Friday, 8 October 2021

(10.00 am)

Presentation by Counsel to the Inquiry about smaller haemophilia centres (continued)

MS RICHARDS: Good morning, sir, we pick up the picture today with Winchester, about which there is, I'm afraid, little by way of contemporaneous documentation.

The Winchester centre, centre number 11, was based at the Royal Hampshire County Hospital and was designated a centre, it would seem, in late 1976.

The director from that point on through into the 1980s was Dr Mavor. Unfortunately we only have one annual return from the relevant period. That's at HCDO0001681.

You'll see it's the annual return for 1982. It identifies Dr Mavor as the director. It doesn't give the number of patients treated during the year, but there are over the page -- we don't need to go over the page, but there are over the page details which would suggest probably five patients being treated.

And then we can see that the therapeutic materials in use during 1982 comprised cryoprecipitate and NHS concentrates, a little more cryoprecipitate than concentrates, but only a little.

So that, I'm afraid, is the limit of the information that we have from annual returns for Winchester.

If we go to CBLA0002213, we can see that, as at July 1985, the Wessex Regional Transfusion Centre and I should have said, Winchester fell within --

SIR BRIAN LANGSTAFF: Just one moment. For some reason my screen is not working. Neither of my screens are. So that needs to be sorted.

Once Soumik is back in his usual seat, we can begin again. I'm sorry about that.

MS RICHARDS: Sir, this is looking at a letter July 1985. It's from Dr Smith, who was the director of the Wessex Regional Transfusion Centre in Southampton, and that was the Transfusion Centre which supplied the haemophilia centre in Winchester. It's to Mr Pettet at BPL, and it's concerning the submission of names to receive heat-treated products from BPL.

We can see from the second paragraph it refers to Dr Mavor sending "the names of the following patients who are on regular Factor VIII treatment for haemophilia".

Sir, it would appear that as of July 1985, three patients in Winchester receiving regular Factor VIII treatment and hence being put forward for the receipt

of heat-treated BPL concentrate at that point in time.

If we go next to DHSC0002247_090, you will see -- and we looked at this letter yesterday in relation to some of the other centres -- that the Winchester centre was also in receipt of the notification from Wessex Regional Transfusion Centre following the discovery that a donor had been diagnosed with AIDS.

If we then go on to CBLA0000010_211, we can see here a follow-up letter, 8 October 1984, from the Wessex Regional Transfusion Centre to Dr Snape at BPL, relating to the contaminated batch HL3186, and it refers to the number of vials "sent to Haemophilia Centres in Wessex, and the numbers returned".

We can see in relation to Winchester it identifies ten vials of this batch having been sent to Winchester and none having been returned.

You don't need to go to the document, I'll just give the reference for the transcript, but DHSC0004180_050, which we looked at yesterday in relation to Salisbury, identified that one patient at Winchester had been transfused with this particular batch of BPL product.

If we go next to CBLA0000010_188 we will see that Dr Mavor at Winchester is identified as the third

recipient of this letter.

Sir, he was also sent the letter from Dr Craske identifying what investigations should be carried out, and raising those issues we looked at yesterday in terms of the question of whether to tell the patient or not about the risk.

If we then go to INQY0000250, if we go to the second page, line 11 or centre 11 is Winchester. You'll see this is based upon the data provided to the Inquiry by UKHCDO, and it suggests one patient testing positive for HIV in 1985.

Again, whether that correlates with the patient who was transfused with the BPL batch or not is not something that we've been able to establish.

I should say, in terms of information about HIV infection at Winchester, there are two further documents. OXUH0002207.

If we look at the very top of the page, we'll see it says:

"AIDS cases reported on AIDS/3 forms received by 08.10.90 ..."

And the AIDS/3 forms you'll recall is one of the forms circulated by Dr Craske back in 1983. So it appears this is part of the Public Health Laboratory Service or CDSC AIDS surveillance programme.

1 If we turn to page 9, if we look four entries up
2 from the bottom, the fourth entry up -- and the column
3 that is the fourth column along from the left is the
4 centre number, so 011 indicates centre 11, Winchester,
5 and it indicates a case of AIDS being submitted to
6 CDSC in July 1988, but if we read along it then refers
7 to what was said to be the first positive test being
8 in July of 1985, which would correlate with the
9 information that we have received from UKHCDO. It
10 also then further indicates that that patient died in
11 1990.
12 You can take that down, thank you, Soumik.
13 The information on that form suggests that it
14 may have been a child, I should say, but again, we
15 have comparatively little information from Winchester
16 so I can't confirm that definitively.
17 There is also if we look at HCDO000119_197,
18 a letter from Miss Spooner to Dr Mavor in November of
19 1990 which refers to a new case of HIV transmission at
20 the centre. What that is a reference to, whether it's
21 a case being picked up late or whether the same case
22 being reported late or, indeed, someone who had
23 transferred to Winchester from another centre, I'm
24 afraid we can't tell, that's all we have.
25 We don't have any contemporaneous documentation

1 to cast any light on the question of Dr Mavor's
2 knowledge of risks of viral infection, I'm afraid, and
3 he does not appear to have been an attender at UKHCDO
4 meetings. However, he was an identified director from
5 the 1970s and there's no reason to think he wouldn't
6 have been sent the minutes or the communications in
7 1983 from Drs Craske, Bloom and Rizza.
8 In relation to hepatitis, there are a handful of
9 documents that show the hospital in the 1970s
10 reporting cases of post-transfusion hepatitis, and
11 then there's one document only in relation to
12 hepatitis, that I'll pick up on, specific to
13 haemophilia, and that's TREL0000180_004.
14 This is a letter not in fact addressed to
15 Dr Mavor but to Dr Greaves at the Royal Hampshire
16 County Hospital in Winchester, February 1978. It's in
17 relation to a particular patient, and it's from
18 Dr Painter at Treloar's.
19 We don't, I think, need to look at the details
20 in relation to the particular patient but if we look
21 at the bottom of the page, the heading "Prognosis", we
22 can see some observations about hepatitis and blood
23 products being communicated to Dr Greaves at Hampshire
24 Hospital.
25 So, picking it up in the third line:

1 "He is at risk from developing Hepatitis
2 secondary to repeated treatment with blood products.
3 At this moment it is not possible to say precisely
4 what the chances of this are but it is not too great,
5 when the alternative of not treating the bleeds is
6 considered."
7 So that's the view being expressed to the
8 hospital in Winchester. What the view was of those
9 treating patients in Winchester in relation to risk of
10 hepatitis and cost benefit analysis, we don't know.
11 **SIR BRIAN LANGSTAFF:** I don't understand that sentence.
12 Perhaps you may be able to suggest a better
13 interpretation to me, but what has the alternatives of
14 not treating the bleeds got to do with the chances of
15 developing hepatitis?
16 **MS RICHARDS:** Nothing at all, logically, sir.
17 **SIR BRIAN LANGSTAFF:** So it just doesn't make any sense?
18 **MS RICHARDS:** No. The alternative of not treating bleeds
19 might be relevant obviously to the balancing exercise,
20 balance of risks, but you're absolutely right, sir, it
21 doesn't have any logical connection whatsoever with
22 the chances of developing hepatitis. It's poorly
23 expressed.
24 **SIR BRIAN LANGSTAFF:** Probably what he's trying to say,
25 I would think, is: we might choose not to give him the

1 product because he might get hepatitis, but we will
2 give him the product because the chances of him having
3 a serious bleed are worse.
4 **MS RICHARDS:** Yes, yes. I suspect that is what Dr Painter
5 meant.
6 **SIR BRIAN LANGSTAFF:** But as expressed, it just doesn't
7 follow.
8 **MS RICHARDS:** And I draw it to your attention because it's
9 one of the few documents relating to Winchester, I'm
10 afraid, that we've been able to unearth.
11 Sir, I'm afraid that's the picture in relation
12 to Winchester, a small centre, and one about which we
13 have comparatively little information.
14 The tour of the UK is going to move now to
15 East Anglia and to Cambridge.
16 The Cambridge Haemophilia Centre was based at
17 Addenbrooke's Hospital in Cambridge. The director of
18 the centre in the 1970s until 1984 was Dr Chalmers and
19 then Dr Seaman took over and was director from 1984 to
20 1990. We have a statement from her at -- we don't
21 need to put it, up Soumik -- but it's at WITN3815002.
22 When Dr Seaman retired, Dr Trevor Baglin took
23 over, and then in due course, in 2004, Dr David Perry
24 became co-director of the centre.
25 We do have a statement from Dr Perry. Again,

I'll just read the reference for the benefit of the transcript, WITN3173004.

The Cambridge Haemophilia Centre was the largest haemophilia centre in the East Anglian region, and it received its supplies of cryoprecipitate and concentrate through the Cambridge Regional Transfusion Centre.

There's some correspondence in the 1970s between the Cambridge Regional Transfusion Centre and Dr Maycock at BPL which casts some light on the position in relation to supplies and shortfalls.

We can pick it up at DHSC0002359_043.

Sir, this is a letter from Dr Darnborough, who was director of the regional transfusion centre in Cambridge, to Dr Maycock, here addressed at the DHSS. If we pick it up in the fourth paragraph, he says this:

"There is, of course, going to be an awkward period when more than half the cryo used at present is diverted to producing concentrate. This problem has been discussed previously at one of our meetings, and I think it does raise this question once again of to whom you are going to distribute the concentrate. I think this also leads on to the organisation of haemophilic centres, and I think it is just as urgent

that the proposed reorganisation of these should be expedited and laid down in a Departmental circular. Most of our cryoprecipitate [so from the Cambridge Transfusion Centre] goes to Addenbrooke's or Norfolk & Norwich, but there are still dribs and drabs going on to other places ..."

Then he raises in the next paragraph a suggestion of looking at figures for current usage of commercial concentrates.

If we then move from March 1975 to the middle of 1976, Dr Darnborough wrote again to Dr Maycock, CBLA0000383, on the topic of Factor VIII production. He says:

"Is there any news yet of how Factor VIII concentrate is going to be distributed from Elstree and, if so, how much is likely to be available?

"We now seem to have reached our June target for donation units processed for fresh plasma for fractionation, ie, approximately at the rate of 12,000 units per annum. If we include also our present rate of production of cryoprecipitate, we now seem to be working at a total rate of about 20,000 units per annum, which is rather more than the total East Anglian target which was altogether 18,500 units per annum."

And he then in the next paragraph, three lines down says this:

"However, it would be nice to know when we can start reducing cryoprecipitate. If Factor VIII concentrate were available to us now, we could very readily divert the present cryoprecipitate production into further fresh plasma."

Then there's a reference to asking Dr Chalmers, who was the director of the haemophilia centre in Cambridge, for his estimates on future usage of cryoprecipitate and concentrate.

If we then go to CBLA0000387.

No? That is the right reference but it may be that you just haven't got the right document.

Let me explain what that document is. It's a letter dated 15 July 1976 from Dr Chalmers, so from the director of the haemophilia centre in Cambridge, to Dr Maycock explaining that the demands which had been made by the centre for concentrate had been extremely small, mainly due, said Dr Chalmers, to the "excellent service we get in the form of cryoprecipitate from Dr Darnborough" and it also records that they now have a number of patients on home treatment using cryoprecipitate.

So Cambridge another example of a centre which

appeared to be happy to use, at least at some point in the 1970s, cryo for home treatment.

He asked for a supply of concentrate, but that was to enable patients to take it on holiday with them.

There is then a series of communications which I, for the most part, won't need to go to, between Dr Darnborough, Dr Chalmers, Dr Maycock, and others, relating to the proposed reorganisation of the arrangements for the supply of products within the East Anglian region. There was a proposal to bring East Anglia into the broader Thames region, and we looked at some of the documents in relation to that when we were looking at the London centres on Wednesday. I'm not going to go back to those.

The only letter I think that we need to turn to, in terms of displaying on the screen, is at CBLA0000410. This is Dr Darnborough to Dr Maycock in August 1976, and you'll see reference in the second paragraph to the issue which I just described, Dr Darnborough's and Dr Chalmers' concern about linking East Anglian supplies to what was described as the Metropolitan regions which was, in fact, London and Greater London. We can see it sets out Dr Chalmers describing the current system in

1 East Anglia as a distinct and very satisfactory
2 system.
3 If we just see the third paragraph we can see
4 there that Dr Darnborough says this:
5 "The other suggestion which I did not like was
6 that possibly the RTCs could distribute commercial
7 Factor VIII as well as NHS Factor VIII and
8 cryoprecipitate. I feel it would be quite wrong for
9 the [National Blood Transfusion Service] to have
10 anything to do with the commercial preparations, and
11 I am very surprised to learn that one Centre is acting
12 as a middle-man in this respect. I would certainly
13 refuse to do this."
14 Whether the position changes in subsequent years
15 is not clear but that would certainly suggest that, at
16 this point in time, the Cambridge Regional Transfusion
17 Centre happy to supply cryoprecipitate, happy to
18 supply NHS concentrates to its Haemophilia Centres,
19 but not willing to act as a supplier of commercial
20 concentrates.
21 I won't put the document up on screen but there
22 is another document from December 1976, the reference
23 being CBLA0000510, which suggested, as an East Anglian
24 allocation of NHS concentrate, the region would
25 receive 60 bottles per month, of which 44 would be

1 allocated to Addenbrooke's.
2 If we then go to CBLA0000533, we can see these
3 are the minutes of a meeting of Haemophilia Centre and
4 Blood Transfusion Directors in December 1976, again we
5 looked at some parts of this when looking at the
6 London centres. If we just go to the second page,
7 about a third of the way down the page there's the
8 heading:
9 "RHA [so that's Regional Health Authority area]
10 04, East Anglia."
11 It identifies there there's one haemophilia
12 centre at Cambridge, so that's the position in late
13 1976, and the designation of a haemophilia centre or
14 associate centre has been proposed for the Norfolk and
15 Norwich Hospital and we will pick up the picture in
16 relation to Norfolk and Norwich shortly.
17 I won't go to the document but, again, just
18 a reference for you and for the transcript. There's
19 a further meeting of this group in September 1977 at
20 CBLA0000657, in which Dr Chalmers reported the
21 Regional Transfusion Centre had now purchased some
22 commercial concentrate, 50,000 units of commercial
23 concentrate, to be used or has been held as a store,
24 and Dr Chalmers reported that, in relation to the
25 haemophilia centre, at that point in time, they were

1 using cryoprecipitate in hospital, and NHS and
2 commercial concentrate for home treatment, with
3 commercial being used to make up for a shortfall in
4 NHS concentrate. So that was the picture as at the
5 autumn of 1977.
6 That's broadly consistent with the recollection
7 that Dr Seaman described in her witness statement,
8 albeit she took over as director only in 1984. She
9 couldn't recall the use of cryoprecipitate from that
10 point onwards. In terms of choice, her statement
11 says:
12 "The centre didn't always have a choice as to
13 what products were available."
14 Then said in relation to patients:
15 "Patients generally accepted what was offered to
16 them as we could not always give them a choice."
17 Turn to consider the numbers of patients then
18 treated at the Cambridge centre, in the period
19 '76 through to '85. The number of haemophilia A
20 patients treated ranges from 33 to 52 during that
21 period, so a reasonably large centre. The number of
22 haemophilia B patients treated fluctuated quite
23 markedly from year to year but was up to 25, and then
24 a very much smaller number of von Willebrand's
25 patients treated during that period.

1 If we look at a handful of the annual returns
2 starting in '76, HCDO0001064, we can see that, in
3 1976, 52 haemophilia patients treated, 25 haemophilia
4 B and the product mostly in use was cryoprecipitate,
5 by a fairly considerable margin. 472,850, or
6 something along those lines, but, in any event,
7 significantly larger than the others. NHS concentrate
8 used in a very small volume indeed, and then a range
9 of commercial concentrates used: Factorate, Hemofil
10 and Kryobulin, the largest of those being Hemofil,
11 73,000.
12 If we then look at 1977, HCDO0001145, we'll
13 again see that the main product in use was
14 cryoprecipitate; no NHS concentrate used at all;
15 Hemofil, 42,000-odd units; and then a small amount of
16 Koate.
17 If we then go to 1978, HCDO0001240, page 7.
18 We'll see that, although cryoprecipitate is still in
19 substantial usage in 1978, its use has now been
20 overtaken by NHS concentrates, so more NHS
21 concentrates used in that year than cryoprecipitate,
22 and a smaller proportion of commercial concentrate,
23 and only one type of concentrate that year: Hemofil,
24 46,000 units.
25 1979, HCDO0001309, shows a continuation of that

1 trend. So increased use of NHS concentrate,
2 224,000-odd; reduced use of cryoprecipitate, although
3 still not insignificant, over 100,000 units; and then
4 the figure for the commercial concentrates in relation
5 to Factorate is unclear. It may be that's 182,400,
6 which would be obviously a substantial usage, but it's
7 not clear whether something has been crossed out
8 entirely, and then we see Hemofil, in any event, used,
9 20,000 units.
10 **SIR BRIAN LANGSTAFF:** Well, if it is going to be more or
11 less the same, just slight increase on the year
12 before, it'll be 24,000 -- or, sorry, 2,400.
13 **MS RICHARDS:** Yes.
14 **SIR BRIAN LANGSTAFF:** Because the total number of units is
15 in the 300,000s, just the year before.
16 **MS RICHARDS:** But a significant increase in the number of
17 patients treated that year. So there'd been
18 36 haemophilia A patients treated in 1978 but 51 in
19 1979 --
20 **SIR BRIAN LANGSTAFF:** Ah, I see. Yes.
21 **MS RICHARDS:** -- which is what led me to think it might be
22 a larger figure but it's not possible to say, I think,
23 with any confidence.
24 **SIR BRIAN LANGSTAFF:** It's not clear, anyway.
25 **MS RICHARDS:** No. If we then pick things up at

1 HCDO0001404, this is the return for 1980. We've now
2 got the split into hospital and home treatment, in
3 terms of how the figures are reported. You can see
4 there -- I meant to do the maths and get ahead of you,
5 sir, for once, on cryoprecipitate but didn't, so we've
6 got the figures in bags there, but only for hospital
7 treatment. So cryoprecipitate not now, it would
8 appear, being used for home treatment.
9 Then we've got the figures in relation to NHS
10 concentrate, Factorate -- so the Armour product -- and
11 then the Hyland product, and we can see fairly large
12 volumes of each being used as at 1980.
13 If we go, for example, to page 4, we'll see
14 these forms that we're now very familiar with, and
15 they show -- the same pattern is repeated on other
16 pages. There are some patients who receive only one
17 type of commercial concentrate but there are other
18 patients who receive more than one type of commercial
19 concentrate. So there's no obvious adherence to
20 a policy of keeping patients on one type of
21 concentrate only.
22 1981 is HCDO0001502. Again, we've only got cryo
23 for hospital treatment. The home treatment figure for
24 Factorate again, I'm afraid, is not clear. So we can
25 see a substantial volume of NHS concentrate being used

1 for home treatment, a substantial volume of the Armour
2 product being used in hospital, and a smaller volume
3 of Hemofil. But precisely what the figure is for home
4 treatment for Factorate, whether -- something appears
5 to have been written over or crossed out. So it's
6 again, I'm afraid, not clear.
7 1982, however, shows something of a shift. So
8 that's HCDO0001605. A significant reduction in the
9 use of commercial concentrates, so NHS concentrates
10 are now, for this year, far and away the main
11 therapeutic product in use.
12 You'll see an entry there, sir, in the home
13 treatment column for cryoprecipitate, but I'm not
14 confident that that is, in truth, an entry for home
15 treatment, as opposed to an attempt to translate the
16 number of bags into the number of units, by reference
17 to the --
18 **SIR BRIAN LANGSTAFF:** It translates exactly as 70 times
19 515.
20 **MS RICHARDS:** So it would appear that only NHS
21 concentrates were being used for home treatment in
22 1982.
23 1983 is HCDO0001701. We can see from it that
24 the amount of the Armour product, the Factorate
25 product, used in hospital has increased, but it's

1 still majority usage of NHS concentrate, and that's
2 the sole product being used for home treatment in
3 1983.
4 Then, lastly, 1984. HCDO0001797. This is the
5 first year which shows Dr Seaman's name on the annual
6 return rather than Dr Chalmers. We can see again
7 cryoprecipitate usage in hospital only and, by
8 a significant margin, the main product in use is
9 NHS concentrate, although both Factorate and Koate are
10 in use. And again, you'll see the reference to
11 Scottish product, which we saw in one of the returns
12 yesterday, down the bottom of the page "Other
13 Materials (please specify) SCOTTISH": 2,200,100,
14 hospital; 22,820, home treatment.
15 How it was that the Cambridge centre came to be
16 using Scottish product, I'm afraid, is unclear. We
17 don't know. So a fairly mixed picture from the
18 returns.
19 In terms of knowledge of risk of hepatitis, HIV,
20 Dr Chalmers attended a fair number of UKHCDO meetings,
21 including a number of meetings in the 1970s at which
22 issues relating to hepatitis were discussed. So he
23 was there, for example, in the 1974 meeting when
24 Dr Craske reported on the hepatitis outbreak in
25 Bournemouth. He was there in 1979, at least for day 1

1 of the UKHCDO meeting, when there was a discussion of
2 the development of hepatitis as one of the outstanding
3 problems in haemophilia today, although it's right to
4 note he wasn't there on day 2, which is when the work
5 of the Hepatitis Working Party was produced. But
6 again, no reason to think he wouldn't have been sent
7 minutes and copies of reports. He was there in 1981
8 when Dr Craske presented a report to the Hepatitis
9 Working Party.
10 There are also a handful of documents showing
11 Dr Chalmers reporting hepatitis or jaundice in
12 patients to, for example, Dr Maycock, and reports to
13 Oxford through the hepatitis survey.
14 Dr Chalmers also attended the October 1983
15 UKHCDO meeting at which Dr Chisholm raised the issue
16 of reversion to cryoprecipitate for home therapy. He
17 would no doubt have been the recipient of Dr Craske's,
18 Professor Bloom's, Dr Rizza's March and June 1983
19 letters to Haemophilia Centre Directors, and we know
20 that Dr Chalmers also received, in relation to
21 a patient who was also a pupil at Treloar's, one of
22 the letters from Dr Wassef which refers to
23 AIDS-related investigations and looking for the
24 "stigmata" of AIDS, and that's in June of 1983.
25 Dr Seaman has in her statement set out her

1 understanding or developing understanding of the
2 knowledge of risk from blood and blood products. By
3 way of summary, she says she acquired her knowledge
4 from colleagues and from journals. She says she
5 wasn't very conversant with the risk of hepatitis and
6 blood transfusion but knew it did occur, and was aware
7 of the risks of using unsuitable donor material.
8 She says her knowledge of HIV and AIDS was
9 gained from experience over time. She thought she
10 probably became aware of the possible association
11 between AIDS and blood products around 1982 but can't
12 be certain.
13 In terms of the process for testing patients for
14 HTLV-III in Cambridge, Dr Seaman's recollection is
15 that testing was carried out by the Public Health
16 Laboratory Service at Addenbrooke's Hospital. Her
17 recollection is that she saw the patients who were
18 HIV positive in person, and discussed the significance
19 of the test result with them. Her recollection was
20 that it was likely that an explanation as to why the
21 test was being done was given at the time the sample
22 was taken.
23 If we look at CBLA0002032, we can see that, as
24 at February 1985, she was writing to Dr Snape at BPL
25 on the issue of supplies of heated Factor VIII

1 concentrate, and she explains in the second paragraph
2 as follows:
3 "This Haemophilia Centre serves a rather rural
4 practice and a large number of our haemophiliac
5 patients live a long way away from the hospital. Over
6 the years we have encouraged the development of home
7 therapy for such patients and I think interests going
8 to be difficult to revert back again to hospital
9 treatment. This will cause a considerable amount of
10 difficulty especially for the mothers of young
11 children who have not instant transport available."
12 Then she expresses concern about the amount of
13 laboratory testing and handling that would need to be
14 undertaken. That's in relation to the proposed
15 protocol which BPL had drawn up for the use of
16 heat-treated material. So she seems to be expressing
17 some concern as to whether the centre can comply with
18 BPL's proposed protocol.
19 And we can see, bottom of the page, so this is
20 as at February '85, she says:
21 "... we are already experiencing difficulty in
22 getting tests performed outside our laboratory on
23 patients who are serologically positive for HTLV-III
24 antibody."
25 There's then a further letter, BPLL0010618. It

1 is a letter dated 19 February 1985. Again it's to
2 Dr Snape from Dr Seaman.
3 She sets out details of patients who might fall
4 within the categories of the BPL protocol for receipt
5 of heat-treated product. We don't need to look at
6 that but if we go over the page, she then, in relation
7 to patients other than those she'd listed on the first
8 page says this:
9 "All the other patients live, I think, too far
10 away to be sure of attaining the correct number of
11 samples and anyhow the majority are already HTLV III
12 antibody positive."
13 So that would suggest that in relation to
14 Cambridge a significant amount of the testing perhaps,
15 as her statement suggests, being undertaken at
16 Addenbrooke's itself had been completed by February of
17 1985.
18 Then if we look at TREL0000039_219, this is
19 a communication late 1986 with Dr Aronstam at
20 Treloar's. It's about an individual patient. If we
21 look at the bottom two paragraphs on this page, you'll
22 see in the paragraph at the top of the screen the
23 reference to writing to Dr Craske. So the question or
24 the possibility of seroconversion through use of
25 heat-treated Armour product was a live issue in

1 relation to patients treated in Cambridge.
2 But then I just wanted to pick up on this last
3 paragraph. She says:
4 "Incidentally, I was speaking to [the patient's]
5 [GP] the other day and thought it wise to mention the
6 seroconversion. Have you written to him officially
7 concerning this or to you wish for me to do so?
8 I have been regularly informing the GPs of all
9 patients registered with this centre who are HIV
10 antibody positive. In addition have you told his
11 mother?"
12 So it would appear the practice at the Cambridge
13 centre was for Dr Seaman to tell GPs. Unclear whether
14 that was with the knowledge and consent of the
15 patients.
16 In relation to this particular patient, it
17 appears she's told the GP that he is HTLV-III antibody
18 positive in circumstances where she doesn't even know
19 if the boy's mother has been told.
20 Again, sir, you'll wish to consider, no doubt,
21 the evidence you've received, both written and oral,
22 from patients who were treated at Cambridge or whose
23 family members were treated at Cambridge. You've
24 heard, for example, oral evidence from a widow whose
25 husband, under the care of Dr Seaman at Addenbrooke's,

1 explained that he was told by letter in January 1985
2 that he had tested positive for HIV.
3 The figures that we have from UKHCDO, in terms
4 of seroconversions in Cambridge, indicate 16 patients
5 identified as positive in 1985, and two in 1986,
6 giving a total of 18.
7 We don't, at the moment, have any information in
8 terms of numbers infected with hepatitis C. But we
9 are hoping potentially to receive further evidence in
10 relation to that, possibly from Dr Baglin.
11 So that's the position in relation to Cambridge.
12 If we turn, then, to the second major East Anglian
13 centre, which was Norfolk and Norwich, and you'll have
14 seen a reference there, in one of the documents we
15 looked at to the suggestion that Norfolk and Norwich
16 be confirmed as an associate haemophilia centre in the
17 1970s.
18 Dr Leslie was director of the Norfolk and
19 Norwich Centre from around late 1976, prior to that
20 he'd been at Southampton. Then from 1979, we see on
21 annual returns Dr Black also being identified as
22 a director of the centre at Norfolk and Norwich.
23 If we pick matters up with the annual returns,
24 we can get a sense of both the size of the centre and
25 the products used. So if we start with 1976, please,

1 HCDO0000020_005, and we go to page 3. We can see at
2 the top there 20 haemophilic patients treated during
3 1976, 13 haemophilia B patients treated.
4 Then if we look at the products used, no NHS
5 concentrates at all in 1976. Cryoprecipitate in use,
6 just under 29,000 units, but that is outweighed by the
7 volume of commercial concentrate in use and we can see
8 four different commercial concentrates used that year:
9 Factorate, Koate, Hemofil and Kryobulin, with the
10 largest in terms of volume being the Armour product,
11 Factorate.
12 We can then pick the matter up in 1977 with
13 HCDO0001190, and we go to page 9. 1977, 13 patients
14 with haemophilia A treated, nine haemophilia B. We
15 can see cryoprecipitate still in use, but now there
16 are NHS concentrates used and, indeed, that is the
17 largest in terms of volume: so 62,000-odd units of NHS
18 concentrate. There are still commercial concentrates
19 in use but to a lesser extent in that year. Very
20 small amounts of Koate and Kryobulin, and then
21 a larger amount, 23,330 units of Hemofil. So a change
22 as between 1976 and 1977.
23 Insofar as 1978 is concerned -- HCDO0001288,
24 page 3 -- you'll see there a significant reduction in
25 the use of cryoprecipitate, from the preceding two

1 years, although still in some use, and that NHS
2 concentrates are the main product in use, just under
3 85,000 units, with only one type of commercial
4 concentrate being used that year: 9,030 units of
5 Hemofil.
6 Then -- sorry, that's 1978, yes. 1979 is at
7 HCDO0001358. This is where we see Dr Black and
8 Dr Leslie both being identified as directors. Very
9 little used in terms of cryoprecipitate; main product
10 in use, NHS concentrates; but both Factorate and
11 Hemofil also being used to a not insignificant extent.
12 If one then looks at the position in 1980, at
13 HCDO0001456, we've now got the breakdown as between
14 hospital and home treatment. Cryoprecipitate used
15 only to a small extent and in hospital. The main
16 product used, again, for home treatment is NHS
17 concentrate. But there are volumes of Factorate being
18 used and Hemofil to -- again, in fairly large volumes
19 and they're used both in hospital and for home
20 treatment, although to a greater extent for the
21 purposes of home treatment.
22 1981, HCDO0001555, it shows almost no
23 cryoprecipitate used at all.
24 If we can just zoom in on the figures -- thank
25 you.

Some of the figures are slightly indistinct but we can see NHS concentrate used both hospital and home, but particularly for home treatment. So 164,000 or so units for home treatment. And then there were two commercial products in use both for hospital and home treatment: Factorate and Hemofil. The volumes there for home treatment seem to be smaller, so it looks like 13,158 units home treatment Factorate, and 2,550 of Hemofil.

The figure for the use of Hemofil in hospital is indistinct but we can see in any event is small. But then Factorate in hospital use seems to be in fairly substantial usage, so just under 72,000 units of Factorate used in hospital --

SIR BRIAN LANGSTAFF: Well, it looks like one bottle.

MS RICHARDS: Oh, for the Hemofil? Yes. Yes. I'm sorry, I'd gone up to the row above that. So for Factorate, 144 -- (overspeaking) --

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: But yes, sir, you're right, it does look like one bottle.

SIR BRIAN LANGSTAFF: Then the number of units in that bottle, to the right-hand side of that, which broadly corresponds, it looks like 225, whereas it's ten bottles is 2550.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So it's the same broad level.

MS RICHARDS: Yes, so Hemofil not in considerable use at all but the Factorate is, in particular for hospital treatment.

In 1982, HCDO0001655, and happily these figures are typed and easier to read, we can see again that the main product in use for home treatment is NHS concentrate, 175,000 plus units, as opposed to 38,000-odd units of Factorate, so again, still substantial usage. Then in relation to hospital treatment it's the Armour product, Factorate, that is in most use, compared with the NHS concentrate and no cryoprecipitate at all in that year used for the treatment of haemophilia A, although we see it is used to a small extent for a carrier of haemophilia A and a patient with von Willebrand's.

Then 1983, again, a similar pattern. It's at HCDO0001751, similar to the previous year. Only NHS concentrate and Factorate, the Armour product, in use. NHS mostly used for home treatment, the Armour product used both in hospital and for home, but not to the same extent as the NHS concentrate.

Perhaps I should just look at 1984 as well, because that does show a significant change. That's

HCDO0001845. So 1984 shows almost no commercial concentrate used at all. The vast majority of treatment is with NHS concentrate, both in hospital and at home, and then a very small volume of Factorate and Koate used.

What prompted that change, and whether it was conscious or simply reflected what was available, I'm afraid we don't know.

In terms of knowledge of risk of viral infection, again, the best guide, because we have little by way of direct evidence in relation to Dr Leslie or Dr Black, is attendance at UKHCDO meetings, and presumably the keeping up to date by reference to medical journals. So Dr Leslie was a fairly regular attender at meetings in the 1970s and was also there in 1981 and '82. Dr Black -- sorry, in 1981 and '83. Dr Black attended in 1982.

There is one further document that may cast some light on the approach to the use of heat-treated products. BPLL0005848. This is Dr Black writing to Dr Lane at BPL in April 1985 about a particular patient due to have knee surgery, a patient with haemophilia B. He says:

"He had a bilateral knee replacement in February 1984 when we gave him approximately

75,000 units of Factor IX. We might be less liberal this time in view of AIDS but this is to give you early warning of a large request from us."

That's the letter from Dr Black to Dr Lane, and then, if we look at CBLA0002221, this is a letter from Dr Black to Mr Pettet at BPL in July 1985, and we can see the first paragraph refers to -- about availability of Factor IX. It is referring to the same patient, I can tell you, as the earlier letter, and it would appear that the view being taken by Dr Black as at the middle of 1985 is that that surgery should be deferred until heat-treated Factor IX material is available, so potentially a shift in thinking from early 1984 when he talked about being liberal with the use of Factor IX through to the middle of 1985.

There is little by way of contemporaneous documentation that casts any light on the way in which patients were tested for HTLV-III or how diagnosis was communicated to them. But there is a chain of correspondence in the 1990s in the context of an application to the Macfarlane Trust, which may cast some light on the matter.

If we look at DHSC0002532_012, we can see this is a letter, July 1995, it's a posthumous application

1 for payment. If we go further down the page, we can
2 see, in the last paragraph, there's a question about
3 whether the patient understood what they had been
4 told, in terms of diagnosis of HIV, or had "retreated"
5 to what's called a "'denial' state".
6 If we go over the page, there is then reference
7 to two further letters, both of which we have if we
8 need to look at, which say this:
9 "The letter from Dr Watkin suggests the former
10 to be most likely ..."
11 In other words, that the patient didn't
12 understand what they'd been told.
13 "... and the description in Dr Leslie's letter
14 of HTLVIII partly supports this since it was never
15 a term widely used. Both Dr Watkin and Dr Emerson
16 indicate 'denial' as a possibility. A combination may
17 be also possible in that the use of the unfamiliar
18 term HTLVIII would make it easier for [the patient] to
19 reject consciously or unconsciously the possibility of
20 being HIV positive."
21 Then this:
22 "One way or another the medical carers did not
23 manage to make sure that [the patient] was aware of
24 his status."
25 That is perhaps even clearer when one looks at

1 the letters referred to. I'm not going to put them on
2 screen now, but if I give you the references, they are
3 DHSC0002532_014, and then the same reference but _015.
4 The view expressed in the first of those letters
5 from Dr Watkin was that the patient hadn't understood
6 the original communication to him to mean that he'd
7 been infected with HIV, and then had been shocked to
8 learn eight years later that was the case. So it does
9 raise a question as to the adequacy of the
10 communication of information about diagnosis and its
11 significance in Norfolk and Norwich.
12 In terms of numbers infected, the information
13 that the Inquiry received from UKHCDO identified 13
14 patients associated with the centre infected with HIV.
15 One identified as such in 1984 -- that may be
16 a reference to a test carried out in 1984 or to the
17 testing later of a 1984 sample, we can't tell which --
18 nine in 1985 and three in 1986.
19 That, sir, is the position in relation to what
20 the contemporaneous material tells us about Norfolk
21 and Norwich.
22 I can then take the position of the other three
23 centres in the region, so Ipswich, Bury St Edmunds and
24 Peterborough, much more quickly because they're
25 smaller centres that may not have been established

1 until later.
2 The Ipswich Hospital had, as directors at
3 various points in the 1980s onwards, Dr Simpson and
4 Dr Dodd.
5 We have a statement from Dr Simpson, we don't
6 need to put it on screen but it's WITN3881001. She
7 was a consultant haematologist at the Ipswich centre
8 from 1986 to 2000. She says that there were there
9 regular but infrequent outpatient sessions, few
10 patients, and if treatment was not straightforward
11 patients would be referred to Cambridge, as being the
12 large regional haemophilia centre.
13 We do have an account from a witness who's given
14 both written and oral evidence to the Inquiry who
15 describes being treated for a bleed in December 1982
16 at Ipswich. That may have been at a point in time
17 when, although patients were treated there, it was not
18 a designated haemophilia centre. He recalls, and
19 indeed told you, sir, in his evidence, about how he
20 was then referred to Addenbrooke's.
21 There are no annual returns prior to 1987 for
22 Ipswich, and that may reflect the fact that it didn't
23 have a formal status until a later stage, the position
24 is not clear.
25 I won't go through the detail of the annual

1 returns but, in terms of size of centre, the '87
2 return shows 18 patients registered at the centre, of
3 whom, in that year, three haemophilia A patients were
4 treated, two haemophilia B and one von Willebrand's
5 patient.
6 Similarly, we have returns for '88, '89, which
7 show similar numbers of patients being treated.
8 There are meetings attended by haematologist
9 Dr Edwards, based at Ipswich, and by Dr Simpson in the
10 1980s, of the Haemophilia Working Party of the
11 Association of Haematologists of the North-East Thames
12 Region. The first that we've identified is
13 December 1984, and there are discussions there about
14 the likelihood of haemophiliacs being HTLV-III
15 positive, and there's a discussion there about the use
16 of commercial concentrates.
17 Dr Edwards attends another meeting of the same
18 group in November '85, where there's a discussion
19 about informed consent, and we have looked at number
20 of these documents, I think with oral witnesses in the
21 past, so I'll just give the references: BART0000676
22 and BART0000674. Dr Simpson attends similar meetings
23 of the group but rather later on in 1989 and 1990.
24 She was also an attender of UKHCDO meetings on
25 a fairly regular basis but, again, that's from the

1 late 1980s on to the 1990s.
2 The only other insight that we have into the way
3 in which treatment was delivered at an earlier stage
4 at Ipswich is through the evidence of the Inquiry
5 witness, from whom you've heard oral evidence, Alan
6 Burgess and the reference there is WITN1122001.
7 I won't repeat his evidence, but it sets out the
8 process, amongst other things, of being informed of
9 diagnosis by letter from Ipswich Hospital.
10 Bury St Edmunds again appears only to have been
11 established as a formal centre later on in the 1980s.
12 So the earliest annual return we have for
13 Bury St Edmunds, which was based at the West Suffolk
14 Hospital is from 1989, which shows seven patients
15 registered but only one patient being treated. The
16 director of what was, in due course, recognised as the
17 haemophilia centre at Bury St Edmunds was Dr Jones and
18 there are also communications from Dr Boothby,
19 a paediatrician, which would show that patients with
20 bleeding disorders were being treated at the hospital,
21 albeit not necessarily under the auspices of a formal
22 recognised centre until a later stage.
23 There are documents that show, again
24 unsurprisingly, a relationship between the hospital
25 and the Cambridge centre as the main haemophilia

1 centre for the east Anglian region. Then there's
2 correspondence which shows communications, for
3 example, from Dr Boothby to BPL looking at reactions
4 to treatment with Elstree Factor VIII.
5 There is also a letter which suggests that
6 diagnostic tests for HTLV-III for any patients
7 associated with the hospital were undertaken by the
8 laboratory at Addenbrooke's Hospital, so, again,
9 consistent with what Dr Seaman's recollection was
10 about the testing arrangements in the East Anglian
11 region; but that, I'm afraid, is the extent of the
12 information we have in relation to Bury St Edmunds.
13 Then lastly, in terms of this region, we have
14 Peterborough. Again, there's little by way of
15 information or documentation.
16 We see identified as directors at various
17 points, Dr Fairham and Dr Wimperis, but the earliest
18 return we have is 1987. Again, that may reflect that
19 that's the point in time at which Peterborough began
20 to operate as a distinct centre, returning data to
21 UKHCDO.
22 Sir, I won't take you to the 1987 return but in
23 terms of the numbers of patients treated, it shows
24 five haemophilia A patients treated and two patients
25 with von Willebrand's. And again, similar numbers

1 over the years that follow.
2 We do have, at DHSC0100026_035, a letter from
3 Dr Darnborough, again, the director of the Regional
4 Transfusion Centre in Cambridge, to Dr Maycock. This
5 October '72. It shows usage of cryoprecipitate.
6 We've got the figures there for a number of hospitals
7 in the region, so we can see Addenbrooke's, the
8 greatest user in terms of volume: 1,115.
9 And then Norfolk & Norwich next in terms of
10 size. Then we can see Peterborough, the next still.
11 So 172 there identified. What precisely that's
12 referring to, we don't know, but it tends to suggest
13 that as with -- we've seen with a number of other, in
14 particular more rural, areas from time to time, there
15 may not have been designated haemophilia centres until
16 later on but patients were nonetheless treated for
17 their bleeding disorder at, often, local hospitals,
18 which only consequently became recognised at a much
19 later stage as haemophilia centres.
20 If we go to IPSN0000146, we can see there this
21 is 1977 and sales of Koate, so a Factor VIII
22 concentrate produced by Cutter. So if we go down the
23 page, we can see sales to Peterborough. That's six
24 entries up from the bottom: 2,900 units of Koate sold
25 in the period November '76 to October '77. So some

1 treatment with commercial Factor VIII concentrates
2 being undertaken.
3 I won't take you to it, but there's then an
4 updated figure which shows a continuing sale of Koate
5 to Peterborough.
6 There's little else by way of contemporaneous
7 documentation. HCDO0000255_688 is a letter from
8 February 1979 from the deputy director of the
9 Cambridge Transfusion Centre to Dr Lane at BPL, and
10 you'll see, in the first paragraph there, reference to
11 a patient at Peterborough District Hospital becoming
12 hepatitis B surface antigen positive after receiving
13 cryoprecipitate and NHS Factor VIII concentrate and
14 also receiving some commercial Factor VIII
15 concentrate.
16 So we can see again, although we don't have any
17 annual returns, some treatment of patients with
18 bleeding disorders being undertaken at Peterborough in
19 the 1970s, and some usage of both cryoprecipitate,
20 NHS concentrate and commercial concentrate.
21 Dr Fairham attended some UKHCDO meetings, but
22 that's really very much later on. So he attended, for
23 example, a meeting in 1990 and 1993.
24 So that's the position in relation to
25 Peterborough.

1 I'm going to depart from East Anglia and move to
2 Bangor. I wonder whether we can take the break five
3 minutes early.
4 **SIR BRIAN LANGSTAFF:** Yes, let's do that before we move to
5 Wales. So we'll take a break until 11.40. 11.40.
6 **(11.10 am)**
7 **(A short break)**
8 **(11.40 am)**
9 **MS RICHARDS:** Sir, I turn now to Bangor. The treatment of
10 patients with bleeding disorders at the Carnarvonshire
11 and Anglesey Hospital in Bangor seems to have led to
12 the establishment of an official haemophilia centre in
13 the second half of the 1970s.
14 If we look, please, Soumik, at HSOC0021833, this
15 is a letter from Dr Korn who became the director of
16 the centre when it was formally established,
17 5 December 1975, to The Haemophilia Society, and we
18 can pick it up in the first paragraph, four lines
19 down. He says:
20 "... we are trying to get treatment for
21 Haemophiliacs in this area, in that we now have
22 haematology cover, and we are able to do tests for
23 quantitative assays and screening, and we have
24 a supply of cryoprecipitate and fresh frozen plasma.
25 We have a small stock of freeze-dried Factor VIII, but

1 with the current economic situation, I am not sure
2 that I am going to be able to replace that particular
3 substance as it is used. As you know, the situation
4 about buying this expensive product is far from clear,
5 and it is difficult for local authorities to find the
6 extra money, which might run into thousands of
7 pounds."
8 You'll see Dr Korn was trying to arrange for the
9 establishment of a designated centre in Bangor in the
10 1970s. It was recognised as an associate centre and
11 submitted its first annual return we think in 1977.
12 Because of its location in North Wales, it had
13 links both with Cardiff and with Liverpool, and the
14 Liverpool links were perhaps the more formally
15 established links. And that gave rise to questions
16 about, from whom or to whom Bangor should look for its
17 supplies. We can see that from CBLA0000438. This is
18 Dr Korn to Dr Maycock at BPL, September 1976. He
19 says:
20 "Dr Lehane, in the Liverpool Regional
21 Transfusion Centre, has advised me to write to you
22 about the availability of FVIII concentrate through
23 the National Blood Transfusion Service."
24 Then he refers to being the haematologist over
25 what is geographically a very large area. Says he has

1 one or two haemophiliacs who would be ideal candidates
2 for home treatment.
3 Then this:
4 "As some of the patients may have to travel up
5 to forty miles for treatment it would be an advantage
6 in suitable cases. Although I have a small supply of
7 the commercially prepared concentrate, the Area Health
8 Authority is not prepared to finance supplies
9 sufficient to treat even one patient on a permanent
10 basis.
11 "I should be grateful if you could tell me
12 whether FVIII concentrate is available to peripheral
13 hospitals through the [NBTS] and I should also be
14 interested to know your predictions about the supply
15 of this product in the future. This is a question
16 I have often been asked and feel unable to answer
17 because I have heard so many varying reports from
18 different sources. Your opinion would be of great
19 value to me."
20 Dr Maycock's response is at CBLA0000442,
21 14 September 1976. He explains in the first main
22 paragraph that:
23 "The supply of fresh plasma for the preparation
24 of concentrate at [BPL] is increasing steadily and
25 I hope it will be possible to begin a routine

1 distribution at the beginning of November."
2 He explains that a letter is in draft form to be
3 sent out. Then says this:
4 "The distribution of the available concentrate
5 should be settled locally between those concerned and
6 I have taken the liberty of sending a copy of this
7 reply to Dr IW Delamore at the Manchester Royal
8 Infirmary, to Dr Dermot Lehane and Dr F Stratton at
9 the two RTCs concerned respectively."
10 And Dr Lehane was Liverpool and Dr Stratton,
11 Manchester Regional Transfusion Centre.
12 Then he says:
13 "Hitherto we at BPL have distributed available
14 concentrate in accordance with our assessment of the
15 needs of patients referred to us. This is a most
16 unsatisfactory method but was preferable to
17 distributing the relatively small supplies over the
18 country which would have resulted in insufficient
19 being available in any given place to deal with
20 a severe bleed.
21 "I hope it will be possible for those concerned
22 in the Manchester, Liverpool and North Wales areas to
23 decide how supplies are to be used. The amount of
24 concentrate available in this area will possibly be in
25 the order of ..."

1 Then it looks like 290 times 200 --
2 **SIR BRIAN LANGSTAFF:** 250, I think.
3 **MS RICHARDS:** 250, probably.
4 **SIR BRIAN LANGSTAFF:** That's international units.
5 **MS RICHARDS:** Units, bottles per month, exactly.
6 We don't need to go to the next lot of documents
7 but the annual returns for the Liverpool Royal
8 Infirmary in 1976 and 1978 identify some patients
9 treated there, in Liverpool, being also under the care
10 of Dr Korn at Bangor. And we also have stock records
11 from what then became the Royal Liverpool Hospital,
12 showing that they distributed to Bangor, Elstree
13 Factor VIII, Oxford Factor IX, and Armour Factorate,
14 in 1980.
15 There's also some evidence, not least from
16 patients or family members with a recollection of
17 treatment there, of links between Bangor and the
18 haemophilia centre in Cardiff.
19 If we go to DHSC0001146, this is now moving
20 forward to 1983 and it's a Mersey Regional Health
21 Authority document. It's a report of the director of
22 the Mersey Regional [Blood] Transfusion Service. But
23 we can see there what's described as the catchment
24 area, covering not just the Mersey region but also
25 North Wales, and indication of the population there.

1 And we know from this and other documents that
2 the Regional Transfusion Centre in Liverpool did
3 supply both cryoprecipitate and whole blood to Bangor.
4 That had been the arrangement, we understand
5 from other documentation, for some decades.
6 If we then turn to CBLA0000699, this is a list
7 or table. It's from 1977. But if we go over the page
8 you'll see it identifies different haemophilia centres
9 by reference to what supra region they belonged to.
10 So it may be quite a useful document overall to
11 understand the organisation and organisational
12 arrangements as between different centres.
13 If we go to page 5, and we look at the bottom
14 half of the page, we can see that Bangor, the various
15 Liverpool centres, Manchester, Lancaster and
16 Blackburn, all fell within what was described as the
17 Manchester Supra Region.
18 If we turn then to the information from the
19 annual returns, looking first at numbers of patients
20 treated at Bangor from 1977 to 1986, the number of
21 haemophilia A patients treated ranged between six and
22 14, on an annual basis, one patient with haemophilia
23 B, and between three and seven patients with
24 von Willebrand's disease.
25 Soumik, if we can have HCDO0001133. This is the

1 first annual return submitted for 1977. We will see
2 in that year nine haemophilic patients, one Christmas
3 disease patient, and we can see in relation to the
4 patient with Christmas disease the treatment was with
5 Oxford NHS concentrate.
6 You'll see there, sir, cryoprecipitate in use,
7 but also NHS factor concentrate, and indeed that's the
8 product in greatest use, followed by cryoprecipitate,
9 and then a range of different commercial concentrates,
10 in smaller numbers, but four different concentrates
11 there used: Factorate, Koate, Hemofil and Kryobulin.
12 If we move to 1978, HCDO0001226, page 3, what we
13 see there is an apparent significant increase in the
14 use of cryoprecipitate in 1978. So the figure's gone
15 up to 137,620, and that's the main source of
16 treatment, followed then by NHS concentrate and then
17 by commercial concentrates, mostly the Armour product.
18 Then in 1979, HCDO0001296, we see a similar
19 pattern. Most of the treatment is with
20 cryoprecipitate, 206,000-odd units, followed by NHS
21 concentrate, 81,500 units, and then not insubstantial
22 volumes of commercial concentrate, just under 43,000
23 units of Factorate, and 20,550 units of Koate.
24 If we then pick the picture up at the following
25 year at HCDO0001390, what we then see is a significant

1 reduction in the use of cryoprecipitate. So 401 bags
2 used in hospital, which would equate to around
3 28,000 units. NHS concentrate, 21,600 units. Then
4 the product in greatest use now is the commercial
5 concentrate, in particular the Armour product,
6 67,000-plus units in hospital, and then Armour's
7 product and Koate are used for home treatment.
8 Then 1981, HCDO0001489. Here, again, we can see
9 the amount of NHS concentrate in use is comparatively
10 small, and the main products in use again are
11 commercial concentrates, predominantly hospital
12 treatment. So comparatively little by way of home
13 treatment, although such home treatment as there is
14 with commercial concentrates, and four different
15 concentrates, commercial concentrates in use:
16 Factorate and Koate the largest volumes, and then
17 Hemofil and a small volume of Kryobulin.
18 What causes that change and that shift in the
19 increased use of commercial concentrates, whether it's
20 conscious, deliberate choice, convenience, supplies
21 and shortages, we don't know.
22 1982 is at HCDO0001592. Here we see no
23 cryoprecipitate used at all for haemophilia A
24 patients. It is used for the treatment of
25 von Willebrand's disease. NHS concentrate used in

1 hospital only, to a relatively small extent. All home
2 treatment is with commercial concentrates and
3 commercial concentrates form the majority of the
4 treatment, in particular the Armour product Factorate,
5 but also Koate and Hemofil., and then a tiny amount of
6 Kryobulin.
7 The picture, then, for 1983, HCDO0001688, again
8 we can see in 1983 no cryoprecipitate at all used
9 other than for the treatment of von Willebrand's
10 patients. Usage of NHS concentrate has increased.
11 The product that is in greatest use is the Cutter
12 product, Koate and that's the sole product used for
13 home treatment. Then the Armour product used at
14 hospital, 27,000-odd.
15 So again, we have more commercial concentrate
16 than NHS concentrate being used in that year, and no
17 cryoprecipitate at all.
18 Then lastly the picture for 1984, HCDO0001784,
19 sees a change. So, here, small amount of
20 cryoprecipitate used, but now by far the main product
21 used is NHS concentrate. It's used for both home
22 treatment and hospital treatment and used
23 substantially more than commercial concentrate.
24 So we can see the figures there: 126,785 units,
25 hospital, and just under 27,500 units for home

1 treatment.
2 Commercial product is still used, just over
3 21,000, hospital, just over 9,000, home treatment.
4 It's all Koate in that year, but it's outstripped in
5 terms of usage by NHS concentrate.
6 Again, I'm afraid, no way of knowing whether
7 that's the reflection of a conscious response or
8 simply reflects what was available.
9 In terms of the transition to heat-treated
10 products in Bangor, if we can look at BAYP0000024_070,
11 this is an internal Cutter document, 5 February 1985.
12 It's an area report for January of 1985.
13 If we pick it up under the second paragraph:
14 "All centres in this region [the region being
15 north and Wales] have converted from non heat treated
16 commercial material to heat treated commercial
17 Factor VIII concentrate. Opinion seems to be divided,
18 however, on the use of non heat treated NHS
19 materials."
20 Then it says:
21 "The following centres are continuing to use
22 non heated NHS material."
23 We can see that includes Wales, Bangor, Swansea
24 and Cardiff. That's the position described as at
25 January of 1985.

1 By February of 1985 -- yes, we will just look at
2 this. BAYP0000024_149. The second paragraph
3 describes opinions still being divided on the use of
4 non-heat treated NHS material.
5 If we go over the page, we're told, in relation
6 to Bangor, towards the top of the page, at D,
7 paragraph 1:
8 "They have switched from regular to heat treated
9 Factor VIII commercial material."
10 And there are sales reports that we've got --
11 I won't go through them -- later in the year, which
12 seem to suggest Bangor returning unheated Koate to
13 Cutter, and from time to time purchasing Koate-HT.
14 If we go then to BPLL0001727, this is a document
15 that appears to have been generated in the context of
16 the HIV haemophilia litigation.
17 If we go to the second page, there's a letter
18 from Dr Korn, who was still the Centre Director in
19 1990, to Dr Lane at BPL, and he says he's been
20 requested to provide information with reference to
21 heat-treated Factor VIII.
22 "Specifically they are asking me when I first
23 used heat treated F.VIII concentrate in this district.
24 My records show that NHS concentrate was supplied by
25 the Blood Transfusion Service for treatment of my

1 patients in the first few months of 1985. I have
2 a record of the batch numbers but no indication in the
3 record whether this was heat treated."
4 Then we can see the information that's then
5 being set out. So we've got a number of batches
6 listed, one of which is identified as heated, HLA3242
7 and someone has written "All other batches unheated".
8 And that appears to be Jonathan Strohm, who was
9 based at BPL, who has identified those batches as
10 being unheated.
11 If I turn to consider what little is known by
12 way of Dr Korn's knowledge of risks of viral
13 infection, Dr Korn was not a regular attender of
14 UKHCDO meetings. He's identified as being present at
15 the meeting in October '77, and a meeting in
16 October '89. And we don't have formal attendees
17 identified for all meetings so it is possible he
18 attended one or more others, but he's not down as
19 attending most of them, but again, presumably, as
20 a recognised Centre Director, would have been sent the
21 minutes, the 1983 correspondence and the like.
22 In terms of numbers infected, the data that
23 we've received from UKHCDO suggests that four patients
24 associated with Bangor were infected with HIV, and
25 they are identified as having -- or they're recorded

1 as having been identified as such in 1985.
2 In relation to hepatitis C, the Inquiry has
3 received some evidence from individual witnesses but
4 we have no contemporaneous documentation showing
5 anything more broadly in terms of policies or
6 practices. An Inquiry witness treated with
7 cryoprecipitate has described herself contacting
8 Dr Korn and then being tested for hepatitis C in the
9 early 1990s. Another records learning of her
10 hepatitis C diagnosis in 1991 by letter.
11 In terms of treatment arrangements, again,
12 you've received some evidence from individuals, and
13 we've referred to that in our written note. There is
14 one document which shows difficulties in treating
15 those with bleeding disorders and those infected with
16 hepatitis and HIV in Bangor, and that's
17 CVHB0000005_029. Well, I can describe it without --
18 I'm afraid we don't have it to display on screen.
19 You may recall, sir, from the evidence of
20 Professor Peter Collins, that in 2011 in Wales, a task
21 group was set up to examine issues relating to,
22 amongst other things, the care and treatment of
23 individuals with bleeding disorders in Wales.
24 A document prepared for that group describes service
25 provision in North Wales, and I'll just read a couple

1 of the relevant sections from the document.
2 So as at 2011, the description was as follows:
3 "The haemophilia centre in Bangor provides care
4 for patients with bleeding disorders in North West
5 Wales. Currently, there are 130 registered patients
6 including 24 patients with haemophilia."
7 Then this:
8 "Given the remote location of the area, these
9 patients are managed locally rather than having to
10 travel long distances for specialist care. However,
11 it is important that they're able to access
12 a comprehensive service that is equivalent to that
13 offered in other centres in Wales. There are several
14 concerns about the current service provision and equal
15 access to standards of care."
16 Then specifically, in relation to those with
17 hepatitis, the document says that:
18 "Patients with inherited bleeding disorders who
19 have hepatitis are referred to a consultant
20 gastroenterologist for management and treatment of
21 liver disease. The Bangor service has seven patients
22 with hepatitis C.
23 "Ongoing monitoring is undertaken in the
24 haemophilia clinic. One patient travels to Cardiff
25 for review in the joint hepatology clinic.

1 Unfortunately, we are unable to undertake ultrasound
2 scan monitoring of these patients for evidence of
3 cirrhosis or hepatocellular carcinoma due to lack of
4 resources in the radiology department."
5 Then, in relation to HIV, the same document
6 says -- and, again, this is the picture as at 2011,
7 the picture in earlier decades may, of course, have
8 been very different:
9 "Patients were referred to an HIV specialist
10 unit that was part of the Mersey, Cheshire & North
11 Wales HIV managed clinical network, and the patients
12 had access to regional expert specialist input from
13 Liverpool."
14 So that's the position described as at 2011.
15 Those are the materials, sir, relating to
16 Bangor.
17 I'm going to now move to Yorkshire and
18 Derbyshire. So we'll start with Derby. From the
19 1970s to 1990s, the haemophilia centre for Derby was
20 based at the Derbyshire Royal Infirmary. If we go to
21 DHSC0100026_068, this is a document from the Sheffield
22 Regional Hospital Board from 1972, and it describes:
23 "Hospital Arrangements for the Diagnosis and
24 Treatment of Haemophilia and Allied Disorders
25 "Recommendations of a meeting of Haematology/and

1 Pathologists with an interest in Haematology held at
2 Derbyshire Royal Infirmary, 5th May 1972."
3 Then under the heading of "Designation of
4 centres for diagnosis and treatment":
5 "At the present time there are four centres in
6 the region where the diagnosis and treatment of
7 haemophilia is undertaken; these are located at
8 Sheffield, Derby, Nottingham and Leicester. The
9 Sheffield and Derby centres are designated by the DHSS
10 as 'Haemophilia Diagnostic and Treatment Centres' ..."
11 Then it goes on to explain that Sheffield was
12 also a Reference Centre.
13 Then the next paragraph says, in the last
14 sentence:
15 "Improvements at Derby would be necessary if it
16 was to retain its designation."
17 Then if we go over the page, paragraph 4, bottom
18 half of the page, we can see it's said there:
19 "It was recommended that close contact should be
20 maintained between the peripheral centres and the
21 Sheffield Haemophilic Centre and the Regional Blood
22 Transfusion Centre. The Blood Transfusion Centre
23 should be supplied with details and a blood sample
24 from patients diagnosed as suffering from haemophilia
25 or a similar condition."

1 So Derby part of this regional network with
2 Sheffield as its main local Reference Centre.
3 The director of the centre at Derby until 1974
4 was Dr Wylie. He then left, Dr White was temporarily
5 in charge, and then Dr Winfield became director of the
6 Derby centre in around 1976 to approximately 1982.
7 Dr Winfield then moved to Sheffield. From 1979 Dr
8 Mayne, Dr Stuart Mayne, was a consultant haematologist
9 at the centre and he's listed as a director alongside
10 Dr Winfield in the 1979 return.
11 Then Dr Deirdre Mitchell worked at the centre,
12 again as a consultant haematologist. She and Dr Mayne
13 are identified as joint directors of the centre in
14 1981 to 1983, and then at various points in the 1980s
15 sometimes she's identified as sole director, sometimes
16 she's joint director with Dr Mayne, and then sole
17 director from 1987 onwards.
18 The Inquiry has a witness statement from the
19 centre's current director, Dr McKernan. She took up
20 that role in 1995. I won't go to her statement, but
21 the reference is WITN3923008.
22 Before we look at the annual returns, there are
23 a couple of documents which just provide an indication
24 of interactions with pharmaceutical companies in the
25 1970s. The first is at SHPL0000071_155. This is

1 an incomplete letter, we've only got the first page,
2 so from an unknown sender, on behalf of a company
3 based in Kent called Serological Products Limited.
4 It's addressed to Dr Eibl, the medical director at
5 Immuno, and it describes a visit in February 1973 to
6 Dr Wylie, the Consultant Haematologist at Derbyshire
7 Royal Infirmary:
8 "He promised that if I was successful in my
9 Application for a Product Licence for Factor VIII
10 Concentrate he would use some and if satisfied would
11 recommend regular purchases by the Hospital Management
12 Committee. This he has proceeded to do."
13 Then I don't think we need to go into the detail
14 of the rest of the letter, but the author of the
15 letter sets out some of Dr Wylie's observations about
16 the product, Kryobulin. We'll see from the annual
17 returns that Kryobulin does feature as one of the
18 products used at Derby.
19 There's a follow-up letter at UHDB -- sorry,
20 it's not, in fact, a follow-up -- it's a letter from
21 the same company, UHDB0000020, Serological Products
22 Limited. This time we know the author, and it's
23 almost certainly, because of the initials, the author
24 of the original letter, Norman Berry. This is
25 addressed to the Chief Technician at Royal Derbyshire

1 Royal Infirmary. It refers to there having been
2 "a kind reception given to our Medical Representative"
3 in July 1974, and then provides an agreement for use
4 of Kryobulin on a regular basis.
5 **SIR BRIAN LANGSTAFF:** I think, although you expressed
6 doubt as to the authorship of SHPL0000071_155, I think
7 that it also got --
8 **MS RICHARDS:** The same initials.
9 **SIR BRIAN LANGSTAFF:** -- NB.
10 **MS RICHARDS:** Yes.
11 **SIR BRIAN LANGSTAFF:** So it does look as though it's
12 Mr Berry reporting back to head office.
13 **MS RICHARDS:** Yes. I agree. Highly likely. We don't
14 have the second half of the letter but you're
15 absolutely right: it's the same initials so it seems
16 highly likely that --
17 **SIR BRIAN LANGSTAFF:** I call it "head office". I mean the
18 overall holding company back in Vienna.
19 **MS RICHARDS:** Yes.
20 Then there's some interaction between Armour and
21 Derby, this time with Dr Winfield, who was the
22 successor director, UHDB0000012. This a letter
23 November 1977. You'll recall when we were looking at
24 Armour materials the other week, we looked at this
25 Factorate 1,540 donors imprint.

1 In any event, we can see this is Mr Bishop
2 writing to Dr Winfield providing details of the
3 contract that's now been awarded in relation to
4 Factor VIII by the Department of Health, setting out
5 the prices. It says at the bottom of the page:
6 "As in previous years, we have tendered our best
7 prices right from the start of the contract in order
8 to ensure the least disruption to the work of your
9 Centre."
10 Over the page -- I'm sorry:
11 "It is not our intention to amend these", it
12 says.
13 Then over the page:
14 "We are very conscious of the fact that all
15 Centres are working to very tight budgets. We are
16 also fully aware of the implications of the new
17 contract prices in respect of maintaining or
18 increasing current levels of treatment and home
19 therapy programmes within the limits of these budgets.
20 "An analysis of the new terms will reveal the
21 true economic advantage of placing some, if not all,
22 of your commercial concentrate business with Armour."
23 Then we saw, I think, potentially this claim or
24 a very similar claim when we were looking at the
25 Armour documents:

1 "By purchasing FACTORATE against a given
2 sterling budget, your Centre will be able to obtain
3 between 50% and 97.5% more Factor VIII concentrate
4 than other commercial products approved for sale on
5 the DHSS contract."
6 Then the next paragraph talks about:
7 "The proven quality of the product, the
8 flexibility of the presentation and the economic
9 advantages outlined above present, we feel, an
10 overwhelming case for the inclusion of FACTORATE in
11 your treatment programme."
12 Factorate was used by the centre to an extent.
13 We will look at it in a moment when we look at the
14 returns. But it is also relevant to note, in the
15 following -- no, in fact, in the same year, 1977. If
16 we look at ARMO0000013, there were reports of
17 jaundice. So this is a letter of 18 May 1977 from
18 Elizabeth Stockman, a registration officer with
19 Armour, reporting to the Medical Assessor on the
20 Committee on Safety of Medicines, and she says:
21 "We wish to inform you we have received reports
22 from three centres of clinical jaundice occurring in
23 haemophilia patients who have received amongst their
24 various treatments our drug, Factorate ..."
25 Then the specific batch is given, P80006.

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1 "The three centres concerned are:
2 "Derbyshire Royal Infirmary (3) ..."
3 Then Leeds and Nottingham.
4 "In all cases the hepatitis has been mild and
5 the patients have all recovered.
6 "At present we are pursuing these reports to
7 acquire full details of the cases and will, of course,
8 send you completed Yellow Forms as soon as possible."
9 Then towards the end of the page, it says that
10 the cases do not follow a clearly defined pattern.
11 So those are some interactions in relation to
12 pharmaceutical companies and the centre at Derby. If
13 we then turn to the annual returns, starting with
14 1976, HCDO0000101_002, we can go to page 2, please.
15 We can see, in 1976, 24 patients with haemophilia
16 identified, and then three with Christmas disease.
17 Then if we look at the product usage, by far and
18 away the main product used is cryoprecipitate, a very
19 small amount of NHS concentrate. Then we can see
20 three different types of commercial concentrate in
21 use, mainly Kryobulin, just 39,500 or so; and then the
22 Armour product, 10,299; and then 7,200 units of
23 Hemofil, but compared with the tiny amount of NHS
24 concentrate and a significant amount of
25 cryoprecipitate.

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1 There are four patients in that year on regular
2 home therapy as well, but we can't tell, I think, from
3 the returns what product they're receiving for that
4 home therapy.
5 If we go to 1977, HCDO0001153, we can see that
6 cryoprecipitate is still the product in main use,
7 82,000-odd units, followed by Kryobulin, 35,500.
8 There's been an increase in the use of NHS
9 concentrate, so it's now nearly 27,500 units but still
10 not as much as cryoprecipitate or commercial
11 concentrates, and then the Armour product, just under
12 7,500 units.
13 If we then turn to 1978, HCDO0001252, page 5.
14 We can see that cryoprecipitate is still the product
15 in greatest use in 1978 but only marginally, and the
16 product used to almost the same extent there is the
17 commercial concentrate Kryobulin, nearly 97,000 units,
18 contrasting with just over 100,000 units of
19 cryoprecipitate. NHS concentrate is used to
20 a substantial extent but not as much: 65,335 units.
21 If we then turn to 1979, HCDO0001416, we now
22 have -- sorry, that's 1980, forgive me.
23 1979 is HCDO0001319, sorry. A similar usage of
24 cryoprecipitate to the previous year. Use of NHS
25 concentrate has gone up --

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1 **SIR BRIAN LANGSTAFF:** (Unclear)
2 **MS RICHARDS:** -- but greatly reduced reliance upon
3 commercial concentrates in 1979. So Kryobulin only
4 just over 9,000 units, and that's in comparison with
5 the 77,000 units of NHS concentrate and 108,000 units
6 of cryoprecipitate.
7 If we then go to 1980, HCDO0001416, we can see
8 there again three products in use: cryoprecipitate,
9 NHS concentrate and Kryobulin. The product in
10 greatest use is, I think, the cryoprecipitate --
11 **SIR BRIAN LANGSTAFF:** Yes.
12 **MS RICHARDS:** -- by some considerable margin. Then,
13 I think, that's 121,000, probably, that works out as,
14 but only in hospitals. So cryoprecipitate not used
15 for home treatment. Then we can see NHS concentrate
16 used to some extent in hospital but predominantly for
17 home treatment, and Kryobulin used both in hospital
18 and for home treatment.
19 When we turn to 1981, HCDO0001514. We see now
20 that Kryobulin usage has declined, it's still used but
21 to a much lesser extent and Factorate is in
22 substantial usage, but so too is cryoprecipitate and
23 NHS concentrate. So the figure for cryoprecipitate,
24 112,420 --
25 **SIR BRIAN LANGSTAFF:** Not a very great reduction.

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1 **MS RICHARDS:** It's not, no. NHS concentrate used
2 substantially for home treatment, and Factorate used
3 both in hospital and for home treatment.
4 So cryoprecipitate usage continuing later than
5 we've seen with a number of other centres. So 1981
6 still very much in use.
7 1982 is at HCDO0001615. We can see that whilst
8 cryoprecipitate is still used, the volume is reduced.
9 It's now just under 67,000 units, and only for --
10 sorry, only in hospital. The product now used to the
11 greatest extent is, in fact, the Hyland product,
12 Hemofil, followed by the Cutter's product, and then by
13 NHS concentrate, then last of all, Kryobulin.
14 So more commercial concentrate used in 1982, and
15 a broader range of different commercial concentrates
16 used in 1982.
17 If we turn to, for example, page 5, we will see
18 these forms which show a number of patients being
19 treated in the course of a year with multiple
20 commercial products. So sometimes two products,
21 sometimes three, sometimes one. So no obvious policy
22 of adherence to a singular type of concentrate.
23 The picture then in relation to 1983,
24 HCDO0001712, we can see that cryoprecipitate is now
25 very much a minority treatment in 1983. It's just

1 over 29,000 units. The product in greatest use is
2 Koate, in the region of 443,000 units, split between
3 hospital and home treatment. And then NHS
4 concentrates, a little over 300,000. So a marked
5 shift from what we've seen in previous years, with
6 Koate now dominating.
7 And then lastly, 1984, which is HCDO0001807,
8 a slightly different picture here. The product in
9 greatest use now is the NHS concentrate.
10 Cryoprecipitate still used, but not to the same extent
11 as we've seen in earlier years. So it's NHS
12 concentrate, followed by the Koate, which is also used
13 to a substantial extent, and then Profilate, the Alpha
14 product, appearing for the first time on the returns.
15 **SIR BRIAN LANGSTAFF:** Well, how much would 662 bags be --
16 **MS RICHARDS:** I was hoping -- (overspeaking) -- sir.
17 **SIR BRIAN LANGSTAFF:** -- at 70?
18 **MS RICHARDS:** You do the maths much more quickly than
19 I do.
20 **SIR BRIAN LANGSTAFF:** It looks like something in the
21 region of 400,000 units. So it's ... unless I've
22 added a nought wrongly.
23 **MS RICHARDS:** Yes, you have added a zero. I'm told
24 46,000.
25 **SIR BRIAN LANGSTAFF:** 46,000.

1 **MS RICHARDS:** I'm looking behind me and I'm looking at
2 some of the maths I did last night of some of the
3 earlier returns: 1,740 bags gave 121,000 units.
4 **SIR BRIAN LANGSTAFF:** Yes, that's right.
5 **MS RICHARDS:** As I say, it's not an insignificant amount
6 of cryoprecipitate compared to some of the other
7 centres, but it very much pales into insignificance
8 conditions compared to the use of concentrate, both
9 NHS and commercial.
10 **SIR BRIAN LANGSTAFF:** Oh, absolutely.
11 **MS RICHARDS:** Turning, then, sir, to knowledge of risks of
12 infection in consequence of use of blood products.
13 Again, the best evidence we have, really -- or
14 the only evidence we really have -- is through
15 attendance at UKHCDO meetings.
16 Dr Winfield was a regular attender. He attended
17 the Haemophilia Centre Directors meetings in '77, in
18 '78 and in '81. We also see Dr Mayne attending in
19 '82. I think Dr Winfield also is present in '83 at
20 a number of significant meetings, although by that
21 point in time he'd moved from Derby to Sheffield,
22 I think.
23 Dr Mitchell attended UKHCDO meetings in '82 and
24 '83.
25 Just in terms of hepatitis in the 1970s, there's

1 a short sequence of correspondence that it may be
2 worth looking at.
3 CBLA0004165.
4 These are communications between Dr Winfield
5 from Derby and Dr Maycock at BPL. The first letter,
6 in March 1977, describes liver function abnormalities,
7 but negative Australia antigen test. If we look at
8 the bottom of the page, we can see the products that
9 have been provided to the child patient:
10 cryoprecipitate, Factorate and Lister factor.
11 Then if we go to CBLA0004156, there'd obviously
12 been a response from Dr Maycock, and then detail is
13 given of units of cryoprecipitate used. I should say
14 this letter is dated 13 April 1977.
15 Then in the last paragraph Dr Winfield says
16 this:
17 "I was wondering if the hepatitis could be of
18 the short incubation type as described by Dr Craske or
19 of the non-A, non-B type described in The Lancet of
20 March 12th, 1977."
21 So it shows there Dr Winfield up-to-date, as it
22 were, with what was being described both by Dr Craske
23 and what was being published in the medical
24 literature.
25 Dr Maycock's response at CBLA0004155, says,

1 19 April 1977, in the second paragraph:
2 "... I have received your letter ... concerning
3 the units of cryoprecipitate ... asking whether in my
4 view the hepatitis could be similar to that described
5 by Dr Craske or of the non-A non-B type described in
6 the Lancet. This is a difficult question to answer
7 and unless hepatitis B antigen or antibody is
8 detected, the possibility of hepatitis A also called
9 non-A non-B should be considered, providing the
10 incubation periods are compatible with either of those
11 diagnoses. I am afraid this not very helpful
12 information, and perhaps you might like to discuss
13 this case with Dr Craske, PHLS Laboratory,
14 Manchester."
15 So some awareness, in any event, in the second
16 half of the 1970s, non-A, non-B hepatitis at Derby.
17 We have no specific documentation in relation to
18 HIV/HTLV-III, save through attendance at UKHCDO
19 meetings and receipt of UKHCDO communications.
20 Dr Winfield did attend the Immuno meeting in
21 January 1983 at London Airport, as well as the
22 Reference Centre Directors meeting in February 1983
23 where AIDS was discussed. But he was by that time,
24 I think, working in Sheffield rather than Derby.
25 We've no documentation casting any light on how

1 the arrangements for testing for HTLV-III were
2 undertaken or how test results were communicated.
3 There is evidence the Inquiry has received from
4 individuals treated at Derby or through their family
5 members which suggests, in one case at least,
6 a communication of diagnosis by phone, and also
7 provides some evidence to suggest that, in relation to
8 a patient, a child patient, admitted to hospital for
9 treatment of something that wasn't specifically
10 haemophilia-related, the staff treating him knew of
11 the HTLV-III diagnosis in circumstances where the
12 child and his parents did not yet know. And our
13 written note gives details of that witness evidence.
14 The only other document which casts any light on
15 how patients with HIV were treated in Derby is at
16 DHSC0002269_083. These are extracts from different
17 Haemophilia Centre Directors, but the one in the
18 middle is from Dr Deirdre Mitchell, who was based at
19 Derby, and she was answering some form of
20 questionnaire and she says this:
21 "I have encountered numerous problems on the
22 wards over the admission of two HTLV3 antibody
23 positive haemophiliacs, both requiring emergency
24 surgery. Problems were due to hysteria and a lack of
25 understanding both on the part of some members of

1 staff and the families and also because in one case
2 a member of the hospital staff and in the other case
3 the family, alerted the media. We are learning
4 however, and are gradually drumming some sense into
5 nursing and other staff."
6 That perhaps provides some insight into the
7 position.
8 In terms of seroconversions to HIV, if we go to
9 INQY0000250 again, Soumik, and go to page 3.
10 You'll see, sir, four lines down, the reference
11 to Derby, centre number 42, and we have there
12 11 patients testing in 1985, one in 1986, one in 1987,
13 giving a total of 13 HIV cases associated with Derby.
14 Then if we look at HSOC0029690_003, please,
15 these are the minutes of an executive committee
16 meeting of The Haemophilia Society in September 1988.
17 If we go to page 3, we see the heading "Grant
18 Applications" about a third of the way down the page,
19 then there's a heading "Dr DC Mitchell, Derbyshire
20 Royal Infirmary", so that's Dr Deirdre Mitchell again.
21 "Dr Mitchell had applied for funding in the sum
22 of £6,900 to support the work of a part-time HIV/AIDS
23 counsellor. In presenting the recommendation of the
24 Officers, the Chairman pointed out that a majority of
25 the working party felt that this should fall to the

1 Regional Health Authority for funding and,
2 accordingly, recommended that the application not
3 succeed."
4 So it suggests at least an awareness on the part
5 of Dr Mitchell that this was something that was
6 required. Whether there was, in due course, any
7 funding made available by the Regional Health
8 Authority to the Derby centre, we don't have the
9 answer to.
10 In terms of ongoing care of patients at the
11 centre with HIV, Dr McKernan's evidence was that
12 patients with HIV were managed by the genitourinary
13 team and had been referred to that team before she
14 took up her role at the Derby centre, 1995.
15 In relation to hepatitis C, Dr McKernan's
16 evidence was that, as far as she is aware, 26 patients
17 were infected with hepatitis C at the Derby centre in
18 consequence of treatment with infected blood products.
19 She has also said in her statement that when she
20 joined the centre in 1995, all patients who received
21 blood products in the relevant periods had been tested
22 for hepatitis C before she was appointed. She was
23 unaware of how the patients had been told, and didn't
24 know what steps had been taken by her predecessor.
25 She does recall one patient who'd been tested

1 who was negative, and says in her statement, because
2 that was a patient with severe haemophilia, that
3 seemed to her to be an unusual outcome, so she
4 arranged for the test to be repeated, and it was then
5 positive.
6 She also refers to knowledge of one patient
7 where there was a delay in informing them of their
8 diagnosis and then she's not in a position, she says,
9 to explain the delay.
10 In terms of treatment for hepatitis C, she says
11 that from 1995 patients with hepatitis C were referred
12 to hepatologists.
13 That's Derby. If I can then turn to York, and
14 the York Haemophilia Centre based at York District
15 Hospital. The Centre Director from around 1974 was
16 Dr Cedric Wylie. We have come across his name
17 obviously in relation to Derby already, but he was
18 moved to York.
19 We've no evidence, I'm afraid, directly from any
20 clinicians who were based at the centre in York.
21 Dr Wylie was the director until the early 1990s.
22 We don't have a clear picture of the facilities
23 or the staffing at the centre in the 1970s and 1980s,
24 but you do have an account from an individual patient
25 who describes there being, at least in the 1960s, no

1 separate centre, and treatment through the haematology
2 department.
3 There is some evidence in relation to the policy
4 of home treatment at WITN1688005. This is a letter
5 from Dr Wylie to a paediatrician, and if we just look
6 at the second paragraph, it's October 1978, it says:
7 "... it is clearly the policy that haemophiliacs
8 should be made self-reliant now that there is
9 a satisfactory availability of effective and
10 continuing therapy."
11 We also have, again in relation to individual
12 patients, evidence of treatment of a child with
13 commercial concentrates. If we go to WITN0995004,
14 this is an extract from treatment records for a child
15 treated at the York centre, and we can see there
16 a pattern of NHS treatment and then, in October 1979,
17 Armour, and that's for someone who was around the age
18 of nine at the time.
19 I won't go to the witness statement of the
20 family member talking about the treatment of their
21 son. I'll give you the reference there only, it's
22 WITN0995001. That statement describes their son being
23 treated mostly with NHS Factor VIII but receiving
24 Armour Factorate when the NHS product was not
25 available.

1 We can then pick up the picture of in terms of
2 what products were used at York, again from the annual
3 returns, beginning in 1976. HCDO0000066_004, page 5.
4 So we have ten patients treated York in 1976,
5 predominantly at that point in time with
6 cryoprecipitate but with a small volume of Kryobulin
7 also in use, 4,000 units.
8 If we then go to 1977, HCDO0001223, page 3, we
9 can see, for the treatment of nine patients in that
10 year, NHS concentrate becoming available.
11 Cryoprecipitate is still the main treatment in use,
12 45,000. 6,645 units of NHS concentrate, and then both
13 the Armour product, Factorate, and the Immuno product,
14 Kryobulin, also in use at the centre in 1977.
15 We don't, I think, have a return for 1978.
16 If we go to 1979, HCDO0001387, we see a rather
17 different picture emerging for the treatment of
18 12 patients that year. Cryoprecipitate usage has
19 plummeted, 300 units described as used. The main
20 product used in that year was NHS concentrates, just
21 over 62,000, but also just under 10,000 units of the
22 Armour product were used.
23 1980, at HCDO0001486, again shows little use of
24 cryoprecipitate. We've got the split now into
25 hospital and home treatment, and we can see that the

1 treatment in most use is NHS concentrate, followed by
2 Factorate and then Kryobulin. And we can see, if we
3 look on the right-hand side of the page, that
4 commercial concentrate or a commercial concentrate was
5 also used in the treatment of a patient with
6 von Willebrand's.
7 If we go over the page, we can see again from
8 the forms in relation to individual patients more than
9 one type of concentrate, and indeed more than one type
10 of commercial concentrate, being used for the
11 treatment in that year of individual patients.
12 Then 1981 is HCDO0001589. 14 haemophilia A
13 patients treated that year, one haemophilia A carrier,
14 one von Willebrand's patient. No cryoprecipitate used
15 at all. The predominant treatment is with NHS
16 concentrate, both in hospital and at home. But there
17 are also four different types of commercial
18 concentrate used: Factorate, Koate, Hemofil and
19 Kryobulin, for both hospital and home treatment.
20 Then 1982 is HCDO0001685. Slightly different
21 picture here. Again, no cryoprecipitate at all for
22 haemophilia A or von Willebrand's patients. The main
23 product in use, and the only product indeed used for
24 home treatment, is NHS concentrate in 1982. And then
25 the Armour product is used, just over 16,000 units, in

hospital. No other commercial concentrates in use that particular year.

1983 is HCDO0000147_002. Should be page 6. And again, we can see no cryoprecipitate used. The main treatment is NHS concentrate, but also in reasonably substantial quantities the Armour product, Factorate. And Factorate again being used for the treatment of patients with von Willebrand's.

Then the return for 1984 should be at HCDO0001874. It's a similar picture. NHS concentrate is the main product in use but also significant usage of the Armour product, Factorate. In that year, von Willebrand's patients treated only with NHS concentrate, and no cryoprecipitate usage again shown.

In terms of knowledge of risks of viral infection, there are, as with many of the centres, a handful of letters or reports of jaundice in the 1970s, in completion of hepatitis survey forms.

There is some attendance by Dr Wylie at UKHCDO meetings in the course of the 1970s. He's an infrequent attender however, although again, presumably had been sent the minutes and associated reports that were pre-circulated.

The data from UKHCDO, in terms of the numbers of patients infected with HIV at the centre, is at

INQY0000250, page 2, please -- sorry, page 3, Centre 50. So York, Centre 50, identifies four patients in 1985, one patient in 1987, giving a total of five patients by 1988.

In relation to how the diagnosis of HTLV-III was communicated, again, there's nothing by way of contemporaneous documentation, but the Inquiry has received witness accounts. Indeed, one of the very first witnesses that the Inquiry heard from described learning his HIV diagnosis from Dr Wylie, having proactively sought testing in the course of 1985, no one from the hospital having contacted him to be tested, and we've provided details in relation to that witness in our written note.

In relation to another patient, one of the few documents we have available is at NHBT0096474_035. This is a letter in 1988, the purpose of the letter is not clear from it. It says:

"I confirm this haemophiliac has been in receipt of the various products as supplied by the Health Authority for the treatment of his haemophilia. I can also confirm that he has sero-converted and is now HIV Positive."

So it's unclear if this was a late test or simply something being reported, with testing having

been undertaken earlier.

"Given the circumstances the presumption is that this is the result of administered contaminated Factor VIII but it is not possible to identify which batch and when this occurred."

You do, sir, have evidence from the family associated with that communication -- I won't take you to it, the reference, for your note, is WITN09950001 -- which describes the mother asking Dr Wylie whether it was safe for her son to continue on Factor VIII treatment, and that was in light of television documentaries, was the recollection, and being told that her son would be at greater risk of stopping treatment than he would of continuing with the theoretical risk of contracting the disease.

There is also evidence of a partner being infected with HIV at HSOC0013446_012. This is a letter from Dr Wylie, still based at York, in April 1989 to the Macfarlane Trust, describing the situation of one of his patients:

"... an excellent hard-working and bright young man whose life has been, like many others, blighted from these circumstances for which he is making a claim.

"He is a severe haemophiliac with moderate

restriction of movement of his limbs on top of which of course acute episodes occur. He has had a stable relationship with the girl mentioned, who unfortunately has become HIV positive and is herself unwell ..."

Then if we look at the last paragraph after a description of the position of the haemophiliac patient, Dr Wylie says:

"As I am sure you understand the circumstances are extremely sad and the prognosis for both these young people must be regarded as very very poor."

We don't, I'm afraid, have information in relation to the number of patients infected with hepatitis C through treatment at the York centre. You have received, sir, witness accounts from individuals treated there who were indeed infected with hepatitis C.

Sir, that's York.

I'm going to move next to the West Midlands. There's quite a lot to cover with Coventry, a smaller volume of documentation in relation to the others. There should be no difficulty in completing that this afternoon, but can I suggest that, rather than starting it now, we break and start at 1.50?

SIR BRIAN LANGSTAFF: Let's do that. 1.50.

1 **(12.50 pm)**
2 **(The luncheon adjournment)**
3 **(1.49 pm)**
4 **MS RICHARDS:** Sir, we turn now to Coventry. The directors
5 of the haemophilia centre at Coventry in the 1970s and
6 1980s included Dr, later Professor, Shinton, and
7 Professor Maurice Strevens. The latter has provided
8 a written statement to the Inquiry. I shall go to it
9 at various stages in the presentation but for your
10 note, sir, it's WITN3808005.
11 Dr Strevens and Professor Shinton were
12 co-directors at Coventry from 1979 to 1991, and then
13 when Professor Shinton retired, Dr Strevens became the
14 sole director of the centre until 2005.
15 The centre was initially based in the
16 haematology department at the Coventry & Warwickshire
17 Hospital. That closed eventually, I think in 2006,
18 and was replaced by University Hospital Coventry.
19 The Coventry Hospital was part of the West
20 Midlands Regional Health Authority and there were a
21 number of other Haemophilia Centres in the region,
22 part of the same regional organisation: Birmingham's
23 Queen Elizabeth Hospital, Birmingham Children's, both
24 of which we have examined in previous hearings, and
25 then Hereford, Shrewsbury, Stoke-on-Trent, Worcester

1 and Wolverhampton, which we'll be looking at this
2 afternoon.
3 The West Midlands regional centres were
4 supplied, in terms of blood supplies and Factor VIII
5 products by BPL, by the Regional Transfusion Centre in
6 Birmingham, and Dr Strevens in his witness statement
7 explains a recollection of working close collaboration
8 with the Birmingham centres, and then with the
9 Regional Transfusion Centre in Birmingham supplying
10 the blood supplies to the whole of the West Midlands
11 region.
12 There was a working party, a West Midlands
13 working party, called the Working Party on the
14 Treatment of Haemophiliacs, which met regularly
15 throughout the 1970s, 1980s and early 1990s. You may
16 recall, sir, we looked at a series of their meetings
17 in the Birmingham presentation in earlier hearings.
18 I'll refer only to two or three documents this
19 afternoon. But I can say that Dr Shinton was a very
20 faithful attender at those meetings throughout the
21 1970s, 1980s, and into the early 1990s, and that
22 Dr Strevens also attended those meetings throughout
23 the 1980s and into the early 1990s.
24 If we go to one meeting from the 1970s at
25 SHIN0000046, these are the minutes of a meeting of the

1 working party May 1974. We can see a range of
2 attendees and there will be some of the names from
3 centres that we look at in the course of the
4 afternoon, but they include Dr Shinton from Coventry.
5 And then if we look at the second paragraph, under the
6 heading "Designation of Centres", it says this:
7 "Dr Stuart referred to the fact that a meeting
8 had been held at the offices of the then Regional
9 Hospital Board some years ago at which it had been
10 agreed that five satellite centres should be
11 established at Stoke-on-Trent, Coventry, Worcester,
12 Shewsbury and Wolverhampton for the treatment of
13 haemophiliacs with cryoprecipitate."
14 So you will see there, sir, the origins of the
15 various centres in the West Midlands region.
16 If we go to page 3, bottom half of the page, we
17 can then see that the summary:
18 "Sir Edward summed up the views of those present
19 as under:-
20 "(1) That the five existing satellite centres
21 should remain in being, and that Hereford should be
22 recognised as a sixth centre for the treatment of
23 haemophiliacs ...
24 "(2) That cryoprecipitate should be retained
25 for use as the main form of treatment for the present.

1 "(3) That the eventual distribution and use of
2 freeze-dried factor VIII concentrate should follow the
3 same pattern as the existing system used for
4 cryoprecipitate.
5 "(4) That an emergency reserve of freeze-dried
6 factor VIII be kept at the Queen Elizabeth Hospital,
7 Birmingham.
8 "(5) That the Working Party currently assembled
9 should meet at regular intervals of six or 12 months.
10 At such meetings, the designated Consultants should
11 supply details of the number of patients treated, and
12 of the facilities available and the type of
13 treatment."
14 And those meetings do indeed take place on,
15 quite often, a six-monthly basis, in the years that
16 follow.
17 Dr Shinton was appointed chair of this working
18 party in December 1978. And if we look at, then,
19 moving forward, to the minutes of a meeting of the
20 working party in December 1982, SHIN0000031, we see
21 there that this is a meeting, 6 December 1982,
22 Dr Shinton is now the chair.
23 If we go over to the bottom of the second page,
24 we can see at this point in time under the heading
25 "Supplies of Cryoprecipitate and Freeze Dried

1 Factor VIII":
2 "Dr Ala [who was a representative of the
3 Regional Transfusion Centre] reported at present that
4 there was an excess supply of cryoprecipitate,
5 possibly due to over-stocking in anticipation of
6 a reduced supply of Factor VIII concentrate from BPL.
7 He understood that the BPL would be resuming normal
8 production soon and the situation should revert to
9 normal. The shortfall in supply of Factor VIII from
10 the BPL had been made up by greater purchases of
11 commercial factor VIII and the [I think it should say
12 'slack'] slock had not been taken up by increased use
13 of cryoprecipitate. There was some doubt about the
14 methods of funding for the purchase of commercial
15 Factor VIII. Dr Stewart agreed to clarify the
16 position."
17 That's an example of the kind of discussions
18 that would take place on a regular basis throughout
19 the seventies and eighties at these meetings, when
20 issues about supply, shortfall, use of cryoprecipitate
21 concentrate from BPL and commercial concentrates, all
22 fell for discussion from time to time.
23 The Coventry was also part of the Oxford
24 haemophilia supraregion, and there were occasional
25 meetings in the 1970s of the Haemophilia Centre

1 Directors and Blood Transfusion Centre Directors
2 within the Oxford haemophilia supraregion.
3 Dr Shinton, for example, attending meetings in
4 July 1976 and June 1978 of that particular group.
5 Turn, then, to consider the numbers of patients
6 regularly treated at Coventry. Dr Strevens'
7 recollection in his statement was that direct ongoing
8 care was provided for around 30 patients on home
9 treatment. His recollection is not far off. The
10 annual returns for the period '76 through to '85 show
11 a range of between 20 and 33 haemophilia A patients
12 being treated, up to five patients with haemophilia B,
13 and up to eight patients with von Willebrand's.
14 If we look at the annual returns, starting in
15 1976, at HCDO0001071, we can see annual return for
16 1976. The director here is identified as Dr Shinton,
17 and indeed Dr Cotter, as well, who then I think left
18 Coventry towards the end of the 1970s.
19 Total number of haemophilic patients treated
20 during the year: 33. Christmas disease patients: 3.
21 Then you will see that by a very substantial
22 margin indeed, the main form of treatment in 1976 was
23 cryoprecipitate. Well over -- or over half a million
24 units of cryoprecipitate used. No NHS concentrate
25 used at all. Three different commercial concentrates

1 in use: Factorate, Hemofil and Kryobulin. Which,
2 combined, add up to 157,685 units of commercial
3 concentrate.
4 So significant volume, but far more in terms of
5 cryoprecipitate usage.
6 If we turn to 1977, HCDO0001152, and we go to
7 page 4., again we can see the numbers of patients
8 treated: 29 haemophilia, two with antibodies, four
9 haemophilia B patients.
10 Again, we can see cryoprecipitate in significant
11 use, although the volume has decreased from the
12 preceding year. So just under 325,000 units. We can
13 see also that NHS concentrate is now being used,
14 apparently for the first time, to a significant
15 extent, just under 192,000 units. But that commercial
16 concentrate, Factorate is the product in greatest use,
17 340,407 units, and then some 26,000-odd units of
18 Hemofil.
19 So for that year, in contrast to the previous
20 year, it's more concentrate than cryoprecipitate, and
21 indeed more commercial concentrate than
22 cryoprecipitate.
23 The picture in 1978 is at HCDO0001249. Page 4.
24 We see a rather different picture in 1978.
25 Tiny amount of cryoprecipitate used. 560 units. No

1 commercial concentrate used at all in that year, and
2 thus the main product being used, NHS concentrates,
3 438,799 units.
4 So a very different picture indeed from the
5 previous year.
6 If we then go to 1979, HCDO0001317, we can see
7 no cryoprecipitate used at all. And the main product
8 in use is NHS concentrate, but commercial concentrates
9 have made a reappearance and are being used to a
10 significant extent, a range of them now, Factorate,
11 Hemofil, and Kryobulin, with the latter being the
12 largest in terms of volume.
13 It's roughly188,000 units of commercial
14 concentrate as against 414,000 or so units of NHS
15 concentrate. The picture in relation to treatment of
16 the Christmas disease patients remains the use of NHS
17 Factor IX concentrate at this centre.
18 When we come to the beginning of the 1980s, the
19 return for 1980 is HCDO0001414. Again, we can see no
20 cryoprecipitate in use for the treatment of
21 haemophilia A patients, although it is used for the
22 treatment of von Willebrand's. And then, again, we
23 have a mix of NHS concentrates and commercial
24 concentrates being used. A little more NHS
25 concentrate than commercial concentrate, but the

1 difference is not vast. And the commercial
2 concentrate in use is predominantly the Armour
3 product, Factorate, with a small amount of Kryobulin.
4 We will see from this that home treatment
5 clearly is well established in Coventry, from the
6 numbers involved.
7 1981, then, HCDO0001512. A very small amount of
8 cryoprecipitate for use in the treatment of
9 haemophilia A. Again, cryoprecipitate is used for
10 von Willebrand's as well as, in that year, for the
11 treatment of a carrier of haemophilia A.
12 The picture there is of NHS concentrate as the
13 main treatment used. That's, I think, 463,000-odd
14 units. Then we have one commercial concentrate in use
15 that year, again it's the Armour product, Factorate,
16 roughly 141,000 units in use.
17 1982 is at HCDO0001614. We can see
18 cryoprecipitate used there simply for the treatment of
19 von Willebrand's, small amount of commercial
20 concentrate being used for von Willebrand's, as well
21 as NHS concentrate. Then, again, treatment really
22 shared between NHS concentrates and Armour
23 concentrates, but now the Armour product predominates.
24 So roughly 522,000 as against something in the order
25 of 424,000 units of NHS concentrate.

1 The balance shifts again the other way in 1983,
2 HCDO0001711. Leaving aside a very small amount of
3 cryoprecipitate used for haemophilia A and for the
4 treatment of von Willebrand's disease patients, we can
5 see again it's NHS concentrates and the Armour product
6 Factorate, but now the main product in use in this
7 year is the NHS concentrate 557,000 or thereabouts,
8 contrasting with around 122, 123,000 units of the
9 Armour product.
10 Then lastly 1984, HCDO0001806. The usage of
11 cryoprecipitate has crept up slightly, although it's
12 still a very small proportion of the overall
13 therapeutic material used, and again it's NHS
14 concentrate in Factor VIII, but now with the NHS
15 concentrate far exceeding the volume of commercial
16 concentrate used, albeit there is still some
17 75,000-odd -- 73,000-odd, units used. Then we can see
18 the FEIBA at the bottom and also DDAVP appearing for
19 the use of patients with von Willebrand's.
20 We'll come back to what Dr Strevens says about
21 product usage and policies shortly but there's no
22 contemporaneous material other than the returns
23 themselves to demonstrate any specific treatment
24 policy at Coventry.
25 If we then turn to Dr Strevens' statement,

1 WITN3808005, and if we pick it up at the bottom of
2 page 10, please, he says this in paragraph 10.1:
3 "The general principles of treatment were that
4 all blood products should be avoided if possible.
5 DDAVP or Cryoprecipitate should be used in preference
6 to factor concentrate if practical and safe."
7 Sir, again, the extent to which that's borne out
8 by the annual returns will be a matter you may wish to
9 consider.
10 "This would only be practical for patients with
11 mild disease and especially if they had never been
12 exposed to factor concentrates. UK concentrate should
13 be used in preference to American products although
14 this had to be tempered by the severely limited amount
15 of UK concentrate relative to demand. Finally
16 attempts would be made to limit the number of
17 different suppliers of American products - subject to
18 availability."
19 In relation to that latter point it is fair to
20 observe that it is a single commercial product in the
21 latter years of the period we looked at that
22 predominates, the Armour product.
23 Then he says in paragraph 10.2:
24 "As far as I can remember all products were
25 supplied from Birmingham (I think the transfusion

1 centre). I think the Birmingham Centre directors
2 devised the purchasing policy and I am confident that
3 they would have been based on the principles outlined
4 above.
5 "In practice this meant that children were
6 supplied with BPL products and adults received
7 American products."
8 Pausing there, we don't, I think, have the data
9 to determine the extent to which that was applied in
10 practice in relation to Coventry, but we know, of
11 course, in relation to Birmingham Children's Hospital
12 that that was not the policy adopted because of the
13 very substantial use of commercial concentrates for
14 children at that facility.
15 In terms of the switch to heat treatment,
16 Dr Strevens deals with that towards the bottom of this
17 page, paragraph 11.2. He says:
18 "Following the development of tests for HIV, the
19 degree of contamination of concentrates became
20 apparent so we switched to heat treated products as
21 quickly as possible."
22 If we then turn on in his statement please to
23 the bottom of the next page, where he talks about
24 cryoprecipitate, this is paragraph 15.1:
25 "In the 1970s, prior to factor eight

1 concentrates, cryoprecipitate was the treatment of
2 choice for bleeding episodes."
3 Then he explains the process with the melting of
4 the bags and the infusion of the cryoprecipitate, and
5 the length of time that would take. If we go to the
6 next page, picking it up four lines down, he says:
7 "The big advantage of freeze dried concentrates
8 was that the product could be at home by patient or
9 parent which led to treatment being given far more
10 quickly as a result, it quickly became apparent that
11 target joints were much less common, patients were not
12 getting arthritis and were able to live a much more
13 normal life."
14 He says, in the last sentence of that paragraph:
15 "I cannot emphasise enough the importance of the
16 introduction of factor concentrates on the lives of
17 patients with severe haemophilia."
18 The next paragraph, 15.2, he says this:
19 "I am aware that some patients in some centres
20 use cryoprecipitate at home ..."
21 Obviously we've seen examples of that. He adds:
22 "I do not think this was a practical
23 consideration for most patients."
24 Then if we turn on to paragraph 17.1, over the
25 page, he says:

1 "As stated previously home treatment with
2 concentrates was firmly established when I started
3 working in Coventry and this naturally evolved into
4 prophylaxis. Cryoprecipitate was never considered as
5 an alternative to concentrates in the context of home
6 treatment.
7 "Cryoprecipitate was always considered the
8 treatment of choice for patients with mild/moderate
9 disease who required infrequent treatment of limited
10 duration and non-life threatening severity. Whenever
11 possible these treatment decisions would involve
12 a consultant haematologist -- day or night. This was
13 regarded as particularly important for patients who
14 had never previously received concentrate."
15 He also recalls the policy of home treatment
16 having been firmly established when he arrived, and
17 the understanding within the centre being that all
18 patients should be offered home treatment as quickly
19 as possible.
20 If we then go to the bottom of the next page,
21 paragraph 20.1, he says:
22 "As a general policy factor concentrates would
23 always be avoided in children with mild or moderate
24 disease and to reinforce this no factor concentrate
25 was issued from the blood bank without the involvement

1 of a haematologist."
2 Sir, it will be a matter for you to consider in
3 due course, but Dr Strevens' account of the use of
4 home treatment for families, in particular children,
5 would make, I think, fairly clear that at least
6 children with severe haemophilia were routinely
7 treated with factor concentrates at Coventry and,
8 again, that would be borne out by the picture that
9 emerges from the annual returns.
10 In terms of what information was given about
11 risks, Dr Strevens says at page 23, please, Soumik, in
12 paragraph 38.1:
13 "The number of new patients commencing factor
14 concentrates in Coventry between 1979 [and the
15 relevance of that being that's the date when he joined
16 the centre in Coventry] and the
17 suspicion/identification of the AIDS virus in
18 concentrates would have been small. Advice given
19 would have been on an individual basis. They would
20 have been warned about Hepatitis B and they would have
21 been offered vaccination prior to commencing therapy.
22 Giving advice about HCV or HIV would have been
23 difficult from around 1983-1985/6 when there were
24 emerging suspicions of AIDS being transmitted via
25 blood products and non A non B not being the benign

1 infection it was once thought to be. Fortunately as
2 far as I can remember we did not have to deal with
3 this situation because of an absence of new patients."
4 Now, it may be correct, as a matter of fact,
5 that there were few new patients in the period he's
6 describing but, of course, that may beg the question
7 of whether information should have been given to
8 existing patients, the provision of information about
9 risks not necessarily being limited to something
10 that's done on a one-off basis only when a patient
11 commences therapy for the very first time,
12 particularly as new and emerging risks come to light.
13 We've made reference in the written presentation
14 notes to a number of the accounts that you've received
15 from individuals treated at Coventry, or whose family
16 members were treated at Coventry, which provide
17 an account of not being given advice, information or
18 warnings about the risks of blood products, either in
19 relation to risks of hepatitis or in relation to risks
20 of HIV.
21 Dr Shinton and/or Dr Strevens were regular
22 attenders UKHCDO meetings, Dr Shinton in the 1970s and
23 1980s, and Dr Strevens in the late 1970s and 1980s.
24 They also regularly attended the meetings of the West
25 Midlands Working Party that we looked at earlier.

1 Dr Shinton attended the meeting at London Heathrow
2 Airport in January 1983. So, sir, that may provide
3 some understanding or context of what they knew or
4 ought to have known in relation to hepatitis and HIV.
5 If we put Dr Strevens' statement back on screen,
6 please, Soumik, WITN3808005, and go to page 16,
7 Dr Strevens sets out in paragraph 22.1, in the bottom
8 half of the page, his understanding about hepatitis
9 risks. He says this:
10 "When I started in Coventry in 1979, Hepatitis B
11 was a clearly defined viral infection and donors and
12 donations were screened for infection. Nevertheless
13 Hepatitis B infection could still infect blood
14 recipients and so all haemophiliacs were routinely
15 immunised as soon as vaccines became available and
16 preferably before they started regular treatment. My
17 understanding of [non-A, non-B] hepatitis was that it
18 was ill-defined and could be due to a number of
19 different viruses or something else completely. It
20 was generally regarded as less severe than Hep B but
21 without a test for the virus(es) little could be said
22 about the nature of the infection. With regards
23 patients receiving concentrates it was recognised that
24 soon after commencing treatment patients experienced
25 what was often a mild illness with minor disturbance

1 of liver function which sometimes settled but could
2 also result in a persistent mild disturbance of liver
3 function. Whether this was due to persistent
4 infection or something else to do with the treatment
5 was not clear. Most doctors did not regard it as
6 a serious problem. However Dr Eric Preston (later
7 Professor) in Sheffield where I trained became
8 increasingly concerned and eventually took liver
9 biopsies from some affected patients. I remember the
10 results being presented at a UKHCDO meeting. The
11 results showed that some had serious, advanced liver
12 disease. HIV infection was the major concern at the
13 time and effective heat treated concentrate was
14 subsequently introduced. When [non-A, non-B]
15 hepatitis was identified as being due to Hepatitis C
16 it was also found that the heat treatment for HIV also
17 inactivated the [hepatitis C] virus."
18 The reference to training at Sheffield reflects
19 the fact that Dr Strevens was a senior registrar in
20 haematology in the Sheffield hospitals, comprising
21 both the adult and children's hospital and I think
22 some time at the blood transfusion centre between
23 November 1975 and November 1979. So he was in
24 Sheffield before he came to Coventry.
25 **SIR BRIAN LANGSTAFF:** It's probably the result of memory

1 working back, but the dating in paragraph 22.1 is
2 plainly wrong --
3 **MS RICHARDS:** Yes.
4 **SIR BRIAN LANGSTAFF:** -- because the time that Professor
5 Preston was reporting was some time before anyone knew
6 of the risk of AIDS being transmitted by blood
7 products.
8 **MS RICHARDS:** Yes. Professor Preston, we know, published
9 a particularly significant study in 1978 --
10 **SIR BRIAN LANGSTAFF:** 1978.
11 **MS RICHARDS:** -- which would have been at the time
12 Dr Strevens was based at Sheffield but it's only fair
13 to point out that Dr Strevens would not have been
14 provided with all of these materials that the Inquiry
15 has looked at --
16 **SIR BRIAN LANGSTAFF:** I'm not blaming him. I'm just
17 saying it's one of the problems of people working back
18 from memory, and that I won't treat this particular
19 chronology as being accurate.
20 **MS RICHARDS:** Yes, and also the reference to hepatitis B
21 vaccination, again that's something that happened
22 rather later --
23 **SIR BRIAN LANGSTAFF:** Yes, it is.
24 **MS RICHARDS:** -- not in the 1970s.
25 In relation to AIDS and HIV, as indicated,

1 Dr Shinton and also Dr Strevens were regular attendees
2 at these various meetings and Dr Shinton, in
3 particular, at that January 1983 meeting. If we go
4 back in Dr Strevens' statement to page 13, at
5 paragraph 15.3 he talks about the risk of infection
6 from concentrates being an emerging issue, and then he
7 refers to the UKHCDO letter from June '83. Then in
8 15.4 says:
9 "In much of the practice of interventional
10 medicine there is always a balance between risk and
11 benefit."
12 Then he says, in the last sentence of that
13 paragraph:
14 "In 1983 there was very little data available
15 about the size of the risks from concentrates,
16 confounded by the absence of tests to predict problems
17 and so treatment was provided in this context."
18 Then if we go on to the next page -- no, sorry,
19 top of page 15, my apologies. Paragraph 18.3, he
20 says:
21 "There was emerging evidence of a link between
22 HIV infection and the use of factor concentrates
23 throughout the early '80s. How this would translate
24 into policy was always going to be difficult.
25 Fortunately we had within the UKHCDO

national/international experts who met to discuss these issues and offer guidance to Haemophilia directors like myself."

Then the document he refers to is the June 1983 letter. He says:

"[That] is a good example of the guidance we were being given. We were of course all free to take or reject the advice. It is always important to address the consequences of extreme actions like stopping all concentrate usage. As an 'older' haematologist I have vivid recollections of the consequences of inadequately treated haemophilia -- something that is too easy to forget. As far as I can remember there was no significant change to home treatment policy."

That's in response to the risk of AIDS.

Then if we move to page 20 -- no, sorry, can we start with page 18. He goes back to the question of developing knowledge of risk in relation to HTLV-III AIDS and, in 26.1, he refers to:

"Cases of unusual immunodeficiency [being] first described in the USA in the early 1980s."

Then in the last sentence of that paragraph:

"There were early concerns that it could represent a blood borne infection and this suspicion

was enforced when similar problems started to be seen in patients with haemophilia who were using recently introduced factor concentrates.

"There was always concern in the UK about the use of American concentrates. The concern was of a non-specific nature -- that is blood should be taken from healthy unpaid volunteers rather than paid donors some from dubious backgrounds and in poor health. The first potential case of immunodeficiency in a UK haemophilia patient was featured in a letter from the UKHCDO in 1983 to all Haemophilia centre directors and included advice about the use of concentrates."

Again, that's the advice letter that we've looked at on numerous occasions. Then he says in 26.3:

"From memory I thought the advice was balanced -- the issue being the dramatic effect on haemophilia care if all concentrates were withdrawn at that stage."

Then, finally, on this issue, if we go to page 20, he says in paragraph 30.1:

"The UKHCDO letter from 1983 alerted us to the issue and in accordance with the advice given, patients continued to receive concentrates. It was in 1985 that the extent of the problem became clear."

So it would appear from that that the June 1983 letter with its recommendations or however they might be termed, did not lead to any change of direction or change of policy on the part of the Coventry haemophilia centre.

If we then pick up the picture in terms of Coventry and the West Midlands in late 1984, SHIN0000026_002, this is a meeting of the West Midlands Working Party, not one of its regular meetings. These are:

"Minutes of the Extraordinary Meeting held on ... 17th December [we know from the context it's 1984] in the Library of the Regional Blood Transfusion Centre, Birmingham, to discuss the implication of AIDS on the provision of concentrate for the treatment of Haemophiliacs."

We can see that the meeting is chaired by now Professor Shinton.

Then if we look underneath the list of apologies, the purpose of the meeting:

"A meeting was held to discuss the implication of the use of Factor VIII concentrate in the light of the death of two haemophiliacs from AIDS."

Then there's a report from Professor Hill, which I think we looked at during the Birmingham

presentation.

Then if we go further down the page to the bottom half of the page:

"The committee accepted that the use of Factor VIII concentrate was associate with a risk of transfusing the AIDS virus."

Pausing there, no doubt, sir, one of the issues you may wish to consider, in due course, is whether these kind of discussions and realisations were taking place timelessly or whether they could or should have been matters that could and should have been considered more comprehensively at an earlier date than December 1984. There is then -- Dr Stewart and Dr Hill inform the committee of various matters, and then we can see the sentence beginning "Unfortunately, the Chairman" -- so that's Professor Shinton:

"... informed the Committee that this [the availability of heat-treated factor concentrates] was unlikely to occur with NHS Factor VIII until 1st April, 1985, but that Armour hear treated material would be available in January 1985. Following discussion, a treatment policy to cover the interim period was agreed upon ..."

So this was intended to be a West Midlands-wide treatment policy with effect from January '85 and,

1 therefore, including but not limited to the Coventry
2 centre:
3 "1. Mildly affected patients -- Haemophilia A,
4 and von Willebrand's ... to be treated with DDAVP or
5 [cryo].
6 "2. Newly diagnosed severe haemophiliacs to be
7 managed wholly on cryoprecipitate.
8 "3. A) Patients with no previous exposure to
9 commercial Factor VIII should continue on NHS
10 Factor VIII."
11 Then, top of the next page:
12 "b) Patients with previous exposure to
13 commercial Factor VIII should continue on NHS
14 Factor VIII if available and heat treated commercial
15 Factor VIII where not.
16 "It was stressed that full discussions should
17 take place with the recipients regarding use of
18 therapeutic material, as the availability and speed of
19 HTLV III screening precluded its use for treatment
20 guidance."
21 So that's the policy with effect from the
22 beginning of 1985.
23 There was a second extraordinary meeting of the
24 working group in February 1985 at SHIN0000025. We can
25 see, again, it's chaired by Professor Shinton,

1 15 February 1985. If we just look at the bottom half
2 of the page, under the heading "Supply of
3 Factor VIII", we can see Dr Ala from the Regional
4 Transfusion Centre reporting to the committee that:
5 "... following a meeting with the Regional
6 Supplies Officer, a supply of heat treated Factor VIII
7 had been negotiated with Armour Pharmaceuticals."
8 Then looking forward to what was anticipated to
9 be NHS heat-treated product available on
10 a named-patient basis.
11 Then if we go over the page, there's
12 a modification of the policy.
13 Sir, under the heading "5. AIDS - Haemophilia
14 Centre Directors Organisation", it says:
15 "The document outlining the views of the
16 Reference Centre Directors on the effects of AIDS on
17 the treatment of haemophiliacs was received. It was
18 given full support."
19 Pausing there, sir. That's no doubt a reference
20 to the AIDS guidance document that was circulated by
21 Professor Bloom following the 10 December 1984 meeting
22 of Reference Centre Directors, Department of Health
23 and others which took place at Elstree, which again
24 we've looked at on a number of occasions.
25 So the minutes continue:

1 "The treatment policy as advocated in the
2 Minutes of the Extraordinary Meeting of 17th December
3 [the West Midlands policy] was at variance with that
4 from the Reference Centre Directors. It was agreed
5 that NHS untreated material should no longer be used.
6 The new treatment strategy now recommended is:-
7 "a) Use DDAVP in mild Haemophilia A and
8 [von Willebrand's] if possible.
9 "b) For Haemophilia A needing blood products
10 "i. 'Virgin' patients those not previously
11 exposed to concentrate, and children, use cryo or
12 heated NHS Factor VIII (if possible).
13 "ii. Severe and moderate haemophiliacs
14 previously treated with Factor VIII, use heat treated
15 NHS Factor VIII, if available or heat treated US
16 commercial."
17 Then:
18 "c) For Haemophilia B
19 "i. Mild Christmas. Fresh frozen plasma if
20 possible (otherwise NHS Factor IX).
21 "ii. 'Virgin' patients and those not previously
22 exposed to concentrate use fresh frozen plasma (or NHS
23 Factor IX concentrate if essential).
24 "iii. Severe and moderate Christmas disease
25 previously exposed to Factor IX concentrate continue

1 to use NHS Factor IX."
2 So that's a further policy development for the
3 West Midlands area in February 1985.
4 And then there's a third meeting, in July 1985,
5 at SHIN0000023. If we go to the second page --
6 I should say, again, it's chaired by
7 Professor Shinton -- there's a further review of the
8 guidelines. Picking it up in the second paragraph:
9 "In view of the shortfall of supplies and that
10 Prof A Bloom ... in a letter to the [BMJ], proposed
11 a policy whereby cryoprecipitate should not be used
12 until HTLV-III screening of donors was established,
13 the committee agreed to review the treatment
14 guidelines."
15 You'll see we now have, for example, no
16 reference to cryoprecipitate, so it's:
17 "... DDAVP in mild haemophilia and
18 von Willebrand's disease if possible."
19 Then we have reference to use of the NHS product
20 8Y in the categories of patients set out.
21 Then if we go further down, just so that we can
22 pick it up for haemophilia B at (d):
23 "... as heat-treated Factor IX -- 9A -- is not
24 available until October 1985, no change in policy is
25 envisaged."

1 So that's a further amendment to the treatment
2 policy in 1985.
3 We then see, bottom of the page, bottom half of
4 the page, a "Regional Haemophilia Policy" in relation
5 to those found to have antibodies to HTLV-III. So
6 covering Coventry but not limited to Coventry:
7 "It was agreed that haemophiliacs with HTLV III
8 antibodies or AIDS related disorders should be
9 followed up at the discretion of the Haemophilia
10 Centre Directors. All haemophiliacs should be
11 screened. Spouses and immediate families should be
12 offered screening for HTLV III antibody. Any
13 haemophiliacs opting out of knowing his status should
14 be advised to behave as though he were HTLV III
15 positive. It was considered appropriate to inform the
16 GP but not the Clinical Medical Officer in the case of
17 children. Dr Hill informed the committee that minor
18 difficulties regarding schooling had been encountered
19 and it was agreed that the Chairman
20 [Professor Shinton] should approach the Clinical
21 Medical Officers to discuss the problems related to
22 the management of haemophiliacs at school in relation
23 to viruses and bleeding.
24 "In view of the caution relating to blood
25 donors, Dr Ala asked that spouses of haemophiliacs be

1 asked to desist from donating blood and their
2 addresses be sent to him so that the donor panel could
3 be modified.
4 "It was thought appropriate to review the
5 HTLV III status in haemophiliacs and spouses every
6 twelve months."
7 Then this:
8 "The committee were unanimous in the opinion
9 that haemophiliacs and spouses, when HTLV III
10 positivity had been identified, should be advised
11 against pregnancy."
12 And we've seen how that affected some
13 individuals in some of the powerful evidence, sir,
14 that you've heard.
15 So those are the Coventry and indeed wider
16 West Midlands discussions in relation to treatment in
17 the end of '84 and the first half of 1985.
18 In terms of the process for testing patients for
19 HTLV-III and informing them of their diagnosis,
20 Dr Strevens was unable to assist. He explained in his
21 statement that Professor Shinton, together with the
22 haemophilia sister, organised the testing of patients
23 for HIV, and indeed later for HCV, and that they would
24 have been responsible -- "they" being
25 Professor Shinton and the haemophilia sister -- for

1 counselling patients.
2 So he was not aware of what the process had been
3 for pre-or post-test counselling.
4 Again, you've had evidence, sir, from a number
5 of witnesses or received written evidence from
6 a number of witnesses regarding the position at
7 Coventry. We've summarised some of it in our written
8 note. I'll just refer to a couple of examples of the
9 evidence.
10 You have evidence, for example, from a patient
11 who says that his parents were not informed by
12 Professor Shinton of a January 1985 HTLV-III result
13 until some eight months later. That's one example of
14 the evidence you've received.
15 Another example is from a witness describing how
16 her husband was tested and informed of his diagnosis,
17 and she described in a witness statement Dr Shinton
18 inviting them to the office for a chat, casually
19 saying, "Your test results are positive", the couple
20 then asking, "What test results?" And Dr Shinton
21 saying the patient had been diagnosed with HIV.
22 The records showed -- the witness explained in
23 her statement -- that the positive test had been
24 undertaken in November 1984, and there was therefore
25 a period of some months before the couple were told

1 the results of the test. So those are two examples to
2 of the evidence that you've received. There are
3 others.
4 In terms of the numbers of patients at Coventry
5 reported to have seroconverted, if we have
6 INQY0000250, please. Page 2. It's centre 21.
7 There's a spelling mistake there, it says "Coventry".
8 If we go along we can see there it records five
9 patients, 1984, ten patients 1985, and one in 1986,
10 giving a total number of HIV cases associated with the
11 centre to 1988 of 16.
12 There is a report at a later West Midlands
13 working party meeting of April 1987 -- I'll give you
14 the reference but I won't turn to the document, it's
15 SHIN000015_001 -- which records Professor Shinton
16 informing the meeting of a late seroconversion at
17 Coventry considered to be related to the use of
18 heat-treated Armour.
19 In relation to hepatitis C, we don't have the
20 figures of the numbers of patients who were infected.
21 Dr Strevens did not know how many were infected.
22 In terms of, then, the treatment arrangements at
23 Coventry for patients diagnosed with HIV and/or
24 hepatitis C, Dr Strevens explains that he took over
25 the haemophilia clinic when Professor Shinton retired

1 in 1991. He recalls at that time patients with HIV
2 were being treated with AZT and his impression was
3 that it was not very effective and patients were
4 deteriorating.
5 And he describes in his statement how,
6 gradually, different and improved therapies became
7 available, and explains that, in due course, a
8 separate clinic for HIV patients in conjunction with
9 a genitourinary medicines specialist was established.
10 In relation to hepatitis C treatment,
11 Dr Strevens' account is as follows: routine review by
12 the haemophilia sister and then various forms of
13 interferon he says were the only types of treatments
14 available during the time he was in Coventry. He says
15 the main risks discussed were of unpleasant side
16 effects and the significant risk of failure.
17 Sir, that's the position in relation to
18 Coventry.
19 With all of the West Midlands centres, a reading
20 of all the minutes of the working party from 1974
21 really through to the 1980s, will provide a really
22 clear picture of the kind of discussions that were
23 taking place in relation to supplies and shortfall.
24 I'm not going to refer to them in any further detail
25 this afternoon, but we have looked at a number of

1 them, as I say, in the course of the Birmingham
2 presentation.
3 Can I then turn to Wolverhampton.
4 The director of the Wolverhampton centre from
5 1976 and during the 1980s was Dr Allen. Wolverhampton
6 was also part of the West Midlands Regional Health
7 Authority, and Dr Allen was also a frequent attender
8 of the meetings of the Working Party on the Treatment
9 of Haemophiliacs, some examples of which we've already
10 looked at.
11 The meeting of the working party for the West
12 Midlands region May 1976 recorded that Wolverhampton
13 had been officially designated as an associate
14 haemophilia centre. As with Coventry, Wolverhampton
15 was supplied by the Regional Transfusion Centre in
16 Birmingham with its blood products, and it too was
17 part of the Oxford haemophilia supraregion, and
18 a meeting in relation to the supraregion was attended
19 by Dr Allen in July of 1976.
20 Wolverhampton was a smaller centre in terms of
21 numbers than Coventry. The number of patients
22 treated, looking at the annual returns from 1976 to
23 '85, were between five and ten haemophilia A patients,
24 up to three haemophilia B patients, and one to two
25 patients with von Willebrand's disease.

1 Our only real guide to product usage comes from
2 the annual returns themselves, for this centre. So if
3 we start with 1976, HCDO0000068_002. And we go to
4 page 4. We can see that in 1976, nine patients with
5 haemophilia treated, three patients with Christmas
6 disease, and then we can see that the main product in
7 use was cryoprecipitate, no NHS concentrates used,
8 some Factorate Armour product, and some Kryobulin, the
9 Immuno product. So roughly 24,500 commercial units,
10 as opposed to 94,000-odd units of cryoprecipitate.
11 The picture shifts by the following year, 1977.
12 HCDO0001220. Page 5. Again, no NHS concentrates in
13 use at all. The volume of cryoprecipitate used has
14 decreased fairly significantly, now down to
15 39,000-odd. And the product in greatest use is the
16 Armour product, Factorate, just under 53,500.
17 If we go to 1979, HCDO0001384, we see a further
18 change: no cryoprecipitate at all in use in
19 Wolverhampton in 1979. The main treatment in use
20 there are NHS concentrates, just over 64,000, with
21 just under 5,000 units of Armour Factorate.
22 The picture throughout in relation to treatment
23 of the patients with Christmas disease is the NHS
24 Factor IX provision.
25 If we then move to 1980, HCDO0001483. Again,

1 we'll see no cryoprecipitate. NHS concentrate in
2 substantial use, but now the product in greatest use
3 is the commercial concentrate, the Armour product. So
4 a total roughly of 155,000-plus units of Armour,
5 combining hospital and home treatment together, as
6 opposed to approximately 92,500 units of NHS
7 concentrates.
8 Again, the extent to which this is the result of
9 shortages, supply issues, or conscious choice on the
10 part of the Centre Directors is not something we can
11 discern from the returns themselves.
12 1981, HCDO0001586, continues the pattern of no
13 cryoprecipitate and the treatment in use being NHS
14 concentrate and the Armour product. But in this year
15 there is more NHS concentrate used than commercial
16 concentrate, roughly 186,000 compared to 127,600.
17 However, if we then turn to 1982, HCDO0001682,
18 whilst we again see no cryoprecipitate for use with
19 haemophilia A patients, it is used for treatment of
20 a von Willebrand's disease patient. But the same
21 picture of NHS concentrate and Armour product emerges,
22 but now more Armour product is used in this year
23 than NHS.
24 The picture for 1983 is slightly unclear. It's
25 HCDO0001778. We can see it's still NHS concentrate

1 and Armour Factorate, and the figures for NHS
2 concentrate are fairly clear: 86,745 hospital,
3 79,000 home treatment. The figure for the Armour
4 product, it's not entirely clear whether that's
5 intended to read 75,000 or, possibly, 175,000.
6 Then, finally, 1984, HCDO0001871, there is some
7 use of cryoprecipitate that year, not a huge amount,
8 30 bags used for the treatment of haemophilia A
9 patients as well as von Willebrand's.
10 The NHS figure, in our note we'd identified that
11 in terms of hospital, 410,533, but looking at it again
12 and bearing in mind the numbers of patients treated,
13 it may be that that's 40,533. It's not entirely
14 clear. In any event, we can see that the product
15 predominantly used that year is NHS concentrate,
16 albeit if we then follow the arrow down, we can see
17 the Armour product also significantly used, both for
18 hospital and home treatment.
19 **SIR BRIAN LANGSTAFF:** It's a huge increase in the amount
20 used if it's 410, but it does look like 410.
21 **MS RICHARDS:** It does look like 410, which is why that's
22 what we put in our notes, but it doesn't seem likely
23 that it would be that much, when one looks at the
24 number of patients treated, which remain largely
25 constant. So the previous year, for example, had been

1 nine haemophilia A patients, this is ten, year prior
2 to that, nine. So it would seem unlikely,
3 notwithstanding the fact that that is what the writing
4 looks like.
5 If I turn to knowledge of risks of
6 hepatitis/HIV, again, nothing by way of direct
7 evidence of Dr Allen's knowledge of risks of viral
8 infection. He did attend, however, UKHCDO meetings in
9 1977, '82, '83 and '84, and would presumably have
10 received copies of the minutes of the meetings on
11 a regular basis.
12 Furthermore, if we go to one of the working
13 party West Midlands Working Party meetings for 1983,
14 SHIN0000030, this is June 1983, and we can see
15 Dr Allen in attendance, and if we go to the bottom of
16 the second page, we can see a reference to AIDS,
17 albeit nothing suggesting a very detailed discussion.
18 So it's under the heading "Supplies of Cryoprecipitate
19 and Freeze Dried Factor VIII", the second paragraph:
20 "Dr Shinton referred to a letter he had received
21 from Dr Ala, who made the point that cryoprecipitate
22 was probably a safer product than Factor VIII
23 concentrate in respect of transmission of [AIDS]."
24 So that's something expressly flagged up to the
25 attendees of this meeting in 1983. It doesn't,

1 however, appear to have resulted, at least insofar as
2 this centre is concerned, with any reversion to
3 cryoprecipitate for the treatment of patients with
4 haemophilia.
5 The only other information in relation to HIV is
6 the data received by UKHCDO. I won't put the table up
7 again on this occasion, but it suggests three patients
8 testing positive for HIV in 1985 at this centre, and
9 no information, I'm afraid, available in relation to
10 the extent of hepatitis C.
11 Can I then move to Stoke, Stoke-on-Trent. The
12 centre was based at what was originally the North
13 Staffordshire Hospital and became the Royal Stoke
14 Hospital and the director from 1976 to 2004 was
15 Dr Ibbotson. We do have a statement from Dr Ibbotson,
16 I'll just give the reference for present purposes,
17 WITN4678001.
18 Again, this centre was part of the West Midlands
19 Regional Health Authority, and Dr Ibbotson was
20 a member of and, indeed, for part of the time,
21 secretary to the West Midlands Regional Health
22 Authority Working Party on the Treatment of
23 Haemophiliacs, whose minutes we've looked at already
24 and was a regular attendee at meetings of the Working
25 Party from 1976 onwards throughout the 1980s.

1 At the working party meeting in May 1976,
2 I don't think we need to go back to it, it's recorded
3 that Stoke is a designated -- or had been designated
4 as a haemophilia centre, contrasting with Shrewsbury,
5 Worcester, Hereford and Wolverhampton, which were
6 designated as associated centres. Again, it appears
7 that the Regional Transfusion Centre in Birmingham was
8 the supplier of blood and blood products to the Stoke
9 centre, and that accords with Dr Ibbotson's
10 recollection in his statement. Again, Stoke was part
11 of the Oxford Haemophilia Supra Region, and
12 Dr Ibbotson attended supra-regional meetings in 1976
13 and 1978.
14 In terms of the numbers of patients treated from
15 1976 through to '85, the range was as follows and it
16 did vary from year to year. The range between 10 and
17 21 patients with haemophilia A, up to four patients
18 with haemophilia B and up to two patients with
19 von Willebrand's disease.
20 Dr Ibbotson in his statement said that he
21 believed that the decision making about the selection
22 and purchase of blood products was a regional
23 decision, which he was not directly involved with. He
24 says he tried to give the British product to patients
25 if it was available. If we pick the picture up then

1 with the Stoke returns and the returns quite often
2 refer to it as being the "North Staffs" centre.
3 1976 returns, HCDO0001121. Sir, we can see
4 there it's described on the form as "North Staffs
5 Haemophilia Centre". The director is Dr Ibbotson, ten
6 patients with haemophilia, four with Christmas
7 disease.
8 Then we can see the figure for cryoprecipitate,
9 I think, is 54,180, so slightly less than the NHS
10 concentrate in use, which was 60,490. Then small
11 amounts of three commercial concentrates, Factorate,
12 Koate and Kryobulin, in use.
13 When we come to 1977, HCDO0001207, we see
14 something of a different picture. A slightly larger
15 number of patients treated, 16 haemophilia, three
16 Christmas disease. Then, in terms of the use of
17 cryoprecipitate, that is significantly increased
18 between 1976 and 1977. The calculation here is done
19 on the basis of a bag having 80 units, we see it
20 elsewhere with 70 units, and the figure then is given
21 as 155,840 units. Whether the calculation of 70 or 80
22 is used, it's clearly cryoprecipitate which is the
23 dominant treatment, as compared to NHS concentrates at
24 14,745 units used.
25 There are then two commercial concentrates used

1 to a lesser extent, Factorate and Kryobulin. The
2 figure for NHS Factor IX concentrate has been put in
3 the wrong table but we can see again it's NHS rather
4 than commercial Factor IX concentrate being used for
5 the treatment of Christmas disease.
6 That's 1977.
7 We don't have the return for 1978. So we have
8 to pick up the picture in 1979, HCDO0001356. We can
9 see that whilst the volume has declined,
10 cryoprecipitate is still the product in greatest use,
11 44,000 units, followed by NHS concentrate, 26,645, and
12 then Armour, just under 7,500 units.
13 In 1980, the picture is slightly different,
14 HCDO0001453. If we zoom into the figures, they're not
15 terribly clear, but it looks as though 30,000 units of
16 cryoprecipitate but solely in hospital, so not used
17 for home treatment. Then it looks like 40,500 units
18 of NHS concentrate used in hospital. Then I'm not
19 entirely sure of the next figure. We thought it was
20 probably 56,000 for home treatment, and then we can
21 see that Armour is the other product used: 34,320
22 hospital, 14,800 used for home treatment.
23 1981, HCDO0001577 --
24 **SIR BRIAN LANGSTAFF:** It's not at all clear, is it?
25 **MS RICHARDS:** It's not, no.

1 **SIR BRIAN LANGSTAFF:** It looks -- standing back from it,
2 it looks like 18,000. But it's anyone's guess.
3 **MS RICHARDS:** It is, really. One can make out a case for
4 a range of different numbers there, unfortunately.
5 If we go then to 1981, HCDO0001577.
6 Oh, I've got -- if we go to the next page. Oh,
7 I see what you mean. That's how it comes out.
8 Okay. I have it in a form which is legible.
9 It's like that, which is why it's appearing like that
10 on the screen, and I can tell you what the figures
11 are.
12 The figure for cryoprecipitate solely in
13 hospital is 24,720 units. The figure for NHS
14 concentrate in hospital is 83,790 units and
15 52,775 units for home treatment. Then the only
16 commercial concentrate used is Armour: 4,995 hospital
17 and 2,295 home treatment.
18 So the use of commercial concentrates rather
19 less in that year, and NHS concentrate the principal
20 product in use, followed by cryoprecipitate.
21 I don't, I'm afraid, know if we've got the
22 return available for 1982. I don't have a hard copy
23 of it. The figures are 16,800 units of cryo, and then
24 for NHS, 35,540 units of NHS concentrate in hospital,
25 47,230 units for home treatment. And then, again,

1 it's only the Armour product that's used by way of
2 commercial treatment: 17,255 units, hospital; 15,790
3 units for home treatment.
4 So NHS concentrate is most in use, followed by
5 commercial concentrate, followed by cryoprecipitate as
6 the treatment still used, but used least of the three.
7 We can display the return for 1983.
8 HCDO0001769.
9 We can see, in 1983, cryoprecipitate still very
10 much in use, although only in hospital, not for home
11 treatment. 58,240 units. The product used most of
12 all is NHS concentrate, 185,746 hospital,
13 112,785 home. And then the only commercial product
14 used is, again, the Armour product, just over 29,000
15 hospital, and then a smaller amount, 2,400, home
16 treatment.
17 We don't need to go to it but the reference for
18 the 1982 annual return is HCDO0001673.
19 We can see the picture that emerges in 1983 in
20 any event is, first of all, NHS, then cryoprecipitate,
21 then commercial. That is at least consistent with
22 Dr Ibbotson having said he tried to use British
23 products when available.
24 Then 1984, last of all, HCDO0001863. The
25 product again used most of all is the NHS concentrate,

1 34,700 in hospital, 133,225 for home treatment. Then
2 cryoprecipitate and commercial concentrate used in
3 quite similar measures: 26,800 cryo in hospital, and
4 then Factorate 21,610 for home treatment and 5,850 for
5 hospital treatment.
6 Sir, that's the pattern in relation to the
7 Stoke centre, which does show continued use throughout
8 this period into 1983, 1984, of cryoprecipitate,
9 albeit not to the same extent as in earlier periods.
10 Dr Ibbotson in his statement recalls patients
11 being keen on home treatment, and that it was
12 supported by The Haemophilia Society.
13 In relation to prophylactic treatment, he says
14 it was left to the decision of haemophiliacs if they
15 wanted to embark on prophylactic treatment. They
16 worked out their usage.
17 His recollection was that patients were informed
18 of the risks of using blood products. And he says,
19 "Patients knew my views on blood products."
20 Although the evidence the Inquiry has received
21 from patients treated at this centre is not extensive,
22 we do have a statement from a patient diagnosed with
23 haemophilia B who says that they were not told that
24 there might be a risk of infection from receiving
25 Factor IX product.

1 In relation to knowledge of risk, Dr Ibbotson
2 attended a number of UKHCDO meetings in the late 1970s
3 and early 1980s. If we go to his statement, please,
4 WITN4678001, and we pick it up at page 7, we can see
5 what he sets out in his statement about his
6 recollection of his knowledge and understanding of
7 risks of infection.
8 Picking it up at paragraph 20, he says:
9 "I considered the use of commercial Factor VIII
10 at higher risk than UK Factor VIII as the history of
11 the donors was limited compared to UK donors. Hence
12 my effort always to receive UK material."
13 Then, in relation to hepatitis, in the next
14 paragraph he says:
15 "I assumed Hep A was not clinically severe. As
16 for Hepatitis B is concerned I had no dealings with it
17 as the patients at North Staffs as none were positive.
18 NonAnonB initially felt to be insignificant but
19 history proved otherwise."
20 And then --
21 **SIR BRIAN LANGSTAFF:** If you just go back a page, rather
22 than forward a page. Yes, what he says at the very
23 top, above the bottom end of paragraph 18.
24 **MS RICHARDS:** Yes.
25 "It was apparent to me that all blood and blood

1 products had a hepatitis risk of non-A and non-B. The
2 greater the number of donors the greater the risk.
3 Over time it is becoming apparent that my views were
4 correct and I did not change them."
5 Thank you, sir.
6 So that's the --
7 **SIR BRIAN LANGSTAFF:** When he says that "they were aware
8 of my views", presumably those were the views he was
9 expressing, were they?
10 **MS RICHARDS:** That would be, I think, a fair reading of
11 his statement. What we don't have, I think,
12 is sufficient accounts from those treated at the
13 centre --
14 **SIR BRIAN LANGSTAFF:** No.
15 **MS RICHARDS:** -- to --
16 **SIR BRIAN LANGSTAFF:** But his view --
17 **MS RICHARDS:** -- (overspeaking) --
18 **SIR BRIAN LANGSTAFF:** -- is that that was his view and he
19 expressed it?
20 **MS RICHARDS:** Yes. Whether -- he talks about his views
21 about preferring British treatment. So whether that's
22 the view, without a further explanation as to why,
23 that he's talking about patients being aware of, I'm
24 not sure was clear from his statement.
25 **SIR BRIAN LANGSTAFF:** Yes. Well, I follow that.

1 **MS RICHARDS:** In relation, then, to the risk of AIDS, and
2 in addition to his attendance at UKHCDO meetings, his
3 statement, picking it up at page 8, says this,
4 paragraph 23:
5 "Initially there was no indication that blood
6 products could cause the transmission of HIV. Over
7 time it became clear that it was a serious developing
8 problem. Unfortunately it was apparent that stopping
9 the use of blood and blood products could not happen."
10 In answer to question 24 he says:
11 "During various meetings it became apparent that
12 there was an association between blood products and
13 HIV in approximately 1983."
14 Then, over the page, his recollection is that
15 patients were switched to heat-treated products as
16 soon as available.
17 Then if we go over to page 10, in answer to
18 question 31 which was about reverting to treatment of
19 cryoprecipitate, he says:
20 "All patients were offered local treatment with
21 cryoprecipitate. Those on home treatment preferred
22 Factor VIII and by the time the full information of
23 HIV was available supplies of heat treated Factor VIII
24 were on stream."
25 Then he's asked in the next question about the

1 meeting of Haemophilia Centre Directors in
2 October 1983, which he was present at.
3 And if we go to the next page, he doesn't recall
4 the discussion. Unsurprising, perhaps, so many years
5 after the event. He says -- in response to the
6 question of whether patients raised with him concerns
7 about factor concentrates, he says:
8 "They did when it became public knowledge.
9 I agreed there was a risk and let them make their own
10 decision after a discussion."
11 Next paragraph he says:
12 "We had no problems in securing Factor VIII."
13 Then in answer to the question, "Were you ...
14 able to get unlimited amounts of cryoprecipitate?",
15 the answer also is "Yes".
16 And then in relation to the decision recorded in
17 the minutes of that meeting, which was that patients
18 should continue to receive NHS or commercial
19 concentrates, he was asked if he agreed or disagreed
20 with the decision, and he says he agreed with the
21 decision.
22 We don't have, I'm afraid, very much information
23 about the process of testing patients for HTLV-III and
24 informing them of their diagnosis. Dr Ibbotson's
25 statement says that there was a full discussion prior

1 to screening and post-screening and that all partners
2 were offered tests when necessary. You do have
3 a statement from a witness, who indeed also gave oral
4 evidence to you, who recalled being told about his
5 diagnosis in 1986 by Dr Ibbotson. It's right to say
6 that's someone who had been treated in Birmingham and
7 then was being told their diagnosis following transfer
8 to Stoke-on-Trent.
9 His account was of being called into
10 Dr Ibbotson's office, the door remaining open allowing
11 people behind him to hear the conversation, and the
12 doctor saying, "Good morning, I see you are HIV
13 positive".
14 In terms of numbers infected with HIV, the
15 figure that we -- or the figures that we have from
16 UKHCDO indicate six patients. Perhaps if we will go
17 to it, INQY0000250, please, second page. Towards the
18 bottom of the second page, Centre 24, North
19 Staffordshire, Stoke-on-Trent, you'll see there it
20 gives a test result for 1981, which, if correct, could
21 obviously only be a test result on serum stored from
22 1981, and then, moving forward to 1985, a figure of
23 five, giving a total of six cases.
24 However, it's also right to note that
25 Dr Ibbotson in his statement -- I'll just find the

1 correct reference -- says, I think, that sera was not
2 stored -- yes. In answer to the question in the
3 statement "Was work undertaken at the centre to
4 establish the time period during which patients
5 seroconverted?", he says:
6 "No work was undertaken as no serum was
7 retained."
8 So whether that figure was one patient testing
9 positive based on a sample from 1981 is correct or
10 not, I'm afraid we can't answer that.
11 **SIR BRIAN LANGSTAFF:** What would be the position if
12 a patient transferred, and their serum was tested from
13 somewhere else?
14 **MS RICHARDS:** Yes, well, that's a possibility, yes. That
15 is certainly a possibility.
16 In relation to hepatitis C, Dr Ibbotson's
17 recollection was of not -- having no patients who had
18 clinical non-A, non-B hepatitis. He couldn't recall
19 how many patients were infected with hepatitis C. He
20 said, as soon as the test became available at the
21 North Staffs lab, patients were informed by him in
22 person of their hepatitis C status and you have some
23 account from a witness of being informed of
24 hepatitis C diagnosis in 1992 by Dr Ibbotson.
25 In terms of the treatment arrangements,

1 Dr Ibbotson's recollection was that patients with HIV
2 were managed locally but offered a referral to
3 Birmingham and that all hepatitis C patients were
4 referred to the Queen Elizabeth Haemophiliac Unit,
5 that's how he described it, although it's also right
6 to note that you have a witness account saying that
7 she received all of her medical treatment at Stoke.
8 Sir, that's the position in relation to Stoke,
9 and probably a good point at which to break before we
10 pick up on the last three centres.
11 **SIR BRIAN LANGSTAFF:** Yes, well, let's come to the last
12 three centres then at 3.40. 3.40.
13 **(3.11 pm)**
14 **(A short break)**
15 **(3.40 pm)**
16 **MS RICHARDS:** Sir, I'm going to deal next with Shrewsbury
17 Hospital. Directors of the Haemophilia Centre there
18 in the seventies and eighties, Dr O'Shea and Dr Rees.
19 Shrewsbury too was part of the West Midlands
20 area, and Dr O'Shea and Dr Rees regularly attended the
21 meetings of the West Midlands Working Party on the
22 Treatment of Haemophiliacs, the minutes of which we've
23 looked at, from the seventies through to the early
24 nineties.
25 Shrewsbury became a designated associate centre

1 in 1976, and in common with the other centres we've
2 been looking at this afternoon, it was supplied in
3 terms of products and blood by the Regional
4 Transfusion Centre in Birmingham.
5 In terms of the numbers of patients treated, the
6 figures from the returns from 1976 through to 1985
7 give a range of between seven and 12 patients with
8 haemophilia A, up to four patients with haemophilia B,
9 and up to five patients with von Willebrand's disease.
10 If we turn, before we look at the returns, to
11 one meeting of the Working Party on the Treatment of
12 Haemophiliacs, SHIN0000036, these are the minutes of
13 a meeting of 19 May 1980, and we can see Dr O'Shea was
14 amongst the attendees.
15 If we go to the top of page 3, this is in the
16 context of a broader discussion about availability of
17 different types of product, at the top of the page it
18 recalls Dr O'Shea saying this:
19 "... he wished to continue using cryoprecipitate
20 at Shrewsbury particularly while BPL Factor VIII was
21 not being produced, but he had been unable to obtain
22 the requested amounts of cryoprecipitate from the BTS.
23 He asked if the production of cryoprecipitate could be
24 increased at the BTS while NHS Factor VIII was
25 unavailable to offset the increased charge on Salop's

1 budget [I'm afraid I don't know what that is a
2 reference to] which would arise from the need to
3 purchase more Commercial Factor VIII."
4 Then Dr Bird, who was based at the Regional
5 Transfusion Centre, indicated it wasn't possible to
6 manufacture more cryo because plasma was needed to
7 send to BPL.
8 Then various other contributions set out,
9 including the suggestion at the end of the second
10 paragraph that reversion to using cryoprecipitate
11 would be a retrograde step.
12 But in any event, I show you that because it
13 gives an indication of Dr O'Shea's thinking, or at
14 least his preferences.
15 If we then turn to the annual returns, 1976,
16 HCDO0000050_004, page 2, we can see seven patients
17 treated with haemophilia A that year, two with
18 Christmas disease. And then we'll see that the sole
19 products in use were cryoprecipitate and Kryobulin,
20 and that the vast majority of usage was of
21 cryoprecipitate.
22 Can I correct a figure in our written note in
23 relation to this centre, where an extra zero had crept
24 in, looking as though 930,000 units of cryoprecipitate
25 were used for the treatment of seven patients, which

1 would have been a little unusual.
2 In any event, the dominant picture there one of
3 use of cryo, and you'll see no NHS concentrates in
4 use, consistent, perhaps, with what we saw reflected
5 in the minutes of that meeting.
6 If we look at 1977, HCDO0001202, and we go to
7 page 7, we can see a similar picture. The product
8 predominantly used is cryoprecipitate, nearly 132,000.
9 No NHS concentrate. And then smaller amounts of three
10 types of commercial concentrate, Factorate, Koate and
11 Kryobulin, used.
12 At 1979, HCDO0001369 -- I should say we don't
13 have the return for 1978, I think. So 1979 shows now
14 the introduction of NHS concentrates, and that's the
15 main product being used in this year. Just over
16 156,000 units. The second in terms of volume is
17 cryoprecipitate, but we can see that the amount of
18 cryoprecipitate used has declined substantially. And
19 then, thirdly, commercial concentrates, Factorate and
20 Kryobulin.
21 If we go then to the annual return for 1980,
22 HCDO0001467, what's interesting in particular here is,
23 first of all, the usage of cryoprecipitate has
24 increased. But secondly, we can see cryoprecipitate
25 being used for home treatment, and it's the main

1 product used for home treatment in 1980, roughly or
2 a little over double the next volume used, which was
3 the Armour product, just under 45,000 units. And then
4 NHS concentrate, 41,385 units used for home treatment.
5 So a different picture from what we've seen
6 elsewhere, with cryoprecipitate being used, by this
7 time, if at all, in hospitals rather than for home
8 treatment.
9 1981, HCDO0001568, again shows continued use of
10 cryoprecipitate for home treatment, albeit that, now,
11 more NHS concentrates are used for home treatment than
12 previously. And we can see Armour is also in use in
13 the centre in that year.
14 However, when we get to 1982, the position
15 changes. HCDO000166. We can see now, in 1982,
16 there's no cryoprecipitate used at all except for the
17 treatment of a patient with von Willebrand's disease.
18 The bulk of the treatment is with NHS concentrate,
19 nearly 166,000 units, and then with Armour Factorate.
20 What accounts for that change I'm afraid we are simply
21 not in a position to assess.
22 Then for 1983, HCDO0001762, similarly, no
23 cryoprecipitate at all, predominant product used NHS
24 concentrate, but also a significant amount of Armour
25 product used for home treatment.

1 Then, finally, 1984, HCDO0001855. Again, no
2 cryoprecipitate. The only products used are
3 NHS concentrates and Armour. But the dominant product
4 in use is the NHS concentrate.
5 There is limited other information in relation
6 to product usage, or information provided to patients.
7 You do have a statement, sir, from one witness who
8 says that neither he nor his parents were ever given
9 information about the risks posed by Factor VIII
10 concentrates at this centre.
11 And likewise, another patient talking about the
12 provision of treatment at Shrewsbury to their son
13 could not recall any discussions about risks with
14 them.
15 Both Dr O'Shea and Dr Rees were members of
16 UKHCDO, and one or other of them seem to have attended
17 a number of meetings in the late 1970s, and then in
18 '85. There isn't attendance at every meeting but,
19 again, it's maybe reasonable to assume they would have
20 received the minutes of those meetings that they did
21 not attend.
22 There's no contemporaneous documentation, I'm
23 afraid, in relation to the process for testing
24 patients, either for HTLV-III or for hepatitis C. You
25 have a couple of witness accounts. One, whose son was

1 treated with blood products there, gives a time frame
2 in terms of testing: testing for HIV in December 1984
3 and the test result being confirmed in March 1985.
4 Not a suggestion there of testing taking place
5 without consent.
6 In terms of the figures infected with HIV, can
7 we go back to INQY0000250, please. Page 2.
8 The figures for Shrewsbury appears towards the
9 bottom of the page. It's centre 23. And what that
10 appears to identify is one patient in 1984 and six in
11 1985, giving a total of seven patients testing
12 positive with HIV, which is a very high proportion of
13 the numbers of patients regularly treated. But we
14 can't cast any light on why that might be the case, or
15 indeed know with any degree of confidence whether
16 that's correct.
17 We don't, I'm afraid, have information regarding
18 numbers of patients infected with hepatitis C.
19 Can I then turn to Hereford. The Centre
20 Director at Hereford was Dr Kramer during the period
21 with which we're concerned. Dr Kramer was also
22 a member of the West Midlands Regional Health
23 Authority Working Party on the Treatment of
24 Haemophiliacs. And the Hereford centre was recognised
25 as a designated associate centre in the course of 1976

1 and it too was supplied with its products by the
2 Birmingham Regional Transfusion Centre.
3 It treated a small number of patients. The
4 figures on the returns from '76 through to '85 give
5 a range of between one and four patients with
6 haemophilia A, up to two patients with haemophilia B,
7 and up to two patients with von Willebrand's disease.
8 The only information we really have is from the
9 annual returns, and I can take those fairly quickly
10 because they show a fairly consistent picture -- or
11 straightforward picture, I should say.
12 So for 1977, to treat three haemophilia A
13 patients, the centre used cryoprecipitate only. In
14 1978, to treat three haemophilia A patients, the
15 centre used cryoprecipitate and NHS Factor VIII.
16 Approximately double the amount of the -- the NHS was
17 approximately double the amount of cryoprecipitate
18 used, but no commercial.
19 In 1979, to treat two patients there was no
20 cryoprecipitate used. The only treatment was with
21 NHS factor concentrate.
22 If we then go to the return for 1980, which is
23 HCDO0001427, we can see three patients treated in that
24 year. The figures are slightly indistinct, but you'll
25 see no cryoprecipitate, and then, for the first time,

1 commercial concentrate used. Armour: 7,750 units.
2 But the main treatment for the purposes of home
3 treatment was with NHS concentrates.
4 And sir, can I correct again, our written note
5 refers to the figure of 27,350 units as being units of
6 cryoprecipitate when it should have been
7 NHS concentrate.
8 In any event, that's the first use of commercial
9 concentrate.
10 In 1981, the precise figures are difficult to
11 discern, but it's just NHS concentrate. Likewise in
12 1982, it's only NHS concentrate. And the same in
13 1983, and in 1984.
14 Dr Kramer does not appear to have been an
15 attender at UKHCDO meetings. Again, however, he was
16 the director of a designated associate centre so would
17 presumably have received copies of minutes.
18 He did participate in and was a member of the
19 regional Working Party on the Treatment of
20 Haemophiliacs. We don't have any information
21 regarding arrangements for testing or provision of
22 information about diagnosis or treatment. What we can
23 say is the UKHCDO data indicates that no patients were
24 infected with HIV at the Hereford centre.
25 Finally, for today, Worcester. Sir, the

1 director at the Worcester centre from 1976 and during
2 the 1980s was Dr Payne. Worcester also, in common
3 with all the other centres that we've been looking at
4 this afternoon, was part of the West Midlands Regional
5 Health Authority. Dr Payne was a regular attender of
6 the meetings on the Working Party on the Treatment of
7 Haemophiliacs within the West Midlands Region through
8 the 1970s and 1980s.
9 Worcester was designated as an associate
10 haemophilia centre in the course of 1976 and, again,
11 our understanding is it was supplied by the Regional
12 Transfusion Centre in Birmingham. It was a small
13 centre, not quite as small as Hereford, but small:
14 haemophilia A patients three to seven treated annually
15 in the period from 1976 to '85; and no more than one
16 haemophilia B patient recorded in the annual returns;
17 and up to three patients with von Willebrand's
18 disease.
19 If we turn to the annual returns, which, I'm
20 afraid, again are our only real source of information,
21 1976, HCDO0000026_004, we'll see that the main
22 treatment used was cryoprecipitate with a small amount
23 of Armour Factorate in use.
24 For 1977, HCDO0001221, page 4, we see, again,
25 still no NHS concentrate, so it's cryo and Armour

1 product only, but now the Armour product is the
2 product most in use: 26,787 units, contrasting with
3 7,680 units of cryoprecipitate.
4 We don't have a return for 1978, so we pick the
5 picture up in 1979, HCDO0001385, which shows
6 a similar, broad picture, no NHS concentrate, small
7 amount of cryoprecipitate, treatment predominantly
8 with the Armour product, 36,135 units.
9 If we can then go to the return for 1980,
10 HCDO0001484, the comparatively unusual feature of this
11 return is that the sole treatment is with commercial
12 concentrate, with Armour, both at hospital and home.
13 So no NHS treatment at all, concentrate or
14 cryoprecipitate for patients with haemophilia A,
15 albeit that plasma and cryo was used for the treatment
16 of a patient with von Willebrand's disease.
17 1981 sees a reversal of the picture.
18 HCDO0001587. This is the first appearance on a return
19 of NHS concentrates. I'm afraid the figures are not
20 easy to read and even fainter are the figures in
21 relation to Armour. Sir, I'm not even going to
22 attempt to try to work out what those are. I just
23 don't think it is possible to do so, but we do see NHS
24 concentrate used for the first time.
25 1982 is HCDO0001683. Happily, the figures here

1 are clear. The product mostly used, NHS concentrate
2 now, no cryoprecipitate at all, but also Armour
3 Factorate, although the Armour is used only for
4 hospital treatment and not, in fact, for home
5 treatment at all.
6 Then 1983, HCDO0001779, again we see a picture
7 of there being only NHS concentrates and the Armour
8 concentrate in use. Predominantly NHS concentrates,
9 a relatively small but by no means insignificant
10 amount of Armour product; cryoprecipitate only used
11 for the treatment of patients with von Willebrand's.
12 Then 1984, HCDO0001872. We see a different
13 picture from the preceding years. No commercial
14 concentrate used. The main treatment is with NHS
15 concentrates and a small amount of cryoprecipitate now
16 used again for the treatment of haemophilia A
17 patients. Again, we don't, I'm afraid, have any
18 understanding as to why that might be the case and
19 whether that was a conscious response or merely
20 a reflection of what was available, or whether there
21 was some other reason.
22 We have nothing by way of direct knowledge or
23 direct information about Dr Payne's understanding of
24 the risks of hepatitis or HIV. He does not appear to
25 have been an attender at UKHCDO meetings. He did,

1 however, attend regularly the West Midlands Working
2 Party meetings and so would have gleaned information
3 from that, in addition to the minutes of UKHCDO
4 meetings.
5 We don't, I'm afraid, have any information about
6 the process of testing and treatment from the
7 documentation, whether for hepatitis or HIV. Nor, I'm
8 afraid, do we have any data about the numbers infected
9 either in relation to HIV or in relation to hepatitis.
10 Sir, that completes the picture for Worcester,
11 and completes the presentations for this week.
12 **SIR BRIAN LANGSTAFF:** Yes, well, thank you very much. So
13 that brings to a conclusion the review of the smaller
14 haemophilia centres. We have to return, have we not,
15 to look at pharma, the pharmaceutical companies, and
16 their knowledge and response to risk, which we do,
17 I think, on 2 November, am I right?
18 **MS RICHARDS:** Yes. I'm just checking my note. Sir,
19 I should just say, in relation to the small
20 Haemophilia Centres, there are, obviously, some
21 Haemophilia Centres we've not yet covered but, as
22 I think I indicated at the beginning of the week,
23 which now seems a very long time ago, those will be
24 covered by way of written notes, and probably not,
25 unless something new emerges from them, by way of oral

1 presentation.
2 The plan is, in relation to all the notes on
3 Haemophilia Centres, which they're currently available
4 to Core Participants and their recognised legal
5 representatives but the plan is to ensure that those
6 are published on the Inquiry's website over the coming
7 weeks, so that they can be read by those who are not
8 Core Participants or who don't have access to the
9 Inquiry's document management systems.
10 **SIR BRIAN LANGSTAFF:** Very well. So there's a break, in
11 that case, until 2 November, when we start again at
12 ten o'clock.
13 **MS RICHARDS:** Thank you.
14 **(4.04 pm)**
15 **(The hearing adjourned until 10.00 am on**
16 **2nd November 2021)**
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I N D E X

Presentation by Counsel to the Inquiry 1
about smaller haemophilia centres
(continued)

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