

Wednesday, 16 June 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Now, Ms Richards, today we have the start of your presentation on the smaller Haemophilia Centres, to be continued tomorrow.

Are you able, for those who are watching at home, to give us any idea of which centres you intend to cover today and in what order, and if you are able, you may not be at this stage, a rough indication of time so that those who are interested in a centre, such as one in Truro, may know when it might be or, for that matter, in Leeds.

MS RICHARDS: I can, I hope. So today, I am going to cover in the following order: Royal Manchester Children's Hospital, Booth Hall, Maelor, Leighton, Blackpool, Lancaster, Blackburn, Sheffield Children's Hospital, Leeds, the Royal Liverpool, Alder Hey and Walton.

That's the order for today. I anticipate that the three Liverpool hospitals will certainly be this afternoon and not this morning. Whether I get through all of those, including Sheffield and Leeds, by the end of the morning we'll see. It's possible but the volume of documentation that's relevant to show varies enormously from centre to centre.

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way of example, if you print out the materials referred to in the presentation notes, there are 48 lever-arch files of documents, and that's condensed down from the vast amount of material that the counsel team and the Inquiry team have looked through, and I'm very grateful for the huge amount of work that's gone into that process. The presentation notes themselves, for today and tomorrow have been disclosed to Core Participants and their recognised legal representatives but I anticipate we should also be able to disclose them on to the website so that all of those who have an interest can read them.

SIR BRIAN LANGSTAFF: Thank you very much.

MS RICHARDS: I should say that, although there are this vast number of documents, in relation to some centres, it is still a very incomplete picture, particularly those centres where we don't have any relevant witness evidence from clinicians who were practising at the material time. So there will be some centres where we can get a very good understanding of the approach to treatment, knowledge of risk, response if any to risk, and some centres where, to use Bruce Norval's metaphor from last week, it's very much an incomplete jigsaw.

SIR BRIAN LANGSTAFF: Yes. A lot will depend as well on the reliability of any return which was made to

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In terms of tomorrow, I'm anticipating starting with the three Scottish centres Inverness, Dundee and Aberdeen; then looking at three centres in the south of England, Southampton, Bristol and Truro, and then move to East Anglia, Cambridge, Norfolk and Norwich; and then there are ten London or Greater London centres, the names of which temporarily elude me. I know we have covered -- we are covering almost all of the remaining London centres, but not quite all, and that will be tomorrow afternoon.

That will, broadly speaking, be the order for tomorrow, so it will start with Scotland, then the south-west, then East Anglia, then the London centres.

That doesn't cover all the remaining Haemophilia Centres that there were at material times, but the amount of work that has had to go into analysing the thousands of documents that we have looked through has meant it has not been possible to do all of them this week. So there will be a second presentation slot at the hearing probably in the autumn, where we look at the remainder of the centres that haven't been looked at, either this week or in the presentations and oral evidence we have heard since September.

I should say the amount of documentation we have looked through is vast, so for today and tomorrow, by

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UKHCDO, I imagine.

MS RICHARDS: Yes, that's right.

There is no real way of testing the reliability of those returns. There's no obvious reason for doubting their accuracy, and there's certainly nothing, for the most part, in the returns that stands out as inconsistent with other bits and pieces of the material that we've seen.

In relation to a number of issues, in particular the matters about testing for HIV, provision of information to patients about knowledge of risk or non-provision of information about knowledge of risk, how patients were told of their diagnosis, how they were treated, the best source for that is likely to remain the individual witness statements from patients and their families.

I will refer to some individual evidence in the course of today and tomorrow but obviously not all of it or even the majority of it. But it forms obviously a very important part of the Inquiry's and your understanding of what was happening.

SIR BRIAN LANGSTAFF: Yes, I wasn't for a moment suggesting that the UKHCDO data, such as they are, were not a reflection of what they had been told, the question is whether they were told enough by everyone,

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1 the accuracy of the person making the return, who was
2 making it, all these issues which we've explored
3 elsewhere, and triangulating that with the information
4 we have from those who have given written statements
5 and other sources is a huge task.

6 **PRESENTATION RE ROYAL MANCHESTER CHILDREN'S HOSPITAL**

7 **MS RICHARDS:** Yes, I'm going to start with the Manchester
8 Children's Hospital.

9 The director of the Centre at the Royal
10 Manchester Children's Hospital at the 1970s and 1980s
11 was Dr Evans. He was also a consultant haematologist
12 at Booth Hall Hospital, which had a small Haemophilia
13 Centre and at Monsall Hospital during that time, and
14 our understanding is that he retired from the National
15 Health Service in 1992.

16 The Centre at the Royal Manchester Children's
17 Hospital was designated a Haemophilia Centre in 1972.
18 I'm not going to go over a lot of the material that we
19 covered in the presentation on the Manchester
20 Haemophilia Centre, in terms of the regional network
21 of how it worked, and how they interacted, but the
22 Children's Hospital was part of that north western
23 regional haemophilia service.

24 The evidence that we have suggests that the
25 Blood Transfusion Service in the northwest, in the

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1 document I want to look at is HCDO0000276_032. This
2 is a document produced by the Haemophilia Society,
3 it's a treatment survey undertaken in 1986 and it just
4 gives a flavour of the relative role of nurses and
5 clinicians at number of centres.

6 If we go to page 9 -- I'm sorry, page 11. My
7 fault, Soumik. I was looking at the internal
8 pagination.

9 If we look at paragraph 6.5, it says:

10 "Nurses. The majority of severely affected
11 patients were dealt with by nurses at 19 centres."

12 Then it says:

13 "The hospitals at which nurses play a major role
14 in treatment are ..."

15 There are number there listed but, for present
16 purposes, we'll see, towards the bottom of that list,
17 Royal Manchester Children's Hospital. So nurses
18 played, it would appear, a significant role in
19 treatment at the centre.

20 In terms of the numbers of patients registered
21 and the products that were used, our best guide, at
22 present, are the annual returns, subject to all the
23 qualifications that you just mentioned, sir. We will,
24 I hope at some point, be able to produce graphical
25 representations in relation to each of the centres but

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1 1980s at least, was purchasing the commercial
2 concentrates following consultation with the
3 haemophilia clinicians, with a budget set by the
4 Regional Health Authority.

5 The Manchester Regional Transfusion Centre then
6 provided other products including cryoprecipitate.
7 We'll see when we look at the returns, as well, the
8 Royal Manchester Children's Hospital filed its own
9 annual returns with UKHCDO but sometimes it also filed
10 the returns of some of the other smaller associated
11 centres in the area. So quite often Booth Hall,
12 Leighton Hospital and Maelor's returns are all sent in
13 alongside the Royal Manchester Children's Hospital
14 returns.

15 The other names in terms of key staff members
16 who crop up in the documents in relation to the
17 Children's Hospital, other than Dr Evans, are
18 Dr Stevens, who was a consultant haematologist, and
19 Sister Alex Shaw, also sometimes referred to as Sister
20 Alex Susman-Shaw, and I'll look at a couple of
21 materials authored by her.

22 If we go to, Soumik, the first document and
23 I should say there are so many documents loaded on the
24 system for today and tomorrow the process of calling
25 them up might be slower than usual. But the first

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1 it's actually a much more time-consuming exercise than
2 the team had thought so we haven't been able to do
3 that for today but at some point I hope we'll have
4 line graphs, as it were, which show a relative usage
5 of concentrates, both NHS and commercial, and of
6 cryoprecipitate.

7 If we start with the picture in 1976 with
8 HCDO0001098 please, Soumik.

9 We have here the 1976 annual return. We can see
10 the number of haemophilic patients treated during the
11 year, 43, one with Factor VIII antibodies, eight with
12 Christmas disease, and then we can see, in broad
13 terms, the balance of treatment. So, by far and away,
14 the main treatment, you'll see there, is
15 cryoprecipitate, at 270,970 units. A much smaller
16 amount of NHS concentrate, Hemofil, 7,000 odd units,
17 and then a little more by way of Kryobulin, just under
18 26,000 units.

19 Then, in relation to the Christmas Disease
20 patients, you'll see there NHS Factor IX concentrate,
21 and that's pretty much the consistent picture in
22 relation to treatment for haemophilia B across all the
23 centres we'll be looking at this week. Almost
24 invariably haemophilia B patients were treated with
25 NHS Factor IX concentrate in the periods that we'll be

8

1 looking at.
 2 If we go to page 3, please, Soumik.
 3 We can see there the treatment of patients with
 4 von Willebrand's disease. Seven patients treated and,
 5 again, cryoprecipitate the predominant form of
 6 treatment: 18,480 units but with a small amount of
 7 Immuno also being used.
 8 If we move then to 1977, that's at HCDO0001183.
 9 If we go, please, to page 7.
 10 We can see there Royal Manchester Children's
 11 Hospital. The figure appears to be slightly faint,
 12 but 41 haemophilic patients treated during the year,
 13 one with antibodies, seven Christmas Disease patients
 14 and, again, we can see the largest in terms of volume
 15 is cryoprecipitate -- just over 250,000 units. But
 16 Hemofil now being used to a greater extent,
 17 137,540 units, a small amount of Kryobulin, and then
 18 again, in terms of haemophilia B, NHS Factor IX.
 19 And if we go to the next page, we can see
 20 there's a separate return for home treatment. You
 21 will see from this that cryoprecipitate was used for
 22 home treatment, and the usage there 30,240 units.
 23 Although it's also right to note that the greatest
 24 volume is Hemofil in terms of home treatment, 109,480
 25 units, a small amount of Kryobulin. But relevant to

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1 we can then see the types of material used. And you
 2 will see that there are some patients who receive both
 3 Hemofil and Kryobulin. So those are the two ticks --
 4 if we look at the third row of patients, the two ticks
 5 there for third one down, for the fifth one down, and
 6 then for the two towards the bottom.
 7 And again, that's by way of example. It's not
 8 the case by any stretch of the imagination for all the
 9 patients. Some receive only one. But it doesn't
 10 suggest any kind of consistent policy of adhering to
 11 only one type of commercial concentrate, still less
 12 any batch dedication system.
 13 We can then move to 1978. That's HCDO0001280.
 14 If we go to page 6, please, Soumik, we can see
 15 49 patients treated during 1978, haemophiliac
 16 patients, two with antibodies. Six haemophilia B
 17 patients.
 18 We can still -- we can see that cryoprecipitate
 19 is still a significant part of approach to treatment
 20 in 1978, so just over 200,000 units of cryoprecipitate
 21 used. A little more than previously by way of
 22 NHS concentrate but still a small amount, 2,200,115.
 23 Profilate, 6,666. And then the largest amount in
 24 terms of commercial concentrate, and it's now almost
 25 as much as the usage of cryoprecipitate, is Hemofil,

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1 see that cryoprecipitate was in fact used at the
 2 Children's Hospital for home treatment in that period.
 3 **SIR BRIAN LANGSTAFF:** Yes, in percentage terms it's
 4 somewhere between 25 per cent and 30 per cent, it
 5 looks.
 6 **MS RICHARDS:** It probably is. I'm going to rely on you
 7 for --
 8 **SIR BRIAN LANGSTAFF:** This is just comparing the units.
 9 **MS RICHARDS:** Yes. Then I don't think we have one for
 10 von Willebrand's. Oh yes, we do, sorry. Page 16.
 11 We can see there the number of patients treated.
 12 It looks like a 5 converted into a 6.
 13 And then if we look at the whole page, please,
 14 Soumik, we can see it's mostly cryoprecipitate but
 15 a smaller amount of Hyland used for the treatment of
 16 von Willebrand's.
 17 It's not clear, I should say, from any of the
 18 documents we've looked at why any commercial
 19 concentrate was being used for the treatment of
 20 patients with von Willebrand's, because a commoner
 21 picture to see is the use of cryoprecipitate alone.
 22 In fact, if we can pick up -- if we go to page 3
 23 of this document, Soumik. You'll see -- and we've
 24 seen this in relation to other centres -- details of
 25 individual patients, obviously names are redacted, but

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1 192,960 units. And then we can see again, in terms of
 2 the Christmas Disease patients, haemophilia B, it's
 3 NHS Factor IX concentrates.
 4 If we go to page 10 we'll see in relation to the
 5 von Willebrand's patients again, it's eight patients
 6 treated during the year. Again, it's mostly
 7 cryoprecipitate, but we see instances of commercial
 8 concentrates being used, so both Hyland and Immuno
 9 products there being used for the treatment of
 10 patients with von Willebrand's disease.
 11 If we then move to 1979, HCDO0001349, this is
 12 the year in which we now see the distinct shift
 13 towards concentrates rather than cryoprecipitate being
 14 the predominant treatment.
 15 So it's 44 patients with -- haemophilia
 16 patients -- I think, in fact, haemophilia A patients,
 17 three with antibodies, Christmas disease patients,
 18 six.
 19 And then if we look at the numbers,
 20 cryoprecipitate still in substantial use, 139,800
 21 units, more by way of NHS concentrate, 96,308, a very
 22 small amount of Profilate, but a much bigger amount of
 23 Hemofil, 239,665, and then 40,000-odd units of
 24 Kryobulin.
 25 Then again, for the Factor IX concentrate,

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1 again, it's NHS in terms of usage.
2 The sheets for individual patients, they're not
3 necessarily complete but they don't for that year show
4 much by way of mixing of products. It is mostly in
5 fact Hemofil that the patients use. I think there's
6 an indication of one patient who receives Hemofil and
7 Kryobulin.

8 In terms of von Willebrand's, we can see very
9 limited -- oh no, that's Booth Hall, sorry. I don't
10 know if I've got the page for von Willebrand's in this
11 document. No, I don't know if we've got the separate
12 page for von Willebrand's to display. But in any
13 event that's the shift we see in 1979.

14 In 1980, if we go to HCDO0001446. It's slightly
15 faint, so if we zoom in, it looks like it's
16 39 patients treated, haemophilia A patients, one
17 carrier, six von Willebrand's patients.

18 And then we can see that the form here, in terms
19 of the annual return form here, distinguishes between
20 hospital and home treatment.

21 We can see cryoprecipitate being used now solely
22 for hospital treatment for haemophilia A patients.
23 The figure there is 115,750 units. Although if we
24 look across to von Willebrand's, we will see that
25 cryoprecipitate is used. It's the sole form of

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1 receive more than one type of commercial concentrate
2 or more than one type of Factor VIII concentrate by
3 looking at the ticks. So there are examples of
4 patients receiving both the Armour product and the
5 Hyland product as well as the Elstree product on this
6 page.

7 And if we go to the next page, again, we can see
8 some examples of patients receiving more than one type
9 of product. So there's an example there of a patient
10 receiving both Hyland and Immuno, I think.

11 So no obvious evidence, again, of any kind of
12 consistent or firm policy of adhering to only one type
13 of concentrate, and no evidence of batch dedication in
14 any of the other documents.

15 If we move to 1981, that's HCDO0001547, we can
16 see number of patients treated, 37. Not quite sure
17 what the significance is of the square brackets in
18 terms of 45, unless that's giving totals. Carriers of
19 haemophilia A, one, von Willebrand's patients, eight.
20 Or maybe that reflects numbers registered, I don't
21 know, rather than treated.

22 Then we can see cryoprecipitate usage. So in
23 terms of haemophilia A, the volume of cryoprecipitate,
24 it's come down, and it's only hospital again, not home
25 treatment. Save for von Willebrand's patients, where

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1 treatment for that year and it's used both in hospital
2 and at home.

3 We can see then NHS factor concentrate,
4 relatively modest amounts, 5,200 in hospital, a little
5 more for home treatment, 43,000-odd. Factor VIII, so
6 the Armour product, being used again. Again, the
7 amount is relatively small in terms of hospital, and
8 then slightly larger, but not much larger,
9 12,240 units, for home treatment.

10 The predominant treatment again is Hemofil,
11 26,330-odd units hospital treatment, and then a much
12 more significant 244,117 units for home treatment.

13 So we can see, by this, a significant number of
14 patients must be on home treatment by this stage, and
15 they're on home treatment with commercial concentrate,
16 mostly Kryobulin, but some usage also both in hospital
17 and at home -- sorry, with Hemofil. Some usage also
18 of Kryobulin both in hospital and at home.

19 If we go to page 3, home therapy, we can then
20 see the separate return for haemophilia B patients,
21 and it's Factor IX concentrate. Four patients treated
22 during the year, and it's Factor IX concentrate both
23 for home and hospital treatment.

24 If we go to page 4, again, we can pick up the
25 circumstance or the occasions in which patients

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1 we see a small amount being used for home treatment
2 and a slightly larger but still quite small amount
3 used for hospital treatment.

4 Then we can see the figures in relation to the
5 commercial concentrates. So there are four different
6 commercial concentrates used at Manchester Children's
7 Hospital this year, Factor VIII, Koate, Hemofil and
8 Kryobulin. We can see the largest figure now is for
9 the Armour product, the Factor VIII, just under 41,000
10 in hospital. Nearly 300,000 units used for home
11 treatment.

12 There's a smaller amount of Koate for hospital
13 and home treatment, 15,000 and 11,000 respectively.

14 A fairly substantial amount, again, of Hemofil,
15 just under 38,000 hospital treatment, 118,687 units
16 for home treatment, and a small amount of Kryobulin,
17 hospital and home.

18 There's reference here as well to porcine
19 Factor VIII being used for the treatment of
20 haemophilia A patients.

21 If we go to page --

22 **SIR BRIAN LANGSTAFF:** Just one question about the
23 demographic of the patients. I don't know if you'll
24 be able to answer this or not. But this is
25 a Children's Hospital --

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1 **MS RICHARDS:** This is.
 2 **SIR BRIAN LANGSTAFF:** -- so do we know what the practice
 3 was of transferring to adult treatment centres? At
 4 what age? Sixteen?
 5 **MS RICHARDS:** We don't -- sorry, I should say I don't know
 6 without checking. We may know. I probably need to go
 7 back to the Manchester presentation, which was now
 8 some months ago, to double check whether we have that
 9 information.
 10 **SIR BRIAN LANGSTAFF:** That then leads on to the next
 11 question, which it may be impossible to answer easily,
 12 but within the range 0 to, say, 16, there will come
 13 a time, if a policy was being adopted of giving
 14 cryoprecipitate or fresh frozen plasma to those who
 15 were the youngest, at which they would switch to
 16 having some form of concentrate. Either commercial or
 17 NHS or both or a mixture. So you'd expect to see the
 18 cryoprecipitate usage being, if it's -- about a third,
 19 roughly, bearing in mind that children are smaller
 20 and, the younger they are, the less product they're
 21 likely to need.
 22 Those are the two variables, it seems to me, and
 23 really how the use of cryoprecipitate correlates with
 24 that or whether it indicates -- the use is so small it
 25 indicates that probably factor concentrate was being

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1 Soumik, doesn't have it on the screen, so I'll just
 2 tell you what it is, we don't need to go to it. But
 3 we see, in relation to the haemophilia B patients for
 4 that year, the same pattern. Relatively small number
 5 of patients, six patients treated, and exclusively
 6 with NHS Factor IX concentrate.
 7 So that was 1981. If we go to 1982,
 8 HCDO0001646. Yes, that's it, thank you. Just zoom in
 9 a bit. We can see the return for 1982, 50
 10 haemophilia A patients treated, one carrier, 11 with
 11 von Willebrand's. Then if we look at the figures for
 12 haemophilia A, cryoprecipitate, solely in hospital,
 13 53,000 odd, for haemophilia A patients. Again, we can
 14 see some home treatment using cryoprecipitate for the
 15 von Willebrand's patients on the right-hand side.
 16 Then we can see the bulk of the treatment in
 17 that year is with Factorate and Koate, so 188,510
 18 units of Factorate for home treatment, just under
 19 200,000 units of Koate for home treatment, and then
 20 Profilate used to a more modest extent for home
 21 treatment, just under 70,000. Relatively smaller
 22 amounts of usage in hospital, and then Hemofil used
 23 for home treatment 14,000.
 24 You'll notice then no NHS Factor VIII
 25 concentrate at all. I should have said that was the

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1 used for those in the youngest groups as well as
 2 older. That's the question which is on my mind at the
 3 moment.
 4 **MS RICHARDS:** Yes. It might become something of a theme
 5 for today, in fact, when we look at Sheffield
 6 Children's Hospital and then, perhaps most strikingly
 7 of all, this afternoon the evidence relating to
 8 Alder Hey Hospital. It may be, if we go to page 4 --
 9 this isn't a piece of work we've done but it may be
 10 something we can do -- sorry, page 4 -- oh. If you
 11 recall, on the document we looked at previously, we've
 12 got those electronic sheets with the ticks, they've
 13 got patient name data and date of birth data, which
 14 obviously we've redacted. We might be able to go back
 15 and interrogate those in unredacted form and see
 16 whether there is any pattern in terms of when we look
 17 at the date of birth and the age of the child, and
 18 then we look at corresponding ticks, whether there is
 19 any particular pattern. The problem is we don't have,
 20 I think, that data for all the relevant years, the
 21 individual patient data, in the returns, but we can
 22 certainly have a look and see whether there's anything
 23 that assists in answering your question, sir.
 24 **SIR BRIAN LANGSTAFF:** Thank you.
 25 **MS RICHARDS:** There are -- there's a further page.

18

1 picture the previous year as well.
 2 I don't know if you have page 3 of this
 3 document, Soumik? Go to page 3. We see the picture
 4 there again for the haemophilia B patients, six
 5 patients treated exclusively with Factor IX
 6 concentrate.
 7 Then if we go to page 4, we can see that the
 8 clearest possible indication from the data here that
 9 there was no policy of treating a patient with only
 10 one type of commercial concentrate, we haven't
 11 followed through individual patients across the years
 12 but we can see here, if we look at the first and
 13 second entries, a patient being treated with four
 14 different -- or two patients being treated with four
 15 different types of commercial concentrate, the same
 16 a few rows further down, and then a number of other
 17 being treated with three different types of commercial
 18 concentrate, and that pattern continues over the other
 19 pages. So whilst there are -- I don't think, looking
 20 at the data we've got, there are any patients that
 21 year treated with only one type of concentrate.
 22 **SIR BRIAN LANGSTAFF:** Yes. It looks as though there may
 23 be two, looking at this page, who had cryo only.
 24 **MS RICHARDS:** Yes, that's right. I don't know whether we
 25 learn anything in particular in terms of the age of

20

1 those. I don't think we necessarily do.

2 **SIR BRIAN LANGSTAFF:** If the date of birth is the year,
3 the column to the left --

4 **MS RICHARDS:** Yes, so for the first patient treated only
5 with cryoprecipitate, it looks like they were born in
6 1980 and the second is 1973.

7 **SIR BRIAN LANGSTAFF:** It tells you nothing very much, does
8 it?

9 **MS RICHARDS:** It really doesn't, no. Then -- I'm just
10 trying to understand if there's any pattern in terms
11 of ages with the others but it doesn't look like it.
12 If we go on to the next page, please, Soumik. If we
13 just look, for example, at the bottom of the page,
14 we've got someone born in 1973, so that's nine years
15 old at this point in time, treated with three
16 different types of commercial concentrate, as were
17 a number of others treated on this. Actually, I think
18 there is one patient at the top of the page treated
19 with only one type of commercial concentrate.

20 Yes, it may be we need to have a look at some of
21 the ages and see whether there's any particular
22 pattern we can discern, sir.

23 In any event, that's 1982. If we then go to
24 1983, HCDO0001744. We can see here, we don't, in
25 fact, on this sheet have the total number of patients

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1 page. We can see most of those, for whom there are
2 ticks and most of those being treated with
3 concentrates are treated with two types of commercial
4 concentrate in that year, some of them also receive
5 a cryoprecipitate, some of them also receive Elstree
6 product.

7 If we then move to 1984, it's HCDO0001837. So
8 we have 56 haemophilia A patients treated, ten
9 von Willebrand's patients treated. The volume of
10 cryoprecipitate, I think, is 84,950 but, again, that's
11 exclusively in hospital, except for those with
12 von Willebrand's, where it is used for home treatment.

13 We can see that there is NHS concentrate used,
14 a small amount in hospital, a larger amount in the
15 home treatment, 126,195 units, but again the bulk is
16 commercial. In this year, we see it's predominantly
17 Profilate, the Alpha product, just over 400,000 units
18 used for home treatment in 1984; just under 70,000
19 units used, or a little under 70,000 units used in
20 hospital; then a smaller amount of Factorate, 2,300
21 units in hospital, 37,517 at home; a much smaller
22 amount of Hemofil; then some usage of porcine
23 Factor VIII; and then, I think at the bottom, in terms
24 of other materials, that's NHS Factor IX, and I think
25 that's probably for the treatment of inhibitor

23

1 treated during the year, although I think we have
2 recorded that data by adding up the individual patient
3 names elsewhere in the presentation. But we've got
4 cryoprecipitate, again only hospital, 76,500 for
5 haemophilia A patients, some home treatment with
6 cryoprecipitate for von Willebrand's patients. We do,
7 in 1983, see NHS Factor VIII concentrate being used.
8 16,490 hospitals, just under 71,000 units for home
9 treatment but the bulk of the home treatment is again
10 still with commercial concentrates, so Profilate,
11 124,166 units for home treatment; Hemofil 259,030
12 units for home treatment; and then smaller amounts of
13 Profilate, Hemofil and a very small amount of Koate
14 being used in hospital treatment in 1983.

15 If we go to page 3, we see the haemophilia B
16 patients again treated exclusively with NHS Factor IX
17 concentrate. If we then go to page 4, we can again
18 see by way of example, no apparent policy of adhering
19 to the usage of only one type of commercial
20 concentrate so the majority of the patients identified
21 there as treated are treated with more than one type
22 of commercial concentrate. They're mostly treated
23 with two and a number of them also treated with the
24 Elstree NHS concentrate.

25 That pattern continues if we go to the next

22

1 patients.

2 Page 3 shows the familiar picture in relation to
3 haemophilia B of treatment with NHS Factor IX.

4 Then if we go to page 4, again, we'll see no
5 obvious indication of any kind of policy of adhering
6 to only one type of concentrate. In fact, the picture
7 is the other way. So there are number of patients
8 treated there with both Elstree and one of the
9 commercial products and there are some, if we look
10 towards the bottom of the page, treated with both the
11 Elstree NHS product and two different commercial
12 products and that same pattern continues over the
13 page. Again, I'm not going to through all the pages.
14 These are just examples but they're not, I think --
15 they're representative examples.

16 So we can see here, again, a number of patients
17 who receive NHS concentrate and then two different
18 types of commercial concentrate.

19 Then just to complete the picture by reference
20 to 1985 and 1986, if we go to 1985 at HCDO0001930, we
21 have, again in terms of von Willebrand's patients,
22 treatment with cryoprecipitate. Then in terms of
23 haemophilia A patients, the bulk of the treatment is
24 with NHS Factor [VIII] concentrate, Profilate, and
25 Koate. So Koate for that year -- and it may be this

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1 is the heat-treated Koate but the returns don't
 2 distinguish -- it's 286,860 units of home treatment,
 3 it's 196000-odd units of Profilate and 180,000 odd
 4 units of NHS Factor VIII concentrate used for home
 5 treatment, and then smaller but not insignificant
 6 amounts used in hospital.

7 **SIR BRIAN LANGSTAFF:** You went down on the [draft]
 8 transcript there as having said the bulk to the
 9 treatment for haemophilia A in this year was Factor IX
 10 concentrate. That's plainly a -- if it was what you
 11 said, then it's not accurate.

12 **MS RICHARDS:** I meant to say Factor VIII, absolutely.

13 **SIR BRIAN LANGSTAFF:** It may simply be a misrecording but
 14 it had better be corrected.

15 **MS RICHARDS:** Yes, if we go to page 3, we can see the
 16 picture in relation to Factor IX, because here we see
 17 for the first time the use of commercial Factor IX
 18 concentrates, and that may reflect the introduction of
 19 heat-treated commercial Factor IX concentrates, so
 20 both NHS and commercial Factor IX being used in 1985.

21 Then, finally in terms of the annual returns,
 22 1986 is at HCDO0002027. We see a shift in the
 23 position for 1986, still roughly a similar amount of
 24 cryoprecipitate being used as in previous years. But
 25 the bulk of home treatment is now with the NHS factor

25

1 **MS RICHARDS:** Yes, precisely.

2 Just in terms of other bits and pieces of
 3 information about the approach to product usage, other
 4 than what we see from the annual returns, if we go to
 5 WITN0553001, you'll see here a statement from
 6 a witness we've heard from orally, Alison Bennett,
 7 about the treatment of her late son. If we go to the
 8 second page and we just look at paragraph 2.1 you can
 9 see she describes there home treatment in the 1970s
 10 using cryoprecipitate. So she says:
 11 "... he was treated with cryoprecipitate
 12 supplied by Royal Manchester Children's Hospital ...
 13 and sourced from [BPL] in Elstree. Fortunately, I was
 14 able to give Alistair his injections and consequently,
 15 we were allowed to begin home treatment in
 16 September 1973 when he was aged 17 months. We used
 17 cryoprecipitate from RMCH."
 18 Then she describes a later shift to
 19 concentrates, she thinks, in about 1978 or 1979.

20 In terms of, again, of the approach to
 21 home treatment, if we look at PRSE0000421, these are
 22 notes from a seminar called Haemophilia Today, held in
 23 Manchester in 1978.

24 And if we turn to page 5, we can see on the
 25 right-hand side there's a talk from -- it's the

27

1 concentrate, 515,715 units at home, just over 100,000
 2 in hospital; and then Koate just over 100,000 used,
 3 104,000 used for home treatment; and 37,746 units of
 4 Hemofil; and then smaller volumes of Koate and Hemofil
 5 used in hospital.

6 That's the pattern of treatment that emerges
 7 from the annual returns.

8 If we then go to --

9 **SIR BRIAN LANGSTAFF:** Just stopping there for a moment.
 10 Do those figures suggest any response in relation to
 11 developing knowledge of either hepatitis C --
 12 non-A, non-B, as it would have been known at the
 13 time -- or HIV -- HTLV-III, as it would have been
 14 known at the time -- infections?

15 **MS RICHARDS:** Well, the figures for 1985 and 1986 probably
 16 do reflect that because they, I think, almost
 17 certainly reflect a shift towards the use of
 18 heat-treated product. Prior to that, there's no
 19 obvious inference arising from the annual returns of
 20 any particular policy or approach to product usage
 21 being shaped by reference to what was or should have
 22 been known about the risks of either hepatitis or HIV.

23 **SIR BRIAN LANGSTAFF:** The pattern that you've demonstrated
 24 appears to just echo the trends of the previous years
 25 and developing it a bit further?

26

1 nursing sister, Alex Shaw at the Royal Manchester
 2 Children's Hospital. If we go to the fourth
 3 paragraph, please, we can see it says:
 4 "A Home Therapy programme began about five years
 5 ago [so that would be around 1973, which is consistent
 6 with Miss Bennett's recollection] with children up to
 7 the age of 16 or 17 years. Out of about 104
 8 haemophiliacs registered [so this now as at 1978] 22
 9 are on home therapy with another 6 in training. Ten
 10 of these 22 patients are very severely affected ..."

11 Then Mrs Shaw is recorded as describing the
 12 benefits of home therapy: largely not having to have
 13 numerous visits to the hospital and that being
 14 advantageous for both children and parents.

15 Then at the bottom of the page, right-hand
 16 side -- thank you -- it also says:
 17 "Mrs Shaw described how Home Therapy provides
 18 prompt and early treatment, cutting out all the long
 19 journeys, the long waiting periods and general
 20 frustration. It also saves the amount of Factor VIII
 21 concentrate used therefore cutting the cost, as
 22 a small dose of Factor VIII or IX stops the bleed
 23 early."

24 Then picking up at the bottom of the page:
 25 "Patients for Home Therapy are selected on the

28

1 capability of parents, or the child himself after the
2 age of 12 years, the co-operation of the child, the
3 severity of the disease, the number of bleeds and the
4 availability of Factor VIII concentrate."

5 Then, if we go to the right-hand column, we then
6 see, third paragraph, she is recorded as suggesting
7 that:

8 "... one of the main disadvantages of Home
9 Therapy is the abuse of the materials used. For
10 example, non-attendance at clinics, abuse of joints,
11 and latterly in the much older patients, drug
12 dependence."

13 Not quite clear what's meant by that.

14 "If these do occur, the patient is immediately
15 withdrawn from the Home Therapy Programme."

16 So there's an insight from the nursing sister
17 into the hospital's approach into home treatment in
18 the seventies.

19 If we then go to HSOC0022606.

20 We have a document authored by Dr Evans. So we
21 can see it's the same year, this is November 1978.

22 Dr Evans' name is on the last page of the document.

23 It's a document about home treatment. So:

24 "Anti-haemophilic factor is produced from human
25 blood and costs the NHS about 12p per unit. It is

29

1 one sentence because one could say this is precisely
2 the kind of document, practical document, given to
3 patients or their parents where it might have been
4 helpful, useful, ethical, to spell out what was
5 understood about the risks of treatment.

6 All one gets is paragraph 4, "After the
7 Injection":

8 "Used syringes and needles should not be put in
9 the dustbin -- they could infect anyone emptying the
10 bins."

11 That's the sum total of the hint about the
12 risks.

13 If we go also to another document, this time
14 authored by Dr Evans and the nursing sister, from
15 1979. It's HSOC0022546.

16 We'll see the date at the bottom, May 1979.
17 It's from the Children's Hospital. It's called an
18 Introduction to Haemophilia.

19 If we go over the page, and I'm not going to go
20 through the detail of it because it's more notable for
21 what's not in it rather than what is, so we can see
22 "Introduction to Haemophilia". There's a heading,
23 "Inheritance", which talks about the genetic origins
24 of haemophilia.

25 If we go to the next page, under the heading

31

1 very important that it is used properly, but we hope
2 that prompt treatment at home will reduce the extent
3 of bleeding and the consequent need for transport to
4 hospital and possible admission."

5 Now, it looks as though this is a document
6 prepared for the parents or, if they're older,
7 patients, the patients themselves.

8 We can see that from the way it's formulated.

9 So at paragraph (2):

10 "For the following bleeds you should consult the
11 hospital and administer treatment at home ..."

12 Paragraph (3):

13 "For the following bleeds you must administer
14 treatment and attend hospital without delay ..."

15 Then if we go a little further down:

16 "If there is any doubt about what to do, always
17 consult us ..."

18 Then it talks about what will be in the pack.

19 If we go over the page, there's a discussion
20 about the technique, not going to go through the
21 detail of that. But you'll see there are detailed
22 instructions provided about how to administer the
23 concentrate.

24 Then if we go to the third page, if we look at
25 "After the Injection", and I'm just going to flag up

30

1 "School and Haemophilia" -- that's it, thank you --

2 I just wanted to draw attention to something which
3 might resonate in light of some of the evidence we
4 heard last week. The bottom paragraph there:

5 "We like to keep our haemophilic children at
6 normal schools as they have a wider curriculum and
7 higher standards of attainment than at a special
8 school".

9 Now the aspiration in terms of education
10 entirely understandable, but it's just the phrase "our
11 haemophilic children".

12 If we go on to page 5 there's a short mention of
13 "Home Treatment", at the bottom half of the page:

14 "Some patients are on home treatment. This
15 means that the injection is given is at home by the
16 parent or the child himself. We hope in time to have
17 all our severe cases on home treatment."

18 And the question of whether older boys could
19 give that treatment at school.

20 Then a reference to "Prophylaxis".

21 "Some children may be able to have an injection
22 to provide cover for a day or so for an important
23 examination, or to tide them over a period when bleeds
24 are particularly troublesome."

25 Some usage of prophylactic therapy, it would

32

1 seem, identified there.
 2 Again, the document doesn't have anything in it
 3 which addresses the question of what the risks of
 4 treatment might be. It's not entirely clear to whom
 5 this document was addressed.
 6 **SIR BRIAN LANGSTAFF:** Well, it may be the school, might
 7 it?
 8 **MS RICHARDS:** It may be.
 9 **SIR BRIAN LANGSTAFF:** Given the -- perhaps they might be
 10 allowed to inject themselves at school?
 11 **MS RICHARDS:** Yes, it may be. It may have been intended
 12 as teaching material. I don't know.
 13 When we looked at the annual returns, sir,
 14 I suggested that the data on them didn't suggest any
 15 policy of adhering to only one type of concentrate.
 16 We can see that perhaps most starkly in a letter from
 17 Dr Evans at TREL0000108_022.
 18 It's a letter from Dr Evans to Dr Aronstam at
 19 Treloars, and it's referring to a specific individual.
 20 It says in the third line:
 21 "We used to use Hemofil and at present we're
 22 using Factorate and Hemofil for our home treatment
 23 patients. I do not think it matters very much which
 24 product you use so long as the boys realise that they
 25 may need to change their concentrate from time to

33

1 it's written in her capacity as the nurse specialist
 2 in haemophilia at that children's hospital.
 3 May be just useful to see what, in broader
 4 terms, from a nursing perspective, was her
 5 understanding of the way in which the Haemophilia
 6 Centres operated.
 7 So, Soumik, if we can go to the right-hand
 8 column on this page. I should say, this was
 9 a publication in Nursing Times in 1981. She
 10 identifies three different types of centres involved
 11 in the treatment of haemophilia: the registered
 12 haemophilia centres, so a number of the kind of
 13 centres that we'll be looking at today; and then:
 14 "The reference centres adopt an advisory role
 15 towards the haemophilia centres."
 16 So again, that's her understanding as nursing
 17 sister of the role of the Reference Centres and then,
 18 point 3, the associate centres and, again, we'll be
 19 looking at a number of associate centres today and
 20 tomorrow.
 21 Then if we go towards the bottom of that column,
 22 she says:
 23 "We began our home treatment programme about
 24 six years ago ..."
 25 I think the evidence is probably that it's

35

1 time."
 2 So it would appear the opposite of a policy of
 3 adhering to only one type of concentrate. And we can
 4 see that again even more starkly from a letter of the
 5 same date, 12th May 1981, again from Dr Evans to
 6 Dr Aronstam, at TREL0000299_010.
 7 This is about a different pupil. It says:
 8 "We used to give [the pupil] predominantly
 9 Hemofil for home treatment but I do not have any
 10 particular choice which product you use. I think it
 11 sensible for the boys to realise that the product may
 12 need to be changed from time to time and not to become
 13 too dependent on one manufacturer's concentrate."
 14 So, again, it would appear the opposite of
 15 a policy of restricting patients to single
 16 manufacturers or batches.
 17 There are some other references in the
 18 documentation to a degree of prophylaxis as well, an
 19 element of prophylaxis in the home treatment
 20 programme.
 21 If we then look at HS0C0002894. This is an
 22 article by the nursing sister, Alex Susman-Shaw, about
 23 home treatment for children with haemophilia. It's
 24 dealing with it more generally rather than exclusively
 25 looking at Royal Manchester Children's Hospital, but

34

1 a little earlier than that.
 2 "... and at our centre we deal with children up
 3 to the age of 16 and 17 years."
 4 So that at least indicates when they passed into
 5 the adult care, presumably, of the Manchester Royal
 6 Infirmary.
 7 And then if we go over the page, right-hand
 8 column, she talks about the storage in relation to
 9 concentrates. So ease of storage of factor
 10 concentrates. It can be stored in a fridge or a cool
 11 room.
 12 "... there is not the problem of immediate
 13 fridge or freezer storage and this can cut the cost to
 14 the social services and other bodies in providing
 15 moneys, particularly for a freezer in order to store
 16 cryoprecipitate, which was the product used before the
 17 introduction of the freeze-dried concentrates now used
 18 more widely for home treatment."
 19 So there, as it were, a money-saving or
 20 practical advantage to using concentrates rather than
 21 a cryoprecipitate for home treatment: you wouldn't
 22 have to spend monies on providing a freezer.
 23 Then if we go to the next page, right-hand
 24 column towards the top of the page. Again, we see the
 25 phrase "our haemophiliac children":

36

1 "It is the policy of our department to try to
2 keep our haemophiliac children in normal schools."

3 Then if we go to the next page, this is where we
4 see a discussion of hepatitis in the case study that's
5 given under the heading "A patient". If we go to the
6 bottom of the page, we can see this -- so it talks
7 about the introduction of home treatment for the
8 particular child. It says:

9 "[The child] was now nine years old. Four
10 months after beginning home treatment he was admitted
11 to hospital with a diagnosis of serum hepatitis
12 (hepatitis B) which was confirmed by tests, but from
13 which he recovered rapidly. It was found that one of
14 the batches of FVIII used in his home treatment was
15 contaminated.

16 "The problem of hepatitis B transmission owing
17 to the use of large donor pools from a high-risk
18 population has been now virtually eliminated. This
19 has been achieved by routinely testing all donations
20 and all batches of FVIII by radioimmunoassay and by
21 using a lower-risk population."

22 So no reference there to non-A, non-B hepatitis,
23 as it would, by 1981, be known.

24 **SIR BRIAN LANGSTAFF:** It is also making a claim for the
25 testing regime which would have taken place wherever

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1 September 1982. It says in the second sentence:

2 "We normally give the young patients with
3 haemophilia treatment with Cryoprecipitate rather than
4 Factor VIII concentrates. In the past we found
5 several developed jaundice when they were given
6 Factor VIII concentrates and I think the incidence of
7 hepatitis is much lower when we use North Western
8 Cryoprecipitate than when we use the imported
9 concentrates. We tend to keep the concentrates for
10 use with patients who are on home treatment, and use
11 Cryoprecipitate in hospital."

12 So, whilst that suggests a policy of using cryo
13 rather than concentrates, it doesn't really assist
14 with understanding what's meant by "young patients"
15 and how young that refers to. Nor is it clear how
16 that matches up with the last sentence, which then
17 talks about cryoprecipitate in hospital but
18 concentrates for home treatment.

19 It does clearly show an understanding of risks
20 of hepatitis associated with imported concentrates,
21 and a reduced risk associated with local
22 cryoprecipitate.

23 **SIR BRIAN LANGSTAFF:** Yes. It may also assume that
24 there's a common knowledge of the age at which
25 children were introduced to home treatment.

39

1 the concentrate derived from. So if, for instance,
2 the donations came to a United States commercial
3 producer, it may have come from centres run by that
4 producer or they may have come from the plasma market
5 in the States, may have come from some of the best
6 developed countries.

7 **MS RICHARDS:** Indeed, and obviously we've seen from the
8 annual returns that this hospital used predominantly
9 commercial concentrates from American pharmaceutical
10 companies and not NHS concentrates, in respect of
11 which it might be thought this claim was talking
12 about.

13 **SIR BRIAN LANGSTAFF:** Well, later on, when we look at the
14 question of Government witnesses and knowledge, and,
15 later on, pharma, we may discover what we understood
16 here to have been the claims made by pharma for their
17 donation screening, and what pharma were telling
18 people, which appears to have been the assumption that
19 Ms Shaw was making.

20 **MS RICHARDS:** Yes.

21 Sir, then in -- there was one letter which
22 partly addresses one of the questions you raised
23 earlier, but not completely. It's NHBT0059262_006.

24 So this is a letter from Dr Evans to Dr Clark at
25 the Lancaster Blood Transfusion Centre,

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1 **MS RICHARDS:** Yes.

2 **SIR BRIAN LANGSTAFF:** Because that won't have been
3 immediately.

4 **MS RICHARDS:** And then if we look at TREL0000248_104.

5 This is, again, a letter from Dr Evans to Dr Aronstam
6 at Treloars -- it's October 1982 -- and it's looking
7 at the position of the treatment of patients with
8 inhibitors, I think. It refers to a practice at the
9 Manchester Royal Infirmary, so the adult hospital, of
10 using several brands of commercial concentrate
11 intravenously daily to desensitise the patients and
12 I think we looked at that issue when we did the
13 Manchester presentation.

14 Then we see Dr Evans voicing a concern in the
15 next paragraph as to whether that would be regarded as
16 acceptable by the ethical committee in relation to
17 paediatric patients.

18 We may pick up -- well, we do see, I think, in
19 relation to a patient, not quite sure whether it's the
20 same patient or not, that there was a degree of
21 a desensitisation programme that was adopted.

22 Perhaps we could look at just one document in
23 relation to that. It's at TREL0000248_095.

24 This is in fact talking about the same patient,
25 and it's Dr Aronstam to Dr Evans. It's July 1983. If

40

1 we look at paragraph beginning "[The patient]
2 inhibitor level", we can see reference there to the
3 "tolerance inducing protocol", so it appears that some
4 kind of desensitisation program was introduced.
5 And it says this:
6 "His tolerance inducing protocol appears to have
7 run out of steam. While we have supplied [him] with
8 enough material to see him through the summer
9 holidays, I have my own reservations as to whether it
10 is ethically right in the current climate. I have no
11 doubt that you will see him sometime during this
12 vacation and would be quite happy to fall in with any
13 decision you might make in this respect. If you do
14 decide to pull him off the protocol, then naturally we
15 would welcome the return of the high potency
16 material."
17 The reference to "ethically right" may be
18 a reference to what was known about AIDS at that time,
19 or may be a reference to the issues mentioned in -- or
20 concerns expressed by Dr Evans in the letter we
21 looked at a few moments ago.
22 You will see from the third paragraph, and this
23 is an issue we will return to next week when we look
24 at Treloars, Dr Aronstam saying, in July 1983:
25 "Clinically he exhibits none of the stigmata of

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1 heat-treated concentrates but the position is unclear.
2 There is certainly evidence to suggest that, at some
3 point in 1985, and by July, the Children's Hospital
4 was using heat-treated Koate product.
5 But if we look perhaps just -- actually just at
6 one further document before we break, BAYP0000024_149.
7 Sir, we can see it's a Cutter report,
8 March 1985. If we go towards the bottom of the page,
9 we can see reference to the Manchester area -- now,
10 that could just be adults rather than children -- but
11 that regular NHS Factor VIII is being used, and by
12 which we understand that to mean unheated Factor VIII
13 being used.
14 Sir, that, I think is all in terms of
15 documentation that I was proposing to go on in terms
16 of product usage. This might be a convenient time at
17 which to break. I should say, this is one of the
18 centres for which there is a lot more documentation
19 than some of the others so this is not reflective of
20 the amount of time that each presentation will take.
21 **SIR BRIAN LANGSTAFF:** Well, let's take a break for
22 20 minutes, and come back at 25 to 12.

23 **MS RICHARDS:** Thank you.
24 (11.15 am)

(A short break)

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1 AIDS. For your information, I enclose some results of
2 our AIDS related tests. We are repeating these tests
3 before the end of term and will let you have the
4 results when they are available".
5 **SIR BRIAN LANGSTAFF:** At this time, in July 1983, UKHCDO
6 had just published its guidance, I think it was six
7 weeks or so after the meeting in May which determined
8 it. So that might have set a climate, it might be
9 reference to that, which was suggesting that it might
10 be wise -- I mean the words are very vague, perhaps,
11 or leave a lot to the individual clinician -- they
12 might be suggesting that the preferred course was to
13 use cryo for the younger children and avoid the risk
14 which might be posed by concentrates.
15 **MS RICHARDS:** Yes.
16 Then, again, just before break, finishing off
17 the information we have in relation to product usage,
18 it's not currently clear at exactly what point in time
19 heat-treated concentrates, whether NHS or commercial,
20 were introduced into the Manchester Children's
21 Hospital. There is a letter from Mr Pettet at BPL in
22 May 1985, which suggests that the Children's Hospital
23 hadn't provided a list of named patients to receive
24 heated Factor VIII concentrates. It is possible that
25 that is because they were using commercial

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1 (11.37 am)
2 **MS RICHARDS:** Sir, I'm going to move to knowledge of risk
3 of hepatitis and AIDS on the part of the Manchester
4 Children's Hospital or, more specifically, Dr Evans.
5 There's little direct material, but we do know that
6 Dr Evans was a regular attendee at UKHCDO annual
7 meetings of Haemophilia Centre Directors in both the
8 1970s and the 1980s.

9 He wasn't present at the October 1983 meeting
10 but Dr Steven has represented him there. And there
11 is, I think, no reason to think he would have been
12 anything other than aware of the discussions that were
13 taking place, the presentations by Dr Craske on behalf
14 of the Hepatitis Working Party, and so on. In
15 relation to AIDS, not only would he have been, as
16 director, a recipient of the letters from Dr Craske,
17 Professor Bloom and Dr Rizza in March and June 1983,
18 but Dr Evans was one of those who attended that
19 January 1983 meeting with Immuno at the London Airport
20 Hotel, at which there was an update on the precise
21 state of knowledge from the States about numbers of
22 haemophiliacs infected, the San Francisco baby, the
23 New England Journal of Medicine article, and the like.

24 That general material may be our best guide to
25 what was or should have been known by Dr Evans and

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1 those working at the Manchester Children's Hospital.
 2 There are possibly, I think, two documents in
 3 relation to hepatitis that it may be worth briefly
 4 looking at. The first is DHSC0100018_099.
 5 So this is a case, a form reporting
 6 post-transfusion hepatitis completed by Dr Evans at
 7 the Manchester Children's Hospital, Pendlebury. It
 8 refers, if we go down the page, under the heading
 9 "Brief Clinical Notes", to it being an 18-month old
 10 boy with newly diagnosed haemophilia.
 11 If we go further down the page towards the last
 12 quarter or so, under the heading "Remarks":
 13 "This appears to be a clear-cut case of serum
 14 hepatitis."
 15 That seems to be the view recorded from Dr Evans
 16 at the Pendlebury. Then, at the very bottom of the
 17 page, it refers to attempts to trace donors. It says,
 18 at the very last line:
 19 "... since the patient is [hepatitis B antigen]
 20 negative the hepatitis may be due to another virus."
 21 That, I think, may have been completed by the
 22 regional transfusion director, Dr Wadsworth, although
 23 it's not entirely clear.
 24 So there in any event from 1973 -- sorry, from
 25 1974, December 1974, was a discussion of hepatitis and

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1 [concentrate] and the hepatitis risk with all
 2 concentrates and it was agreed that the new Hyland
 3 product was just as good as any other product for
 4 everyday use ..."
 5 So there's a particular reference to Dr Evans
 6 and a discussion about the hepatitis risk from
 7 concentrates.
 8 But beyond that, as I say, our best evidence of
 9 what Dr Evans did or should have known will be through
 10 his fairly regular attendance at and participation in
 11 the regular meetings.
 12 **SIR BRIAN LANGSTAFF:** Plus whatever he would have read,
 13 and he, since he wrote in The Lancet later on or about
 14 this time too, no doubt he read that.
 15 **MS RICHARDS:** Yes, absolutely. There's quite a lot of
 16 evidence -- there's obviously the oral evidence we've
 17 heard from a number of clinicians but also some of the
 18 witness evidence we have from clinicians who are not
 19 giving oral evidence. We've asked a number of them
 20 what kind of materials they read. The Lancet is
 21 almost invariably there, a number refer also to
 22 reading the BMJ the New England Journal of Medicine.
 23 Some also say they read the MMWR. So you're
 24 absolutely right, there's no reason to think that
 25 publications such as The Lancet or indeed the New

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1 the recognition of the existence of a virus other than
 2 hepatitis B.
 3 **SIR BRIAN LANGSTAFF:** It's also of interest, because the
 4 description used is not hepatitis B by Dr Evans, but
 5 serum hepatitis.
 6 **MS RICHARDS:** Yes.
 7 **SIR BRIAN LANGSTAFF:** So he's using the portmanteau phrase
 8 which covers any post-transfusion viral infection --
 9 **MS RICHARDS:** Yes.
 10 **SIR BRIAN LANGSTAFF:** -- which creates hepatitis.
 11 **MS RICHARDS:** Yes, precisely.
 12 Then if we go to PRSE0003946. This is
 13 a Haemophilia Centre Directors meeting. It was, in
 14 fact, the Glasgow meeting, 30 September 1980, which
 15 you'll recall was followed by the symposium on
 16 unresolved problems in haemophilia, which it explored
 17 the issue of hepatitis in some detail.
 18 If we go to page 14, there's a reference to
 19 Dr Evans here. It's specifically in relation to a
 20 discussion about a Hyland product:
 21 "Dr Evans raised the question as to whether it
 22 was sensible to encourage the manufacture of the new
 23 low potency factor VIII concentrate, which was cheaper
 24 but not so 'clean' as the other products. There was
 25 some discussion regarding the factor VIII

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1 England Journal of Medicine would have been unfamiliar
 2 to Dr Evans.
 3 **SIR BRIAN LANGSTAFF:** No doubt, given the material we've
 4 already seen, there were links with The Haemophilia
 5 Society, and so whatever concerns the members of The
 6 Haemophilia Society were expressing through that
 7 route, he will be aware of as well.
 8 **MS RICHARDS:** Possibly, yes. His own direct involvement
 9 with The Haemophilia Society, but there certainly
 10 appears to have been -- it's the seminar and so on --
 11 he became, I think, a member of the Society --
 12 **SIR BRIAN LANGSTAFF:** That was later on.
 13 **MS RICHARDS:** -- and trustees, but that was later on.
 14 Sir, I'm not going to go to the underlying
 15 documents but we've got some evidence of patients
 16 being infected with hepatitis B in the 1980s. So
 17 there's a Manchester Children's Hospital patient
 18 infected with hepatitis B in 1984 and recorded as
 19 having passed that on to his mother, and then two
 20 patients in 1986 reported to have been infected with
 21 hepatitis B.
 22 There are then, in relation to HIV, two
 23 documents it's probably worth having a quick look at.
 24 HSOC0012997, this is from the Royal Manchester
 25 Children's Hospital to The Haemophilia Society, so the

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1 links you've referred to there established March 1987.
 2 It is actually from a clinical psychologist in the
 3 Children's Hospital's department of clinical
 4 psychology but it's about, if we look over the page,
 5 "The AIDS virus and how to live with it".

6 If we go to page 14, it's a series of leaflets
 7 directed clearly at patients, child patients. It's
 8 instructive to see what is said here:

9 "Do you mean I am [HIV positive] because of my
 10 treatment?" is the question that's posed.

11 "Yes.

12 "Some years ago some of the freeze-dried
 13 concentrate, imported from America, were infected by
 14 the virus. At that time no-one was aware that this
 15 was so. It took time before it was known that AIDS
 16 was carried by a virus, and longer before it was known
 17 that it was present in blood and blood products.

18 "Knowing this might well make you angry and
 19 upset. It might make you feel angry with the hospital
 20 staff and the treatment too. It might make you feel
 21 how unfair it is for this to happen to you. It is
 22 natural to feel like that. This is what happened and
 23 it is upsetting for you and your family.

24 "The hospital staff had no idea at the time that
 25 their treatment carried this risk."

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1 "... but because AIDS was still rare, the cause
 2 was unknown, the benefit of home treatment with
 3 concentrate was substantial, and a change back to
 4 cryoprecipitate would have disrupted the arrangements
 5 for making freeze-dried concentrate in the UK, this
 6 advice was not followed."

7 **SIR BRIAN LANGSTAFF:** Now, that gives a different reason,
 8 for not changing back to cryoprecipitate. The reason
 9 that we've seen from other documentation, particularly
 10 in relation to the committee safety of medicines
 11 biological sub committee, was that it was simply
 12 supply.

13 **MS RICHARDS:** Yes.

14 **SIR BRIAN LANGSTAFF:** This is not supply.

15 **MS RICHARDS:** It doesn't appear to be.

16 **SIR BRIAN LANGSTAFF:** This was "We can't make as much of
 17 our own factor concentrate as we would have wanted
 18 to".

19 **MS RICHARDS:** That appears to be Dr Evans's reasoning,
 20 yes.

21 We've already looked at an example of the
 22 correspondence between Dr Aronstam and Dr Evans
 23 referring to AIDS --

24 **SIR BRIAN LANGSTAFF:** Just a moment. Could we just have
 25 that document back? I just spotted something in the

51

1 Whether that was, as at 1987, a correct, open,
 2 candid account, it may be a matter that you will wish
 3 to consider.

4 I should say, sir -- I won't go to the
 5 document -- there is evidence to suggest that one
 6 patient at Manchester Children's Hospital may have
 7 been infected with HIV after being treated with
 8 cryoprecipitate only, not with concentrates, and we've
 9 given the documentary reference to that in our written
 10 note.

11 The last document on the topic of knowledge of
 12 risk is STHB0000259, and this is an article published
 13 in Haemophilia 1997, containing Dr Evans' reflections.
 14 It's called "Twenty-one years of haemophilia". If we
 15 go to page 7, please. I just want to I can pick up,
 16 left-hand column, bottom half of the page under the
 17 heading "Haemophilia A", it says this, or Dr Evans
 18 says this:

19 "It was apparent by 1983 that the risk of
 20 infection was greater with concentrates derived from
 21 large donor pools, and advice was given to change from
 22 large pool products to cryoprecipitate ..."

23 **SIR BRIAN LANGSTAFF:** That's reference to Deforges.

24 **MS RICHARDS:** Let me double check, I'm sure you're right.
 25 Yes, you're absolutely right, it is.

50

1 next paragraph. Yes, it's the reference saying, "The
 2 Committee of Ministers of the Council of Europe".

3 **MS RICHARDS:** Yes.

4 **SIR BRIAN LANGSTAFF:** Yes.

5 **MS RICHARDS:** Which again we've looked at, in earlier
 6 hearings.

7 **SIR BRIAN LANGSTAFF:** Thank you. He makes specific
 8 reference to two matters, and to the Desforges
 9 article, and to the Council of Europe.

10 **MS RICHARDS:** Yes. Yes. He also refers -- the
 11 footnote 44 is to Dr Jones's article in the British
 12 Medical Journal in 1983, and he also references.

13 Sir, we looked at an example of communications
 14 from 1983 between Treloars and Dr Evans, there are
 15 other examples -- I'm not going to go to them, but
 16 there are a number of examples of letters being
 17 written by the clinicians at Treloars to Dr Evans and,
 18 as we'll see next week, to other haemophilia
 19 clinicians, in the spring and early summer of 1983,
 20 which talk about looking for the stigmata of AIDS or
 21 carrying out some form of tests or AIDS-related tests.

22 The next topic of some importance in relation to
 23 Manchester Children's Hospital is the means by which
 24 the test results were communicated to patients and
 25 their parents. And we can look at two documents,

52

1 we've heard some oral evidence on this very topic from
2 families. We can look at two documents, WITN0553002,
3 and we looked at this again during Mrs Bennetts oral
4 evidence, I think. So this is a letter from
5 August 1985, and you will see from this that the
6 communication about the child's infection with HIV,
7 HTLV-III, was done by letter.

8 "We have been sending blood examples away from
9 the children with haemophilia and similar diseases to
10 see if they are at risk of AIDS. None of our parents
11 has developed AIDS or has shown any signs of doing so,
12 but all of us, both parents and staff, are anxious
13 about the problem. The results are now coming
14 through."

15 This is August 1985, this letter:

16 "The blood tests on your child Alistair show
17 that he is positive for antibodies to HTLVIII ..."

18 It goes on to say that it doesn't mean he has
19 AIDS but there's a small chance, Dr Evans says, that
20 he may get it:

21 "Of the first 16 patients we that have tested,
22 over 60% have given a positive result. Nearly all of
23 them have been treated with the old factor VIII
24 concentrates made in the USA."

25 So there are number of questions which may arise

53

1 who already knew that they had tested their own child?
2 **MS RICHARDS:** Precisely so. The language is much more
3 consistent with this having been done without
4 knowledge of the families.

5 We have evidence from a witness who recalls
6 there being, in the summer of 1985 two meetings held
7 at Pendlebury --

8 **SIR BRIAN LANGSTAFF:** What is also curious, if that's
9 right as to the interpretation of the first sentence,
10 is the next sentence "all of us, both parents and
11 staff, are anxious about the problem". So, although
12 it appears anxiety has been expressed, it does not
13 seem that the consultant, in response to the
14 expressions of anxiety, has said "We're testing" or
15 "We will test", or anything of that sort.

16 **MS RICHARDS:** Yes. It is right to note that there's
17 a slightly different angle given by Dr Evans in
18 a letter that he wrote to The Lancet, which we will
19 look at in a moment.

20 **SIR BRIAN LANGSTAFF:** Yes.

21 **MS RICHARDS:** But before I go there, yes, just to say we
22 know that -- or we understand from witness evidence
23 we've received that there were meetings to discuss
24 AIDS and HIV in 1985. So it's similar to the kind of
25 meetings we've heard, the group meetings, being held

55

1 in the mind reading that letter, the first and most
2 obvious one may perhaps be why test results of this
3 kind about children were being communicated by letter.
4 This isn't the only example, so if we go to
5 WITN1736002, next page, sir, we see essentially an
6 identical letter or near identical letter, but this is
7 31 May 1985.

8 So, again, testing only being carried out or
9 results only being communicated in mid-1985 in
10 relation to children, which seems fairly late, and the
11 communication in this form, and parents being told
12 there's a small chance that the child may develop
13 AIDS. What the factual basis for that was is unclear.

14 There's also evidence we've received from
15 parents or other family members, infected patients,
16 that they were not aware that they were being tested
17 for HTLV-III.

18 We also have some witness evidence of there
19 being --

20 **SIR BRIAN LANGSTAFF:** It's almost said that they weren't
21 aware in the first sentence, isn't it?

22 **MS RICHARDS:** It's the most obvious inference to draw from
23 the term --

24 **SIR BRIAN LANGSTAFF:** Because why would you say "We have
25 been testing all our children", basically, to someone

54

1 to provide a degree of information, but again, summer
2 of 1985 seems quite late compared to the evidence
3 we've heard about meetings being held in other centres
4 some months earlier than that.

5 So the document I've mentioned a moment ago,
6 which is Dr Evans to The Lancet, is a letter he wrote
7 in September 1987. It is at RLIT0000454.

8 Right-hand side, halfway down the page, there's
9 a letter headed "Human immunodeficiency virus and the
10 law", and this is a letter from Dr Evans.

11 The topic is about how to tell the patients, the
12 children, of the results. But you'll see in the first
13 paragraph what's said is:

14 "When the test was introduced in this centre
15 early in 1985, many parents asked to test their sons."
16 is the way in which it is put by Dr Evans there.

17 Then he says:

18 "We gave the results to the parents, not to the
19 boys."

20 Then he talks about the issue of whether the
21 children themselves should be told and, if so, how and
22 by whom.

23 **SIR BRIAN LANGSTAFF:** What about the next sentence:

24 "Subsequently we have only tested boys with
25 their parents' consent ..."

56

1 **MS RICHARDS:** Yes.

2 **SIR BRIAN LANGSTAFF:** So that implies that previously they

3 hadn't had the parents' consent necessarily.

4 **MS RICHARDS:** It does, yes. We've nothing else that

5 throws any further light on the issue, so your best

6 guide may be those letters that we see.

7 **SIR BRIAN LANGSTAFF:** Yes.

8 **MS RICHARDS:** Then, just in terms of the numbers of

9 patients who were infected with HIV at the Manchester

10 Children's Hospital, there is reference to -- in

11 a letter from Dr Evans, I don't think we need to go to

12 it. He talks in 1987 by looking after over 20 boys

13 and young men with HIV, but that doesn't necessarily

14 mean that they were all infected through treatment at

15 Manchester Children's Hospital.

16 The data we have from UKHCDO -- if we go to

17 INQY0000250. We've got a table which the Inquiry team

18 has created from data provided to it by UKHCDO. There

19 are, as set out here, a number of qualifications to

20 the data. We're told by UKHCDO it's provisional data

21 that they've provided to us, and the table has been

22 put together from it by the Inquiry team and not by

23 UKHCDO.

24 If we go to the third page, please, Soumik.

25 We've got the centre number in the left-hand

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1 told, whether there were delays between tests being

2 undertaken and results being communicated may well be

3 the individual accounts that the Inquiry has received

4 from patients or from family members.

5 There are some documents referring to the --

6 undertaking liver tests over the years. Again, that's

7 consistent with what we've seen in relation, I think,

8 to pretty much all centres.

9 If we go to WITN1244007, this is a letter from

10 Dr Evans, November 1990. And if we look at the last

11 paragraph, Dr Evans says -- and this is referring to

12 elevated results in liver function tests in the 1980s:

13 "These elevations of the serum transaminase are

14 common in haemophiliacs, they are thought to indicate

15 some upset of liver function but a proper diagnosis

16 cannot be made without a live biopsy which entails

17 sticking a needle into the liver."

18 And he says:

19 "... this is not an investigation which is

20 undertaken lightly in haemophilia. It is even less

21 likely to be undertaken in patients with inhibitors.

22 However, the doctors at Sheffield have a particular

23 interest in hepatitis and have done a large number of

24 liver biopsies. They may have other ways of

25 diagnosing hepatitis but on the evidence we have,

59

1 column, Manchester Children's is just over halfway

2 down the table, number 61.

3 We can see there what's said to be a total of

4 16 HIV cases reported to UKHCDO. It's important to

5 emphasise UKHCDO only has information about the cases

6 reported to it. And this is up to 1988.

7 What they appear to show are: seven cases, 1985;

8 two, 1984; one, 1983; two, 1982; three, 1981; one,

9 1979. That presumably reflects retrospective testing

10 on stored samples.

11 **SIR BRIAN LANGSTAFF:** Well, it can't do anything else.

12 **MS RICHARDS:** It can't, no.

13 When that was carried out, whether it was

14 carried out systematically, how reliable those

15 seroconversion ranges are, I'm afraid we don't have

16 any more information which enables us to assess that.

17 But that's the information in terms of provisional

18 data that the Inquiry has received from UKHCDO.

19 The position then in relation to testing for

20 hepatitis C, again, there's no real clear documentary

21 trail -- we can take that down -- and the data so far

22 received from UKHCDO doesn't enable us to place any

23 kind of reliable figures before you.

24 Your best evidence in terms not necessarily of

25 numbers but of when people were tested, what they were

58

1 I cannot say that either of the boys have hepatitis at

2 present although it is possible that they have had

3 such in the past."

4 The slightly odd thing about this letter is if

5 it had been written number of years earlier, one might

6 have been able to understand it, but it is late

7 November 1990, by which time there was at least some

8 available testing for hepatitis C, to which no

9 reference is made.

10 Again, without going into the detail of

11 individual witness statements, the Inquiry has

12 received the evidence from patients at the Children's

13 Hospital who say they were tested for hepatitis C

14 without their knowledge and consent.

15 There are a number of miscellaneous matters in

16 relation to the Children's Hospital, and information

17 from documents that we've set out in our written note.

18 We've set out the studies, trial surveys that we've

19 been able to trace. And we've provided some detail

20 about Dr Evans' subsequent involvement with the

21 Haemophilia Society, but I don't propose to go through

22 any of those documents now.

23 So that's the Manchester Children's Hospital.

24 I'm just going to deal very much more shortly

25 now with some smaller centres from the northwest

60

1 region.

2 So the next is Booth Hall.

3 **PRESENTATION RE BOOTH HALL CHILDREN'S HOSPITAL**

4 Again, it was a children's hospital. Dr Evans

5 was also the director and consultant haematologist

6 there. It had a UKHCDO centre number, but if we look

7 at ... I'll find the right document ...

8 HCDO0000138_012, you'll see this is a document headed

9 "Haemophilia Centres in the UK - Coding used in Oxford

10 1977-82", and we can see the supra-regional groups

11 there listed.

12 If we go over the page, top of the page, we've

13 got the "Manchester Supreregion (Centres 060-079)",

14 and you can see there reference to Booth Hall

15 Children's Hospital. It's got a centre number, centre

16 68. But it, in common with Leighton Hospital, is

17 recorded as being not an official Centre and there

18 being special arrangements.

19 It was -- perhaps no doubt because of both

20 geographical proximity and the role of Dr Evans --

21 closely limited to the Manchester Children's Hospital.

22 There are some documents that describe it as an

23 associate centre of the Children's Hospital, and the

24 annual returns were generally submitted and filed

25 together.

61

1 and analysed the returns, the treatment for

2 haemophilia A patients recorded in the annual returns

3 with this small number is cryoprecipitate. So cryo in

4 1977, 1978, 1979, 1980, 1981, 1982 and 1983, the

5 haemophilia A patients, and in those years when

6 von Willebrand's were treated, were treated with

7 cryoprecipitate. The haemophilia B patients, in the

8 years in which there was any treatment at all of

9 a haemophilia B patient, was with NHS Factor IX.

10 There's no obvious evidence of any home

11 treatment programme either, and the amounts of

12 cryoprecipitate used are relatively small.

13 Because Dr Evans was the consultant

14 haematologist at Booth Hall as well as the Children's

15 Hospital, what I've already said about his knowledge

16 of risk or what might be said to be his assumed

17 knowledge of risk of hepatitis and HIV applies equally

18 in relation to Booth Hall.

19 There are a couple of documents relating to

20 patients at Booth Hall who were treated not because of

21 a bleeding disorder but treated following burns that

22 might be relevant just to look at.

23 So if we go to NHBT0098216. It's a letter,

24 August 1992, from Dr Evans to Dr Love at the Blood

25 Transfusion Service. And there's reference there to

63

1 We can take the document down, thank you,

2 Soumik.

3 I'm not going to go to the annual returns. The

4 numbers of the patients treated were very small.

5 So if we look at -- and I'm just going to take

6 the details from the documents without going to them.

7 So, 1977, there's one patient with

8 von Willebrand's, seven patients with haemophilia A,

9 one patient with Christmas Disease. Treated, 1978,

10 eight patients with haemophilia A, one patient with

11 Christmas Disease. Similar numbers in 1979. 1980,

12 four patients with haemophilia A, one patient with von

13 Willebrand's treated. In 1981, it's three patients

14 with haemophilia A, two with von Willebrand's. 1982,

15 three patients with haemophilia A, one with

16 haemophilia B treated. 1983, two haemophilia A

17 patients treated.

18 And then we don't have, I think, the figures for

19 '84 and '85. 1986, eight patients -- sorry, a number

20 of patients recorded as registered but no patients

21 recorded as treated.

22 So, small numbers of patients.

23 And then, in terms of the treatment that was

24 used, again, I think I can do this without taking time

25 going to the underlying returns, but we have looked at

62

1 a young -- it's said a "young man" -- it's a 12-year

2 old boy -- who has PCP and AIDS, which we think is

3 almost certainly related to transfusion, and then

4 there's reference to treatment at Booth Hall in 1984

5 for burns and receiving units of blood and plasma as

6 well as an exchange transfusion at birth.

7 That's a patient at the hospital treated in '84,

8 and potentially being infected with AIDS as a result

9 of that treatment.

10 There is also witness evidence, I don't think

11 I need to go to the statement, but of another child

12 being treated as a baby at Booth Hall in 1987, and

13 understood to be treated with plasma and infected with

14 hepatitis C.

15 So some broader evidence relating to infection

16 at Booth Hall.

17 We don't have any information about whether

18 bleeding disorder patients at Booth Hall were infected

19 with HIV -- given the limited numbers and the fact

20 that the treatment was with cryoprecipitate only,

21 that's perhaps unsurprising -- or with hepatitis C,

22 other than the two non-bleeding disorder cases I've

23 just mentioned.

24 The other fact to note about Booth Hall was it

25 contained something called the North Manchester

64

1 Regional Virus Laboratory, and there's documentation
2 that we have referred to in our written note to
3 suggest that that laboratory was set up in 1971
4 because the Public Health Laboratory Service in
5 Manchester was unable to meet the demand for its
6 services. It also reflected a geographical advantages
7 in terms of hospitals in northern Manchester being
8 able to access a virus laboratory.

9 There's reference to the North Manchester
10 Regional Virus Laboratory undertaking hepatitis B
11 testing. There's some correspondence between the
12 laboratory and the Public Health Laboratory Service in
13 1985 about HTLV-III testing, although it appears that
14 testing was undertaken at the Public Health Laboratory
15 Service and by Dr Tedder at the Middlesex. But there
16 is then evidence to suggest that in late 1990, the
17 Regional Virus Laboratory at Booth Hall was
18 undertaking hepatitis C testing on Manchester adult
19 patients and some of the data we've got suggests that
20 there was hepatitis C testing on some stored samples
21 as well, because there is reference to samples from
22 '88 and '89 being tested.

23 PRESENTATION RE WREXHAM MAELOR HOSPITAL

24 The next Centre I'm going to mention is Maelor
25 Hospital, which was based in Wrexham in North Wales.

65

1 and blood to Maelor.

2 Again, there are very small numbers of patients
3 recorded as registered and treated, and I think,
4 again, without going to the documents, I can give the
5 data that we have. 1981, the annual returns the shows
6 a single haemophilia B patient treated with NHS
7 Factor IX. 1982 shows again a single haemophilia B
8 patient being treated with NHS Factor IX and one
9 haemophilia A patient being treated with
10 cryoprecipitate in hospital.

11 1983, again, it's only one haemophilia B
12 patient, treated with NHS Factor IX, the same in 1984
13 and 1985. 1986, there's evidence of a haemophilia B
14 patient registered and treated with NHS Factor IX at
15 home. So very limited information about treatment.

16 There are a couple of interesting exchanges of
17 correspondence between a clinician at Maelor and
18 Treloars in relation to two patients, which
19 indicate -- and again, we'll see this pattern when we
20 look at Treloars in more detail next week -- the
21 pattern of the pupil being treated by the Treloars
22 team during school term and then returning during the
23 holidays and being treated by the home centre.

24 And there's a series of letters -- again, we've
25 set out the details in full in our note -- from 1974

67

1 Again, a very small Haemophilia Centre treating
2 a handful of bleeding disorder patients in the 1970s
3 and 1980s. It too is referred to in one of the lists
4 that we have as not an official Centre and being
5 subject to special arrangements, although, like Booth
6 Hall, it had a Centre number. It was Centre
7 number 70.

8 There are a number of names, clinician names,
9 that appear in the documentation. It's not -- we've
10 not found it easy to identify who the director, if
11 there was a formal director, might have been, at any
12 one time. The 1982 and 1983 returns, which again
13 appear to be provided alongside the Manchester
14 Children's Hospital returns, to Oxford, list Dr Owens
15 as director, the 1985 return lists Dr Evans as the
16 director. There are various other names, including
17 a Dr Thompson, and then, from the mid-1980s, Dr Watson
18 and a handful of others that crop up in the
19 correspondence.

20 It would appear that Maelor, as well as having
21 a relationship with the Manchester Children's
22 Hospital, had a relationship with Liverpool, at least
23 in terms of the supply of blood products. So the
24 evidence suggests that the Liverpool Regional
25 Transfusion Centre supplied cryoprecipitate to Maelor

66

1 onwards, showing the patient being treated with
2 cryoprecipitate at Maelor, and then there's
3 a discussion between Treloars and Maelor about home
4 treatment, and reference to the possibility of
5 cryoprecipitate being used at home.

6 It's Dr Kirk at Treloars who mentions that the
7 patient has a deep freeze at home, it's Dr Thompson at
8 Maelor who queries whether the deep freeze would be
9 reliable and Dr Kirk seems to suggest that that's
10 a valid point.

11 What transpires by 1976 is a switch from
12 cryoprecipitate to concentrates, but is right to say
13 that appears to have been the decision of Treloars
14 rather than the Maelor clinician. Then there's a
15 letter referring to Kryobulin being used and Immuno
16 sending that Kryobulin directly to Maelor for use for
17 the patient, that's in 1976. There's reference to
18 that patient being given that treatment on
19 a prophylactic basis and then there are discussions in
20 1977 between Maelor and Treloars about supplies of
21 concentrate for use during school holidays, and
22 there's a debate about whether to use Lister
23 concentrate, which is NHS concentrate, which is all
24 that the Liverpool Blood Transfusion Centre could
25 supply, rather than Kryobulin.

68

1 Then the other records that we have from
2 Treloars essentially show -- reflecting that exchange
3 of correspondence -- the patient receiving
4 predominantly cryoprecipitate until the mid-1970s.
5 Then from 1976, concentrate initially with Kryobulin,
6 but then from 1977 with a range of products not just
7 Kryobulin but Hemofil, Koate and Factorate, as well as
8 NHS Factor VIII.

9 Again, what's interesting about the
10 correspondence perhaps is what's not in there. There
11 are discussions about the development of antibodies as
12 a risk, but no other discussions about what other
13 risks might develop as a result of the treatment
14 course.

15 There's a second exchange of correspondence in
16 relation to a different patient. Again, it's similar
17 themes, I don't propose to go through it, but it's
18 initially contemplating the use of cryoprecipitate,
19 the domestic freezer not thought to be suitable by way
20 of storage. There's a suggestion of contacting
21 a patient's GP and seeing if the cryoprecipitate could
22 be stored there but that doesn't work out, and the
23 patient then being treated with the NHS concentrate
24 from Liverpool but, again, the patient's overall
25 treatment record shows predominant -- treatment with

69

1 described it as an associate centre, so it's status is
2 not entirely clear. Its annual returns were also
3 provided alongside the Manchester Children's Hospital.
4 It's not always clear as to who the director is, so
5 there are references to Dr Howard Allison being
6 director in 1977. The 1982 return refers to the
7 director as paediatrician Dr Chandran/Dr Evans,
8 Dr Chandran is listed in 1983, 1984, and 1985 gives
9 the director as Dr Evans.

10 Again, Leighton was part of the North West Supra
11 Regional Network, there was an occasional reference to
12 Dr Allison attending supra-regional meetings.

13 If we go to -- yes, just -- it doesn't cast any
14 particular light on Leighton, but there's just one
15 document I wanted to flag up NHBT0094580. It's
16 a meeting of the North West Supra Regional Haemophilia
17 Directors. We can see Dr Allison is listed as
18 present. There's some discussion then about supplies
19 and different arrangements in Manchester and Liverpool
20 for supplies of product. But if we go over the next
21 page, this the last two lines that caught my eye:

22 "The business meeting was concluded, to be
23 followed by a scientific session and then a dinner
24 (courtesy of Armour Pharmaceuticals)."

25 In 1986. The available documentation suggests

71

1 cryoprecipitate until 1977, and then a range of
2 different concentrates at the main source.

3 But, again, the treatment decisions appear to be
4 led from Treloars rather than from Maelor.

5 There is little information available about the
6 knowledge of risk on the part of the Maelor
7 clinicians. There's no reference to Dr Owens
8 attending any UKHCDO meetings in the 1970s or in the
9 1980s, and although Maelor had a Centre number it's
10 not clear whether the minutes would have been sent to
11 Maelor, because it was regarded as not an official
12 Centre.

13 There is an exchange of correspondence, the --
14 in relation to the two patients I've referred to,
15 there is, I should have said, a reference to
16 a particular batch of Hemofil being infected with
17 hepatitis in 1974.

18 So that's Maelor.

19 PRESENTATION RE LEIGHTON HOSPITAL, CREWE

20 The next Centre is Leighton Hospital in Crewe.
21 Again, as we saw from one of the documents we looked
22 at earlier, described as not an official Haemophilia
23 Centre, and being subject to special arrangements, but
24 it did have its own Centre number, Centre 69. And
25 there's a letter from Dr Gunson in the mid-1980s which

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1 that Leighton received its blood and blood products at
2 the regional Blood Transfusion Centre at Manchester,
3 at least in the 1980s.

4 Again, in terms of treatment and numbers of
5 patients the figures are -- I think I can take without
6 going to the underlying documents. So the numbers of
7 patients treated are small: 1977, three haemophilia A
8 patients treated with cryoprecipitate; the next return
9 we have is 1980, one haemophilia A patient treated
10 with cryoprecipitate; the same in 1981, one
11 haemophilia A patient with cryo; 1982, two
12 von Willebrand's patients treated with
13 cryoprecipitate; 1983, the same; there's some
14 evidence, again, of the von Willebrand's patients
15 being treated in 1984; and possibly one
16 von Willebrand's patient being treated in 1985 by
17 cryoprecipitate.

18 So, again, a similar pattern to the other
19 smaller centres we've looked at.

20 Little information available about what any
21 individual clinicians at Leighton would have known
22 other than what Dr Evans, as director at Manchester
23 Children's Hospital, would have known. There's no
24 recorded attendance of Dr Allison or Dr Chandran at
25 UKHCDO meetings in the 1970s or 1980s, and because of

72

1 the slightly unclear status of the hospital or the
2 Centre, we can't say for certain that they would have
3 received the minutes, but clearly they're part of
4 a region in which a number of other haemophilia
5 clinicians would have received the minutes and would
6 have participated in the meetings.

7 There's some evidence in the 1995 look-back
8 exercise in relation to patients who received blood
9 transfusions. But no data about numbers of patients
10 infected, if any, with HIV or hepatitis C from their
11 treatment with cryoprecipitate later.

12 **PRESENTATION RE BLACKPOOL HAEMOPHILIA CENTRE**

13 That takes me next to the Blackpool Haemophilia
14 Centre. Again, a very small centre. It's not clear
15 how long or over what period of time there was
16 a centre at the Blackpool Victoria Hospital. There's
17 reference in 1985 to a BPL batch of Factor VIII being
18 issued to Blackpool Victoria. There's reference in
19 1987 to a distribution list for VIIIY, identifying
20 a Centre at Blackpool for which a Dr Flanagan was
21 responsible. Blackpool was given a UKHCDO Centre
22 number, Centre 71, but again the documentation
23 describes it as not being an official centre and
24 special arrangements applying.

25 There's only one available annual return and

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1 information available about Lancaster.

2 It was formally designated as a Haemophilia
3 Centre in 1977, and its director was Dr Douglas Lee
4 from 1977 to 1989, and then Dr David Gorst took over
5 as director in 1989.

6 We have a fairly informative statement from
7 Dr Lee that was prepared for the HIV litigation, and
8 perhaps the easiest thing for me to do is to go to
9 that statement and refer to certain passages in it,
10 because it provides the best information we have about
11 the approach to treatment at Lancaster. It's
12 NHBT0096558_009.

13 Sir, we can see Dr Lee explains that by the time
14 he's doing this statement he's Regional Director of
15 the northwest regional Blood Transfusion Service and
16 had been since April 1989.

17 From January 1976 until that time he'd been
18 appointed to Lancaster Transfusion Centre as
19 consultant in charge. So he was one of those
20 haematologists who worked both on the transfusion side
21 and on the haemophilia side. We can pick that up in
22 the next paragraph. He says:

23 "On appointment at Lancaster, I was asked to
24 organise the treatment of haemophiliacs which was at
25 that time fragmented. This had been divided between

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1 that's for 1990, which shows the treatment of one
2 haemophilia A patient and one haemophilia B patient,
3 and both receiving NHS Factor VIII and IX
4 respectively.

5 The only information we have about -- there's no
6 information about HIV in relation to Blackpool. In
7 relation to hepatitis C, the only information we have
8 is about patients infected through blood transfusions.

9 Again, the way in which the look-back program
10 was rolled out and how patients infected with
11 transfusions learnt of their infection or didn't learn
12 of their infection is something we will be exploring
13 in later hearings.

14 There is a striking gap in relation to the
15 position of one witness who's told the Inquiry he was
16 affected with hepatitis C following blood transfusions
17 at the hospital in Blackpool, received transfusions in
18 1978 and 1981, only learnt he was hepatitis C positive
19 in 2010 when routine tests were being undertaken.

20 But, as I say, the only information we have is
21 about infection with blood transfusions and we'll
22 explore some of that in more detail in later hearings.

23 **PRESENTATION RE LANCASTER HAEMOPHILIA CENTRE**

24 Sir, I'm going to turn now to the Lancaster
25 Haemophilia Centre and there's rather a lot more

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1 three physicians and there was no unifying consultant.
2 There were five or six severely affected patients in
3 the District requiring regular treatment.

4 "Because there was always the doctor on call at
5 the Transfusion Centre, I arranged for the
6 haemophiliacs to attend the Centre if they needed
7 treatment. I organised a roster for the treatment of
8 patients and I also saw them periodically for a review
9 of their general health, the state of their joints,
10 etc, in an Outpatients appointment. Initially almost
11 all the treatment was based on cryoprecipitate. As
12 Factor VIII Concentrate became available, the patients
13 were trained in home treatment. I still saw these
14 patients in Outpatients approximately once a year or
15 when they came in to pick up Factor VIII or
16 alternatively came in for treatment either for a bad
17 bleed or some other reason so that despite there being
18 only occasional formal appointments, there was in fact
19 regular contact. I severed my links with the patients
20 when my present appointment was ratified in April
21 1989. Therefore, in all, I knew these patients very
22 well from approximately 1977 until 1989."

23 He then refers in the next paragraph to
24 Lancaster being:

25 "... an associate centre which deals primarily

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1 with treating haemophilia at a basic level. For most
2 other problems the patients are referred to the
3 haemophiliac reference centre", which was Manchester.

4 He is then commenting on paragraphs in the HIV
5 litigation statement of claim, and I meant to bring
6 that with me, sir, in order to be able to match the
7 paragraphs up to the questions but I don't think it
8 matters in terms of understanding what he says.

9 So if we go a little further down the page, he
10 talks about his main link being with the Manchester
11 Haemophilia Reference Centre, although there was one
12 patient referred to Oxford. He says:

13 "I attended periodic meetings which Dr Wensley
14 would organise, perhaps annually, which provided an
15 update. More recently, Dr Gunson held meetings
16 concerning the purchase of heat-treated Factor VIII.
17 I also had the opportunity to attend the annual
18 meetings of the Haemophilia Directors."

19 Top of the next page, again he says that a new
20 haematologist joined in 1980, but he retained his
21 earlier role in relation to haemophilia care. He
22 refers to some patients having his home telephone
23 number, and then in the next paragraph he says:

24 "The total number of patients between 1977 and
25 1989 would be approximately 10."

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1 second paragraph, he says:

2 "Heat treated ... [concentrates] were used as
3 soon as these were available to me.

4 "... We used NHS Factor VIII for all my patients
5 except one or two. That reflects the privileged
6 position that Lancaster was in in being able to get
7 almost all of our supplies as BPL Factor VIII."

8 Then he refers below to the treatment of:

9 "... two patients with commercial concentrate
10 who in the past had received large quantities of
11 Factor VIII. [And] ... one patient broke his leg and
12 he was on daily doses ... So when commercial
13 concentrates had to be used again it was offered to
14 those two patients if we needed to give it to anyone."

15 Then, if we go over the page, top of the next
16 page, he refers to using small amounts of imported
17 heat-treated Factor VIII from late 1984 from
18 Dr Wensley. Refers to a book called The Cryo Pooling
19 Book, which recorded the batch number of Factor VIII
20 concentrates.

21 And he then turns to knowledge of risk.

22 "I have been aware that haemophiliacs were at
23 risk of acute hepatitis since 1966 when I first became
24 involved with them. I do not know when I became aware
25 that commercial Factor VIII had a higher risk. This

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1 So a small associate centre, but also, as he
2 says in the next paragraph:

3 "An additional commitment was to provide
4 treatment for visiting haemophilia patients ... the
5 North West branch of the Haemophilia Society purchased
6 a static caravan site close to Lancaster and I agreed
7 to receive advance information about visiting
8 haemophiliacs and to provide treatment if necessary."

9 If we go to the top of the next page, he says:

10 "We received as much Factor VIII as was required
11 for treatment on demand and later for home treatment."

12 He deals, under what's headed "Paragraph 92(k)",
13 with being in the hands of Dr Wensley in relation to
14 heat-treated concentrates. He says:

15 "The supply of NHS Factor VIII and the purchase
16 of commercial Factor VIII was channelled through
17 Manchester. Most of the material used in Lancaster
18 was from NHS sources. We believed that this NHS
19 product was less likely to be contaminated than
20 imported products. One positive step which I took was
21 to try to make sure that individual patients were
22 exposed to as few batches as possible."

23 So there some evidence of a proactive attempt to
24 limit exposure.

25 He then refers to heat treatment. Next page,

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1 was a risk faced by anyone who received blood or
2 a blood product.

3 "I believe that I first appreciated the risk of
4 chronic hepatitis to haemophiliacs from Factor VIII
5 and IX in the mid 70s because a colleague in Sheffield
6 was interest in liver damages to haemophiliacs".

7 That may be Professor Preston perhaps.

8 "Any treatment with blood products carried the
9 risk of hepatitis. It could have been obtained from
10 the cryoprecipitate and was indeed passed on in this
11 way."

12 Then, top of the next page, he says:

13 "From 1977 the imported Factor VIII and its path
14 from Manchester to my patients is fully documented.
15 I obtained the Factor VIII from Manchester.

16 "I determined its use (only occasionally when
17 necessary) when supplies of NHS Factor VIII were not
18 available in sufficient quantity ..."

19 Next paragraph he says he used non-heat-treated
20 Factor VIII exclusively until late '84, and then
21 commercial heat-treated as it became available in
22 Manchester, and from April 1985 he believed he used
23 exclusively heat-treated product.

24 At the bottom of the page:

25 "There was a swing back to cryoprecipitate being

80

1 administered to children and mildly affected adults in
2 the early 1980s because of the risk of hepatitis.
3 Dr Wensley has indeed always been a powerful advocate
4 of cryoprecipitate. It is a harder product to make
5 and to administer than Factor VIII, but his thoughts
6 were that yields of cryoprecipitate over those of
7 concentrate are roughly 70% compared to 20%, and the
8 risk of transfused virus are certainly less. He would
9 advise this constantly at haemophilia directors
10 meetings, and I remember he was very much alone on
11 this point at one time."

12 Dr Lee then deals with HIV in the next
13 paragraph:

14 "I became aware of the emergence of HIV/AIDS
15 when the virus was identified as HTLV-III when those
16 papers were published concerning strange illnesses
17 amongst homosexuals.

18 "I cannot exactly recall when I became aware
19 of AIDS; my recollection is of an evolving story from
20 1981 onwards.

21 "Paragraph 92(z)

22 "I kept myself informed by journals and
23 discussions with colleagues, transfusion directors'
24 meetings, and minutes of Haemophilia Directors
25 Meetings.

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1 they had haemophilia of such severity as to make
2 Factor VIII concentrate the only appropriate
3 treatment. And then he refers again to the use of
4 heat-treated, bottom of the page, first to advice from
5 the haemophilia reference directors.

6 I think the date there is wrong, 1982. I think
7 it should be a reference to 1983.

8 Then over the page he says:

9 "Cryoprecipitate was used for children and
10 mildly affected haemophiliacs. I have not used
11 Desmopressin."

12 Then this:

13 "Patients were advised of the risk of HIV
14 infection when it was agreed by the Haemophilia
15 Directors that this was appropriate."

16 Well, we've no evidence of haemophilia
17 directors -- if that's a reference, as I think it
18 might be, to the annual meetings or indeed Reference
19 Centre Director meetings, but we've no evidence of any
20 advice being given about risks of -- communication of
21 risks of HIV infection to patients. The only
22 discussion we really see is from December 1984, that
23 meeting of Elstree, when that's talking about what you
24 tell patients about testing. It's not talking about
25 the logically anterior issue of what you tell them

83

1 "Paragraph 92(aa)

2 "I did become aware of the connection between
3 AIDS and blood products but I cannot remember when. I
4 relied on the meetings of the haemophiliac directors
5 and contact with Dr Wensley for new information since
6 my role was to treat Haemophilia patients rather than
7 to make policy.

8 "I try to read the leading articles in The
9 Lancet every week, and believe that I would therefore
10 have read articles on 15th, 22nd and
11 29th January 1983."

12 Top of the next page:

13 "We only used imported non-heat treated
14 Factor VIII as a second line of treatment -- it was
15 never the treatment of choice. It was not used for
16 children and mildly affected patients."

17 And then third paragraph:

18 "I can remember advising patients who received
19 either of these products that whatever the risk of the
20 treatment was, it was less than the risk of
21 non-treatment."

22 So that doesn't really tell us much about what
23 he actually said the risk of treatment was.

24 And then we can see a reference to there being
25 two patients who seroconverted. The suggestion is

82

1 about the risks of treatment.

2 Then, bottom of the page, he says:

3 "All my haemophiliac patients were tested for
4 HIV infection after appropriate counselling, and that
5 included a full discussion culminating in the patient
6 deciding whether or not they wished to know the
7 results. We were encouraged to test each patient by
8 the Haemophiliac Directors.

9 "Paragraph 92(bi)

10 "Two patients proved to be HIV positive. One
11 did not wish to know and I saw the other personally
12 and explained the full implications."

13 And he says none of the children he treated were
14 tested positive.

15 So that is the evidence from Dr Lee.

16 In terms of other documents, I think the
17 returns -- again, I can -- actually, no, I think, the
18 returns, it might be more useful to look at the actual
19 documents.

20 So if we go to HCDO0001173, we can pick up the
21 picture at page 4. So this is the return for 1977
22 for Lancaster, director, Dr Douglas Lee, and then
23 total number of haemophiliac patients treated during
24 the year, we've got five. And then I think that says
25 "[plus] 8 visitors", so that is presumably to the

84

1 caravan that was referred to in Dr Lee's statement.
 2 And then we can see what's being used there:
 3 predominantly cryoprecipitate, some NHS Factor VIII
 4 concentrate, a small amount of Kryobulin.
 5 If we go to HCDO0001270, we can see, in 1978,
 6 ten patients treated, again predominantly with
 7 cryoprecipitate and NHS Factor VIII concentrate. And
 8 there's, I think, no treatment for haemophilia B, none
 9 for von Willebrand's.
 10 And then 1979 is HCDO0001339, five haemophiliac
 11 patients treated during the year, I think that's
 12 a reference to haemophilia A again, two
 13 Christmas Disease patients. We can see there's
 14 a reference to 837 bottles of cryo being used, and
 15 then the primary treatment is with NHS concentrate,
 16 39,640, and then a smaller amount of NHS Factor IX
 17 concentrate for the Christmas Disease patients.
 18 If we go to page 4, there's one von Willebrand's
 19 patient treated in that year with cryoprecipitate.
 20 If we then move to 1980, HCDO0001434, we've got
 21 11 haemophilia A patients and one von Willebrand's.
 22 The von Willebrand's patient is treated with
 23 cryoprecipitate. Cryoprecipitate is used in
 24 hospitals, 73,000-odd units. NHS Factor VIII used for
 25 hospital and home treatment in smaller amount and then

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1 hospital, 148,000 home treatment. A small amount of
 2 cryoprecipitate used in hospital, and a small amount
 3 of Hemofil used for home treatment.
 4 If we go to 1984, HCDO0001825, there doesn't
 5 appear to be any commercial concentrates used, so just
 6 under 25,000 units of cryoprecipitate, 58,730 units of
 7 NHS concentrate for hospital, and 91,000-odd for home
 8 treatment.
 9 Then I think, lastly, if we look at 1985,
 10 HCDO0001919, there's some usage of Profilate for the
 11 first time. Again, the product mostly used is
 12 NHS concentrate, hospital and home, cryoprecipitate
 13 used to a small extent for haemophilia A patients and
 14 then used for von Willebrand's patients.
 15 So the returns appear to be broadly consistent
 16 with the narrative account given by Dr Lee in his
 17 statement made as part of the HIV litigation.
 18 I don't need to go to the other documents but
 19 there's evidence to suggest that there was a home
 20 treatment programme in Lancaster by late 1977. We
 21 looked at issues relating to shortages of concentrate
 22 in the northwest region during the Manchester
 23 presentation, and there are letters from Dr Lee in the
 24 late eighties which refer to that, but it doesn't
 25 appear to have greatly affected the supply of NHS

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1 we see commercial concentrates being used, relatively
 2 small amounts, 6,140 units of Factor VIII, 604 units
 3 of Hemofil, being used in hospital.

4 I don't think we need go to it but there are two
 5 haemophilia B patients treated solely with Factor IX
 6 concentrate.

7 If we then move to 1981, HCDO0001535.

8 It's not clear whether it's 15 or 16 patients
 9 treated. But in any event, if we look then at the
 10 page -- again, it's things scribbled out here so it's
 11 not entirely easy to read, but there appears then to
 12 result in the usage of 49,600 units of
 13 cryoprecipitate, and then what looks like roughly
 14 78,000 units of Factor IX -- NHS Factor IX concentrate
 15 in hospital, 48,000-odd for home treatment, and
 16 a smaller amount, 14,800 units, of Hemofil.

17 A not dissimilar picture from 1982, HCDO0001634.
 18 So rather less in terms of cryoprecipitate for the
 19 nine patients. But again, the only commercial
 20 concentrate is Hemofil, and the bulk of the treatment
 21 appears to be with NHS concentrates, both in terms of
 22 hospital and home treatment.

23 And if we go to 1983, HCDO0001733, 15 patients
 24 with haemophilia A, one carrier. The bulk of the
 25 treatment is with NHS concentrate. So 198,000

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1 concentrate to Lancaster.

2 In terms of knowledge of risk, again, the best
 3 evidence we have is Dr Lee's own statement and his
 4 attendance at UKHCDO meetings.

5 There are references to various documents -- or
 6 a handful of documents, I should say, in the course of
 7 the 1970s, which refer to post-transfusion hepatitis.
 8 So, for example, in the late seventies and '78, Dr Lee
 9 sent reports of post-transfusion hepatitis to
 10 Dr Maycock. There's a handful of other documents
 11 which refer to hepatitis.

12 But we know that Dr Lee attended most
 13 UKHCDO meetings. He didn't attend the 1979 meeting,
 14 and doesn't appear to have been at the meetings in
 15 '82, '83, and '84, but the evidence we have would
 16 suggest that, as the director of a recognised Centre,
 17 he would have been sent the minutes, and there are
 18 various documents we've got which are letters from
 19 Ms Spooner or Dr Rizza, whoever, saying, "Please find
 20 attached the draft minutes" or "Please find attached
 21 the final minutes of meetings", so they do appear to
 22 have been routinely circulated to directors, and thus
 23 what was discussed would have been known to directors
 24 whether or not they attended the actual meetings.

25 In relation to HIV or other HTLV-III, at the

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1 time Dr Lee would also have been wearing his
2 transfusion hat. As we saw from the statement, he was
3 both a transfusion -- involved in the Transfusion
4 Service as well as the care of those with haemophilia.
5 And there are various documents showing meetings in
6 the course of, in particular, 1985 in which Dr Lee and
7 Dr Gorst are both participating in which the
8 introduction of HTLV-III testing for blood donations,
9 including at the Lancaster Transfusion Centre, is
10 discussed. So that would have been something which he
11 would have been aware of.

12 You'll have seen from Dr Lee's evidence in terms
13 of numbers infected with HIV, Dr Lee's account was two
14 patients. There's no reason to dispute that, or doubt
15 that. The provisional data that UKHCDO supplied to
16 the Inquiry identifies only one patient testing
17 positive, in 1985, but, sir, the UKHCDO data reflects
18 only that which has been reported to it, and so, given
19 that Dr Lee is able to describe the different
20 circumstances of the two patients who seroconverted,
21 it may be a more reliable indication than the UKHCDO
22 data.

23 In terms of testing for hepatitis C, there is
24 evidence to suggest that in 1989, patients who'd
25 received blood transfusions in Lancaster were being

89

1 receive ethical approval for that study.

2 Perhaps if we just look at one document which
3 throws a little light on it, although, as I say, it's
4 with Dr Lee wearing his transfusion hat. It's
5 NHBT0112569_001, please.

6 So this just gives a little information about
7 the -- it's a letter to a GP, October 1992, about
8 a particular patient. It talks about the interest in
9 hepatitis C, since the marketing of a test which
10 detects anti-body to the virus. It refers to the
11 Manchester Centre taking part in a multi-centre study
12 to throw more light on the problem. Again, this is
13 from Dr Lee wearing his transfusion hat.

14 Then it says this halfway down the paragraph:

15 "... it was recognised that an opportunity
16 existed to retain samples from patients transfused
17 during July and August 1991 and to use the new test
18 retrospectively to attempt to establish which
19 donations, positive for anti HCV, would result in
20 seroconversion in the recipient patients, the study
21 has the full ethical approval of the District Ethical
22 Committee."

23 Then he asks about approaching this particular
24 patient, who was the resident in a nursing home, to
25 obtain consent to test the sample which had been

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1 tested for hepatitis C through the Public Health
2 Laboratory Service. And there's correspondence
3 between the Lancaster Transfusion Centre and
4 Dr Craske, asking Dr Craske to do a hepatitis C
5 marker.

6 There's also various discussions and
7 communications to which Dr Lee was party in 1990 and
8 1991 discussing the introduction of the testing of
9 blood donations for hepatitis C at the Lancaster
10 Transfusion Centre.

11 And it's being contemplated -- or there are
12 discussions taking place at least from July 1990
13 onwards, although it appears that, in common with
14 other centres, donations were only tested from
15 September 1991.

16 Again, I don't think I need to go through it for
17 present purposes because it's Dr Lee wearing his
18 transfusion hat, and we may want to look at this more
19 in later hearings, but there's communications between
20 Dr Lee and his local Ethical Committee in 1991 about
21 joining a hepatitis C study designed by
22 Professor Allain at the Cambridge Regional Transfusion
23 Centre.

24 And it was about testing pre-transfusion
25 samples, and post-transfusion samples. Dr Lee did

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1 retained in 1991 and to establish whether or not
2 seroconversion had taken place.

3 So we don't have very much evidence about
4 testing the haemophilia patients for hepatitis C and
5 Dr Lee would have moved on to being in a purely
6 transfusion role by this time. But his own approach
7 in relation to consent in 1992, in relation to the
8 study, appears to have been to seek patient consent.

9 I think that is probably all we have about the
10 Lancaster Centre. As I say, the information in
11 relation to hepatitis C testing and diagnosis for
12 bleeding disorder patients at the Haemophilia Centre
13 is little.

PRESENTATION RE BLACKBURN ROYAL INFIRMARY

14 Sir, I'm then going to deal with Blackburn.
15 I won't necessarily complete it before lunch but
16 I should be able to get a reasonable amount done.

17 Sir, there was a centre at the Blackburn Royal
18 Infirmary from 1977. Dr David Newsome was the
19 centre's director and he has provided witness
20 statements to the Inquiry.

21 He has told the Inquiry in his statement that
22 before he arrived in 1977, haemophilia had not been
23 treated in Blackburn, but the Centre was then set up
24 as an associate Centre of the Manchester Royal
25

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1 Infirmary, the aim being that rather than having to
2 travel to Manchester, patients in the Blackburn,
3 Burnley and Preston area could travel a shorter
4 distance to be treated with cryoprecipitate if they
5 had a bleed.

6 He explains that cryoprecipitate came from the
7 Blood Transfusion Service, would usually be
8 administered by him, but patients would be followed up
9 at Manchester, and he describes how, as time went on,
10 patients were transferred from cryoprecipitate to
11 concentrates, and that decision to switch to
12 concentrates he describes as being essentially taken
13 at Manchester, and then the concentrates would be sent
14 to Blackburn for the patient to pick it up locally,
15 and there is some individual witness evidence which
16 backs that up.

17 The hospital itself in Blackburn closed in 2006
18 and Dr Newsome moved to the New Royal Blackburn
19 Hospital at that point.

20 So, again, his statement has provided an account
21 of most patients -- decisions in relation to most
22 patients being undertaken in Manchester. If they
23 required operations, those would be undertaken in
24 Manchester. He says, occasionally with
25 von Willebrand's patients, operations might be carried

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1 1980, 15 patients with haemophilia A, one with
2 haemophilia B, three with von Willebrand's treated.
3 In terms of the haemophilia A, it was largely
4 cryoprecipitate in 1980, just under 100,000 units
5 used, a small amount of NHS Factor VIII, that was in
6 hospital, no home treatment, and von Willebrand's
7 exclusively with cryoprecipitate, haemophilia B
8 exclusively with NHS Factor IX.

9 It's difficult to read the 1981 return. In
10 terms of numbers, it's 14 patients with haemophilia A,
11 two with haemophilia B, and three with
12 von Willebrand's. Again, it looks as though it's
13 predominantly cryoprecipitate used in hospital, and
14 a small amount of NHS Factor VIII for home treatment,
15 von Willebrand's only with cryoprecipitate,
16 Haemophilia B patients only with NHS Factor IX.

17 There's no 1982 return.

18 The 1983, similar number of patients,
19 13 haemophilia A, three haemophilia B, three
20 von Willebrand's. Just under 44,000 units of cryo,
21 64,400 NHS Factor VIII concentrates, most of that is
22 for home treatment. A small amount of Hemofil, 4,600,
23 no other commercial concentrates.

24 1985, the way in which it describes bottles and
25 units makes it quite difficult to follow. But in 1985

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1 out in Blackburn but, if that happened, his usual
2 practice would be to discuss the patient with the
3 Manchester Royal Infirmary staff to ensure they were
4 happy for him to supervise the Factor VIII regime and
5 to administer it.

6 In terms of returns, I think I'll try and pick
7 up the relevant data without going to the documents,
8 as much as I can. So we have returns from 1978
9 onwards, and to give an idea of the numbers of
10 patients treated, there were 11 haemophilia A patients
11 treated, three patients with von Willebrand's in 1978,
12 treated with cryoprecipitate, NHS Factor VIII and, at
13 that stage, a very small amount of Hemofil. The
14 von Willebrand's patients were treated with
15 cryoprecipitate.

16 1979, 13 haemophilia A patients, one
17 haemophilia B, three von Willebrand's treated. Again,
18 cryoprecipitate used but the greater volume of
19 treatment was with NHS Factor VIII. Then there were
20 small amounts of three different commercial
21 concentrates, Profilate, Hemofil, and Kryobulin, used
22 for hospital treatment. Von Willebrand's patients may
23 need cryoprecipitate, a small amount of NHS
24 Factor VIII, and haemophilia B patients treated with
25 Factor IX.

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1 it's 15 patients with haemophilia A four with
2 haemophilia B, one with von Willebrand's. Again, what
3 we see is predominantly cryoprecipitate and
4 NHS Factor VIII. There's reference, however, to 134
5 bottles of Profilate being used for home treatment,
6 and the return appears to suggest that a bottle might
7 represent 250 units, and that would give 33,500 units.

8 Again, the picture for von Willebrand's patients
9 is exclusively cryoprecipitate, and for haemophilia B
10 patients exclusively NHS Factor IX.

11 Sir, that's the picture that emerges from the
12 returns.

13 There is witness evidence that the Inquiry has
14 about a patient with von Willebrand's disease treated
15 with cryoprecipitate at the Centre in Blackburn and
16 that is the second case we've identified from the
17 materials of a patient being infected with HIV from
18 cryoprecipitate.

19 Dr Newsome in his statement has described there
20 being no particular policies in place in relation to
21 treatment usage when he took up his post. He doesn't
22 recall ever purchasing concentrates. He believes that
23 they obtained them from Manchester Royal Infirmary,
24 both in terms of NHS concentrate. He can't recall
25 ever purchasing commercial concentrate and, again,

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1 assumes or thinks that that was obtained directly from
2 Manchester.

3 Sir, if that's a convenient point to stop, I've
4 got to do a few more minutes after lunch on Blackburn
5 and then move to the other centres.

6 **SIR BRIAN LANGSTAFF:** Yes, we'll take a break now then
7 until two o'clock.

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

9 **SIR BRIAN LANGSTAFF:** So two o'clock.

10 (12.59 pm)

11 (The luncheon adjournment)

12 (2.00 pm)

13 **MS RICHARDS:** So, sir, still with the Haemophilia Centre
14 at Blackburn, in terms of knowledge of risk and
15 response to risk, the records suggest that Dr Newsome
16 was not a regular attendee at UKHCDO meetings. He was
17 there in 1977 and 1978 but he doesn't appear to have
18 attended meetings in the 1980s, however there's no
19 reason to think he wouldn't have received the copies
20 of minutes of the meetings.

21 In his statement, he has said he can't remember
22 how information from UKHCDO reached him and he would
23 have regarded its advice to be precisely that, in
24 other words, to be advice.

25 There's comparatively little contemporaneous

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1 could get hepatitis from a transfusion often blood or
2 blood products. There was a suspicion that American
3 derived Factor VIII could transmit blood borne
4 viruses. We were less concerned with domestic blood
5 within the NHS."

6 Dr Newsome is not able to recall to what extent
7 there was a discussion with patients about the safety
8 to of cryoprecipitate. He says he thinks he would
9 have discussed the rationale for using cryoprecipitate
10 with a patient, but not necessarily the risk of
11 transmission of disease as cryo was deemed safe at the
12 time.

13 In terms of knowledge of risk of HIV, again, as
14 I've said, he didn't attend UKHCDO meetings in the
15 1980s but we -- it may be reasonable to assume he
16 would have received the minutes and the letters that
17 were sent out in 1983. He refers to having realised
18 early on that HTLV-III could be transmitted by blood
19 and blood products, as there was a high incidence in
20 haemophilia patients, but he can't remember exactly
21 when he became aware of that association.

22 He says, in terms of responding to that risk,
23 that he didn't need to change his practice as he
24 wasn't involved in starting patients on factor
25 concentrates, and did not operate on patients with

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1 evidence relating to hepatitis. Dr Newsome has said
2 in his statement it's very difficult for him to
3 remember his knowledge of hepatitis risks at the start
4 of his career in 1974 and he's unable to recall with
5 accuracy how his knowledge developed over time,
6 although he says in his statement that he did realise
7 that hepatitis B could be a lethal infection.

8 He says in terms of relative risks:

9 "Throughout my career I believe that products
10 made by the National Blood Transfusion Service and its
11 successors were relatively safe but that concentrates,
12 particularly of American origin, were not. As time
13 went on, I began to realise that NBTS products were
14 not as safe as I had believed, particularly with
15 respect to hepatitis C."

16 He said he tried to, in order to reduce risks of
17 hepatitis transmission, prioritise the use of
18 NHS products.

19 In an earlier statement he gave, which was in
20 response to an individual witness statement, a patient
21 who was infected following an operation in 1987, he
22 said, at that time:

23 "We knew at the time of the risk of infection
24 from blood products that were pooled and which came
25 from blood outside of the country and that patients

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1 haemophilia, as distinct from patients with
2 von Willebrand's disease who were treated with
3 cryoprecipitate.

4 He doesn't remember changing patients back to
5 cryoprecipitate from concentrate, but he says that
6 would have been a decision taken by the Manchester
7 Centre, that he would then have implemented.

8 In terms of arrangements for testing patients,
9 he has little recollection, in terms of HIV, he is
10 aware, he says, of one patient infected with HIV but
11 doesn't have any knowledge of whether there were any
12 other patients or of numbers infected with
13 hepatitis C.

14 We don't have any data in terms of the material
15 that the UKHCDO has recently provided to the Inquiry
16 in relation to cases in Blackburn, but there is a form
17 from 1991 which is a list of A3 forms submitted by
18 centres to UKHCDO, and that does include one patient
19 from Centre 63, in other words from Blackburn, who is
20 recorded as having tested HIV positive in June 1985,
21 so that may be the one case that Dr Newsome is
22 referring to, or may not.

23 He says he would have informed patients of
24 results in any event in a face-to-face conversation.
25 He can't recall giving any patients a hepatitis C

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1 diagnosis but says if he had done so, he would have
2 done so again face-to-face.

3 Arrangements for treatment of patients with
4 hepatitis C, he would have been largely either under
5 the care of a gastroenterologist or been treated in
6 Manchester.

7 Sir, we do have a handful of witness statements
8 from individuals who were treated at Blackburn.

9 There's a patient with mild von Willebrand's. She
10 received cryoprecipitate prophylactically in relation
11 to a caesarian section. She questioned the need for
12 it at the time. She says she was not told of the
13 risks. She was aware by 1987 of certain risks
14 associated with HIV. She believed that what she was
15 receiving in terms of cryoprecipitate would have been
16 heat-treated, virally inactivated and safe; she was
17 infected with hepatitis C.

18 There's another patient with von Willebrand's
19 who describes being treated both in Aberdeen and in
20 Blackburn, infected with hepatitis C. Again, he says
21 he was never told of the risks of treatment.

22 A patient with severe haemophilia A, whose
23 Factor VIII was consistent with Dr Newsome's
24 description, sent by Manchester to Blackburn to be
25 picked up, was infected with hepatitis C, says no

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1 evidence about the adult Haemophilia Centre. The
2 Children's Hospital operated as a Haemophilia Centre,
3 effectively, in its own right.

4 Prior to 1975 the consultant haematologist at
5 the Sheffield Children's Hospital was Dr Jeremy
6 Guyer(?), but his principal interest was leukaemia, so
7 for that early period paediatric patients with
8 bleeding disorders were primarily cared for by
9 Professor Blackburn, who was the adult haematologist.
10 But in 1975 Dr Lilleyman was appointed consultant
11 haematologist at the Children's Hospital, and he
12 worked in that capacity until 1995. He was a member
13 of UKHCDO over that period of time and he has provided
14 the Inquiry with two statements, and much of the
15 information I am going to refer to was drawn from
16 those statements.

17 Both the documentary evidence from
18 Dr Lilleyman's evidence suggests that there was
19 a close relationship between the adult and children's
20 Haemophilia Centres with haematology trainees
21 effectively doing rotations in relation to both. They
22 were geographically close and Dr Lilleyman says that
23 "We all met at least once a week for journal reviews
24 and discussion of clinical problems".

25 There was also a close relationship with the

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1 advice about risks was given to his parents.

2 Then we have a statement from a patient with
3 severe haemophilia B, infected with hepatitis C
4 through Factor IX. Treated both at Blackburn and,
5 I think, also Manchester Children's Hospital, told
6 that this mother was not told of the risks and indeed
7 was reassured that this was a treatment that was safe.

8 Then there is a patient with severe
9 von Willebrand's, treated with cryoprecipitate,
10 including at home, and that's a patient I referred to
11 earlier, who was a patient infected with HIV and
12 hepatitis C and hepatitis B, who also says that they
13 were given no advice or information about risks.

14 In terms of taking the blood samples, stored
15 samples, Dr Newsome's recollection is that samples
16 were only ever taken as part of a clinical assessment,
17 not taken for research, not aware of any samples being
18 stored for prolonged periods, not aware of patients
19 being tested for HIV or hepatitis without consent.

20 So that's a summary of the picture in relation
21 to Blackburn.

22 PRESENTATION RE SHEFFIELD CHILDREN'S HOSPITAL

23 I'm going to move next, sir, to Sheffield
24 Children's Hospital. You'll recall we've heard oral
25 evidence about and have received further written

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1 Regional Transfusion Centre under Dr Wagstaff. We
2 will explore the operation of the Transfusion Centre
3 hopefully in more detail in hearings later this year,
4 but Dr Lilleyman has described in his statement that
5 Dr Wagstaff, who was the director of the Regional
6 Transfusion Centre, used to do a formal clinical
7 session with him once a week when he came to help with
8 the leukaemia clinic and Dr Lilleyman says Dr Wagstaff
9 was a useful contact for the supply of blood products,
10 in particular, cryoprecipitate.

11 In terms of where products were obtained from,
12 for the Children's Hospital in Sheffield, Dr Lilleyman
13 says there were two sources. The first was direct
14 from the Blood Transfusion Service, fresh plasma and
15 cryoprecipitate, and those products would be delivered
16 direct to the haematology department.

17 The second method, in terms of procuring
18 concentrates, was via the Sheffield Children's
19 Hospital pharmacy, which would order concentrate in
20 turn via the pharmacy at the Hallamshire Hospital.

21 Dr Lilleyman says that the selection and
22 purchase of blood products was a decision for the
23 consultant haematologists and he refers to regular
24 informal meetings between the consultants at the
25 Hallamshire and the consultants at the Children's

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1 Hospital, as well as the wider discussions at UKHCDO
2 meetings.

3 There were also, we know, Blood Transfusion
4 Director and Haemophilia Centre Director meetings
5 which Dr Lilleyman occasionally attended.

6 He says this, in terms of his own approach:

7 "My personal involvement in deciding on which
8 factor concentrate to purchase was frequently to
9 reiterate that for children who were small and
10 required less Factor VIII per dose than adults,
11 cryoprecipitate had many advantages, and for most
12 admissions for joint bleeds, bumps and scrapes, heavy
13 bruises, minor surgery was to be preferred, since it
14 only exposed patients to a very small number of UK
15 donors and reduced the risk of viral transmission that
16 was becoming a recognised problem with large pool
17 fractionation processing."

18 He describes cryoprecipitate as the treatment of
19 choice at the Children's Hospital for all but the most
20 serious bleeds or surgery, particularly after the
21 problems of viral transmission of non-A, non-B
22 hepatitis started to appear. He also refers to the
23 use of tranexamic acid and DDAVP.

24 It is right to note, however, that the Inquiry
25 has evidence from a mild haemophilia A patient who was

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1 annual returns.

2 If we start with 1979, we don't have a '78
3 return, HCDO0001367, we can see here 23 haemophilic
4 patients, two with antibodies, five Christmas Disease
5 patients. And then in terms of the product usage:
6 cryoprecipitate, 76,580, looks like; NHS concentrate,
7 115,492. So that's the largest amount used. But then
8 a not insignificant amount of Factorate, 38,850, and
9 then a smaller amount of Kryobulin, 10,076. And then
10 you'll see that NHS Factor IX concentrate was used for
11 the Christmas disease patients and, in relation to
12 "Other Materials", reference to FEIBA.

13 Then if we go to 1980, HCDO0001465, we can see
14 20 patients -- haemophilia A patients treated, one
15 von Willebrand's. Then if we look at the product
16 usage, for the von Willebrand's patient, perhaps
17 somewhat surprisingly, we see no treatment with
18 cryoprecipitate, but treatment with Factor VIII, the
19 Armour product. For the haemophilia A patients,
20 a very modest amount, comparatively, of
21 cryoprecipitate, a much larger amount of NHS factor
22 concentrate used for home treatment --

23 **SIR BRIAN LANGSTAFF:** Have we attempted to convert the
24 bags into units?

25 **MS RICHARDS:** Ah, no, I should do that. Yes, you're

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1 treated with Factor VIII concentrates, and was
2 infected with hepatitis C as a result.

3 Although Dr Lilleyman in his statement very much
4 focuses on cryoprecipitate, and we'll look at what the
5 annual returns show in a moment, it is relevant to
6 look at a letter from him to Dr Aronstam at Treloars
7 in 1979.

8 It's TREL0000237_068.

9 Actually, sorry, there's a letter to similar
10 effect that's easier to read.

11 TREL0000090_032, please. Sorry, Soumik.

12 So this is a letter from Dr Lilleyman to
13 Dr Aronstam in September 1979. It's in relation to
14 a particular pupil -- or patient, refers to
15 self-therapy in the first paragraph and then it says:

16 "The material that we use, subject to
17 availability, is the Lister concentrate but we also
18 use commercial concentrate (chiefly Factorate by
19 Armour Pharmaceuticals) to make up any shortfalls in
20 supply."

21 And then indicates that they would be happy to
22 provide such materials for the individual patient
23 during the school holidays.

24 In terms of product usage, the best guide to
25 what products were actually used is probably the

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1 right, sir, that is bags, not units, isn't it?

2 I'm not sure whether we have anything which
3 indicates a standard approach from Sheffield. Because
4 ordinarily, the figures are given as units. Or
5 sometimes as bottles, et cetera.

6 In the previous return, 1,094 bottles was
7 76,000-odd units. I'm going to rely upon either --

8 **SIR BRIAN LANGSTAFF:** In which case it's about one and
9 a half times that for this.

10 **MS RICHARDS:** Yes, roughly.

11 **SIR BRIAN LANGSTAFF:** What were the units before?

12 **MS RICHARDS:** Just over a thousand -- it's referred to as
13 bottles but it's probably bags, was 76,580 units.

14 **SIR BRIAN LANGSTAFF:** Yes.

15 **MS RICHARDS:** So we might be looking at something over
16 100,000 units in fact.

17 **SIR BRIAN LANGSTAFF:** Well, it is certainly going to be
18 that, isn't it?

19 **MS RICHARDS:** Yes.

20 **SIR BRIAN LANGSTAFF:** It is going to be roughly, yes, 110.

21 **MS RICHARDS:** Yes, you're absolutely right. Used in
22 hospital. So perhaps a not dissimilar amount to the
23 amount of NHS concentrate used, 113,495 for home
24 treatment and then a much smaller amount in hospital.

25 And then we can see Factorate being used, the

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1 Armour product, 12,000-odd for home treatment, 504
2 units in hospital, and a smallish amount also of
3 Kryobulin used in hospital, 4,340. Then, over the
4 page, tells us there were four haemophilia B patients
5 treated with NHS Factor IX.

6 **SIR BRIAN LANGSTAFF:** What it appears to show is that the
7 treatment in hospital was very heavily weighted in
8 favour of cryo and obviously at home it was the other
9 way round.

10 **MS RICHARDS:** Yes.

11 **SIR BRIAN LANGSTAFF:** There wasn't any cryo used at home.

12 **MS RICHARDS:** Then if we go to 1981, HCDO0001566,
13 20 patients treated with haemophilia A, none with
14 von Willebrand's.

15 If we zoom in on the figure for cryoprecipitate,
16 I think we have got, then, bags, 1,344, but someone
17 has written in what looks like roughly 94,000, which
18 again sounds roughly right.

19 **SIR BRIAN LANGSTAFF:** Yes.

20 **MS RICHARDS:** So hospital treatment again weighted towards
21 cryoprecipitate and then home treatment weighted
22 towards NHS concentrate. 178,750 there.

23 And then you can see just over 9,000 units being
24 used of Factorate, the Armour product. But
25 a significantly larger volume of Kryobulin used that

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1 hospital, we're told, 971 bags. Someone has written
2 in 67,970 in terms of units.

3 NHS factor concentrate is the bulk -- well, is
4 the sole treatment for home treatment, 136,100, then
5 a small amount, 17,535 in hospital.

6 No commercial products there recorded. The only
7 other treatment recorded is Autoplex, towards the
8 bottom of the page.

9 And then again, as is normal, we see the
10 haemophilia B patients, on page 3, being treated with
11 NHS Factor IX concentrate.

12 And then, if we go to 1983, HCDO0000139_004.

13 Seventeen patients with haemophilia A treated.
14 Again, we see cryoprecipitate used in hospital, 1,135
15 bags, there translated by somebody at least as
16 79,480 units. The predominant treatment for home
17 treatment is NHS concentrate, 147,622. And then
18 a small amount of Factorate being used both in
19 hospital and for home treatment, and then we can see
20 Autoplex, as well, towards the bottom of the page.

21 Then for 1984, HCDO0001854, we can see
22 17 patients treated with haemophilia A, three with
23 von Willebrand's. And again, there are no commercial
24 Factor VIII concentrates recorded. So the predominant
25 usage for cryoprecipitate is hospital treatment,

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1 year. So 104,698 units used for hospital treatment.

2 So commercial concentrate usage has increased fairly
3 significantly in 1981.

4 The 1982 return --

5 **SIR BRIAN LANGSTAFF:** Just a matter of curiosity, shortly
6 before this, there had been a price list from Immuno
7 which had priced Kryobulin at two different prices,
8 depending whether it came from American plasma, or
9 American-source plasma, or from European plasma. So
10 if you want to read -- if it's appropriate to read the
11 European as equivalent to the sort of donor base that
12 would feed the NHS, if that's appropriate, then it,
13 broadly, is in the NHS class, if you like, in terms of
14 the donor base that was feeding into it.

15 Do we have any sense as to which, if either, of
16 the Kryobulin was in this case?

17 **MS RICHARDS:** No, I don't think we do. I don't recall any
18 particular interactions with pharmaceutical companies
19 which would shed any light upon that. So we can check
20 but I don't think so.

21 If we go to 1982, then, HCDO0001664.

22 Nineteen patients with haemophilia A, two with
23 von Willebrand's. It looks as though the
24 von Willebrand's patients were treated exclusively
25 with DDAVP. Cryoprecipitate usage is solely in

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1 79,030 units, it would appear, with a small amount
2 being used for home treatment.

3 **SIR BRIAN LANGSTAFF:** Now that's interesting.

4 **MS RICHARDS:** Yes.

5 **SIR BRIAN LANGSTAFF:** So there's been -- because
6 previously we haven't had -- for some time, we haven't
7 had cryoprecipitate used at home.

8 **MS RICHARDS:** That's correct. So yes, a move to that
9 in 1984. And NHS factor concentrate then being the
10 bulk of the product then used for home treatment,
11 168,820 units.

12 **SIR BRIAN LANGSTAFF:** So in the early eighties, the amount
13 of commercial concentrate used is reduced very -- it
14 wasn't high, but from a low base is reduced even
15 further. The use of cryoprecipitate is broadly
16 maintained, drops a little bit, but it starts to be
17 used, perhaps just in one case, I don't know, but for
18 home treatment, and the main focus is on
19 cryoprecipitate in hospital and NHS concentrate for
20 home.

21 **MS RICHARDS:** That's right. A small amount of Autoplex at
22 the bottom, and then for von Willebrand's,
23 cryoprecipitate and DDAVP.

24 **SIR BRIAN LANGSTAFF:** Do we have any explanation as to
25 whether this represented a change in response to any

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1 perception of risk?
 2 **MS RICHARDS:** I don't think so. Dr Lilleyman -- I'll come
 3 on to Dr Lilleyman's knowledge of risk, but he's
 4 pretty clear in his witness statement that he
 5 recognised from an early stage that there were risks
 6 of viral transmission in blood products, and hence he
 7 had a preference for cryoprecipitate, and then for
 8 NHS concentrate over commercial concentrates.
 9 **SIR BRIAN LANGSTAFF:** And did he say anything about, so
 10 far as commercial concentrate was concerned, sticking
 11 with one batch?
 12 **MS RICHARDS:** I'll have to double check that. He used it
 13 to a fairly limited extent and it's very rare,
 14 I think, to see -- I'll have to double check back
 15 through the returns -- a year in which there is more
 16 than one type of commercial concentrate in any event.
 17 **SIR BRIAN LANGSTAFF:** Yes, that was when the Immuno was
 18 being used. There may have been some special reason
 19 for that.
 20 **MS RICHARDS:** Yes, that's possible. I don't think we know
 21 the answer to that.
 22 In any event, that's 1984. Then if we just,
 23 finally, look at 1985, at HCDO0001948, it's a very
 24 similar position. It may of course have been that the
 25 NHS factor concentrate was, at some point during the

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1 and young boys with severe haemophilia."
 2 He refers to the study from the Children's
 3 Hospital published in 1980. We looked at it on
 4 previous occasions. It's the McGrath study,
 5 co-authored by Dr Lilleyman, Dr Triger and
 6 Dr Underwood, Liver Disease Complicating Severe
 7 Haemophilia in Childhood.
 8 He says that that study reinforced the view at
 9 the Children's Hospital that cryoprecipitate was
 10 a safer product than Factor VIII and says:
 11 "We therefore used this product in preference to
 12 Factor VIII concentrate for routine treatment for all
 13 but major surgery in young boys."
 14 That is probably as clear a piece of information
 15 about Dr Lilleyman's own knowledge of risk as one
 16 might require. But he also attended UKHCDO meetings
 17 at which hepatitis and, in particular, Dr Craske's
 18 presentations were discussed. He attended again at
 19 the meeting in November 1979 in which Dr Craske again
 20 gave a further presentation about hepatitis and non-A,
 21 non-B hepatitis, as did Professor Blackburn and
 22 Dr Preston from the adult Haemophilia Centre.
 23 We can also see, it's at ULHT0000001, a letter
 24 from Dr Lilleyman in March 1979, it looks like it's to
 25 the parents of a particular patient, and it's about

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1 year, heat treated. 20 haemophilia A patients, one
 2 von Willebrand's. The sole treatment for the
 3 von Willebrand's patient is recorded as DDAVP. Then
 4 in terms of the haemophilia A patients, we can see
 5 what's said to be 77,000 units of cryoprecipitate used
 6 in hospital, again there's cryoprecipitate for home
 7 treatment, it looks like 24,500 -- no, actually that
 8 might be 2,450 units.

9 Then for the NHS Factor VIII concentrate, the
 10 bulk of it for home treatment, 174,520 but 43,655 used
 11 in hospital. Then we can see use of Hyate C and
 12 Autoplex at the bottom of the page.

13 So that's the data from the returns which is
 14 broadly consistent with the narrative account given by
 15 Dr Lilleyman in his witness statement. He's also
 16 clear in his statement, and this won't be surprising,
 17 given the evidence that the Inquiry has heard to date,
 18 that there was a particular interest in Sheffield in
 19 non-A, non-B hepatitis so he says here:

20 "We in Sheffield realised pretty early on that
 21 there was a potential problem of virus transfer in
 22 blood products used for haemophilia, since non-A,
 23 non-B hepatitis was already recognised as a problem
 24 following the observation that abnormal liver function
 25 tests were not an infrequent finding in both adults

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1 liver biopsies, so again, consistent with the study
 2 that was being undertaken and the particular interest.
 3 He says:

4 "... I will restate our reasons for suggesting
 5 that [the name is redacted] should have a liver
 6 biopsy. Since the introduction of Factor VIII
 7 concentrates for the treatment of haemophilia it has
 8 been noted that quite a few haemophiliacs, both adults
 9 and children, have developed abnormalities of their
 10 liver function as tested from blood samples. Liver
 11 biopsies have recently been performed in some of these
 12 patients, here in Sheffield and in other centres, and
 13 most show evidence of underlying chronic liver
 14 disease. The severity of the liver disease is quite
 15 variable; most show only mild changes which do not
 16 require further treatment except observation. However
 17 occasional patients do show quite marked liver changes
 18 and consideration is then given to further treatment
 19 usually with steroids."

20 It then refers back to the individual patient
 21 and says that they have:

22 "... for the past five months, shown
 23 abnormalities of his liver function in blood tests.
 24 We would therefore like to know the extent of any
 25 changes in his liver cells to decide whether he

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1 requires any further treatment and to help us
2 understand the nature of the relatively new problem."
3 Then talks a little more about the process in
4 terms of undertaking a biopsy.
5 That's hepatitis. As I say, the picture in
6 Sheffield is really very clear.
7 In terms of HIV/AIDS, Dr Lilleyman in his
8 statement says this:
9 "My first inkling of HIV was at a childhood
10 leukaemia meeting in London in 1981 where we learnt of
11 a rare lung infection, PCP, being found in five young,
12 previously healthy gay men in Los Angeles. This was
13 of interest because children on chemotherapy for acute
14 leukaemia are also susceptible to this rare condition
15 because of immunosuppression. By the end of 1981
16 there were 270 reported cases of severe
17 immunodeficiency among gay men in the USA, and 121 of
18 them had died. In June of 1982 the disease was
19 reported in American haemophiliacs. In September, the
20 CDC used of the term 'AIDS' to describe the disease.
21 I first became aware of the association between AIDS
22 and blood products around the time when the matter was
23 raised at the UKHCDO in September of 1982."
24 Two other documents showing Dr Lilleyman's
25 attendance at meetings in 1983, first of all

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1 haematology agenda in the course of 1983.
2 I think through his attendance at UKHCDO
3 meetings his discussions with his colleagues in
4 Sheffield, it can I think fairly be taken that
5 Dr Lilleyman was familiar with the discussions that
6 were taking place at the UKHCDO level.
7 In terms of the arrangements for testing
8 patients, his evidence to the Inquiry, this for
9 HTLV-III:
10 "I think we did not rush to mass HIV testing for
11 our patients who had only received cryoprecipitate or
12 NHS Factor VIII. I cannot remember that we did. For
13 any that wanted reassurance we would have agreed and
14 discussed with the parents what the process involved
15 and what a positive result would mean but I cannot
16 recall any positive results in our haemophiliac boys
17 up to the time I left."
18 Which was 1995.
19 So his recollection in his statement was that he
20 couldn't recall any positive cases of HIV.
21 The data we've received, the provisional data
22 from UKHCDO also doesn't record any positive cases of
23 HIV in Sheffield Children's Hospital patients, but
24 there is a document which suggests that one patient
25 did test positive.

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1 PARA0000013. This is a document we looked at with
2 Dr Parapia, if you recall. Haemostasis Club Meeting
3 8 March 1983, and there's a discussion about AIDS.
4 If we go back to the full page, we can, no back
5 to the last page, there's an update about the data in
6 relation to AIDS, and then, I think it's on the third
7 page, yes, there's a reference then to Dr Lilleyman:
8 "... at present looking at T4 and T8 cell ratios
9 in these patients [that was a particular trial of
10 patients], haemophiliacs and normals."
11 Then if we go to BHSA0000005_049. This is
12 a meeting of the Committee of the British Society for
13 Haematology, this is 4 October 1983. We can see the
14 attendees include Dr Shinton and Dr Bellingham,
15 Dr Lilleyman, Dr Colvin, Dr Hardisty, Professor Bloom,
16 Dr Dawson and Dr Delamore. There's a discussion about
17 a number of matters but if we go to the last page of
18 the document, we can see that the British Society for
19 Haematology are proposing to set up an AIDS working
20 party, specifically in relation to the practice of
21 haematology in the diagnostic laboratory. Dr Rizza
22 and Dr Bloom are two of the four members of that
23 working party, the others being Dr Pinching and
24 Dr Jeffries.
25 So, again, we see, as it were, AIDS on the

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1 If we go to RHAL0000485.
2 Sir, we're not quite sure who scribbled this,
3 but it says, "From section entitled 'Dr Tedder -
4 samples - Sheffield Children's Hospital!'.
5 If we go to page 3, there's then a letter from
6 Dr Preston to Dr Lilleyman:
7 "I have now received the results of the samples
8 which you sent us recently and I enclose a copy
9 herewith."
10 Then the samples are negative until we get to
11 page 8. And you'll see, we've obviously redacted the
12 names, but there's one patient there identified as
13 testing positive.
14 We don't have any more information specifically
15 from the Children's Hospital, but I can indicate,
16 because obviously the Inquiry has access to the
17 unredacted versions of these documents, that is a name
18 of a patient who we know from other material was
19 infected with HIV, and we have some evidence from
20 a family member and are expecting more evidence from
21 a family member which might cast further light upon
22 the circumstances of infection.
23 So, contrary to Dr Lilleyman's recollection and
24 the UKHCDO data, there does appear to be some evidence
25 at least of a Children's Hospital patient, one

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1 Children's Hospital patient testing positive for HIV.
 2 **SIR BRIAN LANGSTAFF:** Yes.
 3 So this is a pretty clear distinction between
 4 Sheffield and the other centres we've been
 5 considering.
 6 **MS RICHARDS:** Yes. The distinction, if we're talking in
 7 particular about children, they become even clearer
 8 when we look at Alder Hey and Treloars.
 9 **SIR BRIAN LANGSTAFF:** Yes. And the children, do we know,
 10 in the case of Sheffield, what age they transferred --
 11 did you tell us during the Sheffield presentation, do
 12 you remember?
 13 **MS RICHARDS:** We didn't have a presentation on Sheffield
 14 as I recall. We heard evidence from Dr Preston and
 15 some from Professor Hay.
 16 **SIR BRIAN LANGSTAFF:** We had evidence from Preston and
 17 Hay.
 18 **MS RICHARDS:** We did and we got a long written statement
 19 from Dr Makris and we had some oral evidence from
 20 Professor Hay.
 21 I cannot recall off the top of my head. I think
 22 we probably do know. I mean, I seem to recall the
 23 point of transfer being roughly mid-teens or late
 24 teens.
 25 **SIR BRIAN LANGSTAFF:** Well, in other places it tended to

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1 products.
 2 We'll explore the position in relation to
 3 Treloars obviously next week. In common with a lot of
 4 other centres that treated children, there is
 5 correspondence between Treloars and the Children's
 6 Hospital in relation to individuals who were pupils at
 7 Treloars and treated at Treloars during the term time
 8 and were then transitioned back during holidays to the
 9 care of the Children's Hospital.
 10 And Dr Lilleyman has said that he didn't
 11 determine what treatment was provided to patients at
 12 Treloars. That was determined by Treloars.
 13 He says that, "We had no control over their
 14 choice of therapeutic products."
 15 He says in his statement:
 16 "By 1980 I was becoming concerned about
 17 hepatitis, and since I had no control on which
 18 products were used with Treloars boys they were more
 19 exposed to American Factor VIII. In 1976 [he's
 20 talking there about a particular case] this would not
 21 have been virally inactivated."
 22 He refers to using a commercial product,
 23 Profilate, in a serious problem with a Treloars boy at
 24 home on holiday where there was a life-threatening
 25 head injury.

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1 be about 16, 17.
 2 **MS RICHARDS:** Yes. I don't recall it being anything
 3 different from that but I will double check, sir.
 4 **SIR BRIAN LANGSTAFF:** So to put it in -- that may be
 5 necessary, to put it in context, but, yes.
 6 **MS RICHARDS:** In terms of hepatitis C, Dr Lilleyman was
 7 unable to recall when the Centre began testing for
 8 hepatitis C. He himself left in 1995. But in fact
 9 the evidence we have from individuals treated at
 10 Sheffield Children's Hospital with factor products
 11 prior to the second half of the eighties was that
 12 their diagnosis with hepatitis C commonly occurred at
 13 other centres because they had, by that time -- by the
 14 early 1990s they had transitioned to adult care and so
 15 they were being diagnosed with hepatitis C and
 16 informed of it at other centres.
 17 So there isn't anything which emerges in
 18 particular from the documentation which casts any
 19 light upon the infection of Sheffield Children's
 20 Hospital patients with hepatitis C.
 21 There is some material from the hepatitis C
 22 litigation from the late nineties showing cases where
 23 the defendant was the Sheffield Children's Hospital,
 24 but they appear to be cases relating to transfusion
 25 rather than the treatment of patients with blood

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1 He says:
 2 "The concept of a special residential school for
 3 boys with haemophilia was a brave and exciting
 4 experiment. It gave the pupils a greater chance of
 5 not missing school because of hospital trips and to
 6 mingle with peers who had similar problems."
 7 And at TREL0000237_072, we can see a letter
 8 Dr Lilleyman wrote commending Treloars. It's right to
 9 note, this is August 1975, so this is before the point
 10 in time in his statement where he says, "By 1980 I was
 11 increasingly concerned about the risks". But he says
 12 here, third paragraph:
 13 "The best place in the country (probably the
 14 world), for haemophiliac school boys is the Lord Mayor
 15 Treloar School in Hampshire. This is the only place
 16 where treatment is available on the premises - no
 17 trips to hospital - and there are already about 80
 18 other severe haemophiliacs there."
 19 And he describes it as being a marvellous
 20 opportunity for the individual.
 21 Last point in relation to Sheffield Children's
 22 Hospital and Treloars is there was a study run by
 23 Dr Kirk at Treloars in which Dr Lilleyman had some
 24 involvement, but he says this about it:
 25 "The proposed Treloar hepatitis study was an

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1 attempt to look at the incidence of hepatitis in
2 a cohort of boys who were restricted to one type of
3 Factor VIII over a period of time, to see whether the
4 incidence and type of hepatitis differed from that of
5 other cohorts restricted to other Factor VIII sources,
6 that is, different Factor VIII concentrates. My
7 contribution was an offer to restrict our boys at home
8 in Sheffield to cryoprecipitate for treatment, with
9 the proviso that we would obviously have to break
10 protocol and give a concentrated form of Factor VIII
11 for serious or life-threatening bleeds."

12 So his perspective of involvement was he would
13 offer the perspective of treatment with
14 cryoprecipitate for the purposes of the study.

15 Sir, that's the Sheffield Children's Hospital.
16 And I would say Dr Lilleyman's statement is an
17 interesting and useful one and I know, sir, you've
18 read it, but others may find it of great interest.

19 I'm going to turn next to the Haemophilia Centre
20 in Leeds, based at St James' Hospital.

21 PRESENTATION RE ST JAMES'S UNIVERSITY HOSPITAL

22 The Centre Director, the sole Centre Director,
23 from around 1970 was Dr Swinburne.

24 She was joined by Dr McVerry in 1985. He moved
25 from Liverpool, and I'll be looking at Liverpool

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1 management of various aspects of clinical care,
2 including haemophilia.

3 There was also a social work service, possibly
4 established in the late 1980s, under a social worker
5 called Sheila O'Rourke.

6 If we then look at a handful of documents, so if
7 we start with DHSC0002359_046, please, we pick up the
8 position in 1975. This is a letter from Dr Tovey,
9 director of the Regional Transfusion Centre in Leeds,
10 to Dr Maycock at the DHSS. And picking it up in the
11 first paragraph, four lines down:

12 "The largest user of cryoprecipitate is the
13 Leeds Haemophilia Centre and they have insisted for
14 years on making their own cryo from fresh frozen
15 plasma supplied by us ..."

16 And he refers to the issuing of fresh frozen
17 plasma donations which they turned into
18 cryoprecipitate. So that reflects what Dr Swinburne
19 recalled.

20 I won't go to the next document we have referred
21 to in the note but there's evidence from a meeting
22 that Dr Swinburne attended, a local Haemophilia
23 Society meeting, that by 1974 there was a home
24 treatment programme of some kind established, and
25 that's consistent with evidence we've received from

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1 shortly, but he moved from Liverpool to Leeds, and
2 they were joint directors until 1992, when
3 Dr Swinburne retired, and then Dr McVerry was the sole
4 director until his retirement in 2011.

5 The documentary evidence we have in relation to
6 Leeds is not terribly illuminating. I'll obviously
7 look at the annual returns, which are helpful, but in
8 terms of other contemporaneous documents they don't
9 paint a very clear picture.

10 We do have some limited evidence from
11 Dr Swinburne, and we have some statements from
12 Dr McVerry and so some of what I say will be drawn
13 from that.

14 Dr Swinburne recalls the Centre having its own
15 lab in which they prepared cryoprecipitate.

16 Dr McVerry recalls when he joined the Centre
17 there was a nurse, there wasn't a specialist
18 haemophilia registrar.

19 In terms of the allocation of responsibilities
20 from 1985 onwards as between Dr McVerry and
21 Dr Swinburne, Dr McVerry's recollection is that he
22 focused on the adult patients and Dr Swinburne took
23 responsibility for the children from that point. And
24 then he says -- or the evidence suggests that at some
25 point between 1985 and 1981 he took over the

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1 a patient who recalls commencing home treatment in or
2 around 1974.

3 If we then look at ARMO0000013.

4 This is a letter dated 18th May 1977 from Armour
5 Pharmaceutical to the Committee on the Safety of
6 Medicines, and we can see in the first paragraph it
7 refers to having:

8 "... received reports from three centres of
9 clinical jaundice occurring in haemophilia patients
10 who have received ... our drug Factorate ..."

11 And Leeds is one of the hospitals there
12 identified.

13 So it's clear that, as at 1977, Leeds must have
14 been using the Armour product, in part at least, and
15 is aware of clinical jaundice in some cases.

16 We also know from other documents that in the
17 course of 1977 the hospital used -- or the centre used
18 Koate.

19 The first return we have is from 1978, and if we
20 go to HCDO0001271.

21 We're going to see in these returns a marked
22 contrast to, by way of example, the Centre we've just
23 looked at, because we see commercial concentrate being
24 the predominant product.

25 So a large number of patients treated,

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1 84 haemophiliac patients, ten Christmas Disease
2 patients and then, if we look at the treatment:
3 cryoprecipitate in limited usage, it would appear,
4 by 1978, 5,000 units; NHS concentrate 590,335 units;
5 the Armour product Factorate 862,053 units; and then
6 Kryobulin, 115,981 units; and then NHS Factor IX used
7 for the Christmas Disease haemophilia B patients.

8 And if we look at page 5, this is just by way of
9 example that we've got a number of these pages, but we
10 can see patients there identified as receiving more
11 than one type of concentrate. So the top line shows
12 a patient receiving the Elstree Factor VIII and
13 Factorate, and Kryobulin, and then there are others
14 for whom there are those three ticks, some also
15 receiving cryoprecipitate. There are some who receive
16 only NHS concentrate and a commercial one. This page
17 has one example of a patient who receives only NHS
18 concentrate.

19 It's a not dissimilar picture if we look, for
20 example, at page 4. Again, you can see from the
21 number of ticks there are some patients receiving, for
22 example, only NHS concentrate. Some who received cryo
23 and Elstree and Armour and Kryobulin, and so on.

24 So there doesn't appear to be any kind of policy
25 in place of restricting patients to one type of

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1 So commercial products -- now only one type of
2 commercial product for this year but very much
3 predominating in terms of product usage or --

4 **SIR BRIAN LANGSTAFF:** Well, it's roughly three times as
5 much --

6 **MS RICHARDS:** Yes.

7 **SIR BRIAN LANGSTAFF:** -- as the NHS.

8 **MS RICHARDS:** Then if we go to 1982, HCDO0001635, 98
9 patients with haemophilia A treated and eight
10 von Willebrand's patients treated. We can see no cryo
11 use for haemophilia A patients, no NHS concentrate
12 used for home treatment but 404, plus 1,000 used in
13 hospital. Then a huge amount of Factor VIII being
14 used. So 2.29 million units of Factor VIII used for
15 home treatment, a smaller amount, 64,485 used for
16 hospital treatment. There's reference to a small
17 amount of porcine Factor VIII treatment being used.
18 Then if we look across to the von Willebrand's
19 patients, we see there von Willebrand's patients being
20 treated with cryoprecipitate, with NHS concentrate,
21 and, in smaller measure, with the Armour product,
22 Factorate.

23 Again, I won't go to the page but for
24 haemophilia B patients it's the consistent picture of
25 NHS Factor IX concentrate.

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1 product, still less in the policy of batch dedication.

2 We don't have the 1979 or 1980 returns. We do
3 know, if we look at MHRA0000083_011, that in 1980
4 Dr Swinburne received direct from Armour some vials of
5 a batch of high potency Factorate, the first paragraph
6 says:

7 "We are supplying with this letter 49 vials of
8 the above batch of our Dried Human Antihæmophilic
9 Fraction ... This batch has not yet been released by
10 the DHSS but they have agreed that the material can be
11 forwarded to you because it is urgently required to
12 meet patient need. We cannot accept any
13 responsibility if the lot is subsequently not released
14 by the DHSS."

15 The next document we have which casts any
16 particular light on product usage is the 1981 return,
17 HCDO0001536. We can see it's a large Centre, 90
18 haemophilia A patients treated, six von Willebrand's
19 patients treated. No cryoprecipitate used except for
20 von Willebrand's disease patients. In terms of NHS
21 concentrate a significant volume used in hospital,
22 592,070, and then 52,750 for home treatment. Then a
23 significant amount of the Armour Factorate product
24 used, so 1,630,256 units for home treatment, just over
25 162,000 or a little over 162,000 for help treatment.

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1 **SIR BRIAN LANGSTAFF:** So for haemophilia A patients here
2 the ratio has moved up in a year having been 3:1,
3 commercial to NHS, to somewhere between 4:1 and 5:1.

4 **MS RICHARDS:** Yes, that's right.

5 If we then go -- that's 1982. 1983 is
6 HCDO0001734, 92 haemophilia A patients, eight
7 von Willebrand's patients. We can see here the
8 proportion of NHS concentrate has increased. So
9 hospital is 571,980, home 877,980. But we still then
10 have a significant volume of the Armour product, small
11 amount in hospital, 23,285, 1.642 million units used
12 for home treatment, and then a small amount of FEIBA
13 and porcine or bovine product. Then von Willebrand's,
14 again, a very small amount of plasma, cryoprecipitate,
15 NHS concentrate and Armour product used for treatment
16 of von Willebrand's. So there is there a significant
17 increase in NHS concentrate but Armour remains the
18 predominant treatment.

19 We don't have the return for 1984,
20 unfortunately. If we pick the picture up in 1985 at
21 HCDO0001920 1930, we see Dr Swinburne has been joined
22 by Dr McVerry as director, and number of haemophilia A
23 parents treated, 83 von Willebrand's patients treated
24 nine. Then we can see, and again, there will no doubt
25 have been some use of heat-treated product during the

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1 course of that calendar year, tiny amount of
2 cryoprecipitate used. Then NHS concentrate, 336,466
3 in hospital, 717,000 for home treatment. We see
4 Profilate being used in 1985, 84,000-odd hospital,
5 514,026 for home treatment, and then continued heavy
6 reliance upon the Armour product, Factorate,
7 385,000-odd in hospital, 1.699 million for home
8 treatment. Again, a small amount of FEIBA. We don't
9 see DDAVP listed, I should say, on these returns.

10 The significance of that might become apparent
11 if we look at the 1986 return, HCDO0002017. I'm not
12 going to go through the details of the treatment in
13 1986 but if we look at the bottom of the page we'll
14 see DDAVP there recorded for the first time.

15 We don't have any other documents which cast any
16 particular light on treatment policies or approach, we
17 just have the fairly stark data that appears from the
18 returns.

19 In relation to knowledge of risk of hepatitis
20 and AIDS, both Dr Swinburne and Dr McVerry were
21 regular attenders of UKHCDO meetings. Dr Swinburne
22 has said in her statement to the Inquiry she also
23 gained information from smaller local meetings, some
24 of which she organised.

25 By way of example, in terms of attendance at

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1 Sheffield, and it was recorded that first time
2 exposure to large pooled Factor VIII concentrates
3 resulted in many cases of hepatitis.

4 We know that Glasgow Symposium on Unresolved
5 Problems in Haemophilia took place, I think,
6 immediately following the directors meeting.

7 Both Dr Swinburne and Dr McVerry were at the
8 October 1981 directors meeting, where Dr Craske
9 presented a pre-circulated report on hepatitis. And
10 just pausing there, it is apparent from a number of
11 the minutes that Dr Craske's reports were provided to
12 directors in advance of the meetings.

13 So presumably those who didn't attend the
14 meetings would nonetheless have received the reports.

15 There was a discussion at that meeting about
16 chronic hepatitis and liver disease. They both
17 attended the September 1982 meeting at which the issue
18 of AIDS was raised and Dr Craske asked directors to
19 let him know if there'd been any cases of the
20 syndrome.

21 They would presumably both have received,
22 Dr McVerry then in his capacity at Liverpool and
23 Dr Swinburne at Leeds, the March 1983 letter in
24 enclosures from Dr Craske with the update on AIDS and
25 the criteria for reporting cases.

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1 meetings, Dr Swinburne attended the directors
2 meetings, the Haemophilia Centre Directors meeting in
3 April 1971 at which Dr Biggs' work on jaundice was
4 discussed. She attended the 1972 meetings at which
5 Dr Biggs provided an update on her work. She attended
6 the 1974 meeting when Dr Craske reported on the
7 hepatitis outbreak in Bournemouth amongst patients who
8 had received commercial Factor VIII. We've looked at
9 all the meeting minutes in earlier hearings so I'm not
10 going to underlying documents.

11 She attended the 1975 meeting at which there was
12 a presentation on the study on jaundice and
13 a discussion about hepatitis liver function tests and
14 pool sizes. She attended the 1977 meeting on which
15 Dr Craske reported on his study of hepatitis in
16 haemophilic patients receiving Hemofil.

17 Both Dr Swinburne and Dr McVerry -- the latter
18 was there representing a different centre -- attended
19 the 1978 meeting at which Dr Craske presented the
20 report of the Hepatitis Working Party.

21 It appears likely that both attended the
22 September 1980 meeting, Dr McVerry at that stage would
23 have been there in his capacity as director for
24 Liverpool, at which Dr Craske discussed various liver
25 biopsy studies being undertaken at The Royal Free and

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1 Dr McVerry was at the October 1983 meeting, that
2 one in which Dr Chisholm raised her concern about AIDS
3 and discussed reversion to cryoprecipitate, and they
4 both, McVerry and Swinburne, attended the
5 September 1984 directors meeting.

6 Dr McVerry has also told us in his statement to
7 the Inquiry that he read the British Journal of
8 Haematology, The Lancet Blood and the New England
9 Journal of medicine. He thought he would have read
10 Professor Preston's 1978 Lancet publication, which
11 we've looked at on a number of occasions but it's
12 right to say he says in his statement, in the late
13 1970s, early 1980s, he said, "We did not know what
14 caused non-A, non-B hepatitis or that it could be
15 serious".

16 In terms of testing for HTLV-III at Leeds, the
17 picture again from the documents is not entirely
18 clear. There is evidence of patients being tested --
19 well, the earliest result we can see is November 1984.
20 In fact, if we just go to -- forgive me, OXUH0002221.
21 If we look at the very top of the page, we see it
22 says, "AIDS/3 forms", so those are the UKHCDO forms or
23 PHLs forms received by the 28 August 1991.

24 Then if we go back to the screen, you'll see
25 there's a heading for "Centre", and if we go over the

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1 page, if we zoom in towards the middle of the page,
2 yes, there's a reference there to Centre 049, that's
3 Leeds, and we can see here an example of a patient who
4 first tested positive for HIV in January 1985.

5 I'm not going to go through the detail of it,
6 but what we can see from that is there were patients
7 who had tested positive for HIV in early 1985, there
8 are references to test results in January, in February
9 1985. There are references to test results in April
10 1985. The earliest we can see, there are two from
11 1984, we don't need to look at the individual entries.
12 There's one from late November 1984, there is one from
13 late December 1984. And then there is one, I think --
14 there's one from March 1985, some more from
15 March 1985, and then there is one from 1986.

16 So perhaps we should go to this. It's page 32,
17 please, Soumik. So if we look -- that's great. If we
18 look just above the heading halfway down the page
19 "AIDS/ARC deaths reported", just above that you'll see
20 an entry for Centre 049, and if we read across we can
21 see the last HIV negative was February 1985, first HIV
22 positive, December 1986.

23 So what it appears to show is a process of HIV
24 testing beginning in late 1984, continuing through the
25 early part of 1985. This is L8 seroconversion

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1 a patient of Dr Swinburne who described being informed
2 of her son's HIV status at a routine check-up.

3 The data we have in terms of numbers infected,
4 if we go to INPY0000250, this is the same table that
5 we looked at earlier. So it's subject to all the same
6 qualifications that this is provisional data, it
7 represents our analysis of material provided to the
8 Inquiry by UKHCDO. But if we go to page 3, we can see
9 Leeds is Centre 49, and we see recorded there six
10 patients who tested positive in 1984; 42 in 1985; and
11 five in 1986. 53 patients infected with HTLV-III,
12 that data suggests.

13 We don't have figures about the numbers infected
14 with hepatitis C, sir.

15 Dr McVerry's recollection was that verbal
16 consent was obtained from patients in relation to
17 hepatitis C testing. There is evidence again that the
18 Inquiry has received from individuals, which suggests
19 that there were delays between tests being undertaken
20 and patients being told their results. Others have
21 said that they were informed of their results, of
22 being infected with hepatitis C at routine
23 appointments or informally. Some describe a lack of
24 information provided to them about hepatitis C and it
25 not being clearly explained.

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1 potentially, well, whether from unheated or from
2 heat-treated products we won't know.

3 Dr McVerry cannot recall, in terms of Leeds --
4 sorry, we can take that down, thank you, Soumik --
5 whether patients were advised that they were being
6 tested for HIV. The Inquiry has received evidence
7 from witnesses who say that they were tested without
8 being told. For example, there's a witness who has
9 been seen from her medical records suggestions that she
10 was -- her bloods were tested on three occasions in
11 between 1986 and 1987 and she wasn't herself ever told
12 of those tests taking place.

13 There's evidence from an Inquiry witness about
14 a meeting being held in the lecture theatre at
15 St James's Hospital, the recollection is that that
16 takes place in the summer of 1986 at which there's
17 a public discussion about HIV. There's another
18 witness who has given evidence to the Inquiry that
19 they weren't informed of their HIV status until
20 three years after the diagnosis.

21 Dr Swinburne in her brief statement to the
22 Inquiry has said that they were as transparent as they
23 could be with patients. Dr McVerry says that patients
24 would have been informed of their diagnosis in person.

25 It's right to note that there's the parent of

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1 Dr McVerry says that in the time he was at the
2 Centre in Leeds, the Centre sought to work with the
3 hospital's liver and infectious disease unit, in terms
4 of the treatment of those with hepatitis, and would
5 seek their input when required.

6 So, sir, in relation to Leeds, what we have is
7 a clear picture of the products that were used from
8 the annual returns, with very significant amounts of
9 commercial concentrates. There's no evidence of any
10 particular risk reduction or minimisation strategy.
11 There is some limited evidence about the process of
12 testing and diagnosis, and in relation to how results
13 were communicated, what information was provided.
14 Your best guide again may be the evidence that the
15 Inquiry has received from individuals who were
16 infected or their family members.

17 Sir, I'm about to move to Royal Liverpool. Both
18 in light of the time and to give my voice a break, if
19 we take the break now --

20 **SIR BRIAN LANGSTAFF:** I think you probably deserve one
21 now. Shall we come back, then, at 25 to four.

22 **MS RICHARDS:** That's fine.

23 Sir, I should say I may not complete Alder Hey
24 today. There's a lot of information about Royal
25 Liverpool and Alder Hey that really shouldn't be taken

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1 too quickly. So it may be that Alder Hey will be --
 2 I might get it started today but we don't finish it
 3 until tomorrow morning. I do not want to rush the
 4 picture that emerges from the data we have there.

5 **SIR BRIAN LANGSTAFF:** Yes, well, for those who have
 6 an interest in Alder Hey then they can expect that at
 7 some point, some convenient point, this evening, we'll
 8 break and hear it fresh -- and the rest of it fresh in
 9 the morning.

10 **MS RICHARDS:** Yes.
 11 (3.12 pm)

(A short break)

12 (3.35 pm)
 13 **PRESENTATION RE LIVERPOOL HAEMOPHILIA CENTRE**

14 **MS RICHARDS:** Sir, I'm going to turn now to the Liverpool
 15 Haemophilia Centre. Liverpool's main Haemophilia
 16 Centre for adults was based at the Royal Liverpool
 17 Hospital. There was a small Centre at the Walton
 18 Hospital, which I'll deal with separately, and then
 19 the Children's Centre at Alder Hey, which I think I'll
 20 deal with, I think now, tomorrow morning.

21 The adult Haemophilia Centre had been housed in
 22 the Liverpool Royal Infirmary but in the late 1970s it
 23 moved to the Royal Liverpool Hospital.

24 In terms of directors, it appears that Dr Black

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1 Centre at the Royal Liverpool Hospital and Alder Hey,
 2 Dr McVerry's recollection was that he thought it was
 3 unlikely that the Royal Liverpool Hospital would have
 4 supplied products, whether cryo or Factor VIII, to
 5 Alder Hey. He thought it would have its own
 6 arrangements for supply.

7 However, if we go to BPLL0010612, this is
 8 a letter from Alder Hey from Dr Martin, consultant
 9 paediatrician of whom we'll hear more tomorrow
 10 morning, in February 1985 to Mr Snape at BPL, and he
 11 says in the third line:

12 "I should say that we normally receive our
 13 factor VIII via the adult centre at the Royal
 14 Liverpool Hospital, whose director is Dr McVerry."

15 In terms of links with other centres, the
 16 Liverpool Centre had important links with centres and
 17 hospitals treating patients in North Wales. If we go
 18 to TREL0000311_027, this is a communication,
 19 July 1977, between the Liverpool Royal Infirmary,
 20 Dr Boulton, and Dr Kirk at Treloar. It refers to
 21 a patient treated at home in Wrexham, and if we pick
 22 it up in the beginning of the second paragraph, it
 23 says that:

24 "[The patient] is not on the list of
 25 haemophiliacs registered at the Liverpool Royal

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1 was the director of the Liverpool Haemophilia Centre
 2 in the first half of the 1970s. In terms of the
 3 second half of the 1970s, sometimes the returns refer
 4 to Professor Bellingham, sometimes to Dr Frank Boulton
 5 and sometimes to both. Dr Boulton's own evidence,
 6 both in a short statement to the Inquiry and his
 7 evidence to the Penrose Inquiry, suggests that he was
 8 consultant and Centre Director in Liverpool from 1975
 9 to 1980, and we then have Dr McVerry taking over from
 10 1980 to 1985 before he moves to Leeds.

11 There was a period of time after Dr McVerry's
 12 departure from Liverpool where the Centre didn't have
 13 a formal director. There were various documents which
 14 refer to a Dr Mackie and Dr Davis taking on the role
 15 of, effectively, of Haemophilia Centre director and
 16 there are number of documents and we'll come on to
 17 this which show the HTLV-III testing and the process
 18 of patients being informed of diagnosis in that period
 19 of time from 1985 to 1986.

20 Professor Hay then took over as the Centre
 21 Director in May 1987 and remained in that post until
 22 November 1994 and, obviously, we heard from Professor
 23 Hay in relation to that period of time, when he gave
 24 oral evidence in November last year.

25 In terms of the relationship between the adult

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1 Infirmary and we do in fact cover the North/Welsh
 2 area."

3 Then there is further evidence, I won't go to
 4 the statement but we have a statement from Dr David
 5 Edwards, a consultant haematologist at Glan Clwyd
 6 Hospital in 1982. He describes the arrangement being
 7 as follows, that all patients with bleeding disorders
 8 would have been registered with either Liverpool or
 9 Manchester, and that Glan Clwyd Hospital essentially
 10 offered a storage and distribution facilities so that
 11 decisions were taken in Liverpool or possibly
 12 Manchester but patients would be able to pick up
 13 materials more locally to North Wales.

14 There's also reference from Dr -- materials
 15 emanating from Professor Hay about patients North
 16 Wales being jointly managed by Liverpool and
 17 haematologists, local haematologists, in the North
 18 Wales area.

19 Liverpool was not a Reference Centre, although
 20 it was a large Centre. Manchester was the Reference
 21 Centre for Liverpool but apart from occasional
 22 supra-regional meetings and Manchester undertaking
 23 some HTLV-III testing, there appear to have been
 24 limited links between Liverpool and Manchester, and
 25 there doesn't appear to have been, for example,

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1 recourse from Liverpool to Manchester for advice.
 2 In terms of the relationship with the Regional
 3 Transfusion Centre, there was a Regional Transfusion
 4 Centre in Liverpool, sometimes called the Liverpool
 5 Regional Transfusion Centre, sometimes called the
 6 Mersey Regional Transfusion Centre. In the 1970s and
 7 1980s it would appear that the Regional Transfusion
 8 Centre provided cryoprecipitate to the Liverpool
 9 Haemophilia Centre but the Centre purchased commercial
 10 concentrates for itself.

11 Again, we have Dr Boulton's evidence to the
 12 Penrose Inquiry both written and oral, in which he
 13 describes having a budget of £40,000 to buy commercial
 14 Factor VIII.

15 We have also a document prepared by Dr Martlew
 16 and Dr Shepherd, so from the Transfusion Centre,
 17 prepared in the context of the HIV litigation --
 18 sorry, prepared in the context of the HIV litigation,
 19 in which they say that the needs for factor
 20 concentrates would be determined by the director of
 21 the Haemophilia Centre, and there was often a need for
 22 the centres to embark upon commercial purchases to
 23 make up the balance for use.

24 We also have a letter from 1981 from the then
 25 director of the Regional Transfusion Centre in

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1 see the amount issued to Haemophilia Centres declines
 2 markedly, so in 1978 it's 12,227. There's then
 3 a slight increase in 1979 and then again in 1980 to
 4 16,355 but then it goes down in 1981 to 7,817 and down
 5 further in 1982 to 3,105.

6 Whether that was a supply issue or a demand
 7 question is not entirely clear.

8 Again, just looking at Liverpool broadly, the
 9 Centre appears to have belonged to two regional
 10 networks. There was a regional haematologists group,
 11 which met at the Mersey Regional Transfusion Centre,
 12 it seems to have been involved both clinicians and
 13 Blood Service representatives. I'm not going to go to
 14 the document but I invite you to note that there was
 15 a meeting of the group in November 1983, attended by,
 16 amongst others, Dr McVerry and Professor Bellingham.
 17 It's perhaps notable, given the date, November 1983,
 18 for the absence of any discussion at all about the
 19 issue of AIDS or HTLV-III.

20 A second regional network was the North Western
 21 Supra Regional Haemophilia Group. If we look at
 22 MHBT0096599_043, and we go to the second page, if we
 23 look at the top of to of the page we can see it's
 24 "Minutes of the North Western Supra Regional
 25 Haemophilia Meeting, May 1985". If we go just

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1 Liverpool saying when they received Factor VIII from
 2 BPL they'd simply dispatch it on to the haemophilia
 3 director and again confirming that commercial
 4 materials were purchased by the individual hospitals.

5 If we look at one other document emanating from
 6 the Transfusion Service this time, it is at
 7 DHSC0001146. It's a 1983, February 1983, report from
 8 the director of the Mersey Regional Blood Transfusion
 9 Service. Perhaps interesting to note in passing on
 10 page 4, the second paragraph, an observation about
 11 self-sufficiency. It says:

12 "For some time self-sufficiency in blood and
 13 blood products free from any commercial persuasion has
 14 been widely advocated ... and it is now NHS policy to
 15 move towards full self-sufficiency during the present
 16 decade. Apart from ethical considerations the cost to
 17 this region of continuing to obtain these products ie
 18 Albumin and Factor VIII from commercial sources would
 19 be substantial."

20 So that's one perspective on self-sufficiency.

21 If we go then to page 11 it's interesting to
 22 note the decline in supply of cryoprecipitate to
 23 Liverpool. So we'll see the date range is 1978
 24 through to 1982. If we look at the item for
 25 cryoprecipitate, it's the third section down. We can

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1 a little further down the page what's notable is the
 2 Minutes of the last meeting:

3 "The last meeting had been held in 1980 and
 4 minutes for this were not available."

5 It doesn't appear as though, in what might be
 6 thought to be a rather critical first half of the
 7 1980s, this supra-regional group was having any kind
 8 of coordinated discussions.

9 We can take that down, thank you, Soumik.

10 In terms of facilities, in the 1970s, prior to
 11 the move to the Royal Liverpool Hospital, it appears
 12 that patients were treated on what's referred to as
 13 the tropics ward of the Liverpool Royal Infirmary, and
 14 there are various documents which make reference to
 15 that.

16 In terms of staffing, Dr McVerry's recollection
 17 is that there was limited staffing at the Liverpool
 18 Centre, there was no nurse or dedicated junior member
 19 of staff. Patients would be admitted to the general
 20 Haematology Ward. If a patient came in for Factor
 21 VIII, one of the centre's experienced technicians
 22 would administer it.

23 You may recall, sir, Professor Hay's evidence
 24 about facilities and staffing at the Royal Liverpool
 25 Hospital at the time of his arrival in May 1987.

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1 Because we have already heard from him in some detail
2 orally, I'm not going to repeat it to any great extent
3 but he referred to there being no haemophilia nurse,
4 specialists or physiotherapy or social worker and
5 finding no joint clinics or multi-disciplinary care.

6 Just before we look at the annual returns, it
7 may be useful also to look at HCDO0000342_011. This
8 may have been a document we looked at with
9 Professor Hay during his oral evidence but, in any
10 event, it's May 1987 and it's him, Professor Hay,
11 writing to Ms Spooner, he has just taken over the
12 haemophilia director:

13 "... on reviewing the patients records I am left
14 with the impression that many of our bleeders have not
15 been registered with Oxford."

16 He says he will be sending various notification
17 forms in that respect.

18 His recollection in his oral evidence was that
19 over 50 per cent of patients hadn't been registered
20 with Oxford prior to his arrival.

21 So turning then to the picture which emerges
22 from the annual returns, we can pick that up in 1976
23 at HCDO0001093. The director is here identified as
24 Dr Boulton, 46 haemophilic patients treated during the
25 year, seven Christmas Disease patients.

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1 units of Kryobulin. So again, we can see a mix of
2 commercial products, although still a large amount of
3 cryoprecipitate in use.

4 If we go to the previous page, we can see
5 von Willebrand's patients predominantly
6 cryoprecipitate, although a small amount of Immuno
7 product used.

8 If we go to page 9, we can see there's
9 a specific form for -- sorry, if we just go up the
10 page, the heading on the form:

11 "Total amount of material supplied during 1977
12 to Haemophilia A Patients on Home Treatment."

13 So we can see a sub-form, as it were, in
14 relation to home treatment. We can see some
15 cryoprecipitate being used for home treatment. But
16 a small amount of NHS concentrate, and then Factorate,
17 Koate, Hemofil Kryobulin being used. Important to
18 note, however, what's said in the comments:

19 "These figures include all patients from
20 Merseyside including children who are normally treated
21 by Dr J Martin either at Alder Hey Children's Hospital
22 or at the Royal Liverpool Children's Hospital, also
23 one patient included from North Wales."

24 **SIR BRIAN LANGSTAFF:** Just before we leave this, we're
25 looking here at the relative volumes of different

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1 Then if we look at the usage of different
2 products, cryoprecipitate is given as approximately
3 460,000 units. So the bulk of the treatment -- or,
4 sorry, a large volume of treatment through
5 cryoprecipitate. A much smaller amount of NHS
6 concentrate, approximately 12,500, and then four
7 different commercial concentrates used. Relatively
8 small amounts of Profilate, Factor VIII and Hemofil,
9 so 11,826, 1,485, 8,809 respectively, but a much
10 larger amount of Kryobulin, 365,545. Then we can see,
11 although the numbers are not entirely clear, NHS
12 Factor IX concentrate being used for the treatment of
13 Christmas disease.

14 So we have here, clearly from 1976,
15 a significant amount of commercial concentrate usage.

16 If we go to the returns for 1977, HCDO0001178,
17 and we turn, first of all, to page 14, we can see this
18 return for 1977 gives the directors as being
19 Dr Boulton and Professor Bellingham, 56 haemophilic
20 patients, eight Christmas Disease patients. Then if
21 we look at the figures, we're told approximately
22 800,000 units of cryoprecipitate, get a very small
23 amount of NHS concentrate relatively speaking, 13,000
24 odd units. 58,723 units of Factorate, 207,330 units
25 of Koate, I think 83,800 units of Hemofil, 94,407

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1 product being used. If we can go back to the page you
2 were showing us a moment ago --

3 **MS RICHARDS:** The main return?

4 **SIR BRIAN LANGSTAFF:** -- the main return --

5 **MS RICHARDS:** Page 14.

6 **SIR BRIAN LANGSTAFF:** -- in the same handwriting. You'll
7 see that the approximate conversion rate for
8 cryoprecipitate is about 80 units per bottle. Go on
9 to what we've just been looking at --

10 **MS RICHARDS:** Page 9.

11 **SIR BRIAN LANGSTAFF:** -- same person appears to be using
12 a factor of about 70 --

13 **MS RICHARDS:** Yes.

14 **SIR BRIAN LANGSTAFF:** -- which is, it's all a bit -- a bit
15 slapdash.

16 **MS RICHARDS:** Yes, it is. They are not entirely
17 consistent in terms of what the precise usage then is
18 of cryoprecipitate units.

19 If we look at page 1 of this document, and we
20 zoom in a little, we'll see a pretty clear indication
21 that there seems to be no policy of adhering to one
22 type of concentrate, so we see from the number of
23 ticks that the patients are receiving in one calendar
24 year Factorate, and Koate, and Hemofil, and Kryobulin.

25 That's 1977. If we go to 1978 at HCDO0001275,

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1 if we turn to page 8, we have Professor Bellingham on
2 this occasion given as the director, 58 patients
3 treated during the year, four Christmas Disease
4 patients, and then if we look at the figures we've got
5 a number of bottles or bags, packs used for
6 cryoprecipitate not translated into units but, in any
7 event, the figure there given 9,500, so we may need to
8 apply an extrapolation from the previous return.

9 NHS concentrates 76,000. No Profilate used that
10 year. Substantial quantity of Factorate, 487,544, and
11 a not insignificant volume of Koate, just over
12 100,000.

13 Then could we go to 1979. That is HCDO0001344.
14 We can see, again, Professor Bellingham identified as
15 director. 49 haemophilic patients treated, five
16 Christmas Disease patients.

17 There purports to be a figure for cryo for the
18 whole region although a line through that, cryo RLH
19 only, 630,000 units; NHS concentrate, 220,000;
20 Factorate, 550,000; a very small amount of Hemofil,
21 750 units; then 150,000 units of Kryobulin; and we can
22 see reference also to DDAVP at the bottom of the page.

23 If we go to page 3, again, we can see evidence
24 of patients being treated with more than one type of
25 concentrate, so we can see a number of patients

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1 receiving the Armour product and the Immuno product,
2 a number of patients who fall within that category,
3 although some who are only receiving cryoprecipitate
4 or some who are receiving concentrate and
5 cryoprecipitate.

6 If we then move to 1981, HCDO0001542, the
7 figures here are faint. If we go in closer, we see
8 50 haemophilia A patients, one von Willebrand's, and
9 if we going as closely as we can on the right-hand
10 side, sir, it looks like 331,000-odd units of
11 cryoprecipitate in hospital; and an increase in the
12 volume of NHS concentrate so 368,820 units in
13 hospital; and then a substantial volume of the Armour
14 Factorate used, 755,354 in hospital, and what looks
15 like 463,756 for home treatment; a small amount of the
16 Cutter product -- well, I say "small", I mean
17 45,000-odd; the figure for Kryobulin is also
18 indistinct, but it's in the 400,000s, it looks like it
19 might be 460,977, for hospital and I think probably
20 also for home treatment; and then 28,000 units of the
21 Speywood product, Humanate, used for home treatment.

22 **SIR BRIAN LANGSTAFF:** This seems to be the year, so far as
23 I can see from the figures and depending a little bit
24 on the accuracy of the -- or reliability of the
25 cryoprecipitate figures, this looks to be the year

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1 treated with both Factorate and Kryobulin, from the
2 two ticks in that column. Again, we don't appear to
3 see at least anything that suggests a consistent
4 policy of limiting exposure by using only one type of
5 concentrate for a patient. So that's 1979.

6 If we go to 1980, HCDO0001440, Dr McVerry is now
7 the director, 54 haemophilia A patients, two
8 von Willebrand's patients. If we look at the figures
9 for the haemophilia A patients we can see
10 a significant volume of usage of cryoprecipitate in
11 hospital, just over a million units; very small amount
12 of NHS concentrate; and then a very substantial volume
13 of Armour product, the Factorate product, 761,698
14 units in hospital, 459,442 for home treatment; Koate
15 used, and we have an identical figure given for both
16 hospital and home treatment of just over 50,490; and
17 then the Kryobulin being used, 192,000-odd in
18 hospital, 187,500-odd for home treatment; and some of
19 the Speywood Factor VIII, also 4,000 units identified.
20 For von Willebrand's patients we can see it is
21 cryoprecipitate only from the right-hand column.

22 Again, if we look at, for example, page 4, we
23 will see a number of patients receiving more than one
24 type of concentrate. So if we're looking at the
25 right-hand side of the page, there are patients

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1 when there's the dramatic switch from one to the
2 other --

3 **MS RICHARDS:** Yes.

4 **SIR BRIAN LANGSTAFF:** -- as a principal form of treatment.

5 **MS RICHARDS:** Yes. In 1981 we can see concentrate
6 predominates --

7 **SIR BRIAN LANGSTAFF:** Very much so.

8 **MS RICHARDS:** -- and it's commercial concentrate
9 predominating.

10 **SIR BRIAN LANGSTAFF:** Yes.

11 **MS RICHARDS:** If we go to page 4, again, this is just one
12 page of a list of pages giving details of individual
13 treatments but again, we can see patients being
14 treated on a number -- oh, a number of patients being
15 treated with more than one type of concentrate, and
16 a similar pattern emerges on other pages. That is not
17 true for all patients but certainly true for some of
18 them.

19 1982, we go to HCDO0001640. 48 patients with
20 haemophilia A, no von Willebrand's treated.

21 We can see a marked decline in the usage of
22 cryoprecipitate, 29,260 units in hospital.

23 A significant increase in the use of NHS concentrate,
24 861,000 plus in hospital, 295,000-odd for home
25 treatment; but the predominant treatment again is with

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1 commercial concentrates, in particular the Armour
2 product, Factorate, so just over 1 million units used
3 in hospital, and just under 750,000 units for home
4 treatment; a smaller but not insignificant volume used
5 of the Koate product, so 106,800 in hospital, 94,500
6 for home treatment; and a significant volume of the
7 Immuno product used in both hospital and home
8 treatment, 333,377 units in hospital, 327,637 units
9 for home treatment.

10 If we go to page 5, again we can see if we zoom
11 in, thank you, a number of patients receiving more
12 than one type of concentrate. So there are patients
13 receiving, for example, both Elstree, so NHS
14 Factor VIII, and Armour. There are patients receiving
15 Elstree, Armour, and Immuno. There's a patient
16 receiving Elstree, Armour, Cutter and Immuno, and so
17 on. So, again, a fairly clear indication that there's
18 no policy of keeping patients on one particular brand
19 of concentrate.

20 1983, we need to go to HCDO0000145_003.

21 If we go to the second page, we can see
22 48 haemophilia A patients, one von Willebrand's. The
23 latter is treated with NHS concentrate.

24 There is, here, getting rather more NHS
25 concentrate used than previously, so relatively modest

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1 The fact that the same figures appear for both
2 hospital and home might give rise to a question of
3 whether this is accurate, because it does seem perhaps
4 a little implausible that we would see precisely the
5 same figures appearing on a number of occasions, as we
6 have here.

7 In any event, that's 1984.

8 The 1985 returns -- it's a bit of a mess --
9 HCDO0001925.

10 It looks like this has been completed by
11 Dr Mackie, because in the course of 1985 Dr McVerry
12 has left. 46 haemophilia A patients treated. Then,
13 if we look closer, we can see -- again, there will
14 have been a switch to heat-treated product, presumably
15 at some point in the course of 1985. The figures for
16 NHS concentrate hospital, 1.237 million. And then
17 it's not entirely clear what the breakdown is -- it
18 might be that's a total figure in fact, I think. And
19 then we have it subdivided, despite where it appears
20 in the form, into H, home treatment, 640,700, hospital
21 treatment, 372,000-odd.

22 So we see NHS concentrate being used and a not
23 dissimilar volume of the Armour Factor VIII being used
24 and then a smaller amount of Hemofil, Kryobulin and
25 Humanate being used.

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1 amount of cryoprecipitate, 17,780; 1.2 million units
2 of NHS concentrate in hospital, just 722,000 plus in
3 home treatment; and then a significant volume of the
4 Armour product, Factorate, 945,880 units, hospital,
5 667,160 for home treatment; and of Koate, an identical
6 figure given for both hospital and home, 181,740.

7 So although there's a significant increase in
8 the use of NHS concentrate -- again, in terms of
9 overall figures, I haven't done a precise calculation,
10 but the commercial concentrates, I think, are still
11 predominating, although perhaps not by much at that
12 point.

13 Then we go to 1984, which is HCDO0001832.
14 45 haemophilia A patients. This is the first year we
15 see more NHS concentrate being used than commercial
16 concentrate, although the volume of commercial
17 concentrate usage is still high. Very limited
18 cryoprecipitate usage, just over 6,000; 1.3 million
19 units of NHS in hospital, 914 plus units in the home
20 treatment; a smaller amount of the Alpha product,
21 Profilate, 8,000 given for both hospital and home; the
22 Armour product, 760,000 hospital, 711,600 for home
23 treatment; and then, again, somewhat curiously, the
24 same volume given for the Cutters, for the Koate,
25 150,340 hospital and home treatment.

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1 There's also a reference towards the bottom of
2 the page to a fairly significant volume being sent to
3 other hospitals, but what that's a reference to is
4 unclear.

5 The other data that we have in relation to
6 product usage, although it doesn't give a complete
7 picture, are some stock record cards.

8 I'll just look at one example. LUHT0000002.

9 We can see these are -- this is 1980 and we can
10 see these appear to be monthly breakdowns of the
11 amount of different products used.

12 We don't have a complete set of these, but they
13 may have been what was used to compile the annual
14 returns. We don't know.

15 In terms of other information relating to
16 treatment policies, we have some evidence from
17 Dr Boulton. Hopefully we will in due course have
18 rather more direct evidence to the Inquiry from
19 Dr Boulton. He talks about -- in his evidence to the
20 Penrose Inquiry, he talks about cryoprecipitate being
21 messy to deal with. He says he did use it in
22 Liverpool, but he thought it was very difficult for
23 home therapy. It was more cumbersome for patients.

24 But, as I say, we may hear more from Dr Boulton
25 in due course.

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1 Dr McVerry's statements, I'm not going to go
2 through the statements themselves, but I can, I think,
3 pull out some of the issues that arise from his
4 statements.

5 He recalls consulting Dr Peter Jones in
6 Newcastle before choosing what products to prescribe,
7 and he recalls Dr Jones having transferred his
8 patients to commercial Factor VIII to address the lack
9 of NHS material. And Dr McVerry says:

10 "Based on Dr Jones's experience, I was
11 encouraged to switch to commercial concentrate for two
12 reasons, first of all availability and reliability of
13 supply. And second [he says] there was a mood at that
14 time to continue using a particular product in an
15 individual patient, as this may reduce the prevalence
16 of factor antibodies arising."

17 The evidence that we have looked at in the
18 returns doesn't, however, bear out that that was the
19 approach that was taken.

20 Dr McVerry also seemed to recall the UKHCDO
21 thinking that a number of commercial companies should
22 be used for commercial factors rather than reliance
23 upon one preferred supplier.

24 He does not appear to have been a fan of
25 cryoprecipitate. He can't recall giving it to

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1 unable to answer some of the questions, and suggest
2 that you direct them to Dr BA McVerry."

3 If we go to page 8, this appears to be
4 Professor Hay's perspective, having come in from '87,
5 as to what had happened prior to his arrival. So if
6 we go further down the page, we can see:

7 "I started to use [heat-treated] Factor VIII in
8 November 1984 in Sheffield. Unheated Factor VIII was
9 used in Liverpool until Summer/Autumn 1985."

10 So that was his understanding of the position in
11 Liverpool.

12 And the next paragraph:

13 "All patients were treated with whichever
14 material was available. No cohorts were treated with
15 any specific product. Many centres treated children
16 with cryo and reserved domestic concentrate to defer
17 the onset of hepatitis."

18 If we go to page 10, top of the page, picking it
19 up on the second line:

20 "Patients were treated with what was available
21 and were not reserved particular products or batches
22 (as was the practice in some centres). There was no
23 pattern of use, and this did not change. All
24 factor VIII used prior to mid 1985 was untreated and
25 after that all was heat treated.

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1 a patient in Liverpool, although it obviously was used
2 in the first half of the eighties.

3 He says in his view cryoprecipitate couldn't be
4 safely undertaken at home, and the received wisdom at
5 the time was that home treatment was better for all
6 patients. He suggests that for mild haemophilia the
7 general approach would have been DDAVP. He doesn't
8 recall many previously untreated patients, or PUPs,
9 but says the general approach would have been treat
10 with DDAVP. If that wasn't viable, then cryo, or
11 Factorate only in the case of an emergency.

12 And then his recollection is that there was
13 a switch to heat-treated product when it became
14 available in around early 1985.

15 There are two documents, however, which give the
16 perspective of two other clinicians on the approach at
17 Liverpool. The first is a document that we think was
18 prepared by Professor Hay in the context of the
19 HIV litigation. So if we go to NHBT0085908, you can
20 see it's:

21 "Response to questionnaire: HIV litigation main
22 statement of claim."

23 It's apparent from the context that it's

24 Professor Hay because it says, second paragraph:

25 "Having taken up post in May of 1987, I am

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1 "In my opinion, insufficient use of cryo was
2 made in this centre. Children and mild haemophiliacs
3 should have been treated preferentially with cryo and
4 possibly with domestic concentrate."

5 "Advice on treatment of adults and children was
6 the same in this centre. In many centres children are
7 treated with cryo for as long as possible to delay the
8 onset of [non-A, non-B] hepatitis. I can find no
9 documentation of advice from my predecessor regarding
10 the use of blood products. I do know that DDAVP was
11 used less here than in other centres."

12 Then if we go to page 12 -- no, sorry, page 14,
13 my apologies. Bottom of the page.

14 Again, we can see in the paragraph, the
15 penultimate paragraph, it says:

16 "I started to use heat treated factor VIII ..."

17 So that's Professor Hay talking about Sheffield:

18 "This did not happen in Liverpool until Autumn
19 1985 when UK heat treated [VIII] became available."

20 Then bottom of the next page, he discusses DDAVP
21 being available in 1977 and then, picking it up in the
22 last few lines:

23 "In those centres enthusiastic about it, its use
24 has not changed in recent years. It is my impression
25 that it should have been used more in this centre in

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1 the early 1980s. Its use was widespread from 1977."

2 So that's Dr Hay's perspective as, I think,
3 given what would have been the likely date of this,
4 the then haemophilia director in Liverpool, looking
5 back at what he had gleaned about the early 1980s.

6 There's then a report from Dr Ludlam from the
7 case of an individual patient treated at Liverpool.
8 It is DHSC0043164_074. It's dated April '92 and it's
9 a draft report by Dr Ludlam. It's on a specific
10 patient.

11 If we go to -- just, again, really to pick up
12 what we learned from it about overall policies and
13 practices in Liverpool, we can see, perhaps to provide
14 some context, bottom half of page 4, there's a --
15 various treatments are described, and the latest one
16 being January of 1983, and then Dr Ludlam observing:

17 "It appears that [this particular patient] was
18 not reviewed at the Royal Liverpool Hospital again
19 until 1987 ..."

20 When the patient was found to be HIV positive.

21 And there's reference to use of the Armour
22 product in 1986.

23 If we go to page 6, there's then a series of
24 questions posed by Dr Ludlam. Picking it up in the
25 fourth line.

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1 NHS factor VIII to be safer than that supplied by
2 commercial manufacturers with respect to hepatitis.
3 His view [Dr McVerry's view] may in part have been due
4 to working in the United States where only commercial
5 concentrates were available."

6 So that's a bit of additional information about
7 what appears to have been the approach taken in the
8 1980s in Liverpool.

9 There are then two other documents from the
10 HIV litigation relevant to understanding policies and
11 approach to treatment in Liverpool.

12 If we go first of all to DHSC0045373_118, these
13 are -- and it's dated July 91. It's called a "Status
14 Report on Medical Negligence Cases", and it refers to
15 a range of cases from different centres. But in terms
16 of Liverpool, if we go to page 21, we pick it up --
17 well, we can see it's a haemophilia B patient, and
18 then if we pick it up in the second paragraph:

19 "According to the Statement of Claim the
20 Plaintiff was told by Dr McVerry in January 1985 that
21 the NHS Factor IX which he was receiving was not
22 heat-treated (in contrast to Factor VIII) because it
23 was 'perfectly safe'. If so (there is of course no
24 record in the notes of this conversation), it must be
25 accepted that this was an unjustified prediction in

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1 "It is not clear why the decision was made to
2 treat him with Factor VIII concentrate on the
3 1st January 1981. Had the supply of cryoprecipitate
4 run out over the Christmas period? To defend the use
5 of commercial factor VIII concentrate in January 1981
6 it would be necessary to demonstrate that
7 cryoprecipitate was ineffective therapy or unavailable
8 despite repeated requests to the Regional Blood
9 Transfusion Centre and in this instance NHS
10 factor VIII would be the next preferred option. Again
11 it would be necessary to demonstrate that NHS
12 concentrate was unavailable. Therefore it would only
13 be justified to use commercial concentrate if the
14 other two forms of treatment were unavailable."

15 Then if we go to the next page, he says:

16 "Dr McVerry, in his evidence [it's not clear
17 what evidence that refers to, perhaps some information
18 sought from Dr McVerry in the course of the HIV
19 litigation], states that cryoprecipitate was not
20 available until after 1980. It would really be very
21 useful to know what attempts he had made to secure
22 a reasonable supply of it. Although he does not
23 distinguish between the perceived side effects of NHS,
24 compared to commercial, factor VIII concentrates there
25 were many in the UK in the early 1980s who considered

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1 the then state of knowledge. In fact, the first
2 seroconversion of a Haemophilia B patient receiving
3 NHS Factor IX concentrate was recorded in the
4 following month ... Although the risks of HIV
5 infection from Factor IX concentrate appeared to be
6 lower than those from Factor VIII, and although this
7 Country was self-sufficient in home produced Factor IX
8 concentrate, which could reasonably be expected to be
9 safer than unheated imported material, it was
10 certainly not justifiable to state that no risk
11 attached to the use of unheated NHS Factor IX
12 concentrate."

13 Then if we just go a little further down the
14 page, the author of this document, we don't know who
15 that was, says that if he [that's the plaintiff] had:

16 "... been warned of even a slight risk from the
17 use of unheated material in January 1985, he might
18 well have opted to revert to the use of fresh frozen
19 plasma ... or of heat-treated imported
20 concentrate ..."

21 So that's one document looking at, again, what
22 is said to have been the approach of Dr McVerry, to
23 treatments of a patient with haemophilia B.

24 And then if we go to DHSC0045721_051, there are
25 a handful of cases -- so this is another status report

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1 from September 1991. There are two Liverpool cases
2 discussed. The first is on the first page. It's the
3 one referred to as JKP 014.

4 "Adult, pleaded as mild haemophiliac but
5 according to Dr McVerry severe haemophiliac who had
6 been under treated in the past. Now deceased.
7 Treated with cryoprecipitate until 1982 and then had
8 a knee operation under cover of NHS concentrate
9 followed by home treatment in April 1983. Reason for
10 this was because he was having problems with his left
11 ankle and according to Dr McVerry this was necessary
12 on clinical grounds. Dr McVerry considers that this
13 case is defensible ...

14 "The state of seroconversion remains unclear but
15 on the balance of probabilities this was as a result
16 of infection with commercial product given during home
17 treatment.

18 "It is intended to seek independent opinion on
19 the merits of the defence."

20 And the second Liverpool case is the bottom
21 of --

22 **SIR BRIAN LANGSTAFF:** Just as a matter of interest in
23 that, just go back up to the top of the page.

24 The third sentence under JKP 014 is:

25 "Treated with cryoprecipitate until 1982 ..."

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1 correctly reported that would suggest no particular
2 policy in relation to the treatment of mild
3 haemophiliacs.

4 **SIR BRIAN LANGSTAFF:** The comment at the end, the last
5 sentence?

6 **MS RICHARDS:** Yes:

7 "... necessary to obtain independent expert
8 evidence as to whether this case is defensible."

9 **SIR BRIAN LANGSTAFF:** It looks from what has been said
10 that the view of the author of this is that it
11 probably isn't.

12 **MS RICHARDS:** Yes.

13 Sir, I note the time. What I just want to do is
14 just deal with couple of other aspects of evidence
15 received by the Inquiry. I've still got quite a lot
16 I'd like to cover in relation to Liverpool, which is
17 not going to be done within a short period of time.

18 So if I can just do the next few observations
19 arising out of witness statement evidence from
20 patients and their families, and then pick up
21 Liverpool in the morning.

22 **SIR BRIAN LANGSTAFF:** Yes.

23 **MS RICHARDS:** I'll deal with the knock-on consequences in
24 terms of other centres after I've done that.

25 So in terms of evidence the Inquiry has received

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1 The earlier reference to what Dr McVerry was
2 saying was you couldn't get cryoprecipitate after
3 1980.

4 **MS RICHARDS:** Absolutely right, sir. Yes.

5 Then if we go to the bottom of page 3, the
6 patient referred to as JKP 43, we know is also
7 a Liverpool case:

8 "Mild haemophiliac adult. He received
9 cryoprecipitate until the beginning of 1981."

10 Same point then arises, sir. Then there is
11 a reference to being given Factor VIII concentrate.

12 Picking it up halfway down that long paragraph:

13 "It is not known when he seroconverted because
14 he did not attend hospital for several years
15 thereafter and his first positive test was in 1987."

16 Maybe the same case that Dr Ludlam was
17 considering but not necessarily:

18 "Dr McVerry comments that no specific priority
19 was given to mild haemophiliacs for treatment with NHS
20 product at the time."

21 Again, reference to obtaining independent expert
22 evidence.

23 So, although it's not directly from Dr McVerry,
24 it's the author of this report recording what they
25 understand Dr McVerry's comments to have been, if

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1 from patients, I'm not going to go to the statements
2 themselves, but we have received several statements
3 from patients with mild haemophilia A who were treated
4 with factor concentrates at Liverpool in the first
5 half of the 1980s. There is one witness, for example,
6 who describes being given Factor VIII in 1982,
7 a patient with mild haemophilia A, and said there was
8 a complete failure by the Royal Liverpool Hospital to
9 mention any risk factors in relation to the use of
10 blood products:

11 "We were told Factor VIII was safer, less bulky,
12 easy to store and easier to use than cryoprecipitate.
13 We were also told it could be used for home treatment
14 and taken on our holidays so that it was overall a
15 much more convenient anyway to be treated. Finally,
16 we were told that everyone's treatment was being
17 switched to Factor VIII."

18 That's a witness who has given oral evidence to
19 the Inquiry.

20 There's also a statement from the widow of
21 a patient with haemophilia B. This may be one of the
22 cases that we've looked at in the documents a few
23 minutes ago. That witness describes her husband
24 asking several times if the Factor IX treatment was
25 heat treated and being told it was. In early 1985,

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1 and this is her recollection, the husband was
 2 specifically told by the nurse, under instruction from
 3 Dr McVerry, that Factor IX, unlike Factor VIII, was
 4 from the UK not the USA and had been heat treated and
 5 was therefore safe to inject without fear of
 6 infection.

7 Without going back, then, to the evidence that
 8 Professor Hay gave to the Inquiry orally, you may
 9 recall his evidence of his impression was that there
 10 hadn't been much use of cryoprecipitate prior to his
 11 arrival in Liverpool and he didn't observe any written
 12 policies in place in relation to approaches to
 13 treatment.

14 Sir, the next topic I'm proposing to deal with
 15 is knowledge of risk of hepatitis and HIV and there
 16 are a number of documents I want to go to in relation
 17 to that. So if we could pick that up tomorrow
 18 morning.

19 **SIR BRIAN LANGSTAFF:** Yes, well, let's do that at
 20 ten o'clock, shall we?

21 **MS RICHARDS:** Yes. In terms of the centres that I would
 22 then aim to cover tomorrow, and acknowledging
 23 realistically that I've not covered as many centres as
 24 I would have hoped to cover today, but I think it's
 25 important not to rush through centres, I would propose

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1 a way which might if you were trying to fit the proper
 2 presentation into a shorter period of time.

3 **MS RICHARDS:** Exactly.

4 **SIR BRIAN LANGSTAFF:** So let's do as you suggest.

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

6 **SIR BRIAN LANGSTAFF:** We'll find time one way or the other
 7 without adding to the overall period of time we take
 8 later on.

9 **MS RICHARDS:** Thank you.

10 **SIR BRIAN LANGSTAFF:** So it's ten o'clock tomorrow.

11 (4.33 pm)

12 (The hearing adjourned until 10.00 am the following day)

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1 to complete the Royal Liverpool Hospital, I can deal
 2 very briefly with the Walton Hospital, because there's
 3 very little information, and then deal with Alder Hey,
 4 about which there's a considerable amount of evidence.

5 Then I will then deal with the centres
 6 I mentioned this morning but not the London ones, so
 7 I'll deal with, probably in this order: the three
 8 Scottish centres, Bristol, Truro, Southampton,
 9 Cambridge and Norfolk and Norwich tomorrow, I hope.
 10 But there were ten London centres that we have
 11 provided written notes of that I was hoping to get to
 12 tomorrow, but which realistically I won't.

13 There are still three further London centres
 14 which we're investigating, and so I think it might be
 15 more convenient and fairer to all concerned if the
 16 London senses are then looked at as a composite whole
 17 at a later date when we then pick up all the remaining
 18 Haemophilia Centres.

19 **SIR BRIAN LANGSTAFF:** Well, I think that's sounds very
 20 sensible. I have in mind that people who are watching
 21 may have a particular interest in one or two centres
 22 only, quite apart from the general issues, which some
 23 of the questions and answers and presentations have
 24 thrown up.

25 If so, it's important not to skim over them in

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(71) yes... - zoom