

Tuesday, 8 February 2022

(10.00 am)

**Presentation by COUNSEL TO THE INQUIRY about THE WESSEX
REGIONAL BLOOD TRANSFUSION CENTRE**

SIR BRIAN LANGSTAFF: Good morning, Ms Scott.

MS SCOTT: Good morning, sir.

SIR BRIAN LANGSTAFF: It's good to see you here in person.

MS SCOTT: Thank you, sir. It's very nice to be back.

SIR BRIAN LANGSTAFF: Yes?

MS SCOTT: This morning, sir, I am going to be giving a presentation on the Wessex Regional Transfusion Centre, from the date that it was established in 1970 until the time when Dr Frank Boulton took over as the director in September 1990.

You will recall, sir, that we heard evidence from Dr Boulton last week about what happened in the Centre from the time that he arrived in September 1990.

The first director of the Wessex Centre was Dr Donald Smith and he took the directorship from the establishment of the Centre in 1970 until stepping down in around, Dr Boulton thought, around 1988 or 1989, we didn't have a precise date for that. What Dr Boulton told us and what we see reflected in the documents is that, having stepped down, Dr Smith was

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Centre Directors, regional scientific advisers and Haemophilia Centre Directors for the supra-regional territory for which Oxford Haemophilia Centre had responsibility and it's from a meeting that took place on 26 July 1976.

We're looking here at the agenda but if we could turn, please, to page 3 of this document. We can see a map, and if we look down at the bottom there we can see that the Wessex RHA is depicted there and, we know from the documents, that the RHA and the Regional Transfusion Centre were not identical but that's the area we're, more or less, looking at; the transfusion centre did not cover the whole of the Regional Health Authority.

If we then turn over, please, to page 5 we get a little bit of information about who was attending this meeting and we can see, as we look down the list of attendees, that we've got an attendee from the Treloar Haemophilia Centre, so that was one of the Haemophilia Centres served by the Wessex Transfusion Centre, Dr Kirk, and we've also got there Dr Rainsford.

Then moving down the list, we can see there Dr Stern, from the Department of Pathology in Bournemouth, again another hospital and area served by

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persuaded to remain for a couple of days a week as a locum medical manager and that is how he describes himself in some of the documentation that we see towards -- in 1989.

Then it looks as though he stepped away entirely at the end of April 1990, and we were certainly told by Dr Boulton that, by the time he arrived in September 1990, there was no director -- there had been no director in place for a little while. He wasn't sure how long. But it looks like that period was May to September 1990.

The Centre itself is based in Southampton and it covered a region which included Hampshire, the Isle of Wight, Dorset and part of Wiltshire. By 1984 we see from the documents that it served 11 district blood banks.

In terms of population, again, the documents tell us that it served a population of about 2.14 million in 1980 and that was rising through the 1980s to 2.3 million in 1987 and, by 1989, it suggested that a better estimate was 2.8 million.

If we can have, Sully, a document, CBLA0000391. We can have a look at a very simplified picture of the area that it covers. This document is the agenda and then the minutes of a meeting of the Blood Transfusion

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the transfusion centre.

Again, moving down we see Dr O'Brien from Portsmouth, again served by the Wessex Regional Transfusion Centre.

If we turn over the page we can see under "Regional Blood Transfusion Centre Directors" attendees, we see Dr Smith from Wessex and then at the bottom -- near the bottom, we see apologies for absence and we see the name there of Dr Chisholm who is from Southampton, again one of the Haemophilia Centres served by the Wessex Transfusion Centre.

Then, sir, if we turn over to page 8 of this document, we see recorded a discussion and a contribution from Dr Smith at the top of that page:

"Dr Smith said that he supplied cryoprecipitate to hospitals in Newport, Dorchester, Salisbury and Winchester. These are not Haemophilia Centres but Dr Smith felt confident that the patients were well cared for at these hospitals. Dr Smith said that he would ask at the next Regional Haematology meeting to see if the centres should be listed and designated as Associate Haemophilia Centres."

Then the view is expressed by Dr Rainsford and Dr Scott that:

"... it was not generally desirable for patients

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1 to be treated at hospitals which were not haemophilia
2 centres."

3 **SIR BRIAN LANGSTAFF:** Just on that, if we go back to the
4 cast list on the page 5 --

5 **MS SCOTT:** Page 5.

6 **SIR BRIAN LANGSTAFF:** -- whereas Dr Kirk is shown as being
7 at the Treloar Haemophilia Centre, the address given
8 for Rainsford, who makes the point that you should
9 only be treated at a centre, is shown as coming from
10 Lord Mayor Treloar College. So he appears to give his
11 address as the college not the centre.

12 **MS SCOTT:** Yes.

13 **SIR BRIAN LANGSTAFF:** It just -- I don't know if anything
14 turns on that point; it's one I will consider in due
15 course, perhaps.

16 **MS SCOTT:** Yes.

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

18 **MS SCOTT:** Then if we turn to another document to give us
19 a snapshot in terms of what was happening at the
20 Centre in 1980, it's NHBT0110056. This is the annual
21 report of the Wessex Transfusion Service for 1980, and
22 we can see in the "Introduction" it says:
23 "This Service was set up by the Wessex Regional
24 Hospital Board in 1970. The Region had previously
25 received its blood supplies from the Bristol and

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1 "The increase in blood collection and handling
2 has exerted considerable pressure on the space
3 available in the Transfusion Centre. Two small
4 extensions have been carried out, one to the Bleed
5 Suite, the other to a prefabricated Class I Clean
6 Room."

7 And we'll see reference to that in some of the
8 documents we look at later.

9 And:
10 "A further two-storey extension is planned for
11 1981/82."

12 Then if we go down to the last paragraph, we can
13 see that it's said that:
14 "The amount of Factor VIII ahf which is provided
15 by the Blood Products Laboratory is insufficient to
16 meet the Regional needs. The reason for this is the
17 existence of the Lord Mayor Treloar Haemophilia Centre
18 at Alton. Consequently, some 3.1 million units of
19 commercial ahf will have been purchased in the current
20 financial year. It is hoped that our plans for
21 expanding our plasma collection will make significant
22 reductions in this."

23 Then we can see at the bottom some of the names
24 of the senior staff team. We've got: Dr Smith,
25 medical director; Dr Barnes, who is deputy medical

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1 [South] London Transfusion Services. Some 55,825
2 donations were collected, processed and distributed in
3 the first full year.

4 "At the re-organisation of the NHS in 1974, it
5 was decided that the Bath and Swindon Health Districts
6 would continue to be serviced by Bristol and Oxford
7 Transfusion Centres: the distances involved made this
8 a logical decision. This, of course, means that the
9 Wessex Transfusion Service is serving approximately
10 2.14 million of Wessex's 2.74 million population."

11 Then the next paragraph, the second half of that
12 paragraph:
13 "As will be seen in the body of this report, the
14 total number of donations collected in 1980 was 86,926
15 with the plasma from about 38,000 going to Factor VIII
16 and Plasma Protein Fraction production.

17 "In 1974 the service changed from bottles to
18 collection of donations into plastic packs."

19 Then if we go down to the bottom of this page,
20 in the last paragraph, halfway through that paragraph
21 we see that a mobile centre was commissioned and had
22 its first session on Monday, 1 September 1980.

23 If we go over the page then, please, we get told
24 a little bit about the buildings, and so on. First
25 paragraph:

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1 director, and we will see quite a lot of
2 correspondence from him later on; then we've got
3 Mr Allison, senior chief MLSO; and Mr Duddridge,
4 regional donor organisation; with Mr Grundy as
5 administrator.

6 We know from other documents that by 1984, the
7 Centre were holding 18 sessions a week and collecting
8 99,000 donations per year and, for the transcript, the
9 reference for that is NHBT0010821_009. Don't need to
10 go to that.

11 And we also know that by 1987 there was
12 a plasmapheresis panel and there seemed to be
13 a preference at the Wessex Centre for manual pheresis
14 rather than automatic.

15 Turning then to high-risk donors -- and again we
16 don't need to go to this, but I'll read this for the
17 transcript -- there is a reference in an
18 executive committee meeting note for
19 The Haemophilia Society of 9 December 1971, which for
20 the transcript is HSOC0029691_142, and the note says
21 this:
22 "Dr Smith has been very pleased at the interest
23 shown in what he was doing."

24 And you will recall -- we'll see of course, sir,
25 that this is a year after the Centre has opened, and

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1 he goes on to say:
 2 "The crews of many ships are volunteering as
 3 blood donors."
 4 Now it is not clear whether those are naval
 5 ships or other kinds of ships but there is reference
 6 in this document which I think is worth going to,
 7 NHBT0108948.
 8 So there is reference in this document we're
 9 just about to look at to naval donors, and we can see
 10 here it's a -- it looks likely an internal note from
 11 Dr Smith dated 27 June 1974, and he says:
 12 "Please could you ask the team clerks,
 13 particularly at Naval sessions, to enquire if there is
 14 any history of jaundice even if the donor has
 15 previously donated. Anyone with a history of jaundice
 16 will not be accepted but I will always write to them
 17 and explain that they can go on our research panel."
 18 So this document suggests that there were
 19 certainly naval sessions and we'll see some
 20 correspondence in due course between the Centre and
 21 a naval hospital. And I will come back to the
 22 question of the donor selection and criteria in
 23 relation to those who have had a history of jaundice.
 24 We can also see from documents that there were
 25 collections from prisons. Could we have, please,

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1 not clear whether it's to one or more than one
 2 transfusion centres to warn them that this donor may
 3 attend a session, not knowing that he has tested
 4 positive for hepatitis B. Hepatitis B, or Hepatitis
 5 Australia antigen.
 6 Can we then look at NHBT0108717_001.
 7 Sir, this is a letter from, again, Dr Smith to,
 8 this time, Dr Maycock on 28 June 1972, and he says:
 9 "I am enclosing information about the incidence
 10 of Australia Antigen in the prison and forces
 11 population in Wessex. It looks to me as if we shall
 12 lose our prison population of donors eventually."
 13 Then he sets out the total tests and the antigen
 14 positives for the general public, HM Forces, and
 15 HM Prisons.
 16 So he, at this point, sir, clearly considers
 17 that the number of antigen positives mean that they
 18 shall lose the prison population of donors
 19 eventually.
 20 But if we look at a document --
 21 **SIR BRIAN LANGSTAFF:** It makes the point beautifully,
 22 doesn't it, in terms of mathematics, because there are
 23 exactly the same number of antigen positive cases if
 24 you combine forces and prisons, combined, as there are
 25 in the general public. If you combine forces and

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1 DHSC0100020_045.
 2 So this is a letter from 9 May 1972 to "Dear
 3 Dr", and we can see it's from Dr Smith, and it's about
 4 a particular patient -- or donor, I should say.
 5 "This donor attended one of our blood collection
 6 sessions at Camp Hill Prison on the Isle of Wight.
 7 Our routine tests showed that he had a positive HAA
 8 test and this was confirmed by the Portsmouth Public
 9 Health Laboratory. These facts were then communicated
 10 to the Governor of the Prison and the Prison Medical
 11 Officer who decided that for medical reasons
 12 (personality difficulties) it would be inadvisable to
 13 let Mr [X] know these results. Liver function tests
 14 were normal.
 15 "I asked the Prison Medical Officer to let me
 16 know when this man would be discharged and he has now
 17 been in touch with me to say he will be going under
 18 the care of the probation officer, Borough High
 19 Street, London, SE1. I regret that we do not know the
 20 donor's address.
 21 "I thought I would let you have this information
 22 so you will be warned if he attends one of your blood
 23 collection sessions."
 24 So it looks, sir, from this that this is
 25 a letter that Dr Smith is sending out -- well, it's

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1 prisons in total numbers, it's just over 4,000, which,
 2 again, multiply by 10, and you get to 40,000. So it's
 3 ten times as likely, on the basis of this, very rough,
 4 to find someone who is antigen positive in the forces
 5 or in prisons compared to the public.
 6 **MS SCOTT:** Yes. Yes, quite.
 7 **SIR BRIAN LANGSTAFF:** I mean, it's only a snapshot and
 8 it's not rigorously statistical, but that's pretty
 9 clear.
 10 **MS SCOTT:** Sir, just noting the date there, 28 June 1972,
 11 and the suggestion that it looks like they'll lose
 12 their prison population of donors eventually, if we
 13 then look at a document for September 1983,
 14 NHBT0008628_001. Ah, that document doesn't seem to be
 15 opening. I don't know whether it's worth pursuing
 16 that or whether the best thing to do is to come back.
 17 **SIR BRIAN LANGSTAFF:** Well, yes.
 18 **MS SCOTT:** I'm being told if we can wait 30 seconds it can
 19 be put up.
 20 **SIR BRIAN LANGSTAFF:** Right. Let's wait. Thank you.
 21 **MS SCOTT:** So, we can see here, "East of Scotland Blood
 22 Transfusion Service ... Scottish Transfusion Directors
 23 Meeting 13.9.83":
 24 "Telephoned survey of England and Wales
 25 Transfusion Centres regarding use of prisons as

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1 a source of donor blood."
 2 If we look down, the fourth Centre down is
 3 Wessex and they say:
 4 "It is several years since they stopped using
 5 the Isle of Wight prisons because.
 6 "1) of increasing medical problems among
 7 prisoners, particularly related to drugs;
 8 "2) the prisons cancelled sessions at 2-3 hours
 9 notice because of prison riots, demonstrations, etc.
 10 "At present, they use Winchester prison,
 11 a short-stay prison for non-violent prisoners, once
 12 a year, but plan to withdraw this session in the near
 13 future."
 14 So it seems from this that there were still some
 15 sessions being undertaken as of September 1983, albeit
 16 plan to withdraw those in the near future, whatever
 17 that means.
 18 **SIR BRIAN LANGSTAFF:** What's the date of this, did you
 19 say?
 20 **MS SCOTT:** September 1983.
 21 **SIR BRIAN LANGSTAFF:** Thank you.
 22 **MS SCOTT:** I'm now going to turn to a handful of documents
 23 to look at the issues that arose in Wessex for
 24 provision of plasma for fractionation. We know that
 25 in 1980, and we've seen documents relating to this in

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1 Then it sets out what it was discussed at that
 2 meeting in terms of an agreement was reached about
 3 sending more packs each week to PFL in Oxford.
 4 Then, if we turn over the page, we can see at
 5 the second paragraph down there:
 6 "A meeting was arranged and held at Oxford on
 7 the 14th March, 1980. Those present were Dr Lane,
 8 Dr Bidwell, Dr J Smith, Mr B Grundy, Administrative
 9 Officer, Wessex ... Mr Allison, Senior Chief MLSO, and
 10 myself, and we were told that Oxford were unable to
 11 increase their handling of plasma to 600 per week
 12 [which is what Dr Smith thought had been agreed at the
 13 previous meeting] and that they were not entirely
 14 happy to process 500. Dr Lane stated that even if we
 15 increased our plasma supply to BPL in 5 litre pools,
 16 there could be no pro rata increase of Factor VIII,
 17 but in due course we would receive some PPF back.
 18 "We had no alternative, therefore, but to cancel
 19 our arrangements about collecting more donations, for
 20 the revenue expenditure would have been about £170,000
 21 with no Factor VIII return on the investment.
 22 Subsequent to the above meeting I wrote to Dr Lane and
 23 received a reply which confirmed our understanding of
 24 the points made above."
 25 Then he goes on to say:

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1 previous hearings, that Wessex were providing plasma
 2 to PFL in Oxford for fractionation. There are
 3 a series of meetings and correspondence that takes
 4 place between PFL, BPL and Wessex as to whether and,
 5 if so, how Wessex can increase their supplier of
 6 plasma in return for more Factor VIII.
 7 If we can pick this up at CBLA0001198. This is
 8 a letter dated 6 November 1980 to Dr Edith Bidwell and
 9 it's from Dr Smith. It sets out the history of this
 10 matter, and he says -- this the second paragraph down:
 11 "Earlier discussions with Dr Lane and Dr Gunson,
 12 former Director of Oxford BTC, had been concerned
 13 with:
 14 "Our desire to send more fresh plasma for
 15 fractionation to Factor VIII and Plasma Protein
 16 Fraction to help with the supply of Factor VIII to
 17 Alton [of course, that's the Lord Mayor Treloar's].
 18 "Our 'sterile' room being at capacity ...
 19 "Our wish to send single transfer packs of FFP.
 20 "Our intent to have a Class 1 clean room ...
 21 "After these preliminary talks and exchange of
 22 letters a meeting was held at Southampton and the
 23 statements below are extracted from the notes prepared
 24 by Dr Bidwell. The date of the meeting was ...
 25 25th June, 1979."

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1 "As soon as the fractionation plants are able to
 2 receive extra FFP, even in 5 litre packs, we will plan
 3 again to increase our donor intake. This has always
 4 been made perfectly clear. We now have a Class 1
 5 clean room in operation, but naturally, like everyone
 6 else, we would like to send single transfer packs."
 7 So that was the position as at 14 March 1980.
 8 Now, this state of affairs, ie Wessex wanting to
 9 send more plasma for fractionation, either to PFL or
 10 to BPL, was the subject of a letter that Dr Aronstam
 11 published in the BMJ, and if we can have a look at
 12 that it's RLIT0000667. It's dated 20 September 1980
 13 and the letter is on the right-hand column, halfway
 14 down that page.
 15 He's responding to some comments made by
 16 Dr Cash, if we could go up a little bit. It's not
 17 terribly good, yes, it's "Factor VIII supply and
 18 demand", "Sir". He sets out that he failed -- the
 19 reason he:
 20 "... failed to mention the availability of
 21 plasma for fractionation as an important aspect of the
 22 problem of national self-sufficiency in blood products
 23 [was because the] Wessex Regional Transfusion [Centre]
 24 has recently offered to increase the supply of plasma
 25 to the Lister blood products laboratory, only to be

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1 told that there was not the capacity to handle the
2 extra plasma.
3 "I think it most important that ..."
4 I can't now read that.
5 **SIR BRIAN LANGSTAFF:** "... the repetitive cry ..."
6 **MS SCOTT:** Thank you:
7 "... the repetitive cry for increased plasma
8 does not obscure the very real need for adequate
9 fractionation potential in England today."
10 Now, that letter prompted a rebuttal from
11 Dr Bidwell which we see at CBLA0001193. So she, in
12 response to that, wrote a letter to Dr Aronstam, dated
13 29 October 1980, referring, in that first paragraph,
14 to the letter we've just looked at. She puts a rather
15 different -- has a rather different interpretation of
16 events. She says this:
17 "The situation is that Wessex was unable to
18 increase the provision of plasma to Blood Products
19 Laboratory in the agreed form, namely 5 [litre] packs,
20 in conformity with all the other Regional Transfusion
21 Centres."
22 So that's slightly different from how Dr Smith
23 was expressing himself in the letter he wrote to her.
24 The letter Dr Smith wrote to her is
25 November 1980, so it is dated after this letter but it

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1 College, and our appreciation of the special
2 difficulties its situation causes the Wessex region --
3 not dissimilar to the special difficulties in Oxford.
4 "Our limited ability to open single packs was
5 made clear to Dr Smith from the beginning.
6 Nevertheless, as soon as we started to accept the
7 single donations from Wessex, Dr Smith ceased to send
8 any 5l packs to BPL, Elstree, and put the whole burden
9 of fractionation of his plasma production for factor
10 VIII concentrate on to this small laboratory at
11 Oxford. It was hardly surprising that he rapidly
12 out-stripped the small amount of spare capacity we had
13 offered. Moreover, despite an initial undertaking to
14 supply plasma from blood collected into CPD
15 anti-coagulant, he switched to ACD, which gives
16 a lower yield for the same amount of work from our
17 staff. It was because he was offering plasma in
18 a non-standard form, that he was told there was not
19 the capacity to handle the extra plasma."
20 Sir, on that point there, of the lower yield
21 using the anti-coagulant ACD rather than CPD, we don't
22 need to look at this but there is a document authored
23 by Dr Jim Smith, CBLA0012012, which says, in his view,
24 that the loss of yield is 15 per cent. So Dr Bidwell
25 there putting a rather different slant on this issue

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1 recalls the events from his perspective prior to this
2 letter being written.
3 She goes on to say this:
4 "The Plasma Fractionation Laboratory, Oxford,
5 had begun to take plasma in single donations from the
6 Oxford RTC in an effort to boost plasma intake from
7 Oxford, in spite of the fact that the only method
8 known to us of opening the present packs (developed at
9 the New York Blood Center) had serious drawbacks, not
10 least the exposure of staff to most unpleasant working
11 conditions (handling packs immediately after immersion
12 in liquid nitrogen). This method is difficult enough
13 on the relatively small scale of our operation at
14 Oxford and would be quite impractical on the scale of
15 operation at BPL, Elstree."
16 Now, sir, my understanding of this is what she's
17 referring to there as the 1 litre packs but it's not
18 entirely clear:
19 "Pending the ability of Oxford RTC to supply
20 plasma up to the limit of the capacity of the Plasma
21 Fractionation Laboratory, I had the support of my
22 staff in volunteering to accept sufficient single
23 donations from Wessex to absorb our 'spare' capacity.
24 This offer was made in the light of the long
25 association between Oxford and Lord Mayor Treloar

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1 than that reflected by Dr Smith in his letter we
2 looked at.
3 **SIR BRIAN LANGSTAFF:** Can I just draw a breath there for
4 a moment. I'm a little puzzled by the dates, because
5 you began this plasma for fractionation by taking me
6 to CBLA0001198 -- can we just have that back up
7 again -- and the date of that is 6 November 1980.
8 **MS SCOTT:** Yes, yes.
9 **SIR BRIAN LANGSTAFF:** So if we -- all the documents you've
10 shown me since came before that.
11 **MS SCOTT:** They do. So this document --
12 **SIR BRIAN LANGSTAFF:** So this is the last word, is it, for
13 the moment?
14 **MS SCOTT:** Well, this is the last word and the reason
15 I took you to it first is because it sets out two
16 earlier meetings. It's the only record that I've
17 found of those two earlier meetings. So --
18 **SIR BRIAN LANGSTAFF:** I see.
19 **MS SCOTT:** -- it sets out the meeting -- sets out earlier
20 discussions, and then a meeting on 25 June 1979.
21 **SIR BRIAN LANGSTAFF:** If we just scroll down we can see
22 that, perhaps.
23 **MS SCOTT:** We can see that halfway down, after (4), so:
24 "After these preliminary talks and exchange of
25 letters a meeting was held at Southampton ..."

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1 And that's 25 June 1979.
 2 **SIR BRIAN LANGSTAFF:** I see.
 3 **MS SCOTT:** Then if we go over the page to page 2, we can
 4 then see, the second paragraph down there:
 5 "A meeting was arranged and held at Oxford on
 6 the 14th March, 1980 ..."
 7 And then -- so that was the reason, sir, that I
 8 took you to that, to the --
 9 **SIR BRIAN LANGSTAFF:** Right, so the dates in date order
 10 was 14 March 1980 is really where this particular
 11 exchange kicked off?
 12 **MS SCOTT:** Exactly.
 13 **SIR BRIAN LANGSTAFF:** Because that was interpreted, as it
 14 appears to be stated here, as saying: You can give us
 15 all you like but we can't cope with it.
 16 With -- and some issue between the 5-litre pools
 17 and the 1-litre, but saying here, clearly, that: It
 18 doesn't matter if it's 5-litre or 1 litre, we can't
 19 cope with it.
 20 **MS SCOTT:** Yes.
 21 **SIR BRIAN LANGSTAFF:** And the correspondence then
 22 followed --
 23 **MS SCOTT:** Indeed.
 24 **SIR BRIAN LANGSTAFF:** -- arguing about aspects of that.
 25 **MS SCOTT:** Indeed.

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1 have, again, another snapshot of what's going on in
 2 Wessex in 1988.
 3 So we've got the date at the top there,
 4 20 October '88. This is an internal memo from
 5 Dr Smith to: Dr Herborn, who we know from Dr Boulton's
 6 evidence was one of the consultant haematologists at
 7 the Centre; Dr Allison, who was the MLSO; and then
 8 Dr J Smith from BPL.
 9 "The Use and Supply of Factor VIII"
 10 And then it says there:
 11 "An estimate of the clinical use of
 12 Factor VIII."
 13 And then if we go down the page there, we can
 14 see a number of different Haemophilia Centres are set
 15 out there and, while it says it's an estimate at the
 16 top there, if one looks at the "NHS Factor 8Y
 17 [international units/per month]" has a star by it, as
 18 does "Commercial Factor VIII iu/month", has two stars
 19 by it, and if we look down the page we can see that
 20 that appears to be, rather than an estimate, a sample
 21 from the actual figures, January to September '88,
 22 calculated as eight months, and sample from first six
 23 months of 1987/88.
 24 It's not entirely clear to me what "sample"
 25 means, because of -- the date of this document is

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1 **SIR BRIAN LANGSTAFF:** I follow. Thank you for that.
 2 **MS SCOTT:** Sir, the matter resolves itself after
 3 1 April 1982, once the pro rata arrangements were
 4 introduced, and Wessex was able to send -- continued
 5 to send single donations to PFL, and received an
 6 assurance from BPL that if they sent plasma in 5-litre
 7 packs, factor concentrates would be returned on
 8 a pro rata basis. And we have -- we don't need to go
 9 to that, but that's set out and confirmed in
 10 correspondence between Dr Smith and Dr Lane, for
 11 example, in a letter dated 13 March 1982. For the
 12 transcript, BPLL0000901_001.
 13 Then shortly after that, arrangements appear to
 14 have changed again, when Wessex stop sending plasma
 15 altogether to PFL, instead sending all their plasma
 16 to BPL.
 17 And sir, we know from other material, and again
 18 we've looked at this -- some of this other material in
 19 other hearings, that the pro rata system was not
 20 applied strictly to Wessex because of the
 21 responsibility that it had for supplying the Lord
 22 Mayor Treloar school. So a special allocation was
 23 made to Wessex to account for this on top of what it
 24 received under the pro rata system.
 25 Sir, if we then turn to NHBT0111301, we can --

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1 October 1988, presumably they had the actual figures.
 2 But it doesn't also seem to correlate with how one
 3 might describe an estimate.
 4 Anyway, I think the point to take from this
 5 page, if we go back up, so we can see all of the
 6 different Haemophilia Centres, that the Lord Mayor
 7 Treloar school is by far the biggest user of
 8 Factor VIII, both in terms of NHS Factor VIII and in
 9 terms of commercial.
 10 Then if we go down to the bottom of that page,
 11 we can see that the:
 12 "BPL estimate we should receive the following
 13 amount of Factor 8Y ..."
 14 And it's split in the months October '88 to
 15 March '99 between the Wessex RTC and Lord Mayor
 16 Treloar's, Wessex RTC getting the bulk of it,
 17 Lord Mayor Treloar's getting some of it.
 18 So clearly quite a lot of Wessex's material
 19 would be going to Lord Mayor Treloar's in 1988.
 20 Then if we turn over the page, we get some
 21 information about the policy:
 22 "The aim would be, in the first instance, to
 23 wipe out the Commercial Factor VIII budget for all
 24 hospitals except Lord Mayor Treloar. If supplies of
 25 Factor 8Y increased further, the LMT budget could then

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1 be reduced."
 2 So we can see that the policy is: Lord Mayor
 3 Treloar's to remain on commercial longer than the
 4 other Haemophilia Centres. That's somewhat different
 5 from other policies we've seen where often children
 6 are given precedence for NHS factor concentrates.
 7 Here we have the opposite.
 8 "If there is no further increase in demand for
 9 Factor VIII, we should be self-sufficient by
 10 December, 1988!"
 11 Then it sets out what the stock is at present.
 12 Moving on, then, to the arrangements for
 13 distribution of concentrates, we know from the
 14 documentation we've seen that prior to December 1976
 15 BPL were sending concentrates directly to the
 16 Haemophilia Centres in the Wessex area. But from
 17 December, this was sent to the Wessex Regional
 18 Transfusion Centre. That was the plan. And we don't
 19 need to look at this but we can see this, for the
 20 transcript, from CBLA0004553, although of course the
 21 document that we've just seen from 1988 makes it clear
 22 that still some product was being sent directly to
 23 Lord Mayor Treloar's in 1988.
 24 If we look at CBLA0001456, we can see a little
 25 bit more about this is.

25

1 have a bit more information in relation to that if we
 2 look at OXUH0003752_005. No, that I don't think is
 3 the right ... No, I didn't mean to take that one up.
 4 Sorry, can we try this one, IPSN0000331_008.
 5 So we can see here this is a meeting in 1978, so
 6 it pre-dates the document we've just looked at by
 7 a few years, but -- and it's the note of a meeting
 8 with Dr Aronstam by a salesperson, a sales
 9 representative from Hyatt, and what it says in the
 10 second paragraph is this:
 11 "All orders for the Wessex area are processed
 12 through the buying office in Winchester" --
 13 **SIR BRIAN LANGSTAFF:** Just pause. I was told, I think,
 14 during the Treloar's presentation, that this was
 15 a Speywood --
 16 **MS SCOTT:** Ah.
 17 **SIR BRIAN LANGSTAFF:** -- rep.
 18 **MS SCOTT:** Can we go to the bottom of the --
 19 **SIR BRIAN LANGSTAFF:** The initials "DW" may, I think,
 20 appear at the bottom, which would tend to confirm
 21 that. Can we have a look?
 22 **MS SCOTT:** Yes, the initials are "DRW".
 23 **SIR BRIAN LANGSTAFF:** Yes, that's the chief exec of
 24 Speywood.
 25 **MS SCOTT:** I beg your pardon, sir. Yes. So ... yes,

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1 So this is a document from the advisory
 2 committee on the NBTS, "Issue of Factor VIII via
 3 RTCs", and we can see at the top right-hand corner "AC
 4 [advisory committee] (81)", that's 1981, as we
 5 understand it, and then it's said to be:
 6 "A summary of information received from Regional
 7 Transfusion Directors Centres ..."
 8 Sir, we've looked at this in previous hearings.
 9 If we turn over to page 2, we can see the title
 10 there, "Issue of Factor VIII via RTCs - Summary
 11 information received from Regional Transfusion Centre
 12 Directors", and the regions set down on the left-hand
 13 column. "Transfusion Centre holds Factor VIII" is the
 14 first column, then "Other products", then "Whose
 15 budget", then "Comments".
 16 If we go over to page 3 we can see what's said
 17 about Wessex. So under the column "Transfusion Centre
 18 holds Factor VIII", yes. "Other products", no.
 19 "Whose budget", RHA (Separate from RTCs).
 20 And "Comments":
 21 "Encounter difficulties in coping with
 22 Haemophilia Centres Directors' individual preferences
 23 for particular brands of Factor VIII and getting
 24 Haemophilia Centres to operate within their budgets."
 25 And the -- what precisely that means, we may

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1 "DRW", and CC'd to Mr D Heath. Yes.
 2 **SIR BRIAN LANGSTAFF:** Yes.
 3 **MS SCOTT:** I think the -- thank you.
 4 So if we look at the second paragraph there, we
 5 can see, second paragraph from the top:
 6 "All orders for the Wessex area are processed
 7 through the buying office in Winchester, but Aronstam
 8 makes the decisions, as he is by far the biggest user.
 9 His first requirement is convenience of
 10 administration, since they often have 15 infusions to
 11 give at a time. The six months study of all
 12 commercial concentrates last year showed Hemofil and
 13 Factorate to be better than Koate in this respect. In
 14 his opinion, solubility is slower with our product.
 15 It's worth going back, if we can provide evidence to
 16 the contrary."
 17 So it may be that the reference in the table
 18 that we just looked at to having difficulties with
 19 Haemophilia Centre Directors -- let me just -- sorry,
 20 sir, let me just get the precise wording for that.
 21 We've lost the --
 22 **SIR BRIAN LANGSTAFF:** It's CBLA0001456, page 3.
 23 **MS SCOTT:** Thank you, sir -- the precise wording of that
 24 document, thank you.
 25 **SIR BRIAN LANGSTAFF:** So CBLA0001456, page 3.

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1 **MS SCOTT:** Yes, so encountering -- what's said in that --
 2 in page 3 of that document is that the Wessex Regional
 3 Transfusion Centre appeared to be encountering:
 4 "... difficulties in coping with Haemophilia
 5 Centres Directors' individual preferences for
 6 particular brands of Factor VIII and getting
 7 Haemophilia Centres to operate within their budgets."
 8 It may be that that's a reference to
 9 Dr Aronstam, and we will see -- we can see from
 10 a document I'm just about to take you to that
 11 Dr Aronstam does indeed express difficulties -- that
 12 he is having difficulties in operating within his
 13 budget.
 14 So we can see, if we look at OXUH0003752_005 --
 15 this is the document I went to earlier -- it's
 16 a meeting from 19 June 1978, Haemophilia Centre
 17 Directors, Regional Transfusion Directors in the
 18 supraregion in Oxford, and we can see just second from
 19 the bottom is Dr Smith attending.
 20 But if we go, please, to page 4 of this, there's
 21 a section which deals with supply of therapeutic
 22 materials, and we can see here, second paragraph down
 23 there:
 24 "Dr Aronstam said that he was encountering
 25 problems because of the change of policy over ordering

29

1 50 severely affected haemophilic boys residing there.
 2 "During 1973 this Centre used [900] units of
 3 Factor VIII ... approximately [650] units ... as
 4 Cryoprecipitate, 50,000 units as Fresh Frozen Plasma
 5 and ... 200,000 units as Human and Animal
 6 Concentrate."
 7 **SIR BRIAN LANGSTAFF:** I think just for the sake of the
 8 transcript, the "900" is 900,000, isn't it?
 9 **MS SCOTT:** Sorry, yes.
 10 **SIR BRIAN LANGSTAFF:** The "650" is 650,000.
 11 The reason I mention it is because it's
 12 comparing the 50,000 and 200,000 I think that you're
 13 going to take us to.
 14 **MS SCOTT:** Yes.
 15 "Our official supply from the Wessex Regional
 16 Transfusion Centre at Southampton is the equivalent of
 17 10,000 bags of Cryoprecipitate or 182 bags per week
 18 throughout the year. I have been repeatedly told by
 19 Dr Smith that this is the absolute maximum production
 20 he is able to make available for me."
 21 And then Dr Aronstam goes on to explain what
 22 he needs to do in order to find the excess material
 23 that he needs. He says in the next paragraph down:
 24 "I have had to obtain these extra materials from
 25 a variety of sources often at very short notice and at

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1 commercial F VIII. Initially he had ordered the
 2 commercial F VIII on prescription directly from the
 3 Commercial firms, but now he had to get it via his
 4 Regional Blood Transfusion Centre and budget ahead for
 5 how much he would need. He did not think that he
 6 would be able to manage within his budget."
 7 And Dr Smith is then recorded as saying:
 8 "... he did not think that there was any problem
 9 in the Wessex Region apart from the one at Alton ..."
 10 Next page:
 11 "... which was a special case because of the
 12 large number of haemophilic boys at the College. He
 13 was awaiting the DHSS's reply to a request for
 14 official recognition of the special situation at
 15 Alton."
 16 And just sticking, then, with the supply to
 17 Treloar's, but going back to 1974 and seeing how the
 18 situation changed, if we could go, please, to
 19 OXUH0000652, we can see a letter 30 April 1974 to the
 20 Department of Health and Social Security. We don't
 21 need to look at it but we will see that -- when we go
 22 to page 2, that it's from Dr Aronstam, and it says
 23 this on page 1, it sets out on page 1 the background
 24 to Lord Mayor Treloar's, and notes that -- if you go
 25 to page 1 -- notes in that first paragraph there are

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1 great difficulty to both myself and the sources.
 2 I have had to beg for materials from other transfusion
 3 centres ..."
 4 And at the bottom of the paragraph:
 5 "I have had to, when all else has failed, buy
 6 off the commercial market and have spent about £1,000
 7 in the past year.
 8 "This situation is quite impossible. We are
 9 never able to plan ahead and there is always the
 10 danger that our sources, entirely unofficial, will dry
 11 up leaving our large pool of haemophiliac boys without
 12 any reserve therapeutic materials for emergencies."
 13 Then over the page he says that he has:
 14 "... calculated that, on the commercial market,
 15 our shortfall of Factor VIII would cost £26,000
 16 annually."
 17 And that it's "imperative that our supplies are
 18 guaranteed" because they're "looking after boys from
 19 all over the country" and it should be regarded as
 20 a "national service".
 21 So that was what Dr Aronstam was telling the
 22 DHSS in 1974.
 23 If we then go on to 1978, to CBLA0000745, you
 24 can see a letter written from Dr Aronstam to
 25 Dr Stafford, a consultant haematologist at Plymouth

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General Hospital, 14 March 1978, and he says this in the second paragraph:

"Your comments about the therapy which [X] enjoyed whilst he was with us provided much food for thought. You may be interested to hear that we now use prophylaxis routinely in many clinical situations, and we feel it can be of positive benefit when some of our boys are going through difficult patches.

"We are obviously more fortunate than you in that the Wessex Region is supplying us with all the material we need for our admittedly enthusiastic program. The climate with regard to prophylaxis appears to be changing and I do hope the wind of change blows your way fairly soon."

So we can see within that four-year period Dr Aronstam's view that the supply problems he's experienced in 1974 appear to be -- have sorted themselves even for what he describes as his admittedly enthusiastic programme of prophylaxis.

Sir, moving on, then, to the material that we have in relation to donor selection, with respect to hepatitis, we can see from NHBT0108678, that there is communication and correspondence between the Wessex Centre and the Department of Public Health at the city of Portsmouth. So this is a letter 25 May 1971 from

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the County Medical Officer of Hampshire, and we don't need to go to those but, for the transcript, one such example is NHBT0108548.

Now we know from material that the Inquiry has seen and indeed looked at in previous hearings that the recommendation -- a recommendation was made by the -- in the second report of the advisory group on testing for the presence of hepatitis B surface antigen and its antibody with respect to the -- whether or not those with a history of hepatitis needed to be -- could in fact give -- remain on the donor panel as long as they had not suffered a bout of jaundice within the previous 12 months.

We know from -- and again we don't need to go to this but we know from NHBT0109112 that Dr Smith was notified about this recommendation by Dr Maycock on 13 June 1975.

Now, it seems that Dr Smith -- we have a memo from January 1977 from Dr Smith, which relates to this, and that's NHBT0108668. Can we go to page 5, please, of this document.

We have here Wessex RTC, "Donors with a History of Jaundice", and if we go to page 7, the end of that memo, we can see it's from Dr Smith, it's distributed to all team leaders, team clerks,

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a Dr Roads, and he says this -- sorry, from Dr Smith to Dr Roads, and Dr Smith says this:

"I am pleased that you will be able to help us about cases who may be blood donors. Towards the end of this year we hope to start testing all our donors for the presence of Hepatitis Associated Antigen, and we may well be able to discontinue the request" --

Sorry:

"I am pleased that you will be able to help us about cases who may be blood donors. Towards the end of this year we hope to start testing all our donors for the presence of Hepatitis Associated Antigen, and we may well be able to discontinue the request that we have made to you."

And what I understand from the documents that this refers to, is the request made by Wessex for those that are investigating cases of notified infectious hepatitis to make enquiries as to whether or not they are blood donors, or indeed any of those that have been in close contact with them are blood donors, and then passing that information on to Wessex Regional Transfusion Centre.

We have examples of notifications being made by the County Medical Officer of Hampshire, so not just the city of Portsmouth Department of Public Health but

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drivers/haemoglobinists and to medical staff, and it's dated 21 January 1977.

If we go then back, please, to page 5, he sets out the background that "We have ... been asked to change our procedure at blood collection sessions", and refers to the circular that appends the second report of the Advisory Group:

"... not to exclude from panels donors with a history of jaundice, provided the donor has not suffered from hepatitis or jaundice during the previous 12 months."

Then he sets out the background. He says this:

"Since 1963, as a precautionary measure, we have not taken donations from persons giving a history of jaundice or hepatitis (other than a history of neonatal jaundice or a history of obstructive jaundice) or who have been in close contact with a case of hepatitis in the past 6 months."

Then:

"Due to the discovery of a sensitive test for Australia antigen and a better understanding of the [illness] we have been asked to change our rules. Both types of hepatitis can be transmitted by transfusion, although Type A is usually spread by the faecal-oral route and Type B by injection of blood."

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1 Then if we go over the page, halfway down that
2 page, he talks about "Type 'B' Serum Hepatitis", and
3 the incubation period. But if we pick it up at the
4 end of that paragraph, we can see:

5 "We find that in Wessex about 1 in 2,000 donors
6 have a positive test (Australia Antigen) with no
7 history of jaundice.

8 "Only about 2% of persons will give a history of
9 jaundice, and I would like to suggest that in the
10 first instance, after you have considered this matter
11 and if you are agreeable, that we should:

12 "1. Test for Australia antigen each prospective
13 donor who gives a history of jaundice or hepatitis
14 longer than twelve months ago. A 5 ml clotted sample
15 will be required and a 2.5 ml EDTA sample will be
16 taken at the same time to estimate the haemoglobin
17 level", and then a finger-prick test.

18 Then if we go over the page:

19 "If the Australia antigen test is negative and
20 the haemoglobin is satisfactory, the donor could then
21 be called to a later session."

22 So those with a history of jaundice, more than
23 12 months ago, will have the sample taken from them
24 and then if negative called back; those with a history
25 of jaundice within 12 months will be deferred.

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1 Dr Barnes in relation to fresh blood labels, and it's
2 dated 13 December 1971, and it says this:

3 "Until the testing of blood donations for HAA
4 becomes more accurate and specific I do not think that
5 we should alter the fresh blood group labels in any
6 way. The test at the moment is only 40 per cent
7 effective and I would not like the clinicians to
8 believe that a patient could not contract transfusion
9 hepatitis after being given HAA negative blood using
10 our present test."

11 So it seems that an enquiry may have been made
12 as to whether or not something should be put on the
13 fresh blood to suggest that it had been tested for
14 HAA, and Dr Smith is saying, no, because the tests are
15 not terribly effective.

16 Sir, perhaps a couple more documents before
17 perhaps we take a short break.

18 Moving on to the question of HIV, just looking
19 at the information that we have about Wessex's
20 experience of the first six months of the first AIDS
21 leaflet, could we look, please, at CBLA0001820, and
22 this again is a table we've looked at on number of
23 occasions. We can see Southampton at the bottom
24 column there. It says:

25 "Distribution method

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1 Then we can see that the procedure changes again
2 in 1982, NHBT0144439, where in another internal memo
3 it said this "Donors with a Medical History of
4 Jaundice":

5 "The procedure dealing with potential donors
6 with a medical history of jaundice or hepatitis has
7 been reviewed and alterations have been agreed.

8 "With effect from 1st January, 1982, the
9 practice of taking 'samples only' from these donors
10 will cease, instead they will be regarded as ordinary
11 donors and will be dealt with in exactly the same way
12 as new donors, both at donor sessions and in the
13 laboratories."

14 Then at paragraph 2:

15 "Donor selection will remain as it is, ie reject
16 if a history of jaundice of hepatitis within the
17 previous twelve months, or a history of close contact
18 within the previous six months", otherwise treat as --
19 in exactly the same way as ordinarily donors.

20 Now, we know from a letter that Dr Smith wrote
21 to the Lister Institute on 4 October 1971, which we
22 don't need to go to but is NHBT0107890, that they
23 started testing donations at Wessex for hepatitis B on
24 the 4 October 1971. I think it is worth looking at
25 NHBT0108997, which is a memo from Dr Smith to

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1 "Distributed with call up cards [August '83 to
2 February '84]

3 "now available at sessions

4 "[Number] used, 71,700 Stock 3,300."

5 Then under "Donor response Effect on
6 Attendance":

7 "NIL."

8 On "Other Comments" it says:

9 "3 homosexual donors as for" --

10 It says "as for advice", I suspect it means
11 "asked for advice".

12 **SIR BRIAN LANGSTAFF:** It looks as though the right-hand
13 margin is missing further up the page --

14 **MS SCOTT:** Yes.

15 **SIR BRIAN LANGSTAFF:** -- so I think you're probably right.

16 **MS SCOTT:** Yes. We get a little bit more information
17 about this from a letter sent to Dr Smithies from
18 Dr Smith which is at DHSC0101658_014, and this is
19 a letter dated 24 January 1985, and he says:

20 "We display a poster at our blood collection
21 sessions together with a notice at the Team Clerk's
22 desk and in addition we have altered the NBTS form 110
23 to draw attention to AIDS.

24 "I think a national poster would be very useful
25 and when the new AIDS leaflet arrives we intend to

40

1 send this to all our donors with their call-up
2 [card]."
3 Then lastly, sir, before taking a break, is
4 a letter from Dr Smith again to Dr Smithies about HIV
5 testing. DHSC0002285_013, and this is a letter dated
6 29 October 1985:

7 "Thank you for your letter about HTLVIII
8 antibody testing of blood donations and blood
9 components.

10 "Our stocks in the Centre and in the hospital
11 blood banks were all negative for the above antibody
12 on the 14th October 1985. This includes fresh frozen
13 plasma and cryoprecipitate."

14 So he seems to be suggesting that they had
15 tested all of those products by 14 October 1985, and
16 then he goes on to say something about heat treated
17 factor products:

18 "As you know we are only using heat treated
19 Factor VIII for the treatment of haemophilia and
20 I have mentioned to our local haematologists the
21 problems that might be present with intravenous ...
22 immunoglobulin."

23 Sir, that is the material that I want to draw
24 your attention to in relation to the Wessex Centre.

25 After the break, I'm going to turn to the HIV

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1 list of this report includes Dr Lane and Dr Smith. It
2 says:
3 "Donor [was] admitted to Bournemouth Hospital
4 with skin rash consistent with Kaposi's sarcoma,
5 leukopenia and anaemia. Biopsy results awaited.
6 Donor admits to homosexual activity but was VDRL
7 negative when he donated blood several days ago (this
8 donation was separated at Wessex RTC but plasma was
9 not dispatched to BPL)."

10 Then it sets out the plasma donation number and
11 when it was collected, 27 March 1984, dispatched to
12 BPL on 6 April and the pack was used in the
13 manufacture of batch HL3186. Then it notes that:

14 "No factor IX was recovered from the
15 cryosupernatant.

16 "No fraction II was recovered from the A + I
17 precipitate.

18 "Fraction V was recovered and is presently held
19 as L938 and L939."

20 Factor VIII batch HL3186 has been distributed:
21 on 10 August, 485 vials were sent to Wessex; and on
22 15 August, 400 vials were sent to Cardiff. There's
23 some handwriting there, sir, which relates to the
24 recovery of those vials, but we will look at -- that
25 same information appears on documents we will look at

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1 contamination incident and I know the Inquiry has
2 heard some information and evidence in relation to
3 that in previous hearings but I will go through the
4 material that we have from the Wessex perspective in
5 relation to that.

6 **SIR BRIAN LANGSTAFF:** Yes. Well, we'll take a break,
7 then, and what do you suggest, quarter of an hour?

8 **MS SCOTT:** Yes, sir, that will be --

9 **SIR BRIAN LANGSTAFF:** So quarter of an hour, and I hope
10 that gives those who are listening remotely time for
11 a proper break.

12 So we'll come back, shall we, at 11.20.

13 (11.03 am)

14 (A short break)

15 (11.19 am)

16 **SIR BRIAN LANGSTAFF:** Yes?

17 **MS SCOTT:** Sir, I'm going to turn, first, to

18 CBLA0000010_183. This, when it comes up on the
19 screen, is a report dated 2 October -- we can see that
20 at the bottom of the page, 2 October 1984, "BPL
21 Internal Report", and if we go back up to the top of
22 the page, we can see it is prepared by Dr T Snape,
23 it's in relation to batch HL3186, it's a report from
24 Dr D Smith of Wessex by telephone on 2 October,
25 received by Dr Snape, and we can see the distribution

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1 in a little while.

2 Then it goes on to set out what the actions
3 were:

4 "Dr Smith (Wessex) was informed of the
5 implication HL3186 [by telephone on 2 October] and was
6 asked to recall all vials including any held by
7 patients for home therapy.

8 "Dr Napier (Cardiff) was unavailable but
9 Mr Booth [the senior MLSO from Cardiff] was informed
10 [on the following day, 3 October, but again by
11 Dr Snape] and was asked to recall all vials of HL3186,
12 including home therapy issues.

13 "Both telephone conversations were [copied] in
14 writing ..."

15 Then the fraction V concentrate was secured and
16 labelled "HELD".

17 Then if we turn over the page, number 4,
18 paragraph 4:

19 "Dr Smith ... was asked to report any plasma
20 from this donor despatched to BPL (or PFL) within the
21 last 5 years ([and it notes that] blood given by this
22 donor on [7 September '83] and [21 November '82] was
23 not used to supply plasma to BPL). Dr Smith was also
24 asked to determine whether the donor had a history of
25 attendance at local special clinics for venereal

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disease.

"Dr Tedder ... was consulted but indicated that he did not wish at the moment to receive samples of plasma fractions since he did not feel test methods presently in use were appropriate. He did however ask to receive a sample from the most recent donation ... and this was arranged ...

"Dr Craske (... Manchester) was consulted and asked to be supplied with a list of haemophilia centres supplied with HL3186 in order to initiate follow-up studies on patients treated with the batch. [Dr Snape] to comply once data is received from Wessex and Cardiff, and given the confirmation of donor's condition."

The Medicines Division was informed of the situation by Dr Fowler, and Dr Snape would supply a copy of the summary report for the director.

Then a late telephone note from Dr Barnes in Wessex and, sir, you'll recall Dr Barnes is the deputy director from Wessex: the donation taken on 21 November '82 was taken at Leeds and time-expired plasma from this donation was sent to BPL on 11 January '83, and "Information on this is to be appended by SH".

Sir, that was the situation on 2 October 1982.

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patients, may I ask for your discretion here and, for the time being at least, to keep this new [I think it should say 'news'] to yourself. When any definite information does become available, either Dr Smith or myself will let you know."

Also on 4 October, could we look at CBLA0000010_209, which is a letter again from Dr Barnes, this time to Dr Snape at BPL, and he sets out the background to the events, and he sets out what's known about the previous donations.

If we could go down the page, please. We can see one from 21 November 1982 taken in Leeds, time-expired plasma pooled and sent to BPL; one from 7 September '83 in Bournemouth, sent to a Portsmouth hospital and not returned, and we'll see what happens to that in due course; 27 March 1984 in Bournemouth, fresh frozen plasma sent to BPL, 6 April 1983, plasma reduced blood sent to one of our Portsmouth hospitals and not returned; and 25 September 1984, Bournemouth plasma separated and frozen, red cells destroyed and then aliquot has been sent to Dr Richard Tedder.

Then it says, in relation to donations 2 and 3:

"We are not getting in touch with the clinicians involved until the diagnosis is confirmed."

Then, if we go over the page, we can see:

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We can see, then, if we move then to DHSC0002247_090, we see a letter dated 4 October 1984 marked "Confidential" from the Wessex Regional Transfusion Centre, we'll see at the bottom from Dr Barnes, the deputy medical director. So we understand that Dr Smith was, in fact, on holiday at this stage. It's sent to the consultant haematologists in charge of the Haemophilia Centres, and then the Haemophilia Centres in the Wessex area are set out there.

It's headed "BPL Factor VIII Batch no HL3186" and refers to Mr Allison's telephone calls to their Blood Bank Chief "yesterday", so that would have been 3 October:

"... asking for the above quoted batch of Factor VIII to be re-called and returned to us."

Then it says:

"The reason for this is that one of the donors whose plasma was incorporated into this pool is now thought to be suffering from AIDS. Investigations are being carried out and the diagnosis should be settled, one way or the other, within the next week or two. In the meantime, may I confirm", the request to re-call all the batches to the Centre.

Then he says this:

"In order to prevent undue worry to your

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"There is also a possibility of a donation before November 1982 in this region, which we are attempting to trace. I will, of course, contact you again when [definitive] information is available."

We'll look at this letter later but I'll give the reference for the transcript now, DHSC0001690, it's a letter from 5 November 1984, which makes it clear that they haven't found any previous donations before 1982.

Now, information about the donor's diagnosis came on 16 October 1984, so some days later, and we see this at DHSC0000247_093.

Sorry, DHSC0002247_093. We can see that this is again a letter from Dr Barnes, 16 October, to all directors of Haemophilia Centres in Wessex, and he says, with reference to the earlier letter we looked at, 4 October and his telephone call of yesterday "my apologies to those I could not contact personally":

"I am extremely sorry to have to tell you that the diagnosis of AIDS has now been confirmed. I understand that Dr Snape ... will be writing to all of us within the next day or two, and that further contact will be made by Dr Craske on the follow-up of your patients. In the meantime, I have been asked to

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1 suggest that a policy of discrete surveillance be
 2 pursued."
 3 We can see there the list of the Haemophilia
 4 Centre Directors to whom this was sent.
 5 Sir, it is not entirely clear what Dr Barnes was
 6 suggesting there by a "policy of discrete
 7 surveillance".
 8 On the same day, a letter was written to the
 9 Surgeon Commander of the Royal Naval Hospital in
 10 Haslar. If we can look at that, please, it's
 11 DHSC0002247_094. This relates to one of the donations
 12 we saw in the earlier letter where it was said that
 13 the clinicians were not being informed about this
 14 incident until more information was known. So this is
 15 taking up -- this is the letter informing the Surgeon
 16 Commander about the donation:
 17 "To confirm my telephone call of yesterday,
 18 I regret to inform you that a blood donation taken
 19 from a donor now known to be suffering from AIDS was
 20 sent to RN Hospital, Haslar, earlier this year, was
 21 not returned to us, and presumably has been transfused
 22 into a patient."
 23 Then details are set out. Then he was informed
 24 that Dr Tedder is aware of the situation, and pleased
 25 to carry out virological studies of the patient and

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1 **MS SCOTT:** Out of the 485 vials sent, they've had, by
 2 8 October, 99 returned.
 3 We move then onto 23 October, DHSC0001111. This
 4 is a memo, a report, if we go over to the second page,
 5 please, a summary -- another report from Dr Snape and
 6 we can see from the bottom that this is dated
 7 23 October 1984, and he sets out the history, and so
 8 on.
 9 Can we turn, please, to page 4 of this report.
 10 We can see there the "Results of factor VIII recall",
 11 so this is 23 October 1984.
 12 "The 400 vials of batch HL3186 despatched to
 13 Cardiff break down ..."
 14 Recovered: 101 out of 150 vials for Heath Park,
 15 Cardiff; 51 out of 60 for Morriston; and Carmarthen,
 16 36 out of 40; and, altogether, they know that nine
 17 patients have been treated with the product in
 18 Cardiff. So a total of 338 vials were recovered with
 19 nine patients receiving the batch, and that's the
 20 situation in Cardiff.
 21 In Wessex, there's no information given about
 22 how many patients have been treated, but they know
 23 that, out of the 485 vials, 187 have been recovered by
 24 that time: so 105 out of 200 from Lord Mayor Treloar;
 25 by now they know that Salisbury and Winchester had

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1 that Dr Craske is carrying out follow-up of patients
 2 who have received plasma or Factor VIII from the
 3 donation and is very willing to offer advice.
 4 So that, sir, is the information we have in
 5 relation to what the dissemination of information
 6 about the incident to clinicians, in the immediate
 7 aftermath.
 8 Turning then, to the action that was taken in
 9 relation to re-call of the product, can we turn,
 10 please, to CBLA0000010_211. This is a letter of
 11 8 October 1984, again from Dr Barnes to Dr Snape, and
 12 he says that he confirms an earlier telephone call and
 13 the number of vials of Factor VIII batch HL3186 sent
 14 to the Haemophilia Centre in Wessex, and sets out
 15 there the Haemophilia Centre that had received batches
 16 and the number that had been returned.
 17 So you'll see, for example, that 70 were sent to
 18 Salisbury, they've had none returned; 22 to -- Lord
 19 Mayor Treloar College, 200 sent to them, 33 returned,
 20 and so on. So out of the 485 --
 21 **SIR BRIAN LANGSTAFF:** Sorry, 22 to Lord Mayor Treloar
 22 College?
 23 **MS SCOTT:** Sorry, 200 were sent to Lord Mayor Treloar with
 24 33 returned.
 25 **SIR BRIAN LANGSTAFF:** Thank you.

50

1 used all the vials that they had been sent; but
 2 Bournemouth had returned, for example, 60 out of the
 3 60 that they had been sent.
 4 If we can then turn, please, over the page to
 5 page 5 of this report, it's worth noting what Dr Snape
 6 is saying on 23 October about the observations on the
 7 incident. He makes two observations. At 5.2, he says
 8 his:
 9 "In this particular instance, the last (and most
 10 damaging) donation was received at BPL on
 11 6th April 1984, pooled for fractionation on
 12 17th May 1984 and issued for clinical use on
 13 10th August 1984. This timetable is consistent with
 14 the five week period of quarantine presently
 15 supportable for fresh frozen plasma and the
 16 irreducible six to eight week delay from pooling
 17 plasma to release of Factor VIII concentrate for
 18 clinical use.
 19 "Enforcement of a three month quarantine period
 20 would not in this instance have avoided the loss of
 21 resource resulting from the plasma pool being
 22 compromised by a single donation; it would almost
 23 certainly have avoided patient exposure to the product
 24 however.
 25 "Enforcement of a six month quarantine period

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would have prevented release of the batch for clinical use; it would also have allowed the donation to be included before pooling, thus avoiding a very expensive reject situation.

"This incident must be an extremely cogent argument for the establishment of cold-storage facilities capable of supporting a six-month quarantine of fresh frozen plasma."

He also makes this observation in relation to the follow-up:

"The appearance of this donor at three different Centres within two years clearly underlines a fundamental problem when carrying out follow-up of donor incidents of this sort. Surely central co-ordination of donor records is unavoidable."

Now, a copy of this report was sent to the DHSS on 24 October '84, we don't need to go to that but, for the transcript, that's PRSE0001658. Can we, though, turn to CBLA0000010_188, which is a document that deals with the follow-up undertaken by Dr Craske of those who were treated with the infected donations.

So we have here the front cover, and we can see it's in relation to batch HL3186, and it's Dr Craske's letter to Haemophilia Centre Directors, dated 20 November 1984. We can see the list of Haemophilia

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"1) Only a proportion of the patients transfused with an infected batch are likely to contract HTLV-3 ...

"2) Some patients who have received commercial factor VIII since [1 January 1980] will already have contracted HTLV-3 infection from other infected batches.

"3) The proportion of patients who are infected with HTLV-3 who will eventually contract AIDS is unknown ...

"4) The long term program notice for patients with HTLV-3 verification is unknown ...

"5) There is evidence that HTLV-3 infection can be transmitted by sexual contact. Therefore some sexual partners of recipients of factor VIII contaminated with HTLV-3 may [now] be at risk.

"6) We cannot yet distinguish those patients who are likely to transmit infection, or who are likely to contract AIDS by means of laboratory tests."

Then he says this, under "Methods of Investigation":

"With the above facts in mind, I propose the following strategy. [First of all]

"(a) Identify all patients who have received factor VIII batch HL3186 ...

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Centre Directors that it's sent to, so those in Wales, and so we've got Swansea there, Carmarthen, Cardiff, as well as those in the Wessex area. It's CC'd to a number of different individuals, including Dr Rizza, Dr Lane, Dr Snape, Dr Smith and the Wessex Regional Health Authority.

If we turn then to the page 2, we can see the letter itself, and it says in the second paragraph down:

"I have responsibility for the epidemiological follow-up of recipients of that is batch to confirm whether any hazard exists, and to assist in the investigation of patients where required. I hope that we can obtain the maximum information from this unfortunate incident, and devise methods for the prevention of the disease. We also need to confirm the association of HTLV-3 infection and transfusion of factor VIII concentrate."

Then, under "Risk to the patient", he says this:

"From the foregoing discussion you will see that it is difficult to be certain of the precise risk of any recipient contracting AIDS, but the following facts may help you to appreciate the position."

Then he sets out, on the following page, six facts:

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"(b) Follow up of patients.

"Patients identified should be followed up at least at four monthly intervals for six years."

Then he sets out details of how that should be achieved.

If we go over the page, please, he also provides them with simplified records forms for the follow-up to be provided to him. It says halfway down that page:

"Follow up should be carried out even if a patient is found to be positive for HTLV-3 antibody in the first specimen tested", ie prior to receipt of the infected batch.

He then sets out that four monthly review and how that should be completed, and that the form should be sent to him in Manchester. He says this:

"The follow-up may be carried out using an alternative of two different strategies:

"i) If the patient has been informed of the risk associated with this contaminated batch of factor VIII, testing could be carried out on each specimen as it is obtained at each four monthly review. In addition, it would be wise to warn the index patient that his spouse may be at risk from contracting HTLV-3 infection as a result of any sexual

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1 contact. A test for HTLV-3 antibodies can be offered
2 [it says] to Directors at the time of follow-up of the
3 index case. Follow-up can be arranged by the Director
4 or in collaboration with the GP as thought necessary."

5 So that's for those cohorts of patients who have
6 been informed of the risk associated with the
7 contaminated batch and then, on the following page, he
8 sets out an alternative strategy:

9 "An alternative strategy would be not to tell
10 the patient of the risk involved but to observe him at
11 regular clinical review four monthly, to collect serum
12 specimens for HTLV-3 antibody examination and send
13 them to me at Manchester. These would not be examined
14 until two years after the initial exposure, or until
15 the patient develops clinical features suggestive of
16 AIDS, or testing is [required] by the Haemophilia
17 Centre Director."

18 Then it says, the next paragraph:

19 "The ethical problems involved in these two
20 alternative methods of follow-up are discussed in
21 an appendix at the end of this letter."

22 If we turn to page 6, we can see that appendix,
23 "Ethical Problems Associated with HTLV-3 Infection in
24 Haemophiliacs":

25 "1) Informing the patient and his family of the

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1 "Any benefit or peace of mind for the patient
2 will be temporary if any other persons exposed
3 develops AIDS. If the patient finds out that he has
4 had this batch, then the trust of the patient will be
5 lost, and the Haemophilia Centre Director placed in
6 a delicate situation.

7 "It is quite likely that any patient who has
8 received commercial factor VIII since 1980, and thus
9 had already possibly been exposed to HTLV-3 infection
10 will not have a greatly increased chance of
11 contracting AIDS, compared with the patient who has
12 received only NHS concentrate until now."

13 Then he says:

14 "In my view option (1) is the only one tenable
15 on moral and ethical grounds."

16 So then if we turn back to page 5:

17 "Should the patient be told?"

18 "Ideally I think he should, but this will depend
19 on many factors, including the amount of anxiety
20 concerning AIDS there is already present at the
21 Centre, and the degree to which the patient is capable
22 of understanding the situation. Every effort should
23 be made to encourage the patient to discuss the
24 problem with his spouse and help them to face the
25 problem together. The General Practitioner should

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1 risks."

2 He sets out the benefits of this:

3 "[It] allows information of the development of
4 HTLV-3 infection to be available to the caring
5 physician as soon as possible, and thereby to identify
6 and treat all complications as they arise where
7 treatment is available.

8 "It also allows the patient's spouse to be
9 informed of the risk [and to take precautions].

10 "It also maintains a trusting relationship
11 between the physician and his patient which is
12 essential if difficult problems arising from HTLV-3
13 infection are to be surmounted.

14 Then the alternative which is entitled
15 "Restricted follow-up":

16 "In this strategy, the identification of
17 patients who contract HTLV-3 infection will not be
18 made for 2 years or at the request of the Centre
19 Director. It will be impossible to warn spouses and
20 advise preventative measures to limit the transmission
21 of infection, since it will not be known when the
22 index patient first contracts HTLV-3 infection. If
23 a patient develops AIDS related illness it will be too
24 late, as the period of maximum infectivity will
25 already have passed.

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1 also be informed by letter."

2 And then:

3 "Other preventative measures

4 "1) When a patient is told of the risk to
5 exposure to HTLV-3 infection he should also be warned
6 that his sexual partner might also be exposed to
7 infection."

8 Then it goes on to discuss barrier methods of
9 contraception.

10 So that is the letter that was sent in
11 November 1984 to all the Haemophilia Centre Directors.

12 We don't have very much information about how
13 that was received save for a couple of documents I can
14 take you to.

15 Can we turn, please, to -- oh, in fact, before
16 I do that I'll just take you to HHFT0001026_004.

17 So this is a letter dated 20 November 1984, so
18 a few days -- the same day, sorry, as the Craske
19 letter we've just looked at. It's a letter from the
20 Wessex Regional Health Authority, and we can see at
21 the bottom the circulation is to those Haemophilia
22 Centre Directors who have received the Craske letter.
23 It is a letter from the regional medical officer and
24 it says "Dear Doctor".

25 First of all it sets out in that first paragraph

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the background to the contamination incident.

Second paragraph relates to the working party being set up by the DHSS to look at the questions raised for the Blood Transfusion Service and the recognition of AIDS, and it's the third paragraph that's of particular relevance:

"I have discussed the subject of AIDS with two members of the Working Party and feel that in the first instance it would be strongly advisable for the patients who received Batch No. HL 3186 of Factor VIII concentrate, or their parents, to be told, with the emphasis of the benefits of treatment by Factor VIII far outweigh the small risk of the patient developing AIDS. I hope you will agree to do this now and let me know thereafter."

Then he goes on to say:

"The public interest in this matter will almost certainly lead to further Press inquiries in Wessex before long. I would like to be able to say that all patients have been informed and that the situation is being closely monitored."

So turning, then, to the material that we have to understand how this was received and what the Haemophilia Centre Directors actually did in terms of telling patients, can we turn to CBLA0000010196.

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what's happened -- well -- told them about what happens other than that he has asked Dr Craske to test the samples that he sent him, which would suggest that those patients at least should have been told. But it certainly gives the impression that there isn't much urgency in times of the time that seems to be taken both by Dr Green and possibly by Dr Craske in understanding whether or not these patients had in fact been infected with HTLV-III.

In August 1988, Dr Lane wrote to Dr Craske -- we don't need to go to it but for the transcript it's CBLA0000010_200 -- wrote to Dr Lane asking him whether a final report had ever been written by Dr Craske resulting from the follow-up that he had undertaken of those patients who had been -- who had received the infected products.

We can look at Dr Craske's response. That's CBLA0000010_202.

It's a response dated 23 September 1988, and he says this at paragraph 2:

"The follow-up we were doing eighteen months ago of this incident was bedevilled at that time by the reluctance of Haemophilia Centre Directors to cause, what they considered to be, an unnecessary worry to their patients, so that a follow-up of the recipients

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Now this is a letter written from --
CBLA0000010_196.

This is a letter written from Dr Green, from the Portsmouth Haemophilia Centre, to Dr Snape, and it's in response to a letter written from -- by Dr Snape to the Haemophilia Centre Directors prompting them to provide information about follow-up to Dr Craske.

And Dr Green says this:

"I object to the tone of your letter. I intend to follow up the patients affected by the transfusion of HL3186 and I reserve to do this in my own time and in my own way. If you had taken the trouble to enquire from Dr Craske you would know that he is in possession of samples from some of my patients and in due time he will be in receipt of samples from all of them."

Then he complains:

"It has taken [Dr Craske] seven weeks to supply [him] with the results of the tests he does" --

I think it should say "have":

"... and I only got them by 'phoning him. Things I dare say will work out in their own time."

This doesn't help us very much with understanding whether Dr Green has put his patients in the first or second category, ie told them about

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who received this product has not been carried out in the formal sense."

Then he says at the fourth paragraph down:

"Your letter prompts me to re-open this enquiry, as we do need to know the outcome of patients who received this and other batches which may have been contaminated with HIV. I will consult my files and let you have a report as to what is known at the present time."

So Dr Craske's analysis of the response from Haemophilia Centre Directors is that they did not want to cause unnecessary worry to their patients, suggesting perhaps that in fact patients weren't told that they had received contaminated product.

SIR BRIAN LANGSTAFF: Well, it looks as though, on the face of it, they've adopted the first of the -- was it the first or the second of the two options?

MS SCOTT: The second.

SIR BRIAN LANGSTAFF: The second of the two options which Craske had put out in his letter, and they've adopted the course which he regarded as morally and unethically unacceptable.

MS SCOTT: Sir, it may be that they haven't even gone that far, because that second option did include follow-up in a formal sense. It did include taking samples and

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1 sending them to Dr Craske. It looks from this as if
2 they haven't even gone down that route, they simply
3 haven't done any follow-up. It may be -- well, sir,
4 you'll have to decide, but it may be that Dr Craske
5 here is saying he hasn't actually had many samples, at
6 all.

7 **SIR BRIAN LANGSTAFF:** Yes.

8 **MS SCOTT:** Even ones that he can't test for the two years
9 or until some other event happens.

10 Now Dr Craske there suggests that he will do
11 a final report but the Inquiry has not found a final
12 report from Dr Craske.

13 So lastly, then, what does the -- what do we
14 know about what happened to the patients? Can we
15 turn, please, to DHSC0004180_050.

16 Sir, this is a report that's neither dated nor
17 authored, but it does give us some more information
18 about the incident in itself and about what happened
19 to the patients, albeit we don't know where it comes
20 from -- we don't know who wrote it, I should say.

21 So it sets out the background to the donor
22 becoming ill in the first paragraph, and second
23 paragraph sets out what was found and that the
24 diagnosis of AIDS was confirmed. It sets out the
25 donation history and his blood group.

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1 Factor VIII batch:
2 "7,000 plasma donations in the pool. 9 patients
3 transfused in Wales and 29 in Wessex. Other units
4 immediately re-called, total batch compromised 485
5 vials sent to Wessex and 400 sent to Cardiff RTC.
6 A total of 338 vials were recovered from Cardiff and 9
7 patients received the batch. In Wessex a total of 187
8 vials were recovered and 29 patients received the
9 batch."

10 Then they set out below the breakdown of where
11 those 29 patients in Wessex were treated, and we can
12 see that eight of those were in Lord Mayor Treloar and
13 eight of those were in Southampton, with Dorchester,
14 Salisbury, and Portsmouth also -- and Winchester also
15 having patients.

16 Then if we go over the page, we see:

17 "25th September 1984. Wessex BTC. Informed by
18 hospital that donor has AIDS. Donation tested and
19 found HTLV-III Positive by Dr Tedder."

20 And the donation was discarded, and then we see
21 that the donor died on 5 November 1984.

22 So that gives us a little bit more information.

23 We also have a few other bits of correspondence.

24 So we can see from a letter written from the
25 Southampton Haemophilia Centre to Dr Snape,

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1 "21st November 1982. Leeds BTC. Red cells
2 unused, time expired plasma sent to BPL ... Two
3 batches of PPF were made and held."

4 Then:

5 "14th February 1983. Birmingham ... Whole blood
6 donation transfused. Further information from
7 Dr Ala."

8 And we don't, I think, have any further
9 information in relation to that.

10 "26th August - 10th February 1984. Wessex BTC.
11 All regular donors sent AIDS leaflets. An AIDS
12 leaflet was received by the donor early in 1984.

13 "7th September 83. Wessex BTC. Whole blood
14 transfused to Mr (SR) following prostatectomy for
15 benign hyperplasia. Later anti-HTLV-III found in
16 serum. Patient later died ... from neoplasm of
17 rectum."

18 Then over the page:

19 "27th March 1984. Wessex BTC. Plasma reduced
20 red cells transfused 2nd April 1984 to patient ... for
21 bleeding peptic ulcer. Follow up ... anti-HTLV-III
22 detected in his serum early November 1984."

23 And that, we can see, is the Royal Naval
24 Hospital in Haslar.

25 Then it goes on to discuss the HL3186

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1 29 January 1985, CBLA0000010_194.

2 We have a letter saying:

3 "Dear Dr Snape,

4 "Thank you for your letter ... regarding
5 follow up of patients treated with Factor VIII Batch
6 HL3186. All eight patients exposed to this batch at
7 Southampton have been informed of the problem and sera
8 from seven of these patients have been sent to Dr John
9 Craske."

10 And one of those patients has been followed up
11 at Lord Mayor Treloar.

12 So that's a letter from a Dr Bell,
13 29 January 1985.

14 Now, we know from another letter written by
15 Dr Bell to Dr Aronstam -- which we don't need to go
16 to, but it's TREL0000110_040 -- that one of those
17 infected from Southampton was Gary Bennett, who has
18 given evidence to this Inquiry, and so I think it's
19 helpful to remind ourselves of what he told this
20 Inquiry in his written statement about being informed
21 about the contaminated product.

22 We find his written statement at INQY0000325.

23 Sorry, I've given you the wrong account, WITN --
24 WITN0297001. Thank you.

25 That's the story of -- that's the first page of

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1 the witness statement. If we could go, please, to
 2 page 5. It starts at para 18:
 3 "I had to go to class room 2A. There were about
 4 ten or 11 of us in this particular age band. The
 5 nurse and Dr Wassef came in and said have you all got
 6 a pen and paper. He then told me personally, if you
 7 have such and such a batch number, and he read the
 8 numbers out. He said you have permission from the
 9 headmaster and I need you all now to use the public
 10 phone outside our dormitory's office and ask your
 11 parents to check if they have that batch number at
 12 home. Not to use it but to return it to your
 13 hospital. That batch number that was read out was at
 14 home, we had got it from Southampton General.
 15 Dr Wassef then left the room. I remember getting off
 16 the seat walking down to our dorms and we were all
 17 lined up in a row outside our dormitory to see our
 18 dorm master, Mr Eggins. He knew why we were there."
 19 "19. I rang home and learned that I had one of
 20 the batch numbers at home. I spoke to my Dad. They
 21 didn't tell us why we had to check these batch
 22 numbers. It was a long time ago but looking back, the
 23 first part I can actually remember. I left college
 24 and went to my hospital to see Dr Chisholm. She knew
 25 my brother and me as we had been seeing her for

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1 product incident.
 2 **SIR BRIAN LANGSTAFF:** Thank you.
 3 **MS SCOTT:** And that brings to a conclusion the
 4 presentation on the early years of the Wessex Regional
 5 Blood Transfusion Service.
 6 **SIR BRIAN LANGSTAFF:** Thank you. So, we take a break now,
 7 do we until 1.00?
 8 **MS SCOTT:** Yes, 1.00, and Dr Lloyd will give evidence
 9 at 1.00.
 10 **SIR BRIAN LANGSTAFF:** And we start at 1.00 because
 11 Dr Lloyd is joining us from Canada, and they are
 12 five hours behind us.
 13 **MS SCOTT:** Yes.
 14 **SIR BRIAN LANGSTAFF:** Very well.
 15 So 1.00 for Dr Lloyd. We'll take -- those of us
 16 who want a lunch break now will have it now.
 17 **MS SCOTT:** Thank you.
 18 (12.03 pm)
 19 (The Short Adjournment)
 20 (12.59 pm)
 21 **SIR BRIAN LANGSTAFF:** Dr Lloyd, can you see me? Dr Lloyd,
 22 can you hear me?
 23 **THE WITNESS:** Ah, I can now. Good afternoon.
 24 **SIR BRIAN LANGSTAFF:** You can see me?
 25 **THE WITNESS:** I can.

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1 years.
 2 "20. I can remember in 1985 I went and saw her
 3 and she changed her tune as I think she knew there was
 4 a crisis as she wasn't laughing anymore. She knew all
 5 of us but her demeanour had changed to a more serious
 6 one. I think she knew and it was as if she was
 7 thinking you don't realise what has happened.
 8 "21. Tony and I learnt at the same time about
 9 the batch numbers. Looking back they had hammered us
 10 with bad batches."
 11 If we go over the page:
 12 "I remember Mum and Dad sitting me down in the
 13 front room and saying you've been infected with HIV
 14 since 1982. This was around 1986. It came through in
 15 a letter to my Mum and Dad from Southampton General.
 16 They received nothing from Treloar, ever. We were
 17 told via a letter from the hospital despite going
 18 there regularly, they never told us face to face."
 19 Sir, you will have to marry up this account of
 20 being told -- or when Gary Bennett was told about the
 21 infection with the letter we looked at from Dr Bell to
 22 Dr Snape of 29 January '85 in which he said that all
 23 the patients had been told of the problem.
 24 Sir, those were the documents that I want to
 25 draw your attention to in relation to the contaminated

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1 **SIR BRIAN LANGSTAFF:** Good. Well, that's the start we
 2 want, at any rate. It's 8 o'clock with you, is it, in
 3 the morning?
 4 **THE WITNESS:** It is, yes.
 5 **SIR BRIAN LANGSTAFF:** Well, thank you very much for
 6 joining us, either after or during breakfast, and
 7 here, as you will know it's 1 pm, in the afternoon.
 8 Ms Richards will ask you the questions in a moment or
 9 two. You are talking to a very small number of people
 10 here in a large hearing room in Aldwych. For reasons
 11 of Covid, which affect us as they do you, we have no
 12 others of the general public or people who are
 13 interested watching directly but they are watching
 14 online. So you will have an audience of about 100 or
 15 more people who very much want to hear what you have
 16 to say.
 17 In a moment, I'm going to ask Mary to invite you
 18 to take the oath, the affirmation and, after that,
 19 Ms Richards will ask you the questions.
 20 Mary, please.
 21 **DR HUW LAWRENCE LLOYD (affirmed)**
 22 **Questioned by MS RICHARDS**
 23 **MS RICHARDS:** Dr Lloyd, can you see and hear me?
 24 **A.** I can. There is a slight delay in your voice but,
 25 yes, I can hear you clearly, thank you.

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1 Q. I'm going to start by just getting an overview of your
2 medical career. You took up your first house officer
3 post in 1975; is that right?
4 A. That's correct, yes.
5 Q. Then, between 1975 and 1979, you had various house
6 officer and senior house officer posts with no
7 particular emphasis on haematology or transfusion?
8 A. That's correct.
9 Q. Then, in 1980, you had your first placement at the
10 Northern Regional Transfusion Service from 1980 to
11 1981, as a locum registrar; is that right?
12 A. That is correct, yes.
13 Q. What led you to that post?
14 A. I was following what would be considered a traditional
15 medical career, working my way up the ladder, I guess,
16 and at that time working in neurology at Newcastle
17 General Hospital, I felt that a career in what one
18 might call the traditional medical format was not for
19 me. I watched some of my colleagues trying to move
20 through the grades doing research jobs, for which they
21 were neither qualified nor interested, and I decided
22 to look for something different, and it was very much
23 by chance that I came to the Blood Transfusion
24 Service.
25 Q. In the course of the year or so that you were there,

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1 that was mainly to look at virology.
2 Q. You also, during this period, had a further period of
3 time at the Regional Transfusion Centre; is that
4 correct?
5 A. Yes, that's right. It was officially a rotation, so
6 I came back into the transfusion centre.
7 Q. Can you remember of that period '81 to '83, can you
8 remember approximately when you were back in the
9 transfusion centre, which year it was?
10 A. It was likely at the end of that rotation, so probably
11 1983. I think I would have started off the rotation
12 by going to the Freeman hospital, and then coming back
13 to the transfusion centre at the end of the period.
14 Q. You tell us in your statement that your time at the
15 haematology department at the Freeman Road Hospital
16 provided insight into hospital blood banking, use of
17 blood products and clinical issues arising from
18 transfusion. What kind of issues arising from
19 transfusion do you recall encountering during that
20 period of your work?
21 A. Well, the Freeman Road Hospital housed Newcastle's
22 cardiothoracic unit, so there were a lot of patients
23 receiving fairly high volume transfusions and platelet
24 transfusions and support for their coagulation status.
25 So the issues that arose, we would see quite a lot of

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1 at that stage, you spent, I understand, some time in
2 each department of the Centre and you've explained you
3 would review donor information and also you became
4 involved in blood banking and component production and
5 the introduction of automated blood grouping, amongst
6 other tasks?
7 A. Yes, that's right. I can't remember the exact moment
8 when we started work on the automated grouping. It
9 might have been while I was still in the locum
10 position it might have been after I obtained
11 a substantive registrar position. But it was about
12 that time we were trying to move from manual
13 operations to a little bit of automation.
14 Q. Then from 1981 to 1983, you were a registrar in blood
15 transfusion and haematology and, as I understand it,
16 that involved receiving training and experience in
17 haematology, pathology and microbiology at the Freeman
18 Road Hospital; is that right?
19 A. Yes, and some clinical biochemistry. So it was all
20 the pathology departments in a big general hospital.
21 Q. You also, during that period, had a secondment to PHL;
22 is that correct?
23 A. Yes, I went to the Public Health Laboratory Service,
24 which had laboratories actually based in the same
25 building as the Transfusion Service in Newcastle, and

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1 patients with non-specific reactions to transfusion,
2 raised temperature, perhaps rigors, and so on. So
3 there would be some investigation to make sure there
4 wasn't an obvious serological reason for it but
5 I don't recall any other really major issues.

6 I think we had one case of a major transfusion
7 reaction and, I think -- and I really only think --
8 that that was a case of a unit of blood being
9 incorrectly -- being given to the incorrect patient
10 and caused a major reaction.

11 So we saw some serious things. I do not recall
12 anything that was related to non-A, non-B, for
13 instance, but then that's -- I don't think people were
14 looking as hard for it as they might.

15 Q. We'll come back to that at a later stage of your
16 evidence, that issue.

17 A. I'm sure.

18 Q. 1983 to 1987 you were then a senior registrar in
19 transfusion and haematology, spending time in each of
20 the three main teaching hospitals in Newcastle. So
21 would that be Freeman Road, Newcastle General and the
22 Royal Victoria Infirmary?

23 A. That's correct.

24 Q. You had a period at the Haemophilia Centre, the
25 Newcastle Haemophilia Centre, at this time. Can you

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1 remember which year that was?

2 **A.** No, I can't now. It would have been at my -- towards

3 the -- in the latter half of that period, because

4 I think I started at the Freeman Hospital then the

5 Newcastle General, and then the Royal Victoria

6 Infirmary, and it was while I was at the Royal

7 Victoria Infirmary that I would have had a period

8 working in the Haemophilia Centre. So yes, towards

9 the -- in the second half of that period.

10 **Q.** How long, very roughly, were you at the Haemophilia

11 Centre?

12 **A.** Very roughly -- very hard to remember now -- probably

13 four weeks. I doubt whether it would have been

14 longer. There were so many other things to fit into

15 that period of time.

16 **Q.** And you had then also during this period of your work,

17 a further period at the Regional Transfusion Centre?

18 **A.** Sorry, you froze then but I think you were asking if

19 I had a further period at the transfusion centre?

20 **Q.** Yes.

21 **A.** And that's correct, yes.

22 **Q.** And you did the second part of your MRCPATH exam

23 having done the first part earlier in the 1980s.

24 **A.** Yes, yes.

25 **Q.** Then in 1987 you took up a post as a locum consultant

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1 management than would be normal for that position,

2 including sitting as the Centre's representative on

3 union negotiations with staff over changes that we

4 were hoping to make.

5 **Q.** And then November 1988 you became the director of the

6 Northern Regional Transfusion Service. I think your

7 title at that point --

8 **A.** Yes.

9 **Q.** -- was medical director and then later became chief

10 executive?

11 **A.** I think I was medical director and general manager.

12 Excuse me. Sorry, this is a problem I have.

13 I was director and general manager from the

14 beginning. It was some years later that we

15 ...[frozen screen]...

16 **Q.** Sorry, you froze then, Dr Lloyd, and we lost the

17 last --

18 **A.** Sorry.

19 **Q.** No, no, not your fault at all. We lost the last bit

20 of your answer.

21 **A.** Yes, I was medical director and general manager from

22 the beginning, and then it was several years later

23 that we reorganised a bit and I became just the chief

24 executive. We also of course at that time, around

25 that time, were able to appoint a new consultant to

79

1 haematologist at the transfusion centre, and then

2 June 1987 to October 1988 you were a consultant

3 haematologist at the transfusion centre.

4 **A.** Yes, that's right.

5 **Q.** What, in broad terms, did that role as a consultant

6 haematologist entail?

7 **A.** I had obviously -- sorry, I shouldn't say obviously.

8 I had quite a number of -- I spent quite a lot of time

9 with interactions with the individual haematologists,

10 particularly when products were requested. It was not

11 unusual for there to be shortages of platelets,

12 particularly, and so we'd be discussing how -- the

13 condition of the patient, their platelet counts.

14 I also looked at information from donors. At

15 the blood donor sessions there was a book which was

16 used to make notes about any particular donor. If

17 there was something that the clerical staff or the

18 nursing staff felt warranted further investigation,

19 a note would be made and each day that list would be

20 looked at and I took my turn at doing it and sometimes

21 would discuss with others who were doing it what was

22 found, were the donations that they had made suitable

23 for use? And obviously in some cases we felt unable

24 to use them.

25 I also became perhaps more involved in

78

1 become the head of our medical services.

2 **Q.** And when you took up the role as director in

3 November 1988, your predecessor Dr Collins moved to

4 the clinical haematologist role; is that right?

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

6 **Q.** I want to ask you next a little about the Centre, its

7 facilities and its arrangements. I've just mentioned

8 Dr Collins, that was Dr Anne Collins, and prior to

9 her --

10 **A.** Yes.

11 **Q.** -- appointment, it was Dr Sheila Murray. Who was

12 director; is that right?

13 **A.** That's right. I met her on one occasion in 1980 just

14 as the transfer from herself to Dr Anne Collins took

15 place.

16 **Q.** In broad terms, what was the geographical reach of the

17 Northern Regional Transfusion Service?

18 **A.** It had a very wide geographical area to cover, one of

19 the largest in England and Wales, with some large

20 areas of low-density population and a few very highly

21 dense pockets of population. So it covered -- it

22 actually took in a little piece of North Yorkshire,

23 which was not part of the Regional Health Authority's

24 remit, the Northern Regional Health Authority's remit.

25 It then, from there, went up to the Scottish border

80

1 and, across to the west side, it took in most of
2 what's now called Cumbria. We did a little bit across
3 the border and I think we sort of snuck into Gretna,
4 but we did not -- there was a small area of south
5 Cumbria which we did not cover. Transport links were
6 very poor and it was covered by the sub-centre at
7 Lancaster.

8 **Q.** Now the centre which you first worked at in 1980 was
9 based in the Institute of Pathology in Newcastle
10 General Hospital, and I think had been since the
11 1950s.

12 **A.** Yes.

13 **Q.** Can you describe to us the facilities there and how
14 adequate or otherwise they were for their purpose.

15 **A.** Yes, that building I believe was opened in 1956. One
16 floor was dedicated to the transfusion service and
17 that would have been at a time when there was very
18 little in the way of processing blood into components,
19 and very little testing -- I think probably only the
20 syphilis test -- and so there was not a lot of space.

21 By the time I arrived there, several things had
22 happened to that facility. The basement, which had
23 never been intended as a laboratory area, part of that
24 had been converted to make a facility for processing
25 blood into components.

81

1 Dr Lloyd. You said it was, and then we missed
2 a little and then you said, "the 1980s".

3 **A.** Okay. I think it was -- yes, I said something like:
4 it was pretty outdated, even by the standards of the
5 1980s.

6 **Q.** An adjective a use in your statement to describe it,
7 in fact, is "Dickensian"?

8 **A.** Yes, sorry about that. Yes, it was in some ways. The
9 thing that sort of struck me was that we would see
10 blood grouping being performed and the results were
11 transcribed by clerks sitting on high stools at wooden
12 benches with great big ledgers. The entries being
13 made in pencil, which of course would be a complete no
14 ...[frozen screen]... after doing repetitive tasks,
15 which did give you that feel of a Dickensian office.

16 **Q.** I'm going to ask you to look at a document with me,
17 Dr Lloyd, just so that I can pick up one point from
18 it.

19 Sully, can we have NHBT0101335_052.

20 **A.** Sorry, can you say that number again?

21 **Q.** NHBT0101335_052, it should come up on your screen.

22 **A.** I was trying to pull it up, but a little too fast for
23 me there.

24 **SIR BRIAN LANGSTAFF:** It's still not there for us.

25 **MS RICHARDS:** Have you got it, Sully?

83

1 A second -- and it only came back to me the
2 other day -- there was a second laboratory annex,
3 a wooden structure, elsewhere on the site, Newcastle
4 Hospital site, which was being used for the infectious
5 disease testing, at that time hepatitis B and
6 syphilis, but also had a facility for producing
7 cryoprecipitate.

8 Then there was a second hut which housed the
9 donor services department, where all the donor records
10 were kept.

11 So when you look at it, it -- to me, even then,
12 it was a very old-fashioned set-up, a little bit sort
13 of cobbled together with these sheds, these huts, and
14 the basement facility.

15 The laboratory equipment was generally old, and
16 laboratory benching -- by today's standards, you know,
17 one would be horrified at the wooden benches and
18 people actually brewing up tea in a laboratory,
19 I recall.

20 The other facility was a garage housing the
21 vehicles. The vehicles were old, not in great
22 condition. Some of them the refrigeration systems
23 were very basic as well for transporting the blood.
24 So it was ...[frozen screen]... in the 1980s.

25 **Q.** Again, I'm afraid we lost a few seconds then,

82

1 **A.** No, say it again? 0101?

2 **MS RICHARDS:** Sorry, we're just having to reload it on to
3 our system here, Dr Lloyd. NHBT0101335_052.

4 **A.** 052. Is that going to come up for me?

5 **Q.** It should come up on the screen in front of you,
6 Dr Lloyd. Can you see it now? It should be displayed
7 on the screen on which you're talking to me?

8 **A.** Yes, it has. Okay. Right, I --

9 **Q.** It should now be in front of you. So it's a letter --

10 **A.** Yes --

11 **Q.** -- from you, June 1987 to the regional scientific
12 officer at the Regional Health Authority. I needn't
13 trouble you with most of the letter, I just wanted to
14 pick up something on page 3, please, Sully, bottom
15 half of the page.

16 Sorry, we're having our own problems with
17 documents here, Dr Lloyd.

18 I actually only need a single sentence, so what
19 I'm going to do --

20 **SIR BRIAN LANGSTAFF:** We're there, I think.

21 **MS RICHARDS:** I might just read it.

22 **SIR BRIAN LANGSTAFF:** It is there, it is up.

23 **MS RICHARDS:** It's not on my screen.

24 **SIR BRIAN LANGSTAFF:** Well, it is on mine.

25 **A.** I do have the document in front of me, page 3, so

84

1 please go ahead.

2 **MS RICHARDS:** I'll read it. My screen is not working,

3 although if everyone else's is, that's fine. I've got

4 a hard copy.

5 The paragraph towards the bottom of the page

6 beginning:

7 "Finally, the concept introduced" --

8 **A.** Yes, I have it.

9 **Q.** "-- that the Centre was designed and commissioned for

10 200,000 donations per annum shows a lack of

11 understanding of current blood transfusion practice."

12 This was the sentence I wanted to ask you about:

13 "The original submissions for this building of a

14 new Transfusion Centre was made in the 1960s, at which

15 time 200,000 donations seemed appropriate. When this

16 Centre was actually planned, transfusion practice had

17 changed dramatically, but to avoid major delays it was

18 decided not to make a new submission to the DHSS.

19 A decision was made to go ahead and build within the

20 confines of the original schedule of accommodation."

21 Now, as I understand it --

22 **A.** Yes.

23 **Q.** -- the service moved in 1985 to a new purpose-built

24 centre but do we understand from this that it was

25 a purpose-built centre based upon designs and thinking

85

1 understand does give a slightly strange impression of

2 the building.

3 **Q.** We can take that down, thank you.

4 Do you have any knowledge of why, it apparently

5 having been identified in the 1960s, that there was

6 a need for a purpose-built proper centre, why it took

7 until the mid-1980s for that to be realised?

8 **A.** No, I have no idea. The only thing that comes to mind

9 is one of the documents that you submitted in that

10 final group was a document from Dr Sheila Murray to,

11 I think, Mark Sackwood, the Chief Medical Officer at

12 the RHA, in which she discusses issues of introducing

13 more plastic bags and producing more cryoprecipitate.

14 So maybe that was a time when there was a sudden push

15 to produce more cryoprecipitate and, also, you know,

16 platelet transfusion was presumably starting to become

17 a possibility, but maybe that was a bit later.

18 So it may have been, and I only say may have

19 been, that Sheila Murray was pushing for a better

20 facility to produce particularly cryo.

21 **Q.** If I can ask you next to look at -- and again it

22 should, I hope, come up on the screen in front of

23 you -- TYWE0000052_005.

24 **A.** I'll get that up for you. No, sorry it's not coming

25 up on mine --

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1 from decades previously?

2 **A.** No, that's not quite the case. I think in this

3 document and this paragraph, what I'm saying is the

4 Regional Health Authority to allow themselves to go

5 ahead and build a new centre at that time, what they

6 felt was fairly quickly, they didn't want to go back

7 and make a whole new submission to the DHSS.

8 So they went ahead using the original envelope

9 of the submission, but what was produced internally

10 had no bearing on the original -- I never saw the

11 original submission, but the new building was, to my

12 mind, well built. I thought the design was very good.

13 There were a few little bits you could argue about

14 but, in general, it was well built, well designed.

15 The architects spent a lot of time on trying to

16 make sure that the flow of people and materials within

17 the building were logical. They grouped departments

18 next to each other where material was required to move

19 between them. So, for instance, the donor services

20 department which didn't actually handle the physical

21 -- you know, the material, the blood, was on an upper

22 floor. The dispatch department was fairly close to,

23 you know, the loading bay.

24 So my feeling was that it was well designed, it

25 was up to date and this particular phrase I can

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1 **Q.** Don't worry, it should, I hope, come up on ours

2 shortly.

3 **A.** -- and it hasn't come up on the screen yet.

4 **Q.** Our document system is struggling today. TYWE --

5 **A.** Yeah, I did -- yeah.

6 **Q.** Ah, it should I hope be on the screen in front of you

7 now, Dr Lloyd, on our screen?

8 **SIR BRIAN LANGSTAFF:** It is on mine.

9 **A.** Oh yes, this is one of --

10 **MS RICHARDS:** Dr Collins's letters.

11 **A.** -- one of these poorly legible.

12 **Q.** Yes, it is. I'll read out the relevant passages. So

13 it's from Dr Collins, it's dated 3 October 1986.

14 **A.** Yes.

15 **Q.** So, by this time, the service has moved into the new

16 centre. It's addressed to Dr Donaldson --

17 **A.** Yes.

18 **Q.** -- the Regional Medical Officer at the Northern

19 Regional Health Authority, and I'm just going to read

20 out the first four paragraphs.

21 "Dear Liam

22 "Your letter of 24th June requested

23 a comprehensive survey of modern Blood Transfusion

24 medicine, as well as complex information not readily

25 available from our many complete but manual recording

88

1 systems. Getting it out is very laborious.

2 "As you are aware, we are understaffed at senior
3 level and now have no purely scientific staff. This
4 means that the increasingly complex clinical and
5 scientific problems have to be handled largely by
6 myself. Being virtually single handed during the
7 summer I have not had sufficient time to devote to
8 this report.

9 "However, Dr Lloyd has rejoined us on the Senior
10 Registrar rotation and is well experienced in the
11 workings of the centre from within and also as a user
12 of the Service.

13 "I have discussed all these matters with him and
14 he has been working hard compiling this preliminary
15 report."

16 The question I want to ask you rising from this
17 document is really about the staffing situation by
18 this time, 1986, and you obviously then returned full
19 time to the Centre in 1977. What do you recall about
20 the staffing problems that Dr Collins is referring to
21 here.

22 A. The problems, I think, were quite significant. Anne
23 Collins, as the director, I don't think -- there was
24 no other full-time consultant. There was some
25 clinical assistants -- I think they called them

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1 antenatal laboratory.

2 A. Yeah.

3 Q. Then if we go to the next page, I wanted to ask you
4 about this next section. So headed "Whole Blood":

5 "This region has a relatively high demand for
6 whole blood. There are many periods during the year
7 when whole blood is not available in the quantities
8 requested, despite some whole blood being returned
9 'out-dated'.

10 "Reasons:

11 "(a) Previous patterns of use. Whole blood has
12 tended to be freely available.

13 "(b) Many surgeons and anaesthetists find it
14 easy to have whole blood available for operations.
15 Plasma blood is available in most cases.

16 "(c) Hospital blood banks maintain stocks of
17 whole blood for emergency use for major trauma and
18 massive haemorrhage."

19 Then there are "Comments", four comments:

20 "(i) Pressure of reduced whole blood supply will
21 force some change in use.

22 "(ii) Education at hospital clinical meetings
23 may help accelerate the changes.

24 "(iii) Changes in hospital blood bank policies
25 in consultation with clinical departments can reduce

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1 clinical assistant grade -- but their ability and

2 their knowledge range was extremely limited. So
3 really, she was working very much on her own. The
4 support from the others there at the time, the other
5 medical staff was really -- didn't touch on what
6 I would call significant clinical issues or the, sort
7 of, management of the Centre.

8 So yes, she had a difficult time. Very little
9 support.

10 Q. Then if we look at a report which may, I think, have
11 been the report produced that's referred to in this
12 letter. It's NHBT0101 --

13 A. I can tell you, NHBT -- (overspeaking) --

14 -- 332_045.

15 A. 332 -- that is the one, you're correct.

16 Q. Good. So hopefully it will come up on the screen
17 again in the not too distant future.

18 Yes, NHBT0101332_045. Thank you.

19 So we can see there a page which has various
20 sections set out. If we go over the page, we can see
21 section 1 is "Major products and services provided by
22 the Northern Regional Transfusion Centre", and then we
23 can see it's red cell products, fresh plasma products,
24 time expired plasma, platelet concentrates, reagents,
25 and then reference to the transfusion laboratory and

90

1 the level of requests.

2 "(iv) Optimal additive red cells provided
3 acceptable alternative to whole blood in most
4 instances."

5 Then you go on in the next part of the document
6 to talk about the optimal additive red cells.

7 What essentially was the issue here that you
8 were recounting in 1986 about the use of whole blood?

9 A. Well, if you looked at the amount -- the percentage of
10 donations that we produced that were issued as
11 whole blood, it was high compared to other parts of
12 the country.

13 I had a chance to look at some figures from
14 elsewhere around the country so I was aware that we
15 were, if not at the top, very close to it. I think we
16 probably were the highest issuer of whole blood, and
17 that sort of seems to go back -- when I was in the old
18 centre in the early part of the 1980s, the laboratory
19 manager always pushed very hard for us to -- for whole
20 blood. To the extent that the Centre production staff
21 were sometimes unoccupied because blood that was
22 expected to be converted was not being converted, it
23 was being left as whole blood.

24 It was a strange situation. We were collecting
25 blood into multiple bag packs designed for producing

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1 multiple components, and yet we left it as whole
2 blood, clipped off the extra blood packs and threw
3 them in the waste.

4 So there is a long history in this Centre of
5 using whole blood, issuing it. And if you look at
6 that, the Centre really, I don't think, had an
7 opportunity to discuss these issues with the
8 hospitals. But also, most -- many to the hospitals
9 outside sort of the two bigger centres, sort of like
10 Newcastle, had no haematologist. The blood bank and
11 haematology was operated by -- was overseen by
12 a pathologist. So that was not their specialty. And
13 there was a big push by Professor William Walker at
14 the Royal Victoria Infirmary to get haematologists
15 into all the hospitals in the region and that was
16 successful.

17 So it would have been hard to make a change at
18 that time and we were putting out lots of whole blood.

19 A second point, and that comes up in another
20 article -- another document, is that -- and I think it
21 was from Anne Collins -- that we are trying to produce
22 blood -- optimal additives or sometimes referred to as
23 SAG-M, saline-adenine-glucose-mannitol, the optimal
24 additive, saying you don't give us -- you have the
25 money to produce this product on a regular basis.

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1 "Has been unable to initiate discussions on
2 plasma supply with RHA. Could not in any case
3 increase supply in present premises. New RTC should
4 open in 1985/6."

5 Then:

6 "Confidence ... in ... achieving target.

7 "Not hopeful of obtaining necessary funding."

8 A. Yeah.

9 Q. So that would suggest --

10 A. I'd say that -- if I might say, there is another
11 document where Dr Collins specifically mentions
12 the problem of erratic supply of optimal additive, or
13 SAG-M, so there is another document, and I'm sorry
14 I can't remember it, but I have seen it. So yes,
15 there's more than one reference to this problem.

16 Q. And then if we pull up CBLA0002392.

17 A. Oh, yes.

18 Q. And if we could go to page 165, please, Sully.

19 This is a document you drew attention to in
20 a recent addendum to your statement, Dr Lloyd.

21 So we've got table 11:

22 "Number of units of red cell products made
23 in 1985/86."

24 Then if we look at the regions on the left-hand
25 side, as I understand it region B is the Northern

95

1 This product is a good alternative to whole blood, but
2 if we can't produce it on a regular basis, on
3 a consistent basis, then the individual hospital users
4 are not going to change over to it.

5 So we had a sort of a little bit of
6 a chicken-and-egg situation there. And so yes, it was
7 a lot of whole blood, and the demand appeared to be
8 there but that's possibly because the education hadn't
9 filtered through that whole blood is not a good
10 product for many patients.

11 Q. Just picking up --

12 A. I hope that answers your question.

13 Q. Absolutely. Just picking up your reference to the
14 document from Anne Collins, CBLA0001800, please,
15 Sully.

16 This is a report by Dr Gunson. If we go to the
17 second page -- if we just go a little closer, please,
18 Sully, into the table.

19 A. I know the document.

20 Q. So we've got the reference there: Northern Regional
21 Transfusion Centre:

22 "1984-5

23 "- Does not expect to separate more plasma than
24 1983/4. Cannot obtain finance for SAG(M)."

25 And then "1985":

94

1 Region, is that right?

2 A. In this table. It's different in different tables.

3 So you can't use B across everything.

4 Q. Well, that's useful to know, thank you, Dr Lloyd.

5 And we can see there highlighted for us on the
6 screen the relevant figures, which show, if we look at
7 the figure under the heading "SAG(M)" a very --

8 A. Compared to most of the other centres.

9 Q. Exactly, a very modest use compared to the other
10 centres.

11 A. You know, it's not only a modest use, it is --
12 emphasises the fact that you couldn't provide this
13 product on a regular basis. If you only make 2,000 in
14 a year, you can't offer it as an alternative to
15 whole blood.

16 Q. And if we go two pages further on, please, Sully, to
17 page 167.

18 This is the second table you referred into your
19 addendum statement, Dr Lloyd. Table 13. I think this
20 is -- region B is still the Northern Region in this
21 table, and we can see there the percentage --

22 A. Yes, a little group.

23 Q. Yeah, "Percentage of Red cell products issued", and we
24 see there, with the exception of region J, which is
25 apparently not offering any --

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1 A. Yes.
 2 Q. -- the Northern Region is offering a modest amount
 3 indeed compared to --
 4 A. 2 per cent.
 5 Q. -- other Centres.
 6 A. Yes, region J was East Anglia for some reason.
 7 I don't know why they didn't use optimal additive.
 8 Q. Then I'll come back to how things changed in due
 9 course, Dr Lloyd, but I'm just trying to get a sense
 10 of what things were like in the first half of the '80s
 11 through to sort of 1986 or thereabouts.
 12 Sully, could we go back, then, to
 13 NHBT0101332_045.
 14 A. What page would you like to look at on that?
 15 Q. Page 8, please.
 16 A. Yes.
 17 Q. In this report, Dr Lloyd, I'm saying this for the
 18 benefit of others, really, you give a snapshot of the
 19 position in relation to the range of different
 20 products used. I'm not going to go through the detail
 21 of it but I mention that so that others listening can
 22 look as appropriate.
 23 But I just wanted to pick up the figures in
 24 relation to cryoprecipitate at the bottom of the page.
 25 You say there:

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1 seems likely that orthopaedic surgery will increase
 2 again as arrangements are made to carry out surgery on
 3 HIV/HTLV III positive patients."
 4 Then we've got the figures for the Royal
 5 Victoria Infirmary's cryoprecipitate use for that same
 6 period, 1982 to 1985 and we can see there the reduced
 7 usage. Then, if we just go a little further down the
 8 page, under the heading "Major Users of Cryo", we then
 9 see the other users: Middlesbrough Group, QEH and
 10 North Tees.
 11 I'll come back and ask you a little more about
 12 issues relating to the Haemophilia Centre in a little
 13 while, Dr Lloyd.
 14 Can I then, just in terms of an overview of the
 15 Centre's work, pick things up with an inspection
 16 report in 1989. NHBT0006234, please, Sully.
 17 I'll just get my own copy.
 18 So we can see the date of the inspection by the
 19 Medicines Inspectorate was July 1989, so you were, by
 20 this time, in post as director and we can see it's
 21 a routine reinspection and the date of the previous
 22 inspection was March 1987.
 23 If we can go, please, to page 3, Sully. Under
 24 the heading "Introduction", we can see here the move
 25 has taken place:

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1 "There has been no significant change in total
 2 usage of this product."
 3 Then we've got the figures from 1982 to '85.
 4 The units showing a fall in '83, a slight rise again
 5 in '84, and then a slight rise again or a further rise
 6 in '85. But not a huge variation.
 7 A. There was -- those numbers -- the differences in those
 8 numbers are not significant. I mean, they are very,
 9 very small differences in the overall picture. And
 10 I think even if you -- I did present a chart with some
 11 other years -- and again, for quite a period we were
 12 running along at around that ...[frozen screen]...
 13 Q. I'm sorry, you froze again, Dr Lloyd. The last we got
 14 was you said, "for quite a period we were running
 15 along at around that"?
 16 A. Around about 5,000. So it stayed at about that level
 17 over quite a long period of time.
 18 Q. If we go to the top of the next page or the first half
 19 of the next page, we can see it says:
 20 "This, however, hides an underlying trend. The
 21 major users were the haemophilia units at Newcastle
 22 and Middlesbrough. The use of cryo at the [Royal
 23 Victoria Infirmary] fell significantly in 1983 and
 24 1984, probably due to a reduction in surgery on
 25 haemophiliacs due to HIV/HTLV III positivity. It

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1 "The Northern Regional Transfusion Centre is
 2 housed in a purpose-built building, opened in 1985 ...
 3 "The Centre serves a population of nearly
 4 3.1 million over a wide geographical area, collecting
 5 around 120,000 donations annually and employing
 6 a staff of 220."
 7 Then we have the staff list there set out. I'm
 8 not going to go through the details of that.
 9 If we go over the page, to page 4, we've got
 10 a list of the products being produced as at -- for the
 11 period April '88 to March 1989. Then, under the
 12 heading "Inspection", I just want to pick up a handful
 13 of points with you there. It says:
 14 "There is a plasmapheresis clinic in the Centre
 15 equipped with 8 Haemonetics machines, the donor panel
 16 currently numbering around 1000. However, apart from
 17 very occasional walk-ins, normal donations are not
 18 collected at the Centre and all normal donor sessions
 19 are mobile. A visit was made to a mobile session held
 20 in Whikham Community Association Hall."
 21 Then the next paragraph tells us that:
 22 "Donor records are not computerised, the 101
 23 card system still being used", and there is then
 24 a description.
 25 Then the next paragraph:

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"If a donor reports having had a recent illness or course of medication, brief notes of this are written onto a page of a duplicate notebook, alongside the [donor] number, and at the end of this session, this sheet, known as the 'Illness Sheet', accompanies the blood to the Blood Components section, where it is used to identify unsuitable donations."

Can you just tell us a little bit more about how that latter procedure operated: the illness sheet and identifying unsuitable donations?

A. Sorry, I lost that little piece.

Q. So, in relation to the procedure described in that paragraph I just read out, the completion of the illness sheet and then its use to identify unsuitable donations, how did that work in practice? Who would identify them as unsuitable and what kind of information would lead to that conclusion?

A. Okay, this was the -- I mentioned this earlier in my evidence today -- that at the sessions there was a book, as it mentions here, a duplicate book, and if there was something that sort of fell outside the normal or the -- that the clerk, who was clerking them in wasn't, sure about, that information would be written on the illness sheet, and if one of the donor attendants or the team leader or, indeed, the medical

101

But this is how it had worked for -- I mean, that illness sheet book, that duplicate book, they had been in use for years, and years, and years. That's how it worked.

Q. Then if we can go to page 9 of this document, I just want to ask you about another aspect of the Centre's operations. So under the heading "Despatch":

"Orders for blood and products are generally telephoned in to the Despatch department but there is also a 'milk run' of set journeys to a number of hospitals. Telephoned orders are first noted onto a piece of scrap paper and then transcribed onto an official order form."

Then it goes on to talk about the orders being put together, the donation numbers, et cetera, all recorded manually "in the Blood Issues Request/Despatch Book. There is a system of using different coloured ink for each type of product but this not always adhered to."

Then if we just go to the fourth paragraph, we can see there it explains what happens with returned packs:

"... (of which there are many) are logged into a Returns book ..."

Then it says:

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officer at the session felt there was some piece of information about which they weren't sure ...[frozen screen]... written in this illness sheet, it came back to the Centre.

Then every morning, the next morning after the day's sessions, the illness sheets were passed to one of the medical staff whose job it was to go through all the illness sheet information, compare it to the known criteria for donation, in some cases to put the donation on hold while further enquiries were made of the donor's general practitioner. Sometimes there'd be, you know, if it was a more junior member of staff doing it, they might refer it to perhaps myself or Dr Collins.

So a decision was made whether or not that donation was suitable. Sometimes the donation was considered suitable for plasma but not for red cells. It varied. Unfortunately, there were -- it highlights an issue that we tried to deal with later which was that we were taking donations from people where we weren't sure if their donations were going to be suitable for full use, which we felt later -- when we came to this issue, we tried to change that round and say we shouldn't take a donation from someone unless we're sure that their donation is suitable for use.

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"... the task of tracing the fate of an individual pack would be extremely laborious and, in some cases, impossible."

Can I just -- again, this is obviously pre-computerisation and we'll come on to the changes that were made over the following years. The process, first of all, of dispatching products, leaving aside the milk run, which presumably was essentially a set of standing orders to different hospitals --

A. Mm-hm.

Q. -- to what extent were you able to deal with the *ad hoc* orders for blood and products being telephoned in or did it give rise to shortages?

A. The telephoned orders, requests for blood, didn't specifically give rise to shortages. The shortages were more of a structural issue with the way that the Centre was -- you know, how much the Centre was producing. So the ...[frozen screen]...

Q. Sorry, Dr Lloyd, you froze again?

A. -- throughout the day but also in the evenings -- yes.

Q. Not your fault at all. You were telling us that it was a structural issue with the way the Centre was -- how much the Centre was producing.

A. Yes, and so whether there was enough blood to, you know, fulfil the regular orders on what's here

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described as the "milk run", although that's not a phrase I ever heard any of our staff use. The orders that came in for *ad hoc* were promptly, dispatched whether it was during the day or whether it was in the middle of the night. They didn't specifically of their own give rise to shortages.

What I can say is, and this is also touched on in the records storage report prepared by the CMO office, DHSS, and you have a copy of it, it's a rambling report but it does say that hospitals that they went to often exaggerated the demand -- exaggerated their order because they knew that their transfusion centre would issue less than the amount they'd asked for. And that was absolutely classical of the Newcastle Centre; people ordered twice as much as they wanted, as they needed, because they knew their order would get cut back, and then one day they would make that large order and it wouldn't be cut back, because there happened to be enough of it around.

So it was a very poor system, a lack of cooperation -- perhaps not cooperation, a lack of understanding between both sides. And that was one of the things we did try and change, was to say our job is to issue what you asked for, not issue what we

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BPL in Elstree. So yes, there was a lot of ...[frozen screen]... was the regular delivery runs, which I think -- I only say I think -- well, particularly for the hospitals outside Newcastle, were pretty much a fixed quantity of each blood group. To the extent that the delivery drivers sometimes had difficulty delivering the order. Northallerton hospital, for instance, I recall it was often mentioned that our delivery to them they couldn't fit it in all into the fridge. So there was a big disconnect there between what we -- the Centre was doing and what hospitals actually required.

Q. And I know, Dr Lloyd, that you weren't involved in the formal hepatitis C look-back that was initiated in 1995 because that coincided with your departure from the Centre. But we can see here a reference to the difficulties in tracing the fate of individual packs.

Prior to the -- this becoming a fully computerised system, was that your experience on -- or were there occasions when you did have to trace the fate of packs and were unable to?

A. We didn't have to trace packs very often. You know, if you go into the HIV era, the number of HIV positive donations in the Newcastle -- for the Newcastle Centre and its catchment area was very, very small. I don't

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think you should have.

So, yes, it was a difficult time, and it required a lot of change to move from it.

Your other issue is -- that was brought up on this is, of course, that everything was manually recorded, and everything -- virtually everything in that Centre was manual.

Q. Then the paragraph I read out relating to returned packs included the phrase in brackets "of which there are many".

A. Yes.

Q. Is that accurate, and why were there many? Was that a feature of people asking for more than they needed?

A. I'm not sure I can give you a definitive answer on that. There certainly were many. The amount of blood that was returned to the Centre unused was considerable. It dropped off later, I think, as demand increased and supply didn't increase a lot, and also with better arrangements between the Centre and the hospitals.

But if you go back into the 1960s and 1970s, you see vast quantities of blood being returned from hospitals unused. You know, thousands of units were being returned unused, which was why the Centre spent a lot of time collecting outdated plasma to be sent to

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recall not being able to trace it.

I mean, this is a report from an inspector. What I would say is that although the Centre had an incredibly manual system, it was a system that had been in place, you know, from almost time immemorial, if I might say, and so people did know how to use it.

It was slow. It was slow. I mean, it could take you days to find out what had happened to a donation. What we did have more of was donors who would phone in after they'd donated, perhaps a week later, and say, "Look, I've come down with a cold", or something, and you would try and -- you needed to retrieve that donation, which had been issued perhaps in two or three parts to hospitals. It could take, you know, a couple of days to actually trace that going back through manual records.

But I think it was ...[frozen screen]...

Q. I'm sorry, Dr Lloyd, we lost a few seconds again.

You said it could take you a couple of days to trace going back through the manual records?

A. Yes, and it was difficult, it was slow, and obviously, as it says there, extremely laborious. But it was possible.

Q. Now, we saw from the beginning of this document that there'd been an inspection in 1987. This was

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1 a routine re-inspection in '89. Do you have any idea
2 whether there had been inspections in the first half
3 of the 80s, and if so, how frequently they'd taken
4 place?

5 A. No, I have no recollection of previous inspections.

6 The '87 one -- maybe I wasn't in the Centre but
7 I certainly don't recall it. And of course, we have
8 to recognise that this was at a time when the Health
9 Service operated under crown immunity, and therefore
10 whatever the inspector might have said or might have
11 recommended, there was no sort of requirement on the
12 centres for or their management, in this case the RHA,
13 to actually get things changed.

14 So yes, we do -- you know, it is -- I don't
15 recall them inspecting before, but obviously, as they
16 said, they had.

17 Q. You tell us in your statement, it's WITN6935001,
18 page 11, so it'll be on your screen, Dr Lloyd. You
19 tell us there --

20 A. Okay.

21 Q. -- about the introduction of the Blood Management
22 Computer Network System. I'm not going to ask about
23 the details of that because you very helpfully set it
24 out in your report, and the Blood Donor Management
25 System, and then the CDIC.

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1 that they might be able to help us and we -- I, in my
2 humble opinion, yes, it helped.

3 Q. Now one of the --

4 A. And if you want to know more about it --

5 Q. No, I think that's fine, thank you. We can take that
6 down, thank you, Sully.

7 Your statement tells us you made a number of
8 organisational changes to the Centre as director.
9 I'll pick up one in relation to donor services later
10 but there's just one I wanted to pick up now. That
11 was the testing of donations for infectious diseases,
12 consolidated through the usage of a single
13 manufacturing system. Now, we'll talk about
14 hepatitis C screening and its introduction at a later
15 stage of your evidence probably tomorrow, but in broad
16 terms what was this single system, and what was its
17 advantage in your view?

18 A. Okay. Before we introduce that, we were testing --
19 you know, for hepatitis B and HIV, and there were two
20 different systems. So we were using completely
21 different mechanics, equipment, for each test. That
22 gave rise to data transfer issues, so you now have to
23 develop two systems of data transfer, two systems of
24 data validation, two systems of authorisation of the
25 transfer of records into your main system.

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1 At the bottom of the page, you explain that you
2 asked Birmingham University Health Services Management
3 Group to carry out an assessment of the management of
4 the Centre and develop a programme of predominant
5 development.

6 What had prompted you to ask for that
7 assessment, and what, again, in broad terms, was it
8 designed to address?

9 A. Well, you have to understand that, you know, myself
10 and, you know, I had a medical training. None of my
11 training included anything on how to manage, which
12 was, you know, a shame. And I became director quite
13 suddenly. There was no opportunity to take any
14 additional sort of training courses. I started to
15 read quite extensively on how to manage, and
16 management issues, and I think together with my senior
17 managers we realised that we did need to improve what
18 we were doing. We needed to become more professional
19 in how we operated and so the -- I had been to
20 a two-day -- a weekend course arranged for new
21 consultants, arranged by the Regional Health
22 Authority, presumably when I first became
23 a consultant, and they -- that little course was run
24 by the people from Birmingham University. And so
25 I sort of knew what sort of style they had, and felt

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1 You also have a training issue. You now have to
2 train your staff on two different systems. You have
3 to -- I mean, it goes on. I keep saying two. But
4 whenever you're using two different sets of equipment
5 it gives rise to a multiplicity of issues. You have
6 to do everything twice. Your quality control is going
7 to be different, your quality assurance programme for
8 it is going to be different, your training is going to
9 be different. It makes it more difficult for staff to
10 change between one machine, one test and another.

11 So we moved to a single system offered by the
12 Abbott Plc, I think the official company we dealt with
13 was based in Germany, but it's an American corporation
14 and they produced equipment which had a much higher
15 level of automation than the equivalent other
16 companies offered. So it integrated a lot more of the
17 quality control into the system, automatic pipetting
18 and delivery of samples.

19 But basically they're using the same system to
20 do different tests, and then the test results come
21 together, and they had one module which brought the
22 test results together, which allowed you to do one
23 authorisation process to release the results into the
24 general computer system or wherever.

25 So it gave you a lot of advantages, not only in

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1 mechanics of running it, the training staff
 2 ...[frozen screen]... run systems.
 3 Q. I'm sorry, Dr Lloyd, we lost you again.
 4 So we last had it when you said it gave you
 5 a lot of advantages, not only in the mechanics of
 6 running it, the training of staff ...
 7 A. And things I've already mentioned. So the quality
 8 control and the single authorisation of results before
 9 they're transferred out for use by the rest of the
 10 system in ...[frozen screen]...
 11 I have to thank the staff who worked there for
 12 really bringing a lot of that to my attention, and
 13 helping recognise that there were some good
 14 alternatives out there.
 15 Q. Can I then ask you a little about the relationships
 16 that you had with other bodies and organisations. So
 17 first of all, relationship with your Regional Health
 18 Authority. How would you characterise the
 19 relationship that you had or, to your knowledge, your
 20 predecessor had?
 21 A. I'll start with my predecessor. Dr Collins did appear
 22 to have difficulty with the Regional Health Authority
 23 and her dealings with it. My understanding from
 24 talking to somebody at the Regional Health Authority
 25 was that they were to some extent unhappy that when

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1 more senior staff at the Regional Health Authority,
 2 particularly Liam Donaldson -- now, I think Sir Liam
 3 Donaldson, you know, he understood issues. He did.
 4 He was -- he understood health care, and I found
 5 that I was able to, you know, we did manage to get
 6 things done. So it became a reasonable relationship.
 7 In the early days there was -- as I mentioned in
 8 my witness statement, there was a lot of detailed
 9 stuff coming from some of the lower areas -- levels of
 10 the Regional Health Authority. And some of that got
 11 pretty tedious, asking us to produce flowcharts and
 12 I think something called a Gantt chart, all sorts of
 13 bits and pieces which really I felt weren't necessary
 14 to the running of the Centre and weren't helping us to
 15 move forward, and there was a lot of detailed stuff.
 16 But as time went on, that became less, and part
 17 of that was of course the move to separate us out into
 18 a clinical agency of the Regional Health Authority.
 19 Q. Now, in terms of relations with other directors of
 20 Regional Transfusion Centres, you were present at what
 21 turned out to be the last Regional Transfusion
 22 Directors meeting in January 1989. It wasn't clear to
 23 me whether it was also your first meeting as
 24 a Regional Transfusion Director, I think it might have
 25 been?

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1 automated blood grouping was brought in, Anne Collins
 2 would not reduce the staff commensurate with that
 3 automation.

4 We had dozens of junior at the time called
 5 technologists or technicians, which we didn't need
 6 once it became automated in that particular
 7 department. So I think there was sort of a little bit
 8 of a stand-off about that. So I think, you know, she
 9 did have difficulties with her dealings with the RHA,
 10 and I am sure we will come back to the RHA's view on
 11 plasma production later.

12 When I took over, I got along reasonably well
 13 with the people at the Regional Health Authority,
 14 initially the regional scientific officer, Mr
 15 Geoff Whittaker and, as time went on, the Regional
 16 Health Authority changed its -- you know, who I dealt
 17 with. I got moved to deal with somebody who dealt
 18 with a number of regional services, Mr Tony Garland,
 19 I think. I'm not great on names. But I was sort of
 20 moved and I got along with them. I wouldn't say, you
 21 know, that every communication was wonderful but, you
 22 know, we got along quite reasonably and they did seem
 23 to start responding to issues that we were able to
 24 bring up.

25 And as time went on, I found that some of the

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1 A. It was.
 2 Q. So your first last and meeting, and I won't display
 3 the minutes because we've looked at them on a number
 4 of occasions but you'll recall, and you note it in
 5 your statement, it suggests that the decision to
 6 disband the meetings was unanimous. Your
 7 recollection --
 8 A. Yes.
 9 Q. -- I think, is different?
 10 A. Yes, recollection is always a tough thing. Sometimes
 11 you recall what you want to recall. But I do note the
 12 informal minutes of that meeting, I think, produced by
 13 Dr Ewa Brookes, which said that the announcement or
 14 the decision to end the meetings was met by universal
 15 silence, and that there had been no discussion about
 16 ending the meetings. So ...[frozen screen]... myself,
 17 you know, my first meeting, I'm the junior, very much
 18 the junior, I'm sure I wouldn't have stood up --
 19 I think you've lost -- I'm sure I wouldn't have --
 20 Q. I can hear you.
 21 A. I'm sure I wouldn't have stood up and said, "No, don't
 22 do this" because, you know, I was -- (a) I wouldn't
 23 have got anywhere because everyone else seemed to be
 24 okay with it and, yes, I was very junior, in terms of
 25 the number of years that all -- most of the others had

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1 served as ...[frozen screen]... Yes, I probably
 2 acquiesced, let's put it that way.
 3 **Q.** We lost you a couple of times there, Dr Lloyd, but it
 4 was clear, I think, what you were saying.
 5 **A.** Okay.
 6 **MS RICHARDS:** Sir, I note the time. I've got couple of
 7 documents I'm going to want to look at, so perhaps do
 8 that after the break?
 9 **SIR BRIAN LANGSTAFF:** Yes, okay. That's a good idea.
 10 Let's take a break now, what shall we say, 25 minutes?
 11 **MS RICHARDS:** Yes, that would be fine.
 12 **SIR BRIAN LANGSTAFF:** So 25 minutes. Let's come back
 13 at 2.40, our time, and that's 9.40, thank you. Your
 14 time.
 15 **A.** 9.40.
 16 **SIR BRIAN LANGSTAFF:** Let me say to you what I say to all
 17 witnesses at this stage, if I haven't said it
 18 previously, and it's this. You're giving evidence.
 19 You must not talk to anyone until you've finished
 20 giving evidence about the evidence you have given or
 21 anything you think you may be asked to say in evidence
 22 but you can talk about anything else you like.
 23 **A.** I understand that, sir.
 24 **SIR BRIAN LANGSTAFF:** 9.40.
 25 **MS RICHARDS:** Thank you, sir.

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1 and together with people from the Department of
 2 Health, DHS, DHSS as what it was at different times,
 3 and a representative from the Scottish Blood
 4 Transfusion Service.
 5 And that is -- I mean that's mentioned by
 6 Dr Ewa Brookes in her informal minutes of that meeting
 7 saying, you know, you may come to rue the moment you
 8 agreed to this meeting ending.
 9 So the National Directorate, to me, had ended up
 10 severing certain lines of communication, so that --
 11 I don't know how other directors felt but I felt that
 12 I was, sort of fed, you know, small snippets of
 13 information and really didn't have a lot of input; and
 14 sometimes that meant that you didn't understand the
 15 context of some things that were happening.
 16 So, yes, the National Directorate, to me, was
 17 a poorly put together ...[frozen screen]... It could
 18 have functioned a lot better within the confines of
 19 what it was given. Sorry, I rambled a bit.
 20 **Q.** That's quite all right a bit.
 21 I want to ask you to look at a document which
 22 was produced by you in March 1991, so approximately
 23 three years into the life of the National Directorate,
 24 NHBT0001864. So the document should be on your
 25 screens, Dr Lloyd. It's "Framework for a National

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1 (2.15 pm)
 2 (A short break)
 3 (2.40 pm)
 4 **MS RICHARDS:** Dr Lloyd, your arrival as director largely
 5 coincided with the creation of the National
 6 Directorate. What was your experience of the National
 7 Directorate and its ability to coordinate or take
 8 decisions?
 9 **A.** Well, if you look at some of the documents that have
 10 been submitted in my correspondence with the National
 11 Directorate, I think that speaks to the fact that I
 12 did not have a very high opinion of that organisation.
 13 I felt that they were poor at making decisions. We
 14 know from Dr Gunson's own statements that he felt that
 15 he had no authority, and that's the case. He was
 16 not -- the National Directorate wasn't set up to have
 17 a line of authority.
 18 On the other hand, if you had recognised that,
 19 you could have worked with people to get agreement,
 20 and what we saw, as we mentioned earlier, as you
 21 brought up earlier, there was the last of the Regional
 22 Transfusion Directors meetings. And, in that -- in
 23 dissolving that meeting, you removed a degree of
 24 coordination which would have been possible, bringing
 25 all the directors together with the national director,

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1 Directorate of the Blood Transfusion Service in the
 2 post White Paper Era", and it's dated on page 6 --
 3 **A.** Right.
 4 **Q.** -- 14 March 1991. You say in the "Introduction" that:
 5 "Since the creation of a National Directorate
 6 there have been significant changes in the NHS."
 7 You describe links with Regional Health
 8 Authorities starting to weaken, and then you say:
 9 "That raises the question of a future role for
 10 a National Directorate."
 11 You suggest that:
 12 "... there is an important and valuable role for
 13 [it], covering in particular the areas of information
 14 on Transfusion Medicine and Transfusion Management and
 15 the provision of a public face ..."
 16 Then if we just go to page 4, if we pick it up
 17 halfway down the page, under the heading "The
 18 authority for a National Directorate", just wait until
 19 we get there.
 20 **SIR BRIAN LANGSTAFF:** Are we on the right page?
 21 **A.** (Overspeaking).
 22 **MS RICHARDS:** Yes, we're on the right page but we need the
 23 bottom half of the page.
 24 Yes, so "The Authority for a National
 25 Directorate".

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1 A. Oh okay.
 2 Q. You say:
 3 "At present the National Directorate is
 4 officially working to a brief dating from 1998. That
 5 brief is out of date ..."
 6 Then skipping over a couple of lines:
 7 "It's long term role appears uncertain unless
 8 a clear role can be developed that fits with the
 9 current White Paper philosophy."
 10 Then you refer to the National Directorate and
 11 the CBLA and then, over the page, next page, you set
 12 out "A Proposal for the way forward". I'm not going
 13 to through the detail of that but just pick it up at
 14 the "Summary", bottom half of the page:
 15 "A re-definition of the role of the National
 16 Directorate, with a clear brief to support the UK
 17 Transfusion Centres and to provide cost effective
 18 information, public relations and certain coordinating
 19 functions is proposed."
 20 Now, we know this isn't what happened and, in
 21 due course, we have the National Blood Authority,
 22 which I'll come on to in a couple of minutes, but what
 23 was it that led you to advocate this redefined role
 24 for the National Directorate? What were you hoping it
 25 would achieve?

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1 into on it?
 2 Q. No --
 3 A. Just to say, I was just flying a kite.
 4 Q. We know there was then a consultation on forming
 5 a National Blood Authority, and there's a response to
 6 that consultation by the Northern Region Blood
 7 Transfusion Service at DHSC0004584_039.
 8 If we go to the third page, under the heading
 9 "Introduction" picking it up in the third paragraph:
 10 "In essence the NRBTS believes that strong local
 11 management with local accountability provides the best
 12 option for the future. This option is outlined in the
 13 section 'Preferred future management arrangements'.
 14 Central coordination is available through a small
 15 organisation operating on behalf of Regional
 16 Transfusion Centres."
 17 Then the next paragraph:
 18 "It is accepted that the strongly independent
 19 stance that we would like to take, whilst possibly
 20 appropriate for ourselves will not be suitable for
 21 a number of Transfusion Centres. It is also accepted
 22 that BPL requires more support to survive."
 23 Then if we just keep the whole of it on screen,
 24 Sully, I think it's fine.
 25 The next paragraph:

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1 A. Goodness, yes, I was obviously ...[frozen screen]...
 2 I was trying to look for something that didn't
 3 require the National Directorate to be completely
 4 brief, redeveloped. In other words, you didn't want
 5 to have to go to the Department of Health and say, you
 6 know, "Create a different beast". So what could the
 7 National Directorate do that would deliver, you know,
 8 value to the transfusion centres? So I'm looking at
 9 certain things.
 10 As an individual transfusion centre director,
 11 I was obviously heavily consumed in running, you know,
 12 what was then a multimillion-pound operation. And the
 13 amount of time available to do some of these things
 14 was limited. So, you know, the time to travel to, you
 15 know, international meetings and get a good
 16 understanding of what was going on from around the
 17 world, you know, that would have been something that
 18 the National Directorate could have done because the
 19 National Directorate doesn't have to actually manage
 20 anything other than a handful of people in an office.
 21 So I was looking for things that they could
 22 deliver, which would help the Transfusion Services,
 23 and so I think that's sort of where it -- where I was
 24 going. Gosh, it's a long time since I wrote this.
 25 I don't know, is there anything else you'd like to dig

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1 "We have assessed various options against the
 2 standards that we believe appropriate for
 3 a Transfusion Service in the United Kingdom ..."
 4 You refer to a proposal put forward by the
 5 Transfusion Centre Directors and Managers. Then you
 6 say:
 7 "The NBA proposal as presented in the
 8 consultation paper does not meet our criteria on a
 9 number of important points. These are amplified in
 10 the section 'Perceived problems in the NBA proposal'.
 11 It does however address the national co-ordination
 12 question, the need for a national image for the NBTS
 13 and the link between the NBTS and BPL. We therefore
 14 support the formation of an NBA but believe it should
 15 be in the form of revised proposals from the
 16 Transfusion Centre Directors & Managers."
 17 I'm not going to go through the whole document,
 18 Dr Lloyd, but can you tell us essentially what it was
 19 that you were proposing and why you were not
 20 supporting the idea of an entirely National Blood
 21 Authority, essentially a single transfusion service?
 22 A. Yes. As I said in that document, you know, what we
 23 were proposing may not have been entirely appropriate
 24 for every transfusion centre. I'm certainly aware
 25 that quite a number of transfusion centre directors

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1 strongly wanted a central service -- organisation.
 2 I guess I had found that I had a really good
 3 group of staff in the Transfusion Centre, at many
 4 levels, and we were able to work together to make
 5 changes. And we could make them quickly. Relatively
 6 quickly. Some of them we could make very quickly.
 7 So you can get things done with a good
 8 management team and good staff. You can get them done
 9 locally. Once you become national, particularly in
 10 the early years, you've got an enormous task to try to
 11 bring disparate organisations together. And certainly
 12 from my point of view, and it's mentioned elsewhere,
 13 I didn't really want to be in a position of just being
 14 told what to do.

15 You know, one was aware that the NBA changed
 16 some of things we did quite quickly, perhaps stupid
 17 things -- changing telephone systems, you know ...
 18 which removed direct outside lines into our dispatch
 19 department, apparently. And I quote that from someone
 20 who worked there after I left.

21 You know, so I'm not a lover of big
 22 organisations, I have to say. I'm not a lover of the
 23 big bureaucracy. So yeah, I pushed for something to
 24 keep us independent, but not ...[frozen screen]...
 25 standards. How you meet them doesn't matter. It's

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1 an organisation, this sort of rather unknown
 2 organisation, you know, yes, that gave me the impetus
 3 to put my CV, my résumé out there.

4 **Q.** Now I'm going to ask you next about the relationship
 5 with Haemophilia Centres.

6 Just before I ask you about that from your
 7 perspective as director of the Regional Transfusion
 8 Centre, can I just come back to the short period of
 9 time you worked at the Haemophilia Centre during your
 10 registrar years.

11 Do you have any recollection of what Dr Jones'
 12 approach to treatment or treatment philosophies were,
 13 based on your own very short time there?

14 **A.** Yeah, very short time. I mean he was a great advocate
 15 for home treatment. And having, you know, knowledge
 16 of what haemophilia had been like for individuals
 17 prior to the availability of factor concentrate and
 18 then prior to the move to home treatment, you realise
 19 that home treatment offered a terrific -- potential
 20 terrific improvement to life. Now we know what
 21 happened.

22 But just the very fact of -- you know, he wanted
 23 patients to live a more normal life, if they could.
 24 So yes, home treatment was, I think, the bedrock of
 25 what was done at that Haemophilia Centre. But

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1 meeting the standard. And if you can meet that
 2 standard, or exceed it, then that's good. So it's not
 3 saying, "Let's just forget about standards and we'll
 4 do our own thing", it's, "We'll do our own thing and
 5 meet what is appropriate."

6 So yeah, you see me being pretty clear on
 7 (unclear).

8 **Q.** And I understand from your statement that
 9 the establishment of the NBA in the form it ultimately
 10 took was a factor in you deciding to leave your post
 11 and move on to pastures new?

12 **A.** I have to put it in context. When I became director
 13 I had said to myself, and I think I've written that in
 14 my witness statement, that I didn't want to stay in
 15 that position for too long. One of the reasons for
 16 that was that I had met a number of other transfusion
 17 centre directors, and sort of felt that perhaps, you
 18 know, they'd started off with great ideas and, and so
 19 on, but had rather stagnated, and I didn't want to let
 20 myself get into that position.

21 So once, you know, by the time the NBA came into
 22 ...[frozen screen]... so the combination of my own
 23 idea, that I didn't want to stagnate, and the fact
 24 that the NBA would really take away my ability to get
 25 things done that I wanted to do, and I'd be subject to

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1 I didn't have time to go into, you know, what his
 2 philosophy was and how long he'd gone down that path.
 3 So I -- and after that, it becomes hearsay.

4 **Q.** One of the documents in the 80s tell us -- tells us
 5 that the haemophilia patients in the Northern Region
 6 area were all managed from the Newcastle Centre rather
 7 than their own more local unit. Do you have any
 8 knowledge as to why that was the case?

9 **A.** I really don't, no. I mean, I know that there were
 10 some sub-centres but I don't even really know how they
 11 were staffed or managed. It did seem to be that
 12 Newcastle was the -- you know, the Centre that managed
 13 and offered management to patients in the whole
 14 region.

15 **Q.** Now I'm going to look in a moment at a letter that you
 16 wrote at the time of the HIV litigation, but before we
 17 do that, just in broad terms, as I understand the
 18 position, in relation to commercial concentrates, the
 19 Regional Transfusion Service had nothing to do with
 20 the ordering or stocking or supply of commercial
 21 concentrates. That was all dealt with directly by the
 22 Newcastle Haemophilia Centre; is that right?

23 **A.** ...[Frozen screen]... Haemophilia Centre and their
 24 pharmacy organisation. We did not order, choose,
 25 supply any of those commercial products.

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1 Q. In relation to the NHS concentrates, the BPL
2 products -- and we'll explore issues of plasma supply
3 a little later on -- but, as I understand it, the
4 Regional Transfusion Centre did have a role there, in
5 the sense it received those products from BPL, and it
6 supplied those products to the Haemophilia Centre?
7 A. Yes. Without going too much into semantics, when we
8 say "supplied", I mean that was just an issue of --
9 a matter of transferring the product. We had, you
10 know, we had a truck that went down to Bio Products
11 Lab, BPL, with plasma, it came back with finished
12 product, the Factor VIII was put into refrigeration,
13 and then it was for the Haemophilia Centre, the RVI,
14 you know, to collect that product.
15 I don't recall them actually ever ordering it.
16 They didn't sort of say, you know, "Can you supply us,
17 you know, ten boxes", it was a case of "We've got the
18 product from BPL, come and get it".
19 Q. If we look then at the letter from the time of the HIV
20 Litigation, TYWE0000064, please, Sully. If we go to
21 the second page, it's a letter from you to a Mr Slack
22 of Crutes Solicitors, heading "HIV Litigation", you
23 say:
24 "Attached is a fairly brief set of answers to
25 the questions put by you recently ... As I only became

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1 Centre. Because we have a vehicle travelling to
2 Elstree carrying raw plasma to that factory, and the
3 van is then returning to Newcastle, we bring back all
4 the Factor VIII and Factor IX allocated to the
5 Northern Region and then despatch it to the
6 Haemophilia Centre. At various times we have held
7 some of this product in stock, awaiting instructions
8 from the Haemophilia Centre to have it sent across.
9 As mentioned elsewhere, there have been times when it
10 has been necessary to remind the Haemophilia Centre
11 that supplies of NHS Factor VIII are available and
12 awaiting collection."
13 Just pausing there in relation to that last
14 sentence, Dr Lloyd, you refer in your statement to
15 Dr Collins showing you boxes of Factor VIII in
16 a walk-in fridge that Dr Collins told you the
17 Haemophilia Centre was reluctant to take; is that
18 right?
19 A. Yes, that's correct, and I think you have also
20 supplied a document which is a letter from Dr Collins
21 to Dr Jones, in which I think she uses the phrase
22 "embarrassingly large supply that hasn't been
23 shifted".
24 Q. Yes and we will just look at that --
25 A. *(Overspeaking)*

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1 Director/General Manager in late 1988 my involvement
2 with, and hence knowledge of, certain aspects of this
3 Litigation is limited."
4 You then refer to having gone a through large
5 quantity of files created by Dr Collins and some files
6 dating back to Dr Murray, and you say:
7 "... clear from my examination of the files that
8 very little was put to paper by the previous Director,
9 or if it was, no copies now exist at the Transfusion
10 Centre."
11 If we go to the next page, there is a heading at
12 the top of the page, "BTC Responsibilities in Relation
13 to the Haemophilia Centre":
14 "The Transfusion Service responsibility to the
15 Haemophilia Centre in this Region is little different
16 to its responsibility to any other Health Service
17 Department or Unit. We provide, within our
18 capabilities, the products that are requested by the
19 Haemophilia Centre. Some of the products we provide
20 are locally produced, including cryoprecipitate and
21 individual packs of fresh frozen plasma.
22 "As far as the supply of Factor VIII and
23 Factor IX are concerned, we have acted purely in
24 a handling intermediary position between the Blood
25 Products Laboratory at Elstree and the Haemophilia

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1 Q. -- TYWE0000015_002. If we just zoom in on the text,
2 please, Sully.
3 It looks like it's 26 August 1983 but I'm not
4 100 per cent sure.
5 A. Yes, that's what I thought.
6 Q. It's from Dr Collins.
7 Thank you, Sully, I think that's right.
8 It's from Dr Collins to Dr Jones:
9 "Dear Peter
10 "We have an embarrassingly large supply of BPL
11 Factor VIII in stock. How about it?"
12 It would appear from what you -- from what
13 Dr Collins related to you, I think, and what you
14 relate in this document, that the Transfusion
15 Service's understanding was that the Newcastle
16 Haemophilia Centre used, to a very substantial extent,
17 commercial concentrates; is that correct?
18 A. As far as I know, they did. We know, and I'm sure
19 we'll get into this at some stage, there was very
20 limited supply of BPL Factor VIII. It would not have
21 met the regional demand, particularly once you start
22 a fairly aggressive home treatment policy. But,
23 despite that, you know, there were still -- obviously
24 there were still some products not getting used
25 immediately. So yes, they used a lot of commercial

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1 product -- concentrate, and you see that in other
 2 documents that have been submitted.

3 Q. If we go to the next page of this document, just pick
 4 up an answer you gave to one of the questions. So
 5 it's TYWE0000064, and it'll be page 4, please, Sully.

6 So paragraph 5 says:

7 "To what extent were there shortages of
 8 Factor VIII?"

9 This, as I understand it, was part of your
 10 answer.

11 "Factor VIII has, since the 1970s, been produced
 12 by the Blood Products Laboratory at Elstree in
 13 quantities less than those required for the treatment
 14 of the haemophiliacs in this country. The level of
 15 shortage in each region has varied because of the
 16 supply of raw plasma, from which Factor VIII is made.
 17 As mentioned elsewhere, I believe that this Region
 18 took a decision in the 1970s to purchase Commercial
 19 Factor VIII rather than invest in the transfusion
 20 centre, with a view to producing more plasma."

21 Can you recall, Dr Lloyd, what the basis was for
 22 your understanding that there had been a positive
 23 decision by the Regional Health Authority, I assume
 24 it's the Health Authority you're referring to there,
 25 to invest in --

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1 having said we won't look at that document, I'm going
 2 to suggest that we do.

3 Sorry, Sully, could we have TYWE0000022.

4 So this is the draft statement from Dr Collins.

5 I just want to pick up on what she says at pages 4 to
 6 5 and then ask if you have any observations or any
 7 reflections of your own based on your conversations
 8 with her.

9 So if we go to page 4, please, thank you.

10 If we pick it up halfway down the page:

11 "A further difficulty arose from the
 12 arrangements which were made from about 1980 onwards
 13 with the distribution of Factor VIII. The system
 14 introduced at that time was known as the 'pro rata'
 15 arrangement, by which [RTCs] were intended to receive
 16 back amounts of blood products in proportion to the
 17 amount of blood plasma sent by Regional Transfusion
 18 Centres throughout England and Wales. Because some
 19 Regional Transfusion Centres, such as the Leeds
 20 Centre, sent a disproportionately large amount of
 21 blood plasma, the northern transfusion service 'lost
 22 out', even when the amount of blood plasma sent to
 23 Elstree increased."

24 Do you have anything or any particular insight
 25 into or understanding of what Dr Collins had in mind

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1 A. Yes.

2 Q. -- commercial concentrates rather than rebuilding the
 3 transfusion centre?

4 A. Okay, at the time I wrote that, I would have been
 5 fairly heavily influenced by comments made by my
 6 predecessor, Dr Anne Collins, because I wrote that
 7 before I was director, and I would have had --
 8 I wouldn't have seen some of the documents that you
 9 now have given me access to over decisions by the
 10 Regional Health Authority.

11 So I am here, I think, pretty much quoting the
 12 view that came from my predecessor without having sort
 13 of hands-on evidence to support that -- those
 14 statements.

15 Q. And I should say, I'm not going to go to it now, sir,
 16 but we do have a draft statement from Dr Collins
 17 produced I think, again, for the purposes of the
 18 HIV litigation.

19 A. Yes.

20 Q. I won't take time with it now, but for the transcript
 21 it's TYWE0000022. I may come back to it in the course
 22 of Dr Lloyd's evidence. But we do have Dr Collins's
 23 input there.

24 A. Yes. I have read that.

25 Q. There are a couple of comments that -- actually,

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1 there, this sense that the pro rata system somehow was
 2 stacked against the Northern Region in some sense?

3 A. Well, not particularly against the Northern Region, it
 4 happen to act against the Northern Region.

5 If you look at some of my -- one of the charts
 6 I presented in my witness statements showing the
 7 pro rata distribution of products in general to the
 8 Northern Region, it shows that over a period of
 9 a number of -- I think it was actually only couple of
 10 years this data relates to, I just didn't happen to
 11 have a larger range of data, but you can see that in
 12 that chart that the amount of plasma being sent to BPL
 13 from the Northern Region stayed the same, but the
 14 amount of product that came back diminished.

15 And that was a fact -- that's how the pro rata
 16 system worked. You took the total quantity supplied
 17 by all transfusion centres and you, you know, divvied
 18 it up, accordingly -- the production accordingly.

19 So if some centres produce more but others stay
 20 the same, the ones who stay the same are going to get
 21 less product back. And that's what Dr Collins is
 22 referring to here. And as I say, I did produce
 23 a small chart showing that in operation.

24 Q. I'll certainly come on to some of the charts that
 25 you've produced, Dr Lloyd, in the course of the

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1 afternoon.
2 Then if we just go to the next page, page 5, so
3 still in Dr Collins's statement, picking it up in the
4 second paragraph she says:

5 "It became apparent that there was a preference
6 at the Haemophilia Centre for commercially produced
7 Factor VIII blood product for the following
8 reasons ..."

9 Then she sets out three: solubility, allergic
10 reactions, and a more attractive presentation of
11 commercial Factor VIII.

12 A. Mm-hm.

13 Q. Now that's what Dr Collins was saying.

14 Do you have any direct evidence or information
15 of your own as to what might have been the preference
16 of Dr Jones for commercially produced Factor VIII
17 product? Is it something you ever discussed with him?

18 A. I mean -- no, I don't think I discussed it with him.
19 I mean, I was certainly aware, because whilst I was
20 a senior registrar at the Royal Victoria Infirmary, we
21 often treated haemophiliacs who came in after hours
22 when the Haemophilia Centre wasn't open, and we used
23 the product that was allocated, you know, for that
24 patient. If that patient was on a certain commercial
25 product, that's what we used.

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1 Q. And it refers to the possibility of collecting plasma
2 from the parents to provide cryoprecipitate for
3 treating their son.

4 Now I'm not going to ask you anything about the
5 individual family concerned, but just as a broad
6 topic, this idea of what I think you refer to in your
7 statement as "family-specific cryoprecipitate", did
8 that take off? Was that something that was done, and
9 had it ever been contemplated before this?

10 A. I don't recall it being done at other times. You
11 know, I read this letter and it -- you know, it
12 obviously brought the issue back to mind, but it
13 wasn't something that I was aware of as a -- certainly
14 wasn't a major component of what we were doing in the
15 transfusion centres. We were obviously prepared to do
16 it, but I don't recall it becoming a frequent --
17 certainly not a frequent issue. We might have done
18 others but I -- honestly, I'm sorry, I can't remember
19 now.

20 Q. Do you know whether what had triggered this possible
21 arrangement was concern about viral infection, or
22 whether it was unrelated to that issue?

23 A. No, I don't know. I didn't deal with the parents, and
24 certainly, you know, it was Dr Jones who worked with
25 the parents to get a suitable means of treatment.

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1 And it's true, the commercial Factor VIII was
2 more easily soluble. In other words you could put the
3 distilled water in -- I think it was distilled
4 water -- into the vial, and dissolve it much more
5 quickly than you could the BPL product. So I
6 actually, you know, have experienced that.

7 I don't know really enough to say about the
8 allergic reactions, the rate of those. But, you know,
9 obviously Dr Collins had some knowledge of that. But
10 I don't know what specifically Dr Jones was saying
11 about that. But, you know, it is the case that that
12 product, the BPL product, was less easy to use, and it
13 wasn't presented, if you like, in a nice package. It
14 didn't come with its -- with everything together. So
15 a little more difficult to use.

16 Q. And then just before we move more generally to issues
17 relating to plasma supply, whilst still on the topic
18 of haemophilia treatment, can I ask you to look at
19 NHBT0078890_022.

20 When it comes up, Dr Lloyd, you'll see it's
21 a letter from you. So it's dated 13 November 1986.

22 A. Yes.

23 Q. It's addressed to the parents of a boy with
24 haemophilia.

25 A. Mm-hm.

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1 So I don't know what discussions took place to come to
2 this conclusion. So I'm sorry, I can't help you
3 further on that one.

4 Q. Thank you. We can take that down, Sully.

5 I'm going to ask you now to look at three
6 documents, all of which, I'm afraid, predate your time
7 as director, but they're three short documents
8 relating to issues of plasma supply and meeting
9 targets, and so on. Then I want to ask you about some
10 observations you make in your witness statement.

11 So the first document is DHSC0002247_077. This
12 is a letter dated 18 October 1984 from the regional
13 general manager at the Northern Region Health
14 Authority to the Department of Health. We can see
15 it's headed "Supply of Plasma to the Blood Products
16 Laboratory".

17 A. Yes.

18 Q. It says this:

19 "Your letter dated 10 August 1984 on this
20 subject was discussed by the Regional Health Authority
21 at its recent meeting when commitment to achieving the
22 target for this Region was reaffirmed but only
23 a qualified assurance with regard to timing could be
24 given in the light of additional capital and revenue
25 resources required and more particularly the need to

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1 build up the number of plasma donors in the Region.
2 In this latter connection, the recent closure of
3 factories in the Region has had a considerable effect
4 on the ready availability of blood donors."

5 So I appreciate you wouldn't have seen this
6 letter at the time, Dr Lloyd, and, indeed, it doesn't
7 even appear to have been copied to Dr Collins. But it
8 suggests an in-principle commitment to meeting the
9 targets and, presumably, the ultimate objective of
10 self-sufficiency but not an equivalent guarantee of
11 being able to do so. Is that, more broadly, a fair
12 reflection of your understanding of the position at
13 around this time, and the position you then inherited
14 later in the '80s?

15 A. Yes, I think so. I think there's another document
16 also from the Regional Health Authority probably from,
17 was it the Regional Director of Resources, which
18 I think may have followed up this letter, which you
19 also, you know -- I didn't see at the time, which
20 gives it perhaps a little more background to it. But,
21 yes, my understanding was that we're not going to put
22 a lot of money into the Centre. It's going to be
23 expensive. We have limited resources, and so, at the
24 moment, yes, we'll -- when you read it, you say: yes,
25 well, we -- we'd like to go along with you, but

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1 "I will let you know when any agreement is
2 reached."

3 So it would appear that Dr Collins is
4 effectively awaiting approval from the Regional Health
5 Authority to take the steps outlined, fairly modest
6 steps, potentially outlined in the third paragraph of
7 her letter.

8 A. Yes, yes. She wasn't -- she felt, you know, she
9 couldn't -- you couldn't -- you can't spend money that
10 you don't have, you know, you don't have the authority
11 to. And so the two things there, the bags containing
12 the optimal additive, SAG-M, were more expensive and,
13 of course ...[frozen screen]... expensive operation.
14 There was a small plasmapheresis centre in the new
15 building with a small number of units. We saw that in
16 the Medicines Control Agency Inspection Report
17 earlier, where I think they mentioned eight
18 Haemonetics machines, although that might have been
19 a little bit later than this.

20 Yes, it was the next year, wasn't it, that
21 report.

22 So she had -- she couldn't go ahead with some of
23 the things that she would have liked to have done
24 because she didn't have the funding to do it.

25 Q. Then I think we see that perhaps most starkly in the

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1 actually we're not going to. Haha.

2 That's what it appears to say. And the little
3 bit about the closure of factories, and so on, is just
4 a little bit of icing on the cake to try to show that,
5 you know, it was going to be difficult.

6 Q. Then I'll just pick up two other documents, they're
7 not, I think, the one you're referring to, but I'll
8 try and find the reference to that later.

9 So the second is a letter from Dr Collins to the
10 DHSS, May '85, DHSC0002269_021, so 1 May 1985, headed
11 "Plasma Procurement for BPL".

12 "I am sorry for my late reply to your letter re
13 Plasma Procurement for BPL. The matter was raised at
14 the recent [Regional Health Authority] meeting,
15 members being advised that additional finances would
16 be required for the proposed plan and that information
17 was still being collected.

18 "I am therefore not in a position to assure you
19 yet of any increased supply from this region.

20 "The new Transfusion Centre building should
21 become available later this year, thus resolving one
22 constraint upon us. The proposal being considered
23 comprises a small increase in routine blood donations,
24 use of SAG-M for a proportion of donations and the
25 shortfall being made up by plasmapheresis.

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1 third letter I wanted to ask you to look at briefly,
2 it's TYWE0000051_004. It's almost illegible but I'm
3 going to read it out. It's Dr Collins to Dr --

4 A. Dr Jobling.

5 Q. -- Jobling, a pathologist --

6 A. Jobling.

7 Q. -- at the Preston Hospital, and it's December,
8 9 December 1985, I think.

9 A. Yes.

10 Q. She says:

11 "I must point out that the Regional Health
12 Authority does not fund this service to be
13 self-sufficient in plasma products."

14 Then she says:

15 "However -- there has been recently a shortfall
16 in supplies of processed material from BPL, and we
17 will now be able to let you have a small additional
18 number of units, as they are correcting this."

19 So again, I think it's fairly obvious what
20 Dr Collins is saying in the first main paragraph
21 there: insufficient funding for self-sufficiency.

22 A. Yes.

23 Q. So those letters really then lead, I think, to some
24 observations you make in your witness statement,
25 Dr Lloyd. So if we could have on screen, please,

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1 Sully WITN6935001, and we go to page 39. So
 2 paragraph 29 says "Barriers to achieving plasma
 3 targets", and you identify three points there:
 4 "Prior to 1985 -- limited and outdated
 5 facilities", which you've already told us about in the
 6 course of your evidence.
 7 **A.** Yes, yes.
 8 **Q.** Then "The Centre's belief that a large proportion of
 9 whole blood was required by the hospitals it
 10 supplied", is the second bullet point.
 11 **A.** Mm-hm.
 12 **Q.** Does that take us back to the issue you referred to
 13 earlier about the very substantial proportion of blood
 14 or -- or products being supplied in the form of whole
 15 blood rather than, for example, the use of the red
 16 cells and SAG-M?
 17 **A.** Yes, yes. I mean, when I started -- as I'm just
 18 reiterating what I said before -- the Centre seemed to
 19 think, at least its laboratory staff at that time --
 20 not later, but at that time -- seemed to believe that
 21 what the hospitals needed was whole blood and that's
 22 what we were going to give them. And the -- we didn't
 23 fractionate -- sorry, not factor -- we didn't separate
 24 a lot of the whole blood into components as we should
 25 have done and, of course, you couldn't put it into an

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1 with a Northern Region receiving less by way of BPL
 2 factor concentrates; is that right?
 3 **A.** Yes. Yes, I mean, you're talking about a close
 4 to 50 per cent reduction in products sent back to the
 5 Northern Region from whatever BPL was producing at the
 6 time. And the Northern Region hadn't done anything
 7 other than stood still. The rest of the world had
 8 moved on.
 9 **Q.** And then, if we turn to WITN6935003, we have, I think,
 10 now, information about the same thing, in the sense
 11 it's plasma dispatched to BPL. This is purely
 12 relating to the Northern Region. And it's now for the
 13 period from the '85/'86 to '93/'94, and we can see
 14 a very significant increase in the amount of plasma
 15 being dispatched to BPL over that period.
 16 **A.** Yes.
 17 **Q.** We'll look at a handful of further documents,
 18 Dr Lloyd, but essentially, how was that achieved, that
 19 increase?
 20 **A.** Okay. My -- if I may start with what I was thinking
 21 at the beginning of that period, perhaps just before
 22 I became director, which was that probably the only
 23 way to get a major change in plasma production was to
 24 go full force into plasmapheresis, as the way some
 25 other centres had done -- Leeds has been mentioned

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1 optimal additive because we didn't have the bags and
 2 the money to, you know, buy them.
 3 So that's definitely what I was talking about
 4 and that's what I'm talking about here.

5 **Q.** Then the third bullet point, "Prior to 1988 the RHA's
 6 approach to funding plasma collection", and that's
 7 really the point that emerges from the correspondence
 8 we've just looked at; is that right?

9 **A.** Yes, yes. Yes.

10 **Q.** Can we then just look at some of the graphs that
 11 you've exhibited to your statement. If we start with
 12 WITN6935013, so this is the supply of fresh frozen
 13 plasma from the Northern Region to BPL, 1981 to 1985.
 14 Can you just -- well, I think this is probably one of
 15 the pieces of information you were referring to
 16 earlier.

17 **A.** Yes, it is.

18 **Q.** The amount in terms of volume supplied remains
 19 relatively static during that period. There are
 20 increases and decreases year in, year out --

21 **A.** Yes.

22 **Q.** -- but there's not a huge difference. But the
 23 percentage, in terms of the percentage contributed by
 24 all centres, we can see significantly reduces over
 25 that period, which results, under the *pro rata* system,

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1 before. But once I got into the job, you know,
 2 I realised that we had a terrific opportunity to
 3 separate a lot more blood, and instead of sending out
 4 whole blood, we would produce products where we were
 5 able to salvage the -- remove the plasma for this
 6 purpose and send the hospitals either concentrated red
 7 cells or we'd reduce that, or we sent them something
 8 in an optimal additive. So we did change our view.

9 We ran a small plasmapheresis operation within
 10 the Centre. We were able to do that with very little
 11 extra cost because we had the facility. We still
 12 had -- we had the machines there, and ... you know, it
 13 needed a bit of staffing and organisation. And that
 14 produced about 4 tonnes of plasma per year throughout
 15 this period.

16 So the bulk of this change is just by changing
 17 the amount of blood that is processed and how we
 18 processed it. So one of the things we did was we
 19 organised meetings with the haematologists and their
 20 senior blood bank staff from across the region, and
 21 they all came to the Centre for a day, and we were
 22 able to present information showing them how much
 23 whole blood they were using and how that compared to
 24 the rest of the country, how much whole blood was
 25 being returned unused, and we initiated a discussion

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with them. And I have to say they were extremely cooperative. I mean, you know, the haematologists across the region understood that whole blood is not a good product to use, you know, generally. A few specific cases, maybe ...[frozen screen]... concentrated red cell products, and using plasma products and so on as needed was something they recognised. And they were able to change and deal with their staff and surgeons, anaesthetists and so on at the hospitals, and allow this change to happen. And I think we did it in two stages. We sort of set a target and then we went to a second stage after a further meeting and said, "Well, can we reduce this further?" And they said yes, of course. And by the end of that period, whole blood was a rare beast. I mean, less -- well under 1 per cent of our output was whole blood.

So most of this was done by working with the hospitals, with people who understood, you know, transfusion and blood banking.

And we also changed our manufacturing techniques to allow us to produce more plasma per pack. We became probably the biggest user of an automated or semi-automated system for separating blood, the Optipress system from Baxter Corporation, which

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moved to the new centre, we were at the top of the league table of producing whole blood. So other centres were able to reduce it, reduce the use of whole blood, so there's no reason why we shouldn't.

I would say that I think, and I don't have terrific information, the Northern Region probably had fewer haematologists in post, particularly outside the -- you know, a couple of the bigger centres, which would have made it more difficult to do. You know, you need a good haematologist, with good transfusion knowledge, who can talk as an equal to the surgeons and the anaesthetists about this. So yes, we could have started -- it could have been started earlier. It would not have been as easy for me to do at this time with so many haematologists in post.

Q. You told us a few moments ago that when you started out as director, at the forefront of your thinking had been using plasmapheresis more. I'm not going to go to the document because you've explained what happened in relation to that, but for the transcript there was a report which you produced in around I think 1988, which is at NHBT0001580, which had a proposal at that time for increasing plasmapheresis.

If we just go, however, to the graph --

A. Correct, yes.

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allowed us to eke out, you know, that extra 10, 20ml of plasma from a lot of the products we produced, at the same time as improving the quality of the product. So it was a multifaceted change, but it was done with very little in the way of capital investment.

Q. If we look at one further graph on this topic, WITN6935002.

This is, I think, a visual depiction of what you've just told us. So percentage of red cells issued as whole blood --

A. Correct.

Q. -- for the period '85/'86 to '93/'94, and we can see its decline too, as you just indicated, and there being a tiny proportion, if any, being issued by the time we get to '93/'94.

A. Mm.

Q. Is there any reason why this could not have been done significantly earlier than it was?

A. Oh, it could certainly have been done earlier. I mean as I said, when I -- just before I started as director, my views were different. I didn't really appreciate the extent of what we could do. It did take a year before I -- well, before I really got into it. So yes, it could have been done. Of course it could have been done. Newcastle was -- even before we

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Q. -- which you produced relating to plasmapheresis donations, which is WITN6935012.

We can see from this an increase in plasmapheresis donations again over the period 85/86 to 93/94. So would it be right to understand although this wasn't the central plank of your strategy for increasing the supply of plasma, nonetheless you were able to achieve a significant increase in plasmapheresis collection?

A. Yes, yes. We got us a small plasmapheresis unit, got some great staff together to run it, and got it up quite quickly to producing the 4 tonnes, and we sort of left it at that, because we seemed to be able to produce plasma from other sources. And plasmapheresis plasma is more expensive. The physical location within the Transfusion Centre had originally been designed as a location for blood donor sessions, so we -- with a very small pheresis section at the far end of it, with room for two machines, I think -- I think that was in the original plans drawn up by Faulkner Browns. So we did a bit of a remake, turned it over to plasmapheresis, and then somewhere in the middle of that, with a lot of help from the staff running that unit, we remodelled it to increase its efficiency, using some ideas that they came up with.

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1 Q. And I think we can get a snapshot of the
2 plasmapheresis facilities at NHBT0003365. This is
3 a short note from Dr Gunson, 14 August 1989, "Notes on
4 Visit to Northern RTC".
5 He discusses issues relating to the plasma
6 targets and the core records in the past of the first
7 section.
8 And then section 2, "Plasmapheresis", we can
9 see:
10 "2.1 Plasmapheresis centre in RTC.
11 "2.2 Eight machines in operation."
12 He gives then details of the staffing.
13 And then 2.4:
14 "Currently there are 1000 donors on the panel
15 which have been recruited in the last six months."
16 Prior to the new centre being opened in 1985,
17 would plasmapheresis have been possible in the old
18 Regional Transfusion Centre?
19 A. I don't think so. I mean that facility was crammed,
20 physically not set up for this. I'm trying to
21 think -- I'm trying to reimagine the building. I
22 really cannot think of anywhere in that building where
23 you could have set up plasmapheresis. You know, you
24 might have built another shed, another hut, in the
25 grounds and used it as a plasmapheresis centre but not

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1 particularly for planned surgery. So we were
2 fortunate in being able to offer it. It was a small
3 operation. But I was very concerned that if
4 autologous transfusion was carried out locally with
5 poor control, you had the risk of blood going to the
6 wrong person or not being stored properly, not being
7 labelled properly, and that would negate the benefit
8 that autologous transfusion was bringing to you.
9 So we did offer it. It didn't have a great
10 uptake. I think it's -- at the end of the contract
11 there's a list of hospitals who that used it in the
12 previous year and I can't remember if it's six in this
13 document or nine. But, you know, it's a small number
14 and a small number of units. But it was an option for
15 people, and, you know, once you've realised --
16 particularly once you start thinking beyond HIV, then
17 autologous certainly makes more sense. If you only
18 think of HIV, then, because of the very low incidence
19 in the Northern Region, it was hard to make a case for
20 it. But certainly with non-A, non-B, and then hep C,
21 the balance does, I think, change.
22 Q. We can take that down, thank you, Sully.
23 A. We should have done more earlier.
24 Q. That leads neatly to my next question for you, which
25 was about your understanding of hepatitis. Before we

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1 in the existing structures. I don't think so.
2 Q. Then if we look at WITN6935024.
3 Now this is just on the topic of
4 autologous transfusion. I don't think we need to look
5 at anything other than the first paragraph, which
6 explains that there's a:
7 "... pre-deposit Autologous Transfusion service
8 for hospitals within the Northern Region. This
9 service is provided on request and aims to ensure that
10 any patient due for planned surgery and for whom there
11 is a likelihood that blood will be required will be
12 able to benefit from [it] ..."
13 Was there the potential for any wider use of
14 this, as a method of collection?
15 A. Yeah, autologous is an interesting topic. I think --
16 and there is some documentation earlier than this date
17 where I actually sort of say I don't think it's really
18 a very good idea -- or not that it isn't a good idea,
19 but it probably isn't necessary from a safety point of
20 view. Perhaps by this time I was -- I'd got to
21 a point where, "Mm, perhaps I shouldn't be quite so
22 sure of myself."
23 And there were patients and their physicians --
24 sorry, their doctors, who really felt that they wanted
25 their patients to have autologous transfusion for --

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1 look specifically at non-A, non-B hepatitis, if you
2 can go back to your training years in the 1970s,
3 Dr Lloyd, what can you recall being taught about the
4 risks associated with blood and blood transfusion, in
5 particular the risks of viral transmission?
6 A. I trained at the Royal Free Hospital which was the
7 centre of liver disease treatment and investigation.
8 So we knew a little bit about it. I was, I think,
9 aware that there was a problem with patients
10 undergoing cardiac surgery. There was a big cardiac
11 surgery unit in the south of England, in Hertfordshire
12 perhaps? I can't remember now.
13 So we were aware of a problem but at what point
14 between -- you know, during my training I became aware
15 of that, I'm not sure. It sort of sits somewhere
16 back -- at the back of my mind that there was this
17 issue. So yes, there was -- I had some understanding
18 and then, obviously, as I went through my --
19 particularly my senior registrar training, where I had
20 to read extensively on transfusion issues, it became
21 much more apparent.
22 Q. We heard evidence a few weeks ago from
23 Professor Marcela Contreras and she told us of writing
24 on chalkboards in the classrooms of medical students
25 the words to the effect "Blood can kill", and

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1 obviously there may be a range of reasons why that
2 might be the case not limited to, but including, viral
3 transmission.

4 A. Mm-hm. Okay.

5 Q. Was that sense of needing to be aware of the dangers
6 of the use of blood and blood products very much part
7 of the thinking at the Northern Regional Transfusion
8 Centre in the '80s or was it not?

9 A. Ooh, I'm trying to think what it was like before I was
10 director, when I was just around as registrar.
11 I don't think -- it wasn't a terrific sort of --
12 I don't sort of see that message up on the chalkboard:
13 it's dangerous. Certainly, it was being used
14 relatively freely, and we were still seeing units
15 being given -- you know, single unit transfusions, and
16 the like. So I don't think there was quite as strong
17 an emphasis as Dr Contreras showed where she was
18 teaching students. So perhaps not as significant, no.

19 Q. Then non-A, non-B hepatitis, can you recall, as it
20 were, the evolution of your understanding of non-A,
21 non-B hepatitis, both in terms of its incidence as
22 a risk of transfusion, and as to its seriousness?

23 A. Taking the risk of non-A, non-B, a lot of what I knew
24 in the earlier days was material that came from the
25 States, and certainly was aware that there were a lot

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1 there was a link. It was statistically significant.
2 I don't recall seeing that sort of information
3 coming out in the UK. We had some studies but they
4 were underpowered. They weren't powered to give us
5 the real knowledge we needed. And they didn't make
6 that firm link with patients who were getting
7 hepatitis. So my knowledge of it, sort of, developed,
8 I think, relatively slowly, and so I got to a point
9 where I -- and I put it in my witness statement -- you
10 know, should we have been doing ALT testing, for
11 instance? Yes, I think we should have been. Was
12 I standing up there shouting from the rooftops, saying
13 should we do it? No, I wasn't, and probably should
14 have done more. But, yes, it took the UK -- for some
15 reason, the UK seemed to have this attitude that this
16 was not a serious disease, and we didn't need to do
17 much about it.

18 We've seen documents, articles, which seemed to
19 imply that it's not a cost effective thing to do.

20 There's a lot of information about, oh well, we're
21 going to lose too many donors. Well, heck, that's the
22 transfusion centre's job, is to replace the donors
23 with safe donors. That was what we should do and, you
24 know, if we lose 1,000 donors we can replace them.
25 You take the Northern Region, we lost thousands and

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1 of differences in the way that, you know, donations
2 were collected in the States, the separation between
3 the voluntary side, under the umbrella of the ABB, and
4 the commercial side. So you got a sense that maybe
5 we're not in as bad a position as they are. And of
6 course, we probably weren't, but it wasn't -- it
7 wasn't a panacea. We weren't wonderful, by a long
8 way.

9 And so you saw that. It then gradually, you
10 know -- there wasn't a -- one of the documents that
11 has been presented to me was a journal article which
12 studies non-A, non-B in the States, I think, in --
13 certainly in two areas: Texas and New York, I'm not
14 sure.

15 Anyway, it's an article that you presented.
16 And, you know, you read that article and you see
17 people have taken care to develop a study over a long
18 period of time, they've got good information, they've
19 used an independent panel to assess the recipients of
20 blood to see if they had hepatitis and whether it was
21 significant, and they were able to test large numbers
22 of donations that went to these patients, and they
23 used some fairly sound statistical analyses which
24 showed that there were, you know, the link between the
25 blood and the hepatitis and the patients, you know,

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1 thousands of wonderful donors because the factories,
2 the shipyards, the steelworks, closed down. We lost
3 those donors, but we made them up. We made up more
4 numbers from those losses than we would have had to
5 have made up from starting the ALT testing. You know,
6 we should have been there.

7 As to its severity, I didn't do a lot of work
8 clinically to actually see it, and obviously you'll
9 read it, but I was very surprised by Dr Gunson's
10 comment around the time of HCV introduction saying
11 that non-A, non-B or hepatitis C, this hepatitis was
12 not a significant disease. I mean that really
13 surprised me, even then.

14 Q. I'll pick up on some of those issues again tomorrow,
15 Dr Lloyd, when we look in more detail at the
16 introduction of hepatitis C testing.

17 Hepatitis B. Now, obviously testing for
18 hepatitis B had been in operation long before you
19 joined the Centre. Can I just ask you couple of
20 questions about --

21 A. No, sorry. Sorry, can I -- can you --

22 Q. Yes?

23 A. Sorry, can you clarify that? You said hepatitis C
24 testing.

25 Q. B, hepatitis B.

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1 A. Oh B, oh yes.
 2 Q. I'm moving to hepatitis B, my apologies. So I just
 3 want to ask you a couple of questions in relation to
 4 hepatitis B testing. If we go to NHBT0072680. This
 5 is a letter you wrote in May 1992 to Dr Castervan at
 6 the Freeman Hospital, and it looks like you've been
 7 asked a question about --
 8 A. Can I just point out, sorry. Please note that that is
 9 not his correct name, that is an error on that letter,
 10 it is Dr Kesteven with a K. But anyway, thank you
 11 Patrick Kesteven, yes, I do recall this.
 12 Q. Thank you. Yes, so you'd obviously been asked
 13 a question about the position in 1974?
 14 A. Mm-hm.
 15 Q. You say:
 16 "According to our records for the whole of 1974
 17 we were still testing for Hepatitis B antigen using an
 18 electrophoretic method."
 19 And then you explain it was definitely less
 20 sensitive than the assay brought in in 1975, probably
 21 missing as much as 20 per cent of the hepatitis B
 22 positivity in the donor population.
 23 Can you recall what had prompted that enquiry?
 24 It looks as though it may have been a case of someone,
 25 a recipient, getting hepatitis B.

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1 may have preferred commercially produced Factor VIII
 2 were ..."
 3 Then we've seen two of the points already
 4 discussed, the reactions --
 5 A. Yes.
 6 Q. -- and solubility.
 7 Then over the page, (c) is about the
 8 characteristics of the commercial product, (d) about
 9 purity. It was (e) I wanted to ask you about. You
 10 say:
 11 "Dr Jones may have considered that the methods
 12 of testing for the presence of the Hepatitis B virus
 13 were better in the United States."
 14 A. Yeah.
 15 Q. Now do you know where that thought came from? Was
 16 that your own thought you were attributing to Dr Jones
 17 or was that your understanding of his actual thinking?
 18 A. I mean, I say there "may have considered", so I can --
 19 I don't recall Dr Jones ever saying that to me. But
 20 what was my reason for saying that? It was
 21 probably -- and I only say probably -- from discussion
 22 with Dr Collins about this. But I don't have any --
 23 I don't think I had anything really firm that I
 24 could -- now that I could say that's why I said that.
 25 And I don't think I can really, you know, say much

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1 A. Yes, I -- no, I've read this letter. I can't remember
 2 what the -- you know, what letter was sent, you know,
 3 came through or question was sent to me about this.
 4 I mean, you look at that, and say maybe Patrick was
 5 being asked to, you know, make a witness statement
 6 for, you know, for litigation. But it goes back, you
 7 know, obviously a lot of years. But no, I don't
 8 recall. I'm sorry.
 9 Q. When you first started work at the Centre in 1980, do
 10 you recall what form of hepatitis B testing was then
 11 in use?
 12 A. No, I don't. I couldn't tell you what the technology
 13 was. I mean I did go into that lab and see it being
 14 done but I can't remember the exact test that was
 15 ...[frozen screen]...
 16 Q. Then if we could look at TYWE0000067, please.
 17 This is another letter to Crutes Solicitors, and
 18 it refers to you having returned a witness statement,
 19 which, if we go to page 3, we can see the statement.
 20 For present purposes I just wanted to pick up on
 21 something you say on page 7, but if we start at the
 22 bottom of page 6, you -- and this was about Dr Jones
 23 again and his choice of commercial produced
 24 Factor VIII. So you've said:
 25 "As I understand it, the reasons why Dr Jones

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1 more on that point.
 2 Q. And do you recall whether -- at any point in the 1980s
 3 or first half of the 1990s when you were at the
 4 Centre, do you recall any cases of
 5 transfusion-transmitted hepatitis B being drawn to
 6 your attention?
 7 A. I don't remember any. And I know we have two areas
 8 there. One is patients who received blood and regular
 9 blood products, and I don't recall having to do any
 10 hepatitis B, you know, look-backs. I might be wrong.
 11 And probably the cases of hepatitis B in the
 12 haemophiliac population, one suspects that, you know,
 13 that was more an issue with the fractionators rather
 14 than the Centre. And obviously the Centre produced
 15 the plasma but the fractionators converted it into the
 16 finished Factor VIII, Factor IX.
 17 So I would imagine that the haemophilia
 18 population who developed hepatitis B, that information
 19 would have been sort of fed back to the -- to, say,
 20 BPL or, if they received commercial product, to the
 21 commercial people, manufacturers, and so you may have
 22 seen a difference in hepatitis B rates between the two
 23 groups. But I wasn't a -- certainly not party to that
 24 information.
 25 Q. Then in terms of transfusion-associated hepatitis more

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1 generally, so leaving aside whether it's hepatitis B
2 or non-A, non-B hepatitis, was there a system for such
3 infections being notified to the Centre or did it just
4 very much depend upon whether a clinician who had
5 a patient who might have a case of
6 transfusion-associated hepatitis, whether they
7 happened to tell you?

8 **A.** Yeah, I don't think there was any sort of proper
9 set-up -- a sort of -- there wasn't like a sort of
10 a document that said, you know, "You will inform us".
11 So I suspect that it would have been very *ad hoc*.

12 And it's quite possible that, you know, they
13 just -- if it was a non-A, non-B hepatitis, then,
14 well, you know, there's was no point in telling the
15 Centre because they're not testing for it. And, you
16 know, it is something that could have been done but
17 no, we didn't do it. But there was certainly non-A,
18 non-B hepatitis around, and you saw that in one of the
19 documents that was presented which references an
20 article by another Dr Collins, at the Freeman
21 Hospital, Dr Collins and James and a couple of others,
22 who actually followed up a number of cardiac surgery
23 patients who developed hepatitis.

24 So it was around, and I don't recall that
25 information sort of flowing back into the Centre.

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1 **THE WITNESS:** I don't know if the technical people can
2 assist for a moment.

3 **MS RICHARDS:** We'll try and get that resolved if we break
4 for five minutes.

5 **SIR BRIAN LANGSTAFF:** Okay, break.

6 (4.20 pm)

7 (A short break)

8 (4.28 pm)

9 **MS RICHARDS:** Dr Lloyd, can you hear me now?

10 **A.** I can hear you clearly, sorry for the interruptions.

11 **Q.** Thank you. I'm going to ask you next about the
12 arrangements for donor sessions and then look at
13 questions relating to donor selection.

14 You tell us in your statement that, in broad
15 terms, the sessions historically could be divided into
16 the general public sessions and industrial sessions;
17 is that right?

18 **A.** Yes, correct.

19 **Q.** The general public sessions would take place in
20 village halls and community centres and the like; is
21 that correct?

22 **A.** That was the usual arrangement, yes.

23 **Q.** Prior to the new centre opening in 1985, were blood
24 donor sessions ever held in the old centre?

25 **A.** I don't think so. I don't think there was a facility,

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1 **Q.** And if cases of hepatitis or transfusion-associated
2 hepatitis were reported to the Centre, was there
3 anybody or organisation to whom the Centre then had
4 a reporting obligation, as far as you can recall?

5 **A.** Not that I recall. No.

6 **MS RICHARDS:** Sir, I'm going to move now to a different
7 topic of -- in relation to the donor selection, and
8 donor arrangements. So I wonder whether if we take
9 our second break now, and then I can pick that up
10 after the break.

11 **SIR BRIAN LANGSTAFF:** Well, let's do that shall we and
12 come back at 4.20. So 4.20, if you please.

13 (3.59 pm)

14 (A short break)

15 (4.19 pm)

16 **MS RICHARDS:** Dr Lloyd, I'm going to ask you a little bit
17 now about the arrangements at donor sessions. You
18 tell us in your statement that the donor sessions --

19 **A.** Sorry, I don't have sound at the moment. I don't have
20 sound at the moment -- should be all right --

21 **Q.** -- can you hear me now?

22 **A.** -- but I can't hear anything.

23 **MS RICHARDS:** Hmm, sir, shall we break for a couple of
24 minutes.

25 **SIR BRIAN LANGSTAFF:** Let's do that.

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1 a room in the old Centre that would take it but, no,
2 I don't recall it.

3 **Q.** Then once you had the new Centre, is it right that
4 there were some blood donor sessions that together
5 place in the new Centre but it wasn't a major part of
6 the Centre's use?

7 **A.** No, it wasn't. The drawing has been shown as a donor
8 facility, a donor room was given over to
9 plasmapheresis, so we allowed -- I say allowed -- we
10 accepted occasional walk-in donors who just thought:
11 well, here's the Transfusion Centre, I'll donate
12 blood. We would take their donations in the
13 plasmapheresis unit.

14 But we did hold some, sort of, full-blown
15 sessions by clearing out the dining room and using
16 that as a site, and we'd bring up a set of beds that
17 would normally be used on a mobile session and we'd
18 set up almost as though it was a mobile facility that
19 happens to be in our building.

20 **Q.** In terms of the geographical reach of the donor
21 sessions, is it right that the sessions took place all
22 over the area but there were fewer sessions in Cumbria
23 because of, I think, transport and road links?

24 **A.** Yes, yes. The road link from Newcastle into the
25 Cumbria area, even to Carlisle, remained sort of --

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1 a city in that area -- was one road, the A69, and
 2 a big stretch of it was not even divided. It was just
 3 single track in each direction. And we ended up --
 4 the arrangement was that the team would go out on one
 5 day and then they'd be put up in a hotel, and then
 6 they would run the session the next day and perhaps
 7 stay overnight another night, do another session, and
 8 then come back. So it was complicated. It was time
 9 consuming. It was expensive. So the Cumbria area was
 10 underserved.

11 Q. You told us in your addendum statement that there was
 12 a satellite office in Middlesbrough, known as the
 13 Teesside office. Did the donor sessions in that area
 14 take place at the Teesside office or was it a question
 15 of mobile questions going out from the Teesside
 16 office?

17 A. No, it was mobile sessions. The sessions essentially
 18 organised the same as the rest of the area, except
 19 that the Teesside office did two things: one, it
 20 looked after the donors in that area, parts of North
 21 Yorkshire, Durham and surrounding areas around
 22 Teesside, Stockton -- anyway; and they also managed,
 23 as I mentioned, the voluntary team of donor attendants
 24 from the British Red Cross and the St John Ambulance
 25 Brigade, somewhat unusual, but interesting.

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1 a lot of walk-in donors that we hadn't invited turning
 2 up. So it's interesting what you find out when you
 3 start getting the information. But, yes, public
 4 sessions were by invitation.

5 Industrial sessions were mainly the individual
 6 companies organised, you know, who would come at what
 7 time, and so we didn't actually send them out
 8 individual letters, and you'll see that factor comes
 9 into play when there was the -- when AIDS leaflets
 10 were to be sent and distributed.

11 Q. Then, if I can just ask you to look at one document
 12 from 1988, NHBT0059596_001. So this is a meeting,
 13 12 January 1988 at which you were present and this is
 14 from the point in time at which you were a consultant
 15 haematologist at the centre but not the director.

16 If we just go to page 5 and pick it up under
 17 "Any Other Business", the second paragraph refers to
 18 you presenting the donor panel statistics for 1987.
 19 You note there'd been a continued fall in the intake
 20 of blood and the number of new donors attending had
 21 fallen still further. Relative decline in the value
 22 of the publicity budget was also noted. Then there's
 23 a further discussion about rejection of donors.

24 Then if we go to the next paragraph, it says:
 25 "Dr Lloyd pointed out that for the recruitment

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1 Q. Then you told us in your main statement that you
 2 thought there was an area just north of the Scottish
 3 border which was supplied by the Regional Transfusion
 4 Centre and you didn't recall any blood donor sessions
 5 being held there but, in your addendum statement,
 6 I think your recollection now is that you didn't
 7 supply that hospital but you did hold donor sessions
 8 in that area; is that right?

9 A. Yeah, I mean that's -- boy, I'm sorry, that's really
 10 rusty. I think we did hold a session, perhaps in
 11 Gretna. I really can't remember. It's so minor, it's
 12 a very, very minor issue. You know, we also crossed
 13 into the Yorkshire Region's area and supplied
 14 a hospital. These are, in the big picture, very
 15 minor.

16 Q. Then, in terms of the general public sessions, were
 17 they based upon donors being called up from the panel
 18 or were they drop-in sessions or was it a mixture of
 19 both?

20 A. We called people to the general public sessions so
 21 they were invited by letter. And so, you know, we had
 22 statistics that showed, you know, how many people we
 23 invited, and how many turned up. We're very proud of
 24 our statistics until we introduced a new computer
 25 system and found out that, actually, there were quite

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1 of new donors we needed additional funding and this
 2 had been requested in the short-term programme for
 3 1988/89. He also felt that if any savings were to be
 4 obtained from reorganisation within BTS then
 5 a significant part of these resources should be
 6 applied to the donor sessions to make them more
 7 attractive. Some discussions followed on ways of
 8 improving the appearance of donor sessions. It was
 9 generally felt that the use of rather dingy church
 10 halls left us with an image that was very similar to
 11 that seen in the 1950s. It was clear however there
 12 was no easy answer to this problem as good quality
 13 accommodation was extremely limited."

14 Then there's a later document, I won't go to it,
 15 but there's an article from 1989 which quotes you
 16 talking about difficulties in attracting donors given
 17 the lack of standards.

18 Do you recall what was -- whether you were able
 19 to do anything about the issue here of not being
 20 attract donors because of -- well, described here as
 21 "rather dingy church halls" and not being attractive
 22 accommodation or "good quality accommodation" to hold
 23 the donor sessions in?

24 A. I mean, we did make some changes in our donor services
 25 department, and tried to focus, get some people in to

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focus on different types of sessions, so that they had more chance of trying to get better accommodation. It was certainly difficult. You know, we were competing with other organisations. If you have an organisation that wishes to use a nice community centre and they're going to use it once a week, then we want to come in on one of their days but only twice a year or four times a year, it -- you know, it's a difficult issue.

So you can't -- it's hard to get better accommodation. It certainly was. Once you have the accommodation available to you, then you can perhaps start trying to make the session run more effectively. But that's obviously another issue.

Q. Do you know what consideration was given when the general public sessions were being held to creating opportunities for privacy, so that donors could speak in confidence perhaps to the medical officer, especially if they're being asked questions about high-risk activities?

A. No, it wasn't good. I think we used to use an area -- we had a screened area in our sessions, which wasn't sort of wonderful, but you could take the donor out of the main area and into this -- an area with screens around. I think it was sometimes used for someone who wasn't feeling very well, as a recovery. And there

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if the numbers dwindle we're not going to sort of say, "Hey, you must, must, must get more people!" But, yeah, it's a valid concern, I agree.

Q. Do you know whether, in the workplace sessions, again, whether there were opportunities for donors to be able to speak confidentially, again in the context of discussions about high-risk activities in particular, it may be particularly problematic for a donor if their colleagues are within earshot, to be candid in response to questions asked.

A. You had the same physical set-up with the screened area so that's sort of really as good as it got.

How close other donors would have been to that would perhaps vary from session to session. You know, in some of the shipyard sessions, you could have difficulty talking to people, they were so far away. You know, a great big hall ...[frozen screen]... where the accommodation is certainly tighter. So -- but the screened area, you know, was available. Not perfect, certainly.

Q. Then I'm just going to ask you to look at couple of the graphs you've exhibited to your statement on the donor numbers. If we start with WITN6935008, please.

Oh no, sorry, my fault, Sully. I've given you the wrong reference. WITN6935006, I meant to start

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was also a screened-off area where they did some work on the bags after collection. So donors could be taken out of the main area. Certainly not perfect but they weren't being -- when you got away from the initial questioning to go into something more detailed, there was an opportunity to go to a slightly more private area.

Q. In terms of the workplace or industrial sessions on which you've already told us the region was very heavily reliant, was any consideration given to concerns that a workplace donor might not be a truly voluntary donor because they may feel pressured to give blood if their employers had arranged a session?

A. Yes, I mean that's a valid concern. I don't recall that we did anything to try to alter that. The donors in workplace sessions, I don't know how much in the -- they were put under pressure. It's hard to tell. You know, perhaps some confidential surveys might have been a good idea. But, yeah, there's always a risk in any group, whether it's a family, you know, members of the family or extended family donating, pressures there. Pressures of work, certainly possible.

We never tried to pressure the workplace to, sort of, push people into donating. It was very much, you know, you'd bring as many people as you can, but

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with, sorry.

So this gives an overall picture of donor numbers from 1947 to 1994 in the region and we can see, obviously, a significant increase overall, but it looks like it remained relatively stable from really the 1970s onwards, some increase when we get on to 1993, with a drop in '87 and, I think, '88 in particular.

A. Yeah.

Q. Do you have any recollection as to what caused that particular drop?

A. Yes, I think there's another chart I've produced which shows employment rates. If you knew the north east at that time, the number of shipyards closing down, you know, steelworks closing down, steel fabricators, it was a very difficult time. We lost -- yeah, we lost a lot of people. And it's very hard, if you lose your job, to bring yourself to come back and donate and do something voluntary would be hard.

Q. Then I won't go to the charts but there are two charts which look at registered donors and industrial donors and then the employment rates, and for the transcript they're WITN6935008 and WITN6935009.

Can I then ask you little about the process for donor screening. I'm going to start by asking you to

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1 look at a national document, CBLA0002307, please.
 2 Oh, no, that's not the document I had in mind at
 3 all.
 4 A. Probably not.
 5 Q. Okay, let's try a different version. DHSC0046337.
 6 Okay, so this is the 1985 version of the
 7 "National Blood Transfusion Service Guidance for the
 8 Selection, Medical Examination and Care of Blood
 9 Donors", and if we go over the page, we can see there
 10 it starts with a section on the "Selection of Donors".
 11 Now, Dr Lloyd, we've got a version from 1977,
 12 a version from 1984. This one is 1985.
 13 A. Yes.
 14 Q. We've got later versions from '87 and 1990. Until you
 15 introduced your own selection booklet, was this
 16 the guidance that was used, do you think, some form
 17 of -- one of the --
 18 A. Oh yes, yeah.
 19 Q. -- versions of this?
 20 A. I mean, this document is very familiar to me. I mean,
 21 you could pull up several from different years and
 22 they don't change a lot, but this was the base for the
 23 selection of donors that we used. I mean, we didn't
 24 deviate particularly from this, it's just that we
 25 tried to make something that was easier for our staff

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1 Q. Yes, if we go then to the bottom of page 6 because
 2 you'll see it says, "See note ix", and then --
 3 A. Okay.
 4 Q. -- note ix is at the bottom of page 6:
 5 "Transfusion of blood or blood products received
 6 in the last six months."
 7 Then it says:
 8 "6 months minimum depending on nature of disease
 9 or injury."
 10 A. Yeah.
 11 Q. In any event, if we then go back to page 4, please,
 12 I just want to pick up a couple of other conditions or
 13 situations.
 14 So the third item down here is "Drug abuse ...
 15 Disqualify." Can you recall what procedures were to
 16 try to assess whether somebody fell into that
 17 category? Were there specific questions that were
 18 asked or was it very much dependent upon that
 19 information being volunteered?
 20 A. I don't think people are going to volunteer to answer
 21 and say, "Do you abuse drugs?" Looking back on this,
 22 you think that perhaps the wording being used was not
 23 really appropriate.
 24 "Am I drug abuser? Oh no, but I did use drugs
 25 once. You know, I did inject myself at that party."

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1 to use so that they could be more effective in
 2 selecting donors.
 3 Q. And if we go to the next page, please, this sets out
 4 the questions that the donor session clerk should ask
 5 about medical history. And then we've got a number of
 6 conditions listed. We can see AIDS would lead to
 7 disqualification.
 8 Blood transfusion in last six months is referred
 9 to the medical officer. Can you recall what the
 10 practice was in the Northern Region if there was
 11 someone with a blood transfusion in the last six
 12 months?
 13 A. Well, they would be deferred, as far as I can recall.
 14 For some reason I thought it was longer than six
 15 months, but yes, we deferred blood donation within the
 16 last six months. I see there in that document it
 17 says, "Blood donation within 4 months",
 18 "Action: Wait", which is don't take. In six months,
 19 presumably meaning between four and six months, "Refer
 20 to MO".
 21 I'm not sure why there was that distinction
 22 between four and six months. I'm not sure what the
 23 logic behind that was. But this is the sort of
 24 document we would have used, and so we would have
 25 followed, you know, that instruction, "Refer to MO".

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1 Is that person a drug abuser? Do they consider
 2 themselves to be a drug abuser? So I think, you know,
 3 our wording is not that -- was not very good. I think
 4 it changed later. But as to weeding out who might be
 5 at risk, I don't think we -- we probably didn't do
 6 a great job at it.
 7 Q. Then if we look further down the page, we've got:
 8 "Hepatitis ... Refer to MO ... See appendix 1"
 9 And we see the same at the top of the next page,
 10 it says, "Jaundice ... Refer to MO ... See appendix
 11 1".
 12 If we just go to appendix 1, page 12, please.
 13 So we can see it's the fifth paragraph down, headed
 14 "Hepatitis".
 15 A. Yes.
 16 Q. "Individuals who give a history of jaundice or
 17 hepatitis or in whose blood anti-HBs is present may be
 18 accepted as donors providing they have not suffered
 19 from jaundice or hepatitis in the previous
 20 twelve months, have not been in close contact with
 21 hepatitis or received a blood transfusion of blood or
 22 blood products in the previous six months ..."
 23 As far as you can recall was that the practice
 24 at the Northern Region, that someone with a history of
 25 jaundice or hepatitis could donate if it was more than

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1 12 months ago? And subject obviously to the HBsAG --
 2 A. I mean, at that time, you know -- at that time I don't
 3 recall that we would have done anything other than
 4 follow this. I certainly don't recall anyone saying
 5 we should have a different arrangement. We
 6 followed -- you know, in this case we followed these
 7 guidelines as they came out every few years. Yeah.
 8 I think that's -- I mean, I don't have documentary
 9 evidence to say that we did anything different. So
 10 yes, we would have followed this.
 11 Q. Then if we come to guidance produced by the Northern
 12 Region itself, if we start with NHBT0007497, we can
 13 see a letter from you to Dr Gunson, January 1994
 14 saying:
 15 "I know you are now getting reasonably close to
 16 producing the Selection of Donors booklet. I thought
 17 you might like to see the version we have introduced.
 18 The main aim in producing this booklet was to put all
 19 the possible information together into one alphabetic
 20 section. This means staff are less likely to have to
 21 jump from one section of the book to another", and so
 22 on.
 23 Then if we go on to NHBT0007498, we've got the
 24 booklet or a version of it dated December 1993 --
 25 A. Yes.

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1 Q. Then if we look towards the bottom half of this page,
 2 "Rationale":
 3 "There are two major considerations with regard
 4 to donating blood. These are:
 5 "(i) That all care should be taken to protect
 6 the voluntary donor from harm, and,
 7 "(ii) That the blood or plasma collected should
 8 be safe for its intended use.
 9 "In addition to this it is the policy of the
 10 NRBTS not to take donations of blood or plasma from
 11 donors unless at the time of collection, it is
 12 believed that the donation is suitable for use. It is
 13 unethical to accept donations from donors in the
 14 knowledge that the donation is unlikely to be used
 15 because it does not meet specifications. Unusable
 16 donations also represent waste of materials, money and
 17 the time and effort of members of staff."
 18 Had that always been the policy of the Northern
 19 Region or was that a shift which you introduced?
 20 A. That was a shift. Perhaps not as massive as it looks
 21 there. But we did collect ...[frozen screen]... it
 22 was --
 23 Q. I'm sorry, Dr Lloyd --
 24 A. -- remember we had -- sorry?
 25 Q. You froze there for a moment. Sometimes when you

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1 Q. -- so probably what you were referring to in your
 2 letter to Dr Gunson?
 3 A. Yes.
 4 Q. If we go to page 5, we can see, under the heading
 5 "Introduction", it provides:
 6 "... the information required to assist staff of
 7 the Northern Region Blood Transfusion Service in the
 8 process of selecting Blood Donors and Donations with
 9 regard to both the safety of the donor and the safety
 10 of the donations for transfusion and for further
 11 processing into plasma derived products."
 12 Do you know whether there have been any -- or
 13 can you recall whether there was any earlier version
 14 of a locally produced booklet or was this the first
 15 time that one had been produced?
 16 A. I think this was the first one. It is marked as
 17 Version 1. So I think don't think we produced an
 18 earlier one of this. It took some time to produce
 19 this and, as I say, it was part of our -- what we were
 20 trying to do was make it easier for the staff to get
 21 the information and use it. This was probably
 22 introduced at about the same -- I think we introduced
 23 the information on medication, might have been a bit
 24 earlier but, yeah, I don't think we did anything
 25 separate prior to this.

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1 freeze I don't think we're losing what you're saying
 2 but I think we might have done there.
 3 A. Okay.
 4 Q. So the last we heard was you said, "But we did
 5 collect", and then we lost you.
 6 A. Okay, yes. We did collect donations that we couldn't
 7 use. Our statistics, as we gradually built up our
 8 information systems in the centre, we realised that we
 9 were taking a lot of donations that weren't either
 10 being used at all, or were only being partially used.
 11 And we felt that was not good for the Centre and it
 12 wasn't good for the ...[frozen screen]... medical
 13 staff meeting, there was a question about someone who
 14 was homosexual and, you know, should we take
 15 a donation from them just, you know, so it looks nice
 16 and then throw it away? Well, no, we shouldn't.
 17 So it was a change. We were trying to do what
 18 we said in this document and, obviously, we hadn't
 19 done it before this time.
 20 Q. Then if we go to page 7, we've got the heading
 21 "Medical Assessment":
 22 "In practice it is impossible to perform a
 23 complete medical and physical examination of every
 24 prospective donor. A significant part of the
 25 assessment procedure will usually rely on answers to

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1 simple standard questions relating to general health,
2 past medical history and medication. This is combined
3 with simple visual assessment of the donor and
4 selected testing of samples collected at the time of
5 donation."

6 Then the next paragraph refers to donors
7 undergoing medical investigations. Then this:

8 "Where doubt exists, the donor should be
9 deferred and permission obtained to contact the
10 Donor's [GP] or other appropriate Medical attendant."

11 Then:

12 "Any active and/or chronic disease which may be
13 transmissible, should be a reason for permanent
14 exclusion."

15 In terms of the "Where doubt exists, defer and
16 seek permission to contact the GP or other" --

17 A. Lost you. In terms of these?

18 Q. The paragraph which begins "Where doubt exists, the
19 donor should be deferred" --

20 A. Yes.

21 Q. -- was that a shift in policy at this time?

22 A. I think we were moving more to excluding, if we were
23 in doubt, rather than collecting the donation and
24 perhaps following up afterwards. Now, in terms of the
25 safety of the blood we collect, you might argue that

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1 recall that ever having happened in the past and so
2 now we were bringing medical officers in for --
3 whether it was a day or an afternoon, I can't
4 remember -- but we had training sessions. So we --
5 you know, trying to change the, sort of, attitude and
6 our approach, and it's very hard to know if we were
7 successful.

8 Q. You talk in your statement about trying to ensure that
9 donors were informed about donation criteria before
10 attending, to avoid them wasting their time if they
11 turned out to be ineligible.

12 A. Mm.

13 Q. Was that done by sending out standard literature with
14 the call-up cards, then?

15 A. Well, in one of my documents that I attached to my
16 witness statement, you'll see a leaflet that we
17 produced. You'll see it stands out. It's white with
18 a lot of red lettering on it and most of the text is
19 blue with headings in red. I can't remember what
20 number it was but we produced -- that was one of the
21 things we produced and sent out with all the call-up.
22 And that --

23 You know, the thought process, if you've come to
24 a session it's taken you a long time, perhaps, to get
25 there. You may be with a family member or a friend,

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1 that doesn't make a big difference, as long as you
2 have a doubt, and that is acted upon, donation is put
3 on hold, and then we follow it up. That's probably
4 not a dramatic change because we were all -- you know,
5 we'd always done that. But what we're trying to do is
6 actually not take the donation in the first place.

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

8 What systems or processes did you put in place
9 to try and avoid donors whose donation might well end
10 up getting rejected from attending in the first place?
11 How did you tackle that issue?

12 A. I mean, two things. One is with a document like the
13 selection document you've just seen, and working with
14 the staff to -- who went out and did this work, to try
15 to, you know -- when I started, there were very few
16 training sessions for anybody. So, you know, we
17 gradually introduced more training, gradually
18 introduced standard operating procedures, which staff
19 were required to read and understand and be shown to
20 understand. So that we were trying to get the session
21 staff to understand what we were trying to do as
22 an organisation.

23 So we did a lot more training and I think for
24 the first time we started having training sessions
25 back in the Centre for the medical officers. I don't

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1 and then we go into the peer pressure thing, and
2 you're presented with an AIDS leaflet at the session,
3 that's a little bit late, a little bit harder to get
4 out. If you've had that in the privacy -- you know,
5 a letter sent to you personally, you might be able to
6 make an informed decision prior to making -- going out
7 to a session. So try and give them more information.

8 And it wasn't just about, sort of, the safety
9 issue it was also about looking after the donors and
10 making things easier. There were a lot of simple
11 things where donors are not able to donate, so -- and
12 they only found that out after they'd come to the
13 session. So give them that information before the
14 session, it may save them the journey to a church
15 hall, which might be, you know, a few miles away. And
16 so it will save them time and effort and hopefully
17 mean that if circumstances change they'll be more
18 prepared to come back again.

19 Q. The letter that you referred to that you exhibited to
20 your statement is WITN6935020.

21 A. Yes.

22 Q. It's not, I think, dated but I think it must be after
23 1989 because, if we just look at the letter on the
24 right-hand side:

25 "Dear Donor,

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1 "On behalf of the Blood Transfusion Service in
2 the North East and Cumbria, I would like to take this
3 opportunity to thank you for your willingness" --
4 **A.** Yes, we put a date.
5 **Q.** -- "to help us by donating blood."
6 "During 1989 there was an increased demand for
7 blood and blood components and I am very pleased to
8 say that many more donations of blood were given,
9 helping us to meet that need. This year it is clear
10 that even more blood is being used and still more
11 donors will be needed."
12 Then the next paragraph talks about the value
13 placed upon the voluntary nature of the donation.
14 Then if we just go, next paragraph down:
15 "In this leaflet there is information about
16 donating blood which I hope you will find useful. In
17 particular it is designed to help avoid the annoying
18 situation where after going to a blood donor session
19 you find that your donation cannot be accepted because
20 you may have taken some tablets recently, or perhaps
21 you have travelled to certain foreign countries
22 recently."
23 Then there's an opportunity to telephone
24 a number for further information, and then the next
25 paragraph says:

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1 put out.
2 **Q.** Then, if I can ask you to look at your statement,
3 WITN6935001, page 10. It'll be the bottom half of the
4 page, please, Sully, when we get to it.
5 So, in that long paragraph at the end, just over
6 halfway down, you say:
7 "In the past many donations were labelled for
8 'laboratory use' because of limitations in the
9 donation process."
10 What kind of limitations were you referring to
11 there?
12 **A.** The donation process doesn't mean, in that context,
13 just putting the needle in the arm. It's the whole
14 process of the session, and selecting the donor and --
15 so it is the whole process. So -- and then it refers
16 to the fact that new documentation was produced to
17 support the clerical staff, providing clear
18 information.
19 So we -- this is part of this process: let's not
20 do what we did in the past and collect blood for which
21 we really had no use.
22 **Q.** We can take that down --
23 **A.** It's not fair to the donors.
24 **Q.** And then what, if any, systems were in place at the
25 Northern Regional service to ensure that a donor who

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1 "... I hope that this leaflet will help you
2 avoid a wasted journey or a long wait at the session."
3 I'm going to ask you separately about some
4 specific issues relating to the AIDS leaflets but, in
5 terms of this kind of letter, this personal letter
6 being sent out to donors, was this the first time that
7 this was done in 1990, probably, I think, or was this
8 something that had been done earlier, do you know?
9 **A.** Oh dear, I can't remember. I happen to have a copy of
10 this leaflet in one of my old files here. So, you
11 know, it sort of brought it back. But I can't
12 remember -- it's the sort of thing that we would
13 have -- we were trying to do. So I wouldn't be
14 surprised if we hadn't done it a little bit earlier
15 but, you know, 1990, did we do it before 1990
16 ...[frozen screen]... first.
17 **Q.** I'm sorry --
18 **A.** -- given the timing -- and, oh --
19 **Q.** We missed a bit there. So you said --
20 **A.** Okay.
21 **Q.** -- you asked the rhetorical question: did we do it
22 before 1990? Then we lost it for a few seconds.
23 **A.** Okay. Looking at the timing and thinking back about
24 our thought processes of changing how we, you know,
25 dealt with donors, this is probably the first one we

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1 had been excluded from giving blood in your region
2 would not give blood in another region? Was there any
3 way of ensuring that?
4 **A.** Oh no, no, I don't think so. If we excluded someone,
5 I don't think there was any -- I don't recall sort of
6 a system of broadcasting that information to other
7 transfusion centres.
8 **Q.** And do you recall any occasions in which your service
9 was notified by another regional service of a donor
10 who'd been excluded? Or deferred?
11 **A.** I do not recall that happening. It's a lot of years
12 ago, but I don't recall it, no.
13 **Q.** I just then want to pick up on a couple of what might
14 be regarded as high-risk groups. So prison donations,
15 first of all. If we look at NHBT0008628_001. This is
16 a document that was put up together for a Scottish
17 Transfusion Directors' meeting in September 1983. It
18 says:
19 "Telephoned survey ..."
20 **A.** Yes.
21 **Q.** "... of England and Wales Transfusion Centres
22 regarding use of prisons as a source of donor blood."
23 **A.** Yes.
24 **Q.** I think this may have been an exercise undertaken by
25 Dr Brookes, but I --

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1 A. I think it probably was.
 2 Q. And obviously it sets out the position in relation to
 3 a number of regions. But if we go over the page, the
 4 second region is yours, Newcastle.
 5 "Long ago stopped holding session is Durham and
 6 Northallerton but continued to use an 'Open' prison in
 7 West Cumberland which housed 'civil crime' prisoners
 8 (bigamy, fraud, etc).
 9 "Latterly they had noticed an increase in
 10 incidence of hepatitis B markers and discovered that
 11 prisoners from Walton Jail (Liverpool) were being sent
 12 there for their pre-release 6 months.
 13 "This session has now been dropped, so that
 14 Newcastle now holds no prison sessions."
 15 Now that's as at autumn 1983. Do you know
 16 yourself how long before that this practice had been
 17 dropped?
 18 A. No, I don't. I mean, I do -- you know, I recall, and
 19 I think I said it in my initial witness statement,
 20 that I thought we didn't hold sessions at prisons, in
 21 my time, and I mean by that going back to 1981,
 22 1980/81, when I first worked in the transfusion
 23 centre. But then I saw this, and obviously it makes
 24 it possible that we held sessions at that facility in
 25 Cumberland after 1981, but prior to ...[frozen

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1 A. That's my best recollection. I sort of feel that it
 2 was something that she told me early on, certainly
 3 when I was still a registrar, or locum registrar. So
 4 it's the '80/81, possibly '82, but I sort of feel that
 5 it was probably in the earlier part because I do
 6 recall, you know, this thing: we don't do sessions in
 7 prisons anymore. And that came from other people as
 8 well.
 9 Q. You tell us in your statement this, you say:
 10 "I recall from informal discussion with staff in
 11 the Centre that it was known that prisoners were given
 12 privileges for donations such as cigarettes. This
 13 went against our policy --
 14 A. Yes.
 15 Q. -- of not offering inducements to donate."
 16 A. Mm-hm.
 17 Q. Were you being told or led to understand that that was
 18 something that was being given out by the Transfusion
 19 Service or by the prison?
 20 A. I mean, first of all, that was not -- those sessions
 21 weren't occurring at the time. This was a historical
 22 information. But those -- the cigarettes were given
 23 out, as far as I -- you know, they were given out by
 24 the prison staff. We didn't -- unless I'm extremely
 25 mistaken, we didn't supply cigarettes. But I think

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1 screen]... Dr Anne Collins telling me that they had
 2 stopped -- actually telling me this information: that
 3 they had stopped taking blood from prisons because of
 4 the higher rate of hepatitis B markers. So she did
 5 tell me that. And she would have ...[frozen
 6 screen]... one maybe, you know, I can't be absolutely
 7 sure but it was in that early phase when I was first
 8 starting working there, and I recall her telling me
 9 about this.
 10 Q. We lost you for a couple of seconds, a couple of
 11 occasions, Dr Lloyd. I'm just going to read back
 12 broadly what you said and see whether we caught all
 13 of it.
 14 So you said it may be "possible that we held
 15 sessions at that facility in Cumberland after 1981".
 16 Then you referred to Dr Collins telling you that
 17 they'd stopped because of the higher rate of
 18 hepatitis B markers.
 19 A. Mm-hm.
 20 Q. Then you say you can't be sure but it was in that
 21 early phase when you first started working there and
 22 you recall her telling you about this.
 23 So is it right to understand it's in the 1980/81
 24 period that is your best recollection of when she told
 25 you this?

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1 the prisoners would get a benefit of some cigarettes
 2 for donating. And that came from the prison.
 3 Q. And then do you recall whether the Northern Region
 4 collected blood from military institutions, barracks
 5 or Air Force bases or the like?
 6 A. Yes, we did. I'm pretty sure that we went to
 7 Catterick barracks, near Northallerton, actually in
 8 north Yorkshire. And we also went to a small --
 9 I think it was -- I can't remember if was run by the
 10 Royal Navy or the Royal Air Force, a munitions depot
 11 in the Carlisle area. So we certainly did those two.
 12 The munitions depot would have been a slightly
 13 different beast to the Catterick garrison, but yes, I
 14 believe we did.
 15 Q. And were there any US bases where donation sessions
 16 were held?
 17 A. No, as far as I -- well, I know we didn't do any
 18 sessions at US bases, and I don't know that there were
 19 any US bases in our region. There might have been an
 20 Air Force base and some facilities around the North
 21 York Moors, but no, we didn't do any sessions at US
 22 bases.
 23 Q. Can you recall whether any active consideration was
 24 given to the position of those donating at military
 25 sessions, that, again, they may not be truly voluntary

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1 or it may be even more difficult for them to admit to
 2 high-risk activities than it might be in other
 3 settings?
 4 A. Yeah, yeah. Yes. No, I don't think we did give
 5 consideration to it. I don't recall us discussing
 6 that. So yes, they -- you know, "You, you and you
 7 will donate today". It's certainly possible.
 8 Q. And then you referred earlier to the position of
 9 people coming along with family members to donate and
 10 the difficulties that might arise there.
 11 A. Mm-hm.
 12 Q. I just want to pick that up by reference to a document
 13 you exhibited to your statement, WITN6935018.
 14 Some notes, I think authored by you, headed
 15 "Transfusion - Do We Have Any Choice?" I'm going to
 16 come back to what you say elsewhere in this document
 17 tomorrow, but if we just turn to page 4, halfway down
 18 the page it says:
 19 "This leaves two more areas:
 20 "Predeposit and something that I have not
 21 mentioned before - Directed donations."
 22 Then you say:
 23 "Directed donations are those made by family or
 24 friends for a patient. This sounds like a good idea.
 25 My 'brother', 'sister', 'aunt', 'uncle', 'best

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1 family to donate for another family member or for
 2 a friend in hospital, so we direct the donations
 3 because they must be safer. And I was saying: well,
 4 no, there's not really any evidence that they're
 5 safer. And in fact they may be less safe because they
 6 are under social pressure, as you've alluded to in
 7 other cases, they're under social pressure to donate.
 8 So I -- perhaps around that time directed donations
 9 was something being talked about, so I thought it
 10 would be a good thing to bring up in a talk.
 11 Q. I want to then pick up the issue of AIDS. How and
 12 when, as far as you can recall, did you first become
 13 aware of AIDS and it's potential transformation
 14 through blood or blood products?
 15 A. It's hard to remember when. I mean, you know, during
 16 training, you know, you read a lot so you know that
 17 there's a problem. And, you know, I recall reading
 18 the -- the earliest journal articles talking about
 19 this new disease, that something was happening. So,
 20 you know, we're going back to the very early days of
 21 this, because I recall these articles and they're
 22 saying, "Well, we don't know what's causing it".
 23 There were even people saying with haemophiliacs it
 24 might be due to some odd change in the constitution of
 25 Factor VIII by fractionation which is impairing their

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1 friend', 'neighbour' cannot possibly be at risk of
 2 HIV/Hepatitis/Venereal Disease etc, hence much safer
 3 than the blood donor."
 4 Then if we look in the next -- sorry, at the
 5 bottom of the page. You say:
 6 "... Voluntary donors are safer."
 7 This is the last three lines:
 8 "Family members who are not volunteer donors are
 9 therefore ordinary members of the population with
 10 a higher risk of HIV infection and other infections."
 11 We haven't, I think, with other witnesses,
 12 discussed this particular category of potential
 13 donors, the directed donation. What was your thinking
 14 here?
 15 A. I mean, these were just notes I made for myself ready
 16 to give a talk at a hospital -- at a hospital I--
 17 anyway. Um, my thought process, as you see there, it
 18 can't -- you know, "Someone in my family can't
 19 possibly be at risk". You sort of have this innate
 20 feeling that your family and friends must be, you
 21 know, very good, very clean living or whatever. And
 22 so if you -- and this was very much about directed
 23 donations not going to an ordinary voluntary session.
 24 Q. Yes.
 25 A. So it would be nice to -- you know: let's get our

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1 immune system.
 2 So I've been aware of transmission certainly
 3 since, you know, some of those early articles started
 4 to confirm out in the States.
 5 Q. Again, putting it back in the context of your own
 6 career, you were in that period, 1982 through to say
 7 1984, that was your I think senior registrar training
 8 when you were doing the rotation between the different
 9 hospitals?
 10 A. Mm-hm.
 11 Q. So do you recall any sense in the haematology
 12 community at that time any particular sense of urgency
 13 or concern about the potential threat that AIDS posed?
 14 A. Goodness. Um ... I don't recall that terrific sense
 15 of urgency. I mean, I recall seeing some of the first
 16 haemophiliacs who were exhibiting signs and symptoms
 17 associated with AIDS when I was at the RVI. So, you
 18 know, people -- we knew there was -- this was going
 19 on, this was happening, but did we know it was
 20 happening amongst non-haemophiliacs? People receiving
 21 regular transfusions? No, I don't think we did.
 22 It would have been unusual, because the number
 23 of people we -- donors we picked up once we started
 24 testing for HIV, the numbers were very, very small.
 25 So the likelihood of this being an issue that was

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1 being brought to people's attention on a regular
2 basis, with people getting it from transfusion in the
3 Northern Region was low. We knew about it from other
4 regions, and certainly I don't think there was
5 a terrific -- I don't feel a terrific sense of urgency
6 amongst the general transfusion population -- you
7 know, haematologists. But you should ask them.

8 **Q.** And just in terms of seeing haemophilic patients with
9 early signs at the Royal Victoria Infirmary, again,
10 just trying to put that in a chronological context,
11 you told us earlier that you thought your RVI
12 placement was the third of the three.

13 **A.** Mm-hm.

14 **Q.** So would that have been around 1986, then, that you
15 were there?

16 **A.** Um ...[frozen screen]... '86, I'm trying to --
17 I honestly, you know, my -- one of the things I found
18 about this whole business is that I have difficulty
19 putting things into sort of chronological order, and
20 I do find at times that I am not quite sure. So
21 I wouldn't like to be sure but I, you know, as you
22 said, I believe my RVI placement was the third of four
23 in that block so it would have been in the latter
24 part. So you're probably about right.

25 **Q.** Then perhaps just one more document before we finish

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1 second paragraph under that records:
2 "The transmission by blood or blood products is
3 now well documented, and this includes 'needle stick'
4 injuries in staff handling infected materials,
5 intravenous drug abusers sharing needles and patients
6 receiving blood or certain blood products. It appears
7 that Human Albumin Solutions (PPF) do not transmit the
8 virus, nor do intramuscular preparations of
9 immunoglobulin. Factor VIII concentrate is known to
10 transmit HTLVIII, and one case is documented of
11 a patient who had received only UK produced
12 [Factor VIII] concentrate developing AIDS."

13 Then if we just go to the next page, it's the
14 last long paragraph --

15 **A.** You can see there's a lot of pages -- a lot of pages
16 missing. I think that has "Page 12" at the top.

17 **Q.** It does.

18 **A.** I didn't attempt to reproduce the whole thing.

19 **Q.** It says:

20 "Prospects for limiting the spread of the
21 disease including encouraging homosexual men to limit
22 the number of partners they have, to use condoms, and
23 presumably once known to be HTLVIII antibody positive,
24 to refrain from sexual contact."

25 Then you go on to talk about the implications

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1 for today, WITN6935027. These are handwritten notes.

2 Are they your handwritten notes?

3 **A.** They are indeed.

4 **Q.** They're remarkably legible, in that case:

5 "The Acquired Immunodeficiency Syndrome and the
6 Human T-Lymphotropic Leukaemia Viruses.

7 "Notes made at a symposium held at the London
8 School of Hygiene and Tropical Medicine on
9 3rd April 1985. With some additional material from
10 a Brief review published in Blood, February 1985, and
11 the Interim guidelines from the Advisory Committee on
12 Dangerous Pathogens."

13 So it looks, Dr Lloyd, as though you attended
14 this symposium in April 1985. Can you recall what
15 prompted you to attend?

16 **A.** This was a major issue -- I mean, AIDS -- and so, yes,
17 I wanted to go to this. It wasn't just a, sort of,
18 a routine one of the conferences coming up.
19 I certainly wanted to go to this. It was -- and as
20 you can see -- I mean, what you see here, I only
21 reproduced a couple of pages, the first and last, and
22 perhaps the one in the middle. It was a longer
23 document and I took a lot of notes.

24 **Q.** If we go to the second page, there's a heading, nearly
25 halfway down, "Mode of Transmission", and then the

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1 for transfusion:

2 "For blood transfusion, all donations should be
3 screened for HTLVIII antibody -- as tests are now
4 available, although not yet as commercial kits.
5 Potential donors from risk groups must be excluded as
6 far as possible. Effective literature and advertising
7 campaigns should be used. All plasma for processing
8 should be tested and treatment of finished products
9 should be carried out to render the product
10 non-infective. Heat treatment of [Factor VIII]
11 concentrate may render the product non-infective, but
12 at the cost of a 50% reduction in potency and a
13 resultant increase in [cost]."

14 So do you recall anything more in relation to
15 that symposium, any further discussions about the
16 implications for blood transfusion and the measures
17 that should be implemented in the Transfusion Service?

18 **A.** No, I don't. I mean, I have the document, and if you
19 want to see my whole document, I'm quite happy to scan
20 it and let you read it. But now, off the top of my
21 head, I can't remember all the other things that
22 were -- that I wrote. But, obviously, this sort of
23 colours your -- informs your view of the issues,
24 certainly. I mean, we can see that we've got
25 a problem.

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1 **SIR BRIAN LANGSTAFF:** Well, a slightly different tack, can
 2 we just go back to the page before?
 3 **MS RICHARDS:** Yes, it's page 2. WITN6935027, page 2.
 4 **SIR BRIAN LANGSTAFF:** It's not this page, maybe the next
 5 page, maybe the page before that.
 6 Yes, I think this is it, thank you.
 7 Just something that caught my eye as we flicked
 8 through this, it's the third sentence under
 9 "Introduction":
 10 "The number of cases of AIDS reported to the
 11 Communicable Disease Surveillance Centre at Colindale
 12 was 140 as at March 1985."
 13 So the context of this is, as you have set out
 14 from the seminar earlier, that 140 had been reported,
 15 it's a figure which doubles every six months or so.
 16 So that gives some idea of the background, against
 17 which you were considering screening and safety of
 18 donations.
 19 **A.** Mm-hm. Oh yes.
 20 **SIR BRIAN LANGSTAFF:** Those were the cases of AIDS, so
 21 that's the manifestation of an infection, which, if
 22 the cases of AIDS are doubling, the infection must
 23 have been doubling before that, so it all depends how
 24 long people have actually been infected, and --
 25 **A.** Yes.

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1 the English experience in -- as at March '85 in the
 2 States, it's recording over a thousand cases by the
 3 end of '86, or suggesting. Yes, thank you very much.
 4 **MS RICHARDS:** Sir, I'm going to pick up next with
 5 Dr Lloyd's -- some of the measures that he referred to
 6 on the page we looked at a few minutes ago, how they
 7 were implemented in Newcastle in terms of leaflets and
 8 so on, but given the time, perhaps we should pick that
 9 up tomorrow morning.
 10 **SIR BRIAN LANGSTAFF:** Yes.
 11 **MS RICHARDS:** Tomorrow afternoon, Dr Lloyd's tomorrow
 12 morning.
 13 **SIR BRIAN LANGSTAFF:** Dr Lloyd, your 8 o'clock again, if
 14 you're kind enough to be with us in your early
 15 morning, we should be very grateful.
 16 For us --
 17 **A.** That's absolutely no problem.
 18 **SIR BRIAN LANGSTAFF:** For us, it's 10.00 in the morning
 19 for our next presentation.
 20 **MS RICHARDS:** Yes, and then we'll pick matters up with
 21 Dr Lloyd at 1.00 tomorrow, our time.
 22 **SIR BRIAN LANGSTAFF:** So until 10.00. Thank you very
 23 much.
 24 (5.32 pm)
 25 (The hearing adjourned until 10.00 am the following day)

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1 **SIR BRIAN LANGSTAFF:** -- been able to pass it on.
 2 **A.** Yes.
 3 **SIR BRIAN LANGSTAFF:** So if one traces it back, there
 4 could be actually quite a lot of people in society who
 5 might unwittingly wish to donate blood who would be
 6 coming forward.
 7 **A.** Yes, the number -- you know, you go -- well, as I'm
 8 sure you know, I'm sorry, you start off by getting
 9 infected and you don't -- there's virtually no
 10 indication that you're infected. Then there's
 11 a period of -- whether it was, you know, depending on
 12 the person, one, two, three, four, five years while
 13 they're infectious but haven't got any overt symptoms.
 14 So that's significant, particularly in the period
 15 before HIV testing.
 16 After HIV testing was introduced, the really
 17 significant period is that bit between being infected
 18 and becoming antibody positive and presumably a small
 19 number of people going on who were infectious but
 20 weren't seroconverting, weren't becoming HIV positive.
 21 But, you know, this meeting, you know, does -- it
 22 really opened your eyes.
 23 **SIR BRIAN LANGSTAFF:** Yes.
 24 **A.** This was a significant issue we're going to face.
 25 **SIR BRIAN LANGSTAFF:** And it goes on to say that that's

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