well, not on our own -- sorry,
 16 I was mixing us up with military sessions. No, in our
 17 case there were -- the numbers were so small -- and
 18 I was going to say hepatitis B incidence was higher,
 19 which apparently was the case nationally. As I say,
 20 in our case the numbers were so tiny that I don't
 21 think -- I don't know if we ever found a hepatitis B
 22 positive in my time. But -- sorry, I'm losing my
 23 train of thought.

24 Sorry, could you repeat the question?

25 Q. Yes, it was why you didn't bring it to an end as

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1 there is an argument that they should have.
 2 Q. Now, the second category I wanted to ask you about
 3 which you mentioned a moment ago is military
 4 donation -- sources. What role did collections from
 5 military sources play in the work of NIBTS?
 6 A. I think it was quite a significant contribution,
 7 especially in the 70s, continuing in the 80s. I think
 8 the numbers were becoming less and less. There were
 9 still some army sessions into the 90s, certainly. But
 10 the numbers had become very small. But certainly in
 11 the 70s, when of course there was such a large army
 12 presence in Northern Ireland, yes, there was quite
 13 a significant contribution. Quite a lot of sessions.
 14 Q. Was consideration given ever, to your recollection, to
 15 the possibility, again, that those serving in
 16 the military might not be truly voluntary donors, or
 17 might, if they had engaged in high-risk activities,
 18 be in difficulty in being truthful about that in donor
 19 sessions?
 20 A. Perhaps -- I was aware, certainly it was our
 21 experience that there was a higher incidence of
 22 hepatitis B among army donors, certainly. That was
 23 the case. I can't remember how much consideration
 24 I would have -- I mean, I think certainly during the
 25 70s and even into the 80s, I would almost say we

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1 a practice earlier.
 2 A. Yes, I simply did -- I began to get information that
 3 the higher incidence of hepatitis B was a cause for
 4 concern. The onset of AIDS was clearly an influencing
 5 factor because for the first time you started to -- or
 6 at least in my case, the first time you started to
 7 think in terms of whole groups of donors, whole -- not
 8 just individual donors being assessed on an individual
 9 basis, but whole groups who might have, statistically,
 10 had an increased risk. So when I -- and I remember
 11 communication with Dr Gunson, who gave us the figures.

12 I don't remember, meetings I had, being told
 13 that this -- it being discussed very much. Then
 14 I heard about the Medicines Inspector view on some
 15 sessions, and that was certainly quite an influencing
 16 factor. And when that information came through
 17 I decided to stop it forthwith.

18 Q. Looking back now, and having regard not only to the
 19 fact that prisoners might be regarded as being
 20 a higher risk group, but also the fact that they may
 21 be less well placed to give candid answers to
 22 questions, maybe less truly voluntary as donors, do
 23 you think that prison donation should have stopped
 24 long before October 1983?

25 A. I think there is an argument for that, yes. I think

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1 were -- you can never say totally dependent on these
 2 donors, but they were a valuable source of donors at
 3 a time when we were struggling at times to maintain
 4 the blood supplies. So I think that was -- that would
 5 have been a big factor.
 6 Q. Then the third category I wanted to ask you about is
 7 those who have used drugs, intravenous drugs.
 8 Now this is before we get to the AIDS leaflet,
 9 which is the next topic I am going to ask you about.
 10 How were donor attendants or medical officers at donor
 11 sessions expected to evaluate whether somebody might
 12 have a history of drug use? Other than the obvious,
 13 that if they rolled up their sleeve and there were
 14 needle track marks you might see them, if it was the
 15 correct arm. But other than that, what steps were
 16 taken to try to reduce the chances of using donations
 17 from drug users?
 18 A. Other than the questions that are -- would have been
 19 in the questionnaires, I think it would have been
 20 based on interview and the general assessment.
 21 I can't remember that there would have been very much
 22 specific beyond that asked of donors that might have
 23 uncovered that kind of thing.
 24 Obviously in Northern Ireland it was -- we had
 25 a particularly low incidence of intravenous drug use,

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1 very low, and it was probably directly related to
 2 the Troubles, in fact, the actual control exercised by
 3 paramilitaries. Hard to think of an advantage of
 4 paramilitaries but it looked as if -- that was always
 5 my information from public health doctors, that there
 6 was a very low incidence of intravenous drug use in
 7 Northern Ireland in that -- during that period. And
 8 it was probably related to the Troubles, actually.

9 **Q.** I am going to ask you next about AIDS and the response
 10 to AIDS from the Transfusion Service's perspective.
 11 If we go to your witness statement again,
 12 Dr McClelland, WITN0892001. If we go to page 63,
 13 please. So at the bottom of the page you say this:

14 "My earliest recollection of HTLV III/AIDS was
 15 of reading reports from the US about AIDS being
 16 associated with Haemophilia. I believe these reports
 17 were in MMWR bulletins (1981/82). I also recall an
 18 AABB meeting [that's the American Association of Blood
 19 Banks, I think] (in or about 1982, I think) at which
 20 AIDS and its possible relevance to blood transfusion
 21 was discussed on the fringes of the meeting.
 22 Subsequent to this, I would have been aware of reports
 23 appearing in the scientific literature which provided
 24 increasingly convincing evidence of a single infective
 25 agent, including the first report of a child, in which

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1 point to be the most likely cause, an infective agent.

2 **Q.** Now I'll ask you in a moment about the AIDS leaflet,
 3 and its introduction and use in the service. Before
 4 I do that, do you recall whether Dr Mayne or the
 5 Eastern Health and Social Services Board, or the
 6 Northern Ireland Department of Health or anyone asked
 7 you if you could increase the production of
 8 cryoprecipitate so that people with haemophilia could
 9 be treated, at least on an interim basis, with
 10 a product that was safer in terms of potential AIDS
 11 transmission than factor concentrates? Did anyone
 12 ever ask you to do that?

13 **A.** No, I don't remember anyone asking me to do that. No.
 14 I don't.

15 **Q.** If we go back to your witness statement,
 16 Dr McClelland, WITN0892001, page 41, bottom half of
 17 the page. So the subparagraph (e) you were asked "how
 18 quickly the NIBTS could have increased its manufacture
 19 of cryoprecipitate, had it wished to, during the early
 20 1980s", and you say this:

21 "As I recall, in the early 1980s, NIBTS could
 22 have readily returned production to what it had been
 23 in the late 1970s (around 10,000 packs per annum).
 24 I believe there would have been the capacity to
 25 increase this substantially to, say, 20,000 packs

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1 the only risk factor appeared to be blood
 2 transfusion."

3 Do we understand from this, Dr McClelland, that
 4 you yourself read the MMWR bulletins?

5 **A.** Yes, yes I can't -- I think it may have come via the
 6 CDSC, or it may have come direct. I can't recall
 7 exactly, but I think it was a weekly bulletin, yeah,
 8 and yes, there was -- I'm not sure -- one, I continued
 9 to have it, but yes, I remember reading the -- a lot
 10 of information on AIDS in that.

11 **Q.** And you referred there to the first report of a child
 12 in which the only risk factor appeared to be blood
 13 transfusion. That is, I think, probably a reference
 14 to the child -- the Californian child, we refer to it
 15 from time to time as the San Francisco baby case,
 16 reported in --

17 **A.** Yes.

18 **Q.** -- I think the MMWR in December 1982.

19 So would it be right to understand that, as a
 20 result of what you read as set out here, by the end of
 21 '82/beginning of '83, was it your understanding that
 22 the likely cause of AIDS was an infective agent, as
 23 you describe here, that could be transmitted in blood
 24 or blood products?

25 **A.** Yes, I think that's right. That did seem at that

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1 per annum (at a guess). Some additional equipment and
 2 staffing would have been required, but this had
 3 already been acquired in order to produce the large
 4 increases in [fresh frozen plasma] going to PFC."

5 So had you been asked, it looks as though you --
 6 it wouldn't have been a problem for you to increase,
 7 fairly substantially, the production of
 8 cryoprecipitate?

9 **A.** Yes, I think it would have been possible. Yes.
 10 Yes -- I mean I -- this is my belief. I think at the
 11 time, looking back, that it would have been possible,
 12 if there had been a clear demand and a clear policy
 13 emerged, that we should reprioritise our production in
 14 that way.

15 **Q.** I asked you a few minutes ago if you were ever asked
 16 by Dr Mayne or anyone else to do so. Can I put it the
 17 other way round: did you ever raise it as a possible
 18 course of action with Dr Mayne or anybody else?

19 **A.** No. No. I don't think so, specifically. I can't
 20 remember -- I mean Dr Mayne and I would have discussed
 21 various aspects of Factor VIII and cryoprecipitate,
 22 and so on. I don't remember any clear steer that
 23 there would be -- that this was the -- this was the
 24 appropriate approach at that time. And -- sorry. And
 25 I don't recall saying or suggesting to her that we

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1 should do that either.

2 **Q.** We can take that down. Thank you.

3 Now, the leaflets that were then produced in

4 relation to AIDS and blood donation, we start by just

5 having a quick look at BPLL0007247.

6 This, Dr McClelland, is the leaflet that was

7 produced in England and Wales with the involvement of

8 the Department of Health and issued at the beginning

9 of September 1983. I'm not going to go through the

10 details of its content with you but, as far as you can

11 recall, was this the leaflet that went into

12 circulation in the Northern Ireland Blood Transfusion

13 Service?

14 **A.** Yes, yes, it was.

15 **Q.** Now, we know from other witnesses, most recently the

16 other Dr McClelland in Edinburgh, who gave evidence

17 last week, that some other centres introduced their

18 own form of leaflet earlier than this, rather than

19 waiting for the Department of Health. Did you give

20 any consideration, as far as you can recall, to

21 producing your own leaflet?

22 **A.** I don't think we did, seriously. I would have been

23 aware, and was aware, that this national leaflet was

24 in the pipeline. I would have considered, in our

25 context in Northern Ireland, assessing the likely risk

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1 let me just pick it up at the bottom of page 2, so you

2 can see the context in the minutes. So the bottom of

3 page 2 has the heading "AIDS":

4 "It was noted that since the last meeting, the

5 UK leaflet [that's the document I just showed you] had

6 been produced and, the Ministers of Health having made

7 statements on the matter, the leaflets were being

8 distributed. The method of distribution had been left

9 to the Directors who reported as follows ..."

10 Then we can go to the next page, four paragraphs

11 down, there's the heading underlined "[Northern]

12 Ireland":

13 "Dr McClelland had not yet received the leaflets

14 but would make them available at donor sessions once

15 he did."

16 Do you know why there'd been, it appears,

17 a delay in those leaflets being sent to Northern

18 Ireland?

19 **A.** I don't recall. I would be pretty sure that they

20 would have arrived soon after this date but, no, I

21 can't really say for sure.

22 **Q.** Then if we go to DHSC0101652_002, this tells us about

23 how leaflets were used at the Northern Ireland centre.

24 So this is a letter from you to Dr Smithies at the

25 Department of Health in London, 25 January 1985:

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1 that it would be appropriate to follow the national

2 line. As I say, all the indications that we had would

3 have been that the risk was likely to be low, based on

4 incidents of other -- well, incidents of any --

5 I don't know if there were any cases of AIDS in

6 Northern Ireland at this point. There might have been

7 one or two that were, kind of, imported.

8 I think we -- if you look at -- looking at risk

9 activity, we've already mentioned drug abuse or

10 intravenous drug abuse, which was very low -- at

11 a very low level. So what evidence -- we had

12 incidence of hepatitis B, as well. So what evidence

13 we had indicated that we were one of the -- likely to

14 be one of the most low-risk regions, not one of the --

15 I can imagine if we'd been in the situation of perhaps

16 London or Edinburgh, I'm sure ourselves and BTS and

17 Department of Health, and so on, might well have

18 considered that we should look at measures to --

19 additional measures that we should take. But, given

20 the situation at that time, I don't think we did think

21 it would be -- we thought it would be appropriate to

22 follow the national -- the national approach.

23 **Q.** If we then look at PRSE0002617, you'll see this is

24 an SNBTS directors meeting, 13 September 1983, at

25 which you were present. If we go to page 3 -- sorry,

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1 "Thank you for your letter on the subject of

2 prevention of transmission of AIDS through blood

3 donation.

4 "In Northern Ireland the following approach has

5 been adopted. Until recently, we relied on the

6 display of AIDS leaflets on all sessions. From about

7 6 weeks ago, we had been handing a leaflet to each

8 individual donor. The drawbacks which have been

9 noticed are, firstly, that donors often have

10 insufficient time, in practice, to read the leaflet

11 properly before donating. Secondly, a few individuals

12 have shown resentment at being handed the leaflet.

13 A potential problem is, of course, the difficulty for

14 any donor to exclude themselves at a donor session,

15 but perhaps not surprisingly it is one we have not

16 been made aware of.

17 "I am sure it is desirable to send an AIDS

18 leaflet to each donor with the call-up letter. At

19 present this is not possible since we use post cards

20 to call donors and have not the clerical capacity to

21 send enclosed leaflets. During the coming year this

22 will change, with the advent of a computerised donor

23 call-up system, combined with the use of an automatic

24 envelope. The problem of informing donors who are

25 not called individually will of course remain, ie

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1 those who donate at their place of work. We are now
2 supplying local organisers at such sessions with AIDS
3 leaflets.

4 "I hope this information is of some help and I
5 look forward to receiving the updated AIDS leaflet."

6 It would appear from that, Dr McClelland,
7 that from the introduction of the leaflet in or around
8 September 1983 to about six weeks before this letter,
9 so sometime perhaps in the first half of
10 December 1984, the leaflets were simply being left or
11 displayed at the sessions; is that correct?

12 **A.** I think so, yes, yes. I think so. I think that's
13 what this letter would -- that would be my
14 recollection as well. Yes.

15 **Q.** And so that would really depend upon the donor picking
16 up the leaflet and reading it, would it not? It runs
17 the risk that a lot of donors might not become aware
18 of the contents of the leaflet?

19 **A.** Yes, yes. Yes, that's right. Yes. It's -- yes. And
20 this would have been -- this approach -- I mean,
21 I think we would have sent the leaflet out if we'd had
22 the capacity to do it at the outset. But I think we
23 had -- and our donor admin and recruitment staff did
24 have real concerns about the impact or potential
25 impact of this on donor attendances. And in a society

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1 Did you ever consider whether there was any
2 other way in which this kind of information could be
3 disseminated to potential donors in advance of the
4 receipt of the automatic envelope and the
5 establishment of the computerised call-up system? Was
6 thought given to there being some form of public
7 health campaign or a display of posters or anything
8 along those lines in that period from the autumn of
9 1983 to 1985?

10 **A.** I think there may have been some public information on
11 this. I don't know if there was an actual specific
12 targeted campaign with direct relevance to blood
13 donation. But I think the message may have been
14 included with the general campaign about AIDS, that
15 would have been general messaging about AIDS that
16 would have included that message not to give blood for
17 people in high-risk groups, but I can't remember the
18 details.

19 **Q.** What about amending the questionnaire? Now I know you
20 did that slightly later on --

21 **A.** Yes.

22 **Q.** -- but did you consider in September 1983 or
23 thereafter at least taking the step of amending the
24 questionnaire to add a question, "Have you read the
25 AIDS leaflet? Please tick if you have", to at least

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1 like Northern Ireland, we had quite a conservative
2 society, I think we had reason to have those concerns.
3 So I probably felt that there may be some merit in
4 this sort of gradual approach to introducing this
5 leaflet, which was something very different to
6 anything that had come before.

7 So yes, we -- it had its drawbacks, in terms of
8 effectiveness, but we did introduce the mailing as --
9 as soon as we were able to. It might seem a sort of
10 trivial problem, the problem of including something in
11 an envelope. Every -- you must -- regard every day,
12 the staff would be sending out maybe, at a guess,
13 anywhere between 500 and 1,000 postcards. So it
14 really would have been quite a clerical task to take
15 this on at that point.

16 **Q.** I think it's right that it was only in 1982 that
17 homosexuality ceased to be illegal in Northern
18 Ireland.

19 **A.** Correct.

20 **Q.** And so the chances of -- or that might mean that
21 potential donors might be even more reluctant than
22 they might otherwise be to, as it were, admit to being
23 in a high-risk category that until very recently had
24 been potentially exposing them to criminal
25 prosecution.

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1 prompt people to be aware of the leaflet?

2 **A.** Again, I -- with regard to a lot of donor information
3 in use at that time, unfortunately I don't have any
4 documentation to look -- to consult and to really
5 prompt my memory, so to enable me to give reliable
6 answers to questions like that. I think I mentioned
7 we did introduce a general -- for the first time
8 a questionnaire for donor -- also already mentioned
9 the oral interview with the donor attendants. We did,
10 I think, from -- again, I can't remember the date --
11 introduce a questionnaire initially for new donors,
12 donors to complete at the session, and that was --
13 that did, I think -- that certainly did include
14 some -- something about "Have you read the AIDS
15 leaflet?" And as I say, that may well be '85, '86,
16 that sort of time, before that was introduced. But
17 that's all I can think of in that area.

18 **MS RICHARDS:** Sir, I note the time. And I'm going to move
19 on next to the question of anti-HTLV-III screening.

20 Sir, I've probably got about another 45 minutes
21 of questions -- or up to 45 minutes of questions
22 myself for Dr McClelland, and then we obviously need
23 to give Core Participants the opportunity to suggest
24 questions. We could -- entirely a matter for you
25 whether we in fact break now until the morning, or

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1 whether we continue now in the knowledge that we'd
 2 probably have to sit late in order to accommodate the
 3 opportunity for CPs to suggest questions? Or we
 4 simply go on to the normal time of 4.30. It's
 5 entirely a matter for you.

6 **SIR BRIAN LANGSTAFF:** Well, let me ask Dr McClelland what
 7 he would like.

8 Dr McClelland, can you hear me?

9 **A.** Yes, sir.

10 **SIR BRIAN LANGSTAFF:** There's a choice. Counsel will have
 11 about 45 minutes or so more questions for you. We're
 12 going to take a break now anyway for half an hour, so
 13 that would start at 3.45 or 3.50. So it will be after
 14 4.30 by the time she's finished, just after.

15 But what then happens is that we allow
 16 Core Participants to ask questions or put forward
 17 questions to her which arise from having listened to
 18 your evidence and read your statement, questions they
 19 would like answered, so that she may ask those of you.
 20 And that may be -- she has to field those questions.
 21 That's going to take half an hour, and that will get
 22 us into after 5, and then I just can't say how long
 23 those questions would be.

24 My sense is that you've probably had enough for
 25 today, or you're getting close to it, but this is

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1 **SIR BRIAN LANGSTAFF:** Then let's do that.

2 Well, we'll take a break now until shall we
 3 say 3.45. So 3.45.

4 **THE WITNESS:** Thank you.

5 (3.21 pm)

6 (A short break)

7 (3.45 pm)

8 **SIR BRIAN LANGSTAFF:** Yes?

9 **MS RICHARDS:** Dr McClelland, the next issue I want to ask
 10 you about concerns the introduction of the screening
 11 for HIV. Did you have any involvement in the national
 12 decision making regarding the introduction of HIV
 13 screening?

14 **A.** I think the short answer is no, no, not involvement,
 15 not on any of the actual advisory committees or
 16 anything of that nature.

17 **Q.** Do you know whether the Department of Health and
 18 Social Services of Northern Ireland had any
 19 involvement?

20 **A.** In the introduction of testing, I -- well, I'm not
 21 absolutely sure about that. Yeah, I'm not sure.

22 **Q.** Did you have any concerns, as far as you can recall,
 23 about how long it took to introduce screening for HIV?
 24 Which was 14 October 1985, I think.

25 **A.** Well, I was certainly very -- I thought it was

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1 a matter for you to tell me, not for me to tell you,
 2 and so you may prefer -- but it's a matter for you --
 3 may prefer to take a break now and come back at 10.00
 4 in the morning, in which case I would think we will be
 5 finished by probably, I would have thought, no later
 6 than 12, but it's certainly going to be just an
 7 hour-and-a-half, two hours, something like that in the
 8 morning.

9 It's up to you. What would you like to do?

10 **A.** Well, I'm happy enough to press on until 5 o'clock,
 11 or -- you say either way we're taking a break now?

12 **SIR BRIAN LANGSTAFF:** Either way we're taking a break now,
 13 having a cup of tea or a break. Then there will be
 14 another break, as I say, around about 4.30 or so, for
 15 questions then to be asked or put to Ms Richards.
 16 That break will be 20 minutes, half an hour, depending
 17 how long it takes for those questions to come in, and
 18 then there will be the asking of those questions, and
 19 then that will be it for the day and that will be it
 20 for your oral evidence to us.

21 **A.** Yes. Yes.

22 **SIR BRIAN LANGSTAFF:** So you get it over with, if you
 23 like, all today. If you're up for it. But you can
 24 have a break now if you'd rather.

25 **A.** I'm happy to press on.

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1 a very -- very keen to get started. I was certainly
 2 very keen that we get started as soon as possible.

3 I was also well aware of a lot of the issues
 4 around testing. I mean, we weren't involved in
 5 evaluations of any of the tests. We hadn't that kind
 6 of expertise in evaluating new tests. But I was aware
 7 of the issues, the fact that -- the problems with the
 8 early tests in relation to sensitivity, specificity,
 9 reproducibility, how problematic it could be if you
 10 had the wrong sort of test that might result in having
 11 to, I don't know, repeat batches of tests and they get
 12 called up -- I mean, we obviously had to get tests
 13 completed by -- before the end of the working day, the
 14 next working day after collection. So one could see
 15 a lot of practical problems emerging.

16 So when I was aware that there was, you know,
 17 what sounded like a better test, a second generation
 18 test, I was -- probably welcomed that with some
 19 relief, because one could foresee great problems from
 20 all the information we were getting about the initial
 21 test.

22 **Q.** Can I ask you to look at DHSC0000481.

23 This is a letter from Dr Smithies,
 24 25 October 1985, to you. She says in the first
 25 paragraph:

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1 "We have been receiving much public and
2 Parliamentary concern about the use of stocks of blood
3 and blood products held in Regional Transfusion
4 Centres and hospital blood banks which have not been
5 tested for anti-HTLV III."
6 "I am writing to ask if you would put in hand
7 measures to test any remaining stocks which you have
8 already supplied to blood banks or have in store
9 wherever this is practicable."
10 Then she asks if you would let her know as soon
11 as possible what action had been taken.
12 Now I don't think we've traced a reply to this
13 letter, but can you recall what steps either had been
14 taken in advance of this letter or were subsequently
15 taken on this issue of testing blood and blood
16 components held in stock?
17 A. Perhaps I should just say I assumed, when I first saw
18 this, that I would have replied, and then it says
19 "Copy for information", I'm wondering was I just
20 included or was I actually being asked this question?
21 So I'm not sure if -- hundred per cent sure if there
22 is a response anywhere to Dr Smithies -- but as --
23 with regard to what we actually did. The problem is I
24 really can't remember the exact details on this and
25 unfortunately there is no documentation from the time.

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1 So that's as much -- really, as much detail as
2 I can provide.
3 Q. And then can I just ask you to look at one later
4 letter on a similar theme.
5 NIBS0000046 -- sorry?
6 A. Sorry, I've lost picture.
7 Q. Have you got the picture back now?
8 A. I've lost the -- yes, I've lost picture. You're not
9 moving.
10 Q. Can you hear me, Dr McClelland?
11 A. I can hear you, yes. Just a moment, I've just lost
12 the picture. I can hear. I can hear you.
13 Q. We'll just see if the technician can assist with the
14 picture.
15 SIR BRIAN LANGSTAFF: Yes, we'll just take a break offline
16 for five minutes and see if we can get it sorted.
17 So we'll take a break for five minutes, and see
18 if we can get it sorted.
19 (3.54 pm)
20 (A short break)
21 (3.57 pm)
22 SIR BRIAN LANGSTAFF: Yes.
23 MS RICHARDS: Dr McClelland, can you see and hear me?
24 A. Yes, indeed.
25 Q. Good. Sir, could we look at NIBS0000046, page 2.

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1 I remember discussing this issue at some length
2 with staff at our meetings. We had the regular
3 meetings with the microbiology lab and -- which were
4 actually minuted, but those don't seem to be around
5 either.
6 I remember discussing this issue, and the fact
7 that we needed to take measures to try to ensure that,
8 as far as possible, everything was tested, certainly
9 that went from BTS and preferably used in hospital
10 blood banks.
11 I know there was a certain thing -- I'm almost
12 certain we started a little bit early. I can't
13 remember whether -- it might have been two weeks,
14 three weeks. I just can't remember. I'm almost
15 certain we started testing somewhat early.
16 I also think we ran down our stocks, because
17 I seem to remember discussing this, the stocks of
18 frozen -- fresh frozen plasma and cryo. Those are two
19 measures.
20 With regard to any other measures, such as
21 discarding untested product or component, I just
22 cannot recall what we did. It would obviously have
23 involved some sort of a judgment call, with looking at
24 the desirability to have everything tested against
25 maintaining supplies.

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1 It's a letter from you, 23 May 1986, to Dr Maw in the
2 department of genitourinary medicine at the Royal
3 Victoria Hospital. You say, in the first paragraph:
4 "As you well know, a number of measures have
5 been taken recently to reduce the risk of transfusion
6 transmitted HTLV III infection, ie donor selection,
7 HTLV III antibody screening (since October 1985) and
8 heat treatment of certain blood products. Clearly
9 these precautions are not fool-proof and it would be
10 helpful for us to be made aware of any known HTLV III
11 antibody POSITIVE individuals who have donated blood
12 recently."
13 There are two reasons, and it's the first I want
14 to ask you about.
15 "Some blood products which have been prepared
16 from source plasma collected 3-4 years ago are still
17 being issued. While the highest-risk products are
18 being heat treated (probably effectively) some others
19 are not. The current policy is that if a batch of any
20 blood product is known to be contaminated with an HTLV
21 III antibody POSITIVE donation, this batch is
22 discarded even if heat treated."
23 Dr McClelland, the question is this: which
24 products were still being issued that have been
25 prepared from source plasma collected three to

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1 four years ago, and therefore untested; what kind of
2 products would you be referring to there?
3 A. I think I must have been referring to products like
4 immunoglobulins of various kinds; obviously, albumin
5 was always pasteurised, regarded as very safe;
6 factor VIII was being heat treated. I think I was
7 trying to get across the message that -- to Dr Maw
8 that the, you know, the problem of HIV hasn't --
9 hadn't gone away totally with regard to blood
10 transfusion and blood product treatment.

11 So that -- yeah, there was still some risk or
12 potential risk. But I think I was referring here to
13 immunoglobulins, probably.

14 Q. Thank you. We can take that down. Thank you.

15 I wanted to ask you next, then, about surrogate
16 testing for non-A, non-B hepatitis. We know that
17 surrogate testing was not introduced. Was this
18 something which, in Northern Ireland, consideration
19 was given to introducing, irrespective of what was
20 happening in the rest of the United Kingdom?

21 A. I don't think serious consideration was given to
22 introduction of surrogate testing. It was certainly
23 something we were keeping a very close eye on the
24 developments. A little bit like the same argument
25 with regard to HIV, that any evidence we had would

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1 requiring strictly new funding. Each Director should
2 let Dr Cash know what funds would be required in
3 his/her region, assuming that both core testing and
4 ALT would be undertaken in the Transfusion Centres."

5 Now, that's obviously referring to the position
6 in Scotland, but you were present at this meeting and,
7 to some extent at least, were a partner with the
8 Scottish directors. Do you recall whether you agreed
9 with this recommendation from your Scottish
10 colleagues?

11 A. I really can't remember at this distance. Clearly in
12 Scotland, they had particular issues with regard to
13 things like product liability and the competition
14 for PFC, or with PFC products and so on.

15 I would not have been enthusiastic about the
16 idea of introducing this, I think, as far as our own
17 situation in Northern Ireland was concerned, in the
18 absence of more evidence that it was justified. So
19 yeah, I think that would probably have been my feeling
20 about it.

21 Having said that, if it had been approved,
22 I think we would have been required to introduce it if
23 we wanted to continue the relationship with PFC.
24 I presume that would have been the case, if this had
25 been approved.

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1 indicate that the risk was likely to be less in
2 Northern Ireland than the rest -- than the rest of the
3 UK. And, of course, when we introduced hep C testing,
4 that actually proved to be the case. It also
5 mentioned about very little intravenous drug use, and
6 so on.

7 So to be honest, I think the answer would be we
8 didn't. We would have followed the national --
9 a national decision making.

10 Q. Then if we look at PRSE0004163.

11 This is an SNBTS directors meeting,
12 3 March 1987, and you are recorded as present.

13 If we could turn to page 6, please. Sorry, can
14 I pick it up bottom of page 5, Sully.

15 So the heading at the bottom of the page was
16 "Surrogate testing for [non-A, non-B hepatitis]", and
17 there's a reference to the reconvening of a working
18 party on transfusion-associated hepatitis. If we go
19 over the page, picking it up in the second paragraph
20 it says:

21 "The Directors discussed the options open to
22 Scotland and agreed the following:

23 "To recommend to the SHHD that surrogate testing
24 for [non-A, non-B] should be implemented with effect
25 from the 1 April 1988 as a national development

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1 Q. As someone who attended both the SNBTS directors'
2 meetings and the Regional Transfusion Directors'
3 meetings in England and Wales, do you recall whether
4 there was any difference of approach between Scotland
5 on the one hand and England and Wales on the other
6 hand with regard to the question of surrogate testing?

7 A. Um ... I don't remember a lot about this. I do
8 know -- I think I do seem to remember that when
9 Professor Cash mentioned this at an RTD meeting, that
10 this was going to be done, that there was a lot of
11 concern raised about it. But I really can't remember
12 any detail.

13 Q. Can I come, then, to the introduction of screening for
14 hepatitis C, which was introduced in the autumn of
15 1991, September 1991.

16 Did you understand this to be a decision for the
17 Department of Health in London as to whether, and if
18 so when, hepatitis C screening should be introduced?

19 A. Yes, I did. I did indeed. It was always my
20 understanding that this -- this would await DHSS
21 approval. They had all the advisory machinery, the
22 access to all the best advice. Yes, I did assume
23 that. And it was obviously also my understanding that
24 we were -- that between the transfusion services, that
25 there would be a common starting date as well.

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1 Q. Now --
 2 A. So yes.
 3 Q. Other countries were introducing hepatitis C
 4 screening, other European countries, for example,
 5 introducing hepatitis C screening earlier than the
 6 United Kingdom. Do you recall being concerned about
 7 that?
 8 A. Yes, I think I was concerned. Yes. I mean, I was
 9 very -- thought it was a really exciting development
 10 when the test -- the virus was identified and the test
 11 became available, and my feeling was that we wanted to
 12 introduce it as quickly as possible.
 13 I obviously wanted -- I realised there were
 14 a lot of problems to be resolved before we could do
 15 that, but yes, I was -- I remembered -- probably it
 16 was beginning to feel, especially during '91 -- a
 17 feeling of frustration about not starting, about the
 18 delays.
 19 Q. Apart from the wish to abide by a national starting
 20 date, were there any particular practical reasons why
 21 hepatitis C screening could not have been introduced
 22 in Northern Ireland earlier than it was?
 23 A. I can't remember if we would have had access to the --
 24 if we would have been in a position to start very much
 25 earlier than we did, in terms of access to the assays

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1 of discarding untested product. You know, making that
 2 judgment call with respect to supplies, certainly --
 3 obviously, discarding a lot of red cells would almost
 4 certainly have put our supplies in jeopardy.
 5 So I don't think we had to do that, but -- and
 6 I can't be sure, there's nothing documented that I can
 7 call upon.
 8 Q. I'm going to move now to a different issue, which is
 9 the question of transfusion practice and the better
 10 use of blood. Can I invite you to look at
 11 BHCT0000143.
 12 You'll see there that at the head of the page
 13 it's addressed to "Members of the Northern Ireland
 14 Advisory Committee on Blood Safety". This is a letter
 15 sending out the agenda in September 2002.
 16 Do you recall when the Northern Ireland Advisory
 17 Committee on Blood Safety was set up?
 18 A. I can't, I can't remember. It would have been related
 19 to, probably, the Better Blood Transfusion Initiative
 20 by the CMOs across the UK, I think. I can't be sure,
 21 no. I can't remember.
 22 Q. Don't worry. If we go to page 3, please. These are
 23 the minutes of a meeting of this committee in
 24 September 2001 and we can see that you were in
 25 attendance, as indeed was Dr Brian McClelland. Then,

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1 or having the equipment in place. I suspect we --
 2 well, I think we did start a little -- a bit earlier,
 3 but I can't recall how much earlier we could have
 4 started. As I say, that's as much as I can remember.
 5 Q. Do you recall if the question of starting earlier was
 6 ever consciously considered by you or discussed with
 7 the Department in Northern Ireland or the Board?
 8 A. It was always my understanding that this was
 9 a Department of Health decision, that the go-ahead --
 10 we went ahead when we got the go-ahead from the
 11 Department of Health and -- the Department of Health
 12 in Northern Ireland and the Department of Health in
 13 London, or both together.
 14 Q. Then I've already asked you in relation to the HIV
 15 screening about what arrangements were made for the
 16 testing of blood or components already held in stock
 17 at the date the screening of donations started. What
 18 was the position in relation to hepatitis C? Can you
 19 recall whether steps were taken to recall products
 20 that had been unscreened from hospital blood banks or
 21 elsewhere?
 22 A. I'm afraid my position on this is exactly the same as
 23 for HIV. I cannot recall the details. I believe we
 24 did start somewhat earlier, and it was really
 25 a question of assessing how much we could do in terms

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1 if we go to the bottom of the page, you will see
 2 there's a reference there to "Transfusion Medicine --
 3 Guidelines on the Administration of blood and blood
 4 components and the management of transfused patients".
 5 There's a reference to work being done in the
 6 Belfast City Hospital by the Blood Transfusion
 7 Committee. Then the second line records that the City
 8 Hospital would be happy to share its guidelines,
 9 et cetera, with other Hospital Transfusion Committees.
 10 Do you recall at all when hospital transfusion
 11 committees were first set up in Northern Ireland?
 12 A. Yes. Well, I think -- well, not exactly. Sometime
 13 I think before this.
 14 One thing, if I may, maybe one relevant point
 15 about the role of the NIBTS in encouraging better
 16 practice. From the mid-90s or just before, we --
 17 I managed to get approval to appoint a third
 18 consultant in blood transfusion, NIBTS, and the main
 19 reason for -- or the main rationale for justifying
 20 that was for this purpose: because I saw that there
 21 was a role, an important role for someone who was
 22 expert, who had real interest and expertise in
 23 clinical transfusion to be appointed.
 24 And as a matter of fact we managed to get
 25 a training post agreed, a training programme in

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transfusion medicine. And that was approved. We made an appointment, Dr Keiran Morris was appointed. He, as Brian McClelland mentioned, had done part of his training in the Edinburgh Centre and then completed his training with us. And he was appointed a consultant in I think 1995, '96.

I mention that because he was the driving force behind a lot of these initiatives. He sat on all the transfusion committees around the province, and was involved in a lot of these initiatives that are referred to and considered by this committee.

Sorry, that's a long winded answer.

Q. No, no, you've in fact anticipated and therefore avoided the need for a couple of my further intended questions, Dr McClelland.

If we just go to page 5, which will be the next page. You'll see there's a heading at paragraph 7, "vCJD update". I'm not proposing to ask you about the details of the position in relation to vCJD. But in the paragraph just above the heading "Report from NIBTS", we can see it says:

"CMO enquired if information was available on blood usage by speciality and consultant. Dr M McClelland said that a considerable amount of information was held in the NIBTS and that he would

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Service Circular":

"Better Blood Transfusion
"Appropriate Use of Blood."

And what we can see it's "For action by: Health Authorities", et cetera, "For information to: Chief Medical Officers", and we can see that's across the country, Wales, Scotland, Northern Ireland.

If we go over the page, I only want to show you one sentence, really. Top of that page under the heading "Summary":

"This Health Service Circular replaces", then there's reference to a 1998 circular, Better Blood Transfusion.

So there are two initiatives referred to here, one in 1998, this one in 2002, on the issue of Better Blood Transfusion. I'm not going to ask you about the detail of the work that was done in response to those initiatives but can you think of any good reason why those kind of initiatives could not have been introduced back in the 1980s or even earlier?

A. I would say it really wasn't given the priority by the Departments of Health. There would have been efforts made at a professional level but, I mean, with Better Blood Transfusion Initiative you had the full backing of the CMOs. And it was given the necessary priority,

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make this available."

Then if we can just go back to the screen as it was, the context, I think, of the CMO's enquiry and your response, doctor, is the previous sentence, which recorded Dr Brian McClelland stating that there should be a target of 10 per cent reduction in blood usage.

What kind of information did the NIBTS hold about blood usage by speciality and consultant by this time?

A. I'm trying to think. I could imagine Dr Morris, Dr Keiran Morris, who was with us, might well have had that sort of information from his sitting on transfusion committees. I can't think that we would -- it was information that we would have been collecting on an ongoing basis. So I know I've made the offer here to provide the information, I'm just wondering where it came from. Maybe through Dr Morris's work.

I'm sorry, I'm afraid that's all I can say about that.

Q. Don't worry. The meeting goes on to consider various aspects of the Better Blood Transfusion initiative.

If I can just ask you to look at page 27, which is, I think, an appendix to these minutes.

This is a circular dated July 2002, a "Health

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and that, in turn, then would have encouraged clinicians to be getting involved in it.

The other point, not quite, that I would perhaps mention, is that around this time, for the first time, we started to get some research work on real meaningful -- really meaningful clinical trials on the use of blood in certain situations, which really hadn't been before. Sometimes said that, you know, if blood had just come -- had been invented as a new drug, it wouldn't have got a licence, because there wouldn't have been enough information to -- it's a bit facetious, perhaps, but because it wouldn't have had the necessary evidence for benefit.

I think around this time we started to see some genuinely well done clinical trials on the use of blood in certain situations, which -- some of which showed that we were -- probably were over-using blood, and that started to have a real impact on clinical practice. So, I mean, that's just one point I would make in addition to the general initiative. I don't think back in the 1980s there was that evidence or that real interest in the -- evaluating the real -- evaluating the way in which blood was used, clinically, it intended to follow the sort of standard practice.

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1 **Q.** Now, the last topic I want to ask you about,
 2 Dr McClelland, is the HCV look-back exercise, which
 3 was undertaken in 1995. Now, again, as I understand
 4 it, the Northern Ireland hepatitis C look-back was
 5 undertaken in accordance with the national -- the
 6 decision to have a national look-back. Was any
 7 consideration given within Northern Ireland to doing
 8 a look-back earlier than 1995 and, if not, why not?
 9 **A.** Certainly would have been keen. I think we would have
 10 been very keen to get on with doing this, in the same
 11 way as we had been doing with HIV. But, in the case
 12 of look-back, there was a very clear understanding
 13 that this was something that the Department -- we had
 14 to await a departmental decision on. Obviously, it
 15 involved the full cooperation of the hospitals,
 16 haematologists, and clinicians. I don't think we
 17 could really have, in our situation, I don't think we
 18 could have taken that initiative without department
 19 support.
 20 **Q.** Then if we could look at NIBS0001089. This is
 21 a report headed "HCV Lookback -- NIBTS Experience".
 22 The introduction explained that the procedures were
 23 announced in April 1995 and goes on to outline what
 24 they envisaged. Then the third paragraph explains
 25 that:

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1 blood bank. In a further 36 cases we have had no
 2 reply from hospital clinicians notified and it is very
 3 unlikely that we will obtain any further information.
 4 These cases reflect incompleteness of record keeping
 5 in the clinical notes or patient records could not be
 6 obtained. There are several examples of blood
 7 components issued from the hospital blood bank where
 8 it is not possible to confirm that units have in fact
 9 been transfused. This has highlighted a failure in
 10 institutional blood transfusion practice and
 11 documentation procedures which is being addressed
 12 through the Hospital Transfusion Committees. This is
 13 perhaps the single-most important finding from NIBTS
 14 HCV lookback exercise and it will be interesting to
 15 see if it is reproduced elsewhere. 64 components can
 16 be accounted for. 8 were in fact not transfused and
 17 there are completed records of their discard. 31
 18 recipients were deceased. This is likely to be an
 19 underestimate as most transfusion recipients are lost
 20 to short follow-up. It is likely that there are more
 21 deceased recipients among those for whom we have not
 22 received a reply although this remains unconfirmed.
 23 25 recipients of potentially infectious units were
 24 identified, though 3 were not considered suitable for
 25 counselling by their GPs (these were 3 females aged

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1 "It was anticipated that there would be problems
 2 with this exercise, not least of which would be
 3 documentation failures both in the Regional
 4 Transfusion Centres and in hospital blood banks and
 5 incompleteness of record keeping in patients' clinical
 6 notes. In some cases [potentially] infectious units
 7 were transfused some 30 years previously."

8 Before I just ask you to look at the conclusions
 9 of this report with me, Dr McClelland, who was it
 10 within the Northern Ireland Blood Transfusion Service
 11 who was in charge of the look-back exercise from the
 12 service's perspective? Was it you or Dr Bharucha or
 13 someone else?

14 **A.** Dr Bharucha was the main person involved in all of the
 15 detail. My own involvement would have been -- been
 16 just generally to ensure that it was being carried
 17 out, but no, she was the one who coordinated the
 18 programme.

19 **Q.** And then if we just look at the findings or
 20 conclusions pages 6 to 7, so if we start with page 6,
 21 I think this is a draft report. But in any event,
 22 hopefully the figures are accurate. So the heading
 23 "Results" halfway down the page:

24 "56 blood components could not be accounted for.
 25 20 components could not be traced by the hospital

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1 85, 86 and 87 years respectively). The remaining
 2 22 recipients were offered counselling, testing and
 3 where appropriate treatment and their results are
 4 presented in detail."

5 Again, I'm not going to ask you about the
 6 detailed figures, and there is a later set of figures
 7 which are -- I'll just read the reference without
 8 asking you to look at it. It's NIBS0001295.

9 What I wanted to ask you about here is just the
 10 more general point about failures in documentation,
 11 incompleteness of record-keeping, lost records, and
 12 the like.

13 First of all, is there anything in what
 14 Dr Bharucha, if she were the author of this report,
 15 has set out here that you would disagree with in terms
 16 of her observations?

17 **A.** No, no, I don't think so at all. No. No surprises
 18 there at all.

19 **Q.** Secondly, this was obviously being done in 1995 and
 20 1996. Had there been any earlier attempts in Northern
 21 Ireland to carry out audits, for example, of
 22 record-keeping in hospital blood banks and in
 23 hospitals more broadly in Northern Ireland? Just to
 24 see what the standard of record keeping was?

25 **A.** There may well have been, but I can't remember any

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1 detail, no. I remember there were guidelines issued
 2 about record-keeping in general, urging hospitals to
 3 review their record-keeping, but I can't remember.
 4 I don't think NIBTS would really have been involved in
 5 that. It was a lot easier for -- I'm not saying we
 6 were in any way perfect, but there were a lot more
 7 opportunities for error and failure to trace, and so
 8 on, at the hospital level than at the Transfusion
 9 Centre level.

10 **MS RICHARDS:** Sir, those are my questions for
 11 Dr McClelland. If we could take, however, a further
 12 break now to see what questions CPs might want to
 13 suggest.

14 **SIR BRIAN LANGSTAFF:** Do you have any sense how long you
 15 might need?

16 **MS RICHARDS:** I'm afraid, I don't, sir. I'd certainly ask
 17 for 20 minutes. It might be I need longer but I --

18 **SIR BRIAN LANGSTAFF:** Well, shall we say not earlier than
 19 20 minutes from now, so you have at least 20 minutes
 20 but if you're back by then, we'll see. When we are as
 21 ready to start as soon as after that as we can, we
 22 shall.

23 **MS RICHARDS:** Thank you, sir.

24 **SIR BRIAN LANGSTAFF:** So, until 4.50 pm, maybe later, if
 25 you keep on getting questions.

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1 recollection was that the change from December 1984
 2 onwards did not apply to factor concentrates,
 3 commercial concentrates, which continued to be ordered
 4 and supplied directly by the Haemophilia Centre.

5 Can I just ask you to look at one document in
 6 relation to that, which we didn't look at earlier.
 7 BHCT0000503.

8 You'll see the date of this document is
 9 1 August 1985. If we go to the next page first of
 10 all, you'll see this is in fact the first page, and
 11 it's about Factor VIII usage by the Northern Ireland
 12 Haemophilia Reference Centre. We understand this to
 13 be a document authored by Dr Mayne.

14 If we go back to the first page, it's the second
 15 page of the document but the first on our system, just
 16 if we could look at the first paragraph, halfway down
 17 that paragraph there's a sentence that reads:

18 "From December 1984 all commercial material and
 19 NHS material has been ordered by us through the
 20 Regional Blood Transfusion Service, to enable at long
 21 last a regional budgeting system for the haemophilic
 22 population of Northern Ireland."

23 Now, as I understand your evidence earlier,
 24 Dr McClelland and, indeed, I think the later document
 25 that we looked at from 1989, your recollection, as

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1 (4.31 pm)

2 (A short break)

3 (4.50 pm)

4 **MS RICHARDS:** Dr McClelland, I have just a handful of
 5 further questions for you. First of all, when in
 6 late 1982 or in the course of 1982 you became aware
 7 from reading US reports of the likely connection
 8 between blood and blood products and AIDS, do you
 9 recall having any specific discussions with Dr Mayne
 10 about the implications of that in terms of the use of
 11 US imported factor concentrates?

12 **A.** Yes, as I said, Dr Mayne I saw on a very regular
 13 basis, almost weekly basis, and yes, it certainly
 14 would have been a topic of conversation. With regard
 15 to implications for blood products, yes, I mean,
 16 Dr Mayne was supportive of the Scottish link-up and
 17 therefore -- you know, the -- which involved the use
 18 of NHS products, and obviously the advantage of that
 19 was a lower risk of infected --
 20 transfusion-transmissible infection.

21 I can't really be more specific than that.

22 **Q.** Okay.

23 Now I asked you about the arrangements in
 24 relation to commercial concentrates, how they were
 25 ordered and provided, and your evidence, or your

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1 I understand it, is that this is incorrect: commercial
 2 material was not ordered through the Regional Blood
 3 Transfusion Centres?

4 **A.** No, it was not ordered through the Regional Blood
 5 Transfusion Centre, no. After ordering the product,
 6 the commercial Factor VIII products, the invoices
 7 would have been forwarded to the Transfusion Centre,
 8 if you like, or/stroke the Eastern Board finance
 9 department, for payment. But no, they would not have
 10 been ordered by us.

11 **Q.** Thank you. We can take that down. Thank you.

12 Next question on a different topic, were the
 13 Northern Ireland Blood Transfusion Services, donor
 14 recruitment and donor exclusion policies and practices
 15 subject to inspections by SNBTS or the PFC?

16 **A.** I can't remember. I would -- I can't remember
 17 exactly. But I would imagine that during some or all
 18 of those audits, there would have been some checks
 19 made on our donor selection policies to check that
 20 they were in compliance with the Scottish policy.

21 **Q.** Then the plasma that was collected via
 22 plasmapheresis -- and this is in the period prior to
 23 your move in the '90s to the new building -- was that
 24 sent to PFC?

25 **A.** Yes, that was really all sent to PFC. Yes.

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1 Q. Were any additional tests such as ALT or other tests
2 done for plasmapheresis donations?
3 A. Well, not related to infection -- transmissible
4 infection. There were no additional tests. Any
5 additional tests would have been related to the
6 particular reason for, like antibody or measurement or
7 something. But not related to safety transfusion,
8 transmissible infection, et cetera.
9 Q. What was your understanding as to the reasons for the
10 increased rates of hepatitis B amongst the military?
11 A. Oh, ha! I don't know. I mean, I suppose in
12 Northern Ireland the evidence was that the native
13 population, if you like, had a particularly low
14 incidence. But I think it would be speculation for me
15 to say what the reasons might be.
16 Q. Given the fact that homosexuality in the military
17 remained illegal until 2000, what consideration, if
18 any, was given to the particular risks of continuing
19 collections from the military, particularly given the
20 fact that hepatitis B and HIV had similar transmission
21 routes?
22 A. Um, there were -- we were selective to some extent
23 with military sessions in that certainly if a regiment
24 or whatever had been abroad in the recent past,
25 certainly in the -- six months to a year, I can't

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1 soldier -- or all the barracks and units within
2 Northern Ireland, or running some specific leafleting
3 sessions for military donors?
4 A. There weren't specific leaflets for military donors,
5 I don't think.
6 Q. But in relation to the general AIDS leaflet, was any
7 thought given to trying to ensure, other than at
8 ordinary donor sessions, that that leaflet was made
9 available, for example by providing it to the military
10 institutions from which you might then seek donations?
11 A. You are referring to the AIDS leaflet --
12 Q. Yes.
13 A. -- for blood donors?
14 Q. Yes.
15 A. So -- sorry, I'm not sure that I fully understand.
16 I don't think -- I don't think we did provide any
17 additional information.
18 Q. The thrust of the question was this, Dr McClelland,
19 let me put it in a better way, I hope: you told us
20 earlier that, for quite a prolonged period of time
21 after the leaflet was first introduced, it was simply
22 left at the donor sessions for the reasons you've
23 already told us.
24 A. Yes.
25 Q. Given that there was potentially a high risk from

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1 remember exactly, we would not have gone to those
2 centres. But with regard to the specific point you
3 made, yes, it's probably a valid point that some
4 consideration might have been made.
5 Q. Completely different issue now.
6 We were looking earlier at documents relating to
7 the notification of cases of transfusion-associated
8 hepatitis. And you may recall one of the documents,
9 I think probably one of the ones authored by
10 Dr Bharucha, said that notifications from general
11 practitioners were rare. Was any thought given to
12 running some kind of awareness-raising campaign for
13 GPs in relation to that particular problem?
14 A. I can't remember any campaign specifically for GPs.
15 I think one of those documents that was shown, I think
16 maybe does refer to -- or it was a letter, my letter
17 to Dr Gunson regarding an expectation that the numbers
18 might increase, and I think that probably followed
19 communication that went out from the Eastern Board at
20 our urging, that doctors should be encouraged to
21 start -- to notify these cases. I don't know if GPs
22 were included in that. They could well have been.
23 Q. And then, given the Transfusion Service's reliance
24 upon military donations, was thought ever given to
25 providing the AIDS leaflet directly to every

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1 military donors, that the -- the question was really
2 whether steps could have been taken to at least
3 highlight the risks of donation to the military by,
4 for example, delivering a load of the leaflets to the
5 various barracks, and so on, within Northern Ireland.
6 A. Yes. I think we may have done the same where we would
7 have done for workplace sessions, where we would have,
8 and I'm fairly sure we did, deliver leaflets in
9 advance to the local contact or organiser, the
10 leaflets for distribution or distribution in whatever
11 was appropriate way. I think we would have done the
12 same with the military as that. But I'm not
13 completely certain.
14 MS RICHARDS: Thank you.
15 Sir, those are the additional questions I'm
16 proposing to ask from those suggested by
17 Core Participants. I'm just going to see whether
18 Dr McClelland's legal representatives have any
19 questions. No.
20 SIR BRIAN LANGSTAFF: Well, I have no questions of my own.
21 MS RICHARDS: Dr McClelland, is there anything you would
22 wish to add?
23 THE WITNESS: Um, just two things very quickly. Just
24 I hope my evidence has been of some little bit of help
25 at least in respect of the position in Northern

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1 Ireland and, secondly, just to the infected and
 2 affected, I just hope at the end of this marathon
 3 process that some of the questions they've been asking
 4 for so long will be answered, they will get answers to
 5 those. That's all.

6 **MS RICHARDS:** Sir Brian.

7 **SIR BRIAN LANGSTAFF:** Well, certainly your evidence has
 8 been of help to us. We have a better and fuller
 9 understanding of the way in which the Northern Irish
 10 service was run and structured and, although you've
 11 struggled with some memories going back as long as you
 12 have, you haven't complained about that at all, and
 13 I just want to thank you for trying, and thank you for
 14 your staying power in lasting until 5 o'clock this
 15 evening from starting at 10, so thank you very much
 16 for that, and for your evidence.

17 **MS RICHARDS:** Sir, the Inquiry now won't be sitting
 18 tomorrow, because we've managed to complete
 19 Dr McClelland's evidence today.

20 **SIR BRIAN LANGSTAFF:** So looking ahead, then?

21 **MS RICHARDS:** Looking ahead, on Thursday we will be
 22 hearing from Dr Gabra and on Friday from Dr Boulton.

23 **SIR BRIAN LANGSTAFF:** Yes.

24 **MS RICHARDS:** I'm asked to mention, sir, that an update
 25 about the Inquiry's timetable, both for the hearings

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1 between now and Easter, and then the hearing plans for
 2 the rest of the year, will be published on the
 3 Inquiry's website, I'm told, imminently.

4 **SIR BRIAN LANGSTAFF:** Yes, I think people will see that we
 5 have a full year in anticipation, though we remain
 6 determined to finish as soon as we reasonably can,
 7 consistent with reasonable thoroughness.

8 Until tomorrow -- until Thursday --

9 **MS RICHARDS:** Thursday.

10 **SIR BRIAN LANGSTAFF:** -- ten o'clock.

11 **MS RICHARDS:** Thank you, sir.

12 **(5.05 pm)**

13 **(The hearing adjourned until 10.00 am on Thursday)**

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