Tuesday, 27 October 2020

(10.00 am)

SIR BRIAN LANGSTAFF: This week is Birmingham and Bradford.

Presentation by MS RICHARDS

MS RICHARDS: Sir, yes. We start this morning with looking at some of the documents we referred to in the written note we've produced about Birmingham Haemophilia Centres, with particular focus upon the Birmingham Children's Hospital. That will be this morning.

This afternoon we will hear from Professor Franklin, who was the director of the Queen Elizabeth Hospital in Birmingham from 1983 to 1992, and his evidence will continue probably until tomorrow lunchtime. Then tomorrow afternoon we'll hear from Dr Wilde, who took over as director at the Queen Elizabeth Hospital in 1992, and then on Thursday we hear from Dr Parapia who was director at the Bradford Haemophilia Centre.

So starting with Birmingham, the documents I propose to refer to in the course of the morning will relate to the following issues: an overview of the centre and its facilities; supplies of blood products and treatment policies; knowledge of risk of

hepatitis and HIV; and testing for and treatment for HIV and hepatitis.

I won't be dealing with Professor Hill's time as chair of UKHCDO. We may well look at that in a hearing at a later stage, either when we look at vCJD, sir, or in the course, possibly, of a presentation on the work of UKHCDO over the years, but I won't be dealing with that today.

So haemophilia care in Birmingham, we know, was split between the Children's Hospital and the Queen Elizabeth Hospital. They were in fact designated jointly as a single haemophilia centre, although their patient population was different and they were obviously different hospitals.

The Children's Hospital director, until the middle of 1976, was Dr Jillian Mann, and she was then succeeded by Dr Frank Hill. The centre director at Queen Elizabeth Hospital was Professor Stuart until he was succeeded by Dr Franklin, now Professor Franklin, in 1983.

We can get a snapshot of numbers of patients if we go to SHIN0000045, please, Henry. If we could go to the last two pages, please. Thank you.

So we can see this is as at 1974. We have a summary in relation to the Queen Elizabeth Hospital,

491 patients registered, 103 attending for treatment, of which 80 haemophilia, 15 Christmas disease, 8 von Willebrand's.

We can see there the "Facilities", described as a 24-hour advisory service; specialist consultant service for surgical, dental, physiotherapy and social care; home therapy programme instituted, and I will come on to the home treatment arrangements; reference laboratory service; educational facilities, and then:

"Available factor concentrates: cryoprecipitate, freeze-dried Factor VIII and freeze-dried Factor IX."

Then in relation to the Children's Hospital we can see:

"Number of patients registered: 120.

"Number attending for treatment: 80 [sic]."

50, haemophilia; 10, Christmas disease.

SIR BRIAN LANGSTAFF: 60, in fact.

MS RICHARDS: Sorry, 60, yes.

50, haemophilia; 10, Christmas disease and then 7,900 units of cryo and 231 bottles of Oxford Factor IX administered.

Again, we will look back to that.

"Six children are receiving home care at the moment ... several more have applied" and then the same facilities.

Sir, for your and, indeed, others' benefit, although I won't go to the details of the rest of the document now, similar figures are set out for other haemophilia centres within the West Midlands region, of which the most sizeable at the time were Coventry and North Staffordshire, as well as a number of rather smaller ones. We have similar data there.

Could we have up, please, Henry, SHOC -- sorry, I should say, although both hospitals were jointly designated as a single haemophilia centre, they were not designated as a reference centre, and it was, in fact, a number of years until the Children's Hospital was recognised as what was then called a comprehensive care centre. The reference centre for the West Midlands region remained the Oxford Haemophilia Centre during the 1970s and 1980s until 1989.

Henry, could we then have HSOC0019918_011, please. The screen has gone ominously blank ...

Thank you.

So this is a document from 1976. If we go -- it's a Haemophilia Society document. If we just go to the second page, we can see a theme which continues really over a number of years about what's said to be insufficient funding for a full range of facilities in Birmingham. So if we could go to the heading

"Application for Grants" -- thank you -- the second paragraph refers to Dr Hill having been appointed as director at the Children's Hospital and having:

"... applied to the appropriate authorities for funds for new equipment to assist in the research projects ..."

We don't know what those are at this time, sir.

"... and diagnostic facilities that were planned both there and at the Queen Elizabeth Hospital. It had been made clear to him that equipment that he needed, to the cost of £4,000, could not be provided through the usual channels although he hoped to obtain the rest."

Then there's a welcoming of his appointment and it's reported that that could only help to improve the service in Birmingham, which had deteriorated and about which there had been several complaints. We don't have details, sir, of what those complaints were at that time.

We know also from documents -- I won't go to the individual documents -- that there had been concerns about a lack of a full-time nursing sister at both the BCH and QEH. There were also concerns expressed in contemporaneous documents in the 1970s about limited technical staff available to perform diagnostics, and

issues over the adequacy of and funding for laboratory facilities in Birmingham continued really for a number of years, well into the 1980s.

If I turn then specifically to Dr, then Professor, Hill, he was a registrar in pathology at the United Oxford Hospitals in the early 70s -- 1971 to 1973. He -- according to a statement he provided to the Inquiry in response to an individual witness statement from a patient, he says in relation to his career, he spent 11 months in laboratory and adult haematology in Oxford and six months in blood transfusion and immunopathology.

He then moved to the Great Ormond Street Hospital and was there between 1973 and 1976 and it's there, his statement says, he received training in paediatric, laboratory and clinical haematology.

He was then, in July 1976, appointed as full-time consultant and director of the centre at the Birmingham Children's Hospital. His statement suggested that he divided his time between the Children's Hospital, where he had primary responsibility and conducted eight sessions a week, and the Queen Elizabeth Hospital, so the adult hospital, where he provided two sessions a week, including, his statement says, running a haemophilia

and haemostasis clinic.

SIR BRIAN LANGSTAFF: Pausing there for a moment, that says July 1976 appointed as full-time director. The document which is still on screen is a document which is dated April '76 and says he's now been appointed director. So it's probably, perhaps, I don't know, was it the time between his appointment and actually taking up the post formally or is the second date, that in July, simply wrong?

MS RICHARDS: I don't know, sir. We can check. He certainly took up his appointment as director in 1976 succeeding Dr Jillian Mann, but we can check the precise date and track down any discrepancy.

The division of responsibility between the Children's Hospital and Queen Elizabeth Hospital appears to have continued until 1992. At that point he ceased to have any involvement with the Queen Elizabeth Hospital, at least directly, and remained full time at the Children's Hospital until his retirement from clinical practice in 2008.

Sir, the first main topic I'm going to look at in the documents is issues relating to supplies of the various blood products for treatment in the West Midlands region and the treatment policies that were adopted in Birmingham in particular in the

second half of the 70s and first part of the 1980s.

Henry, could we go back to SHIN0000045. So 0000045.

We looked at the statistics in terms of numbers of patients at the end of this document but you will see this is a set of minutes of something called the "West Midlands Regional Health Authority Treatment of Haemophiliacs". It then became referred to subsequently as a working party. This meeting is 18 December 1975. We can see not yet in attendance, because Dr Hill's not arrived, but Dr Mann is there and Dr Stuart, representing the Queen Elizabeth Hospital.

If we go halfway down the page, to the bottom half of the page, we can see a heading:

"Availability of Cryoprecipitate and freeze-dried Factor VIII."

And there is a detailed discussion about supplies of cryoprecipitate and supplies of Factor VIII.

So we can see Dr Bird, who I think was from the regional transfusion centre at the time, explaining that there was an expectation of receipt of cryoprecipitate, and it's said:

"... at the present rate of demand it would be

impossible to meet the West Midlands Region's need ..."

That is, I think, for cryoprecipitate.

"... and also supply to the Lister Institute with the amount of fresh plasma they require."

There's a reference to financial allocations having been made by the DHSS but these not being sufficient and the Regional Health Authority having agreed to increase the blood donor teams and give high priority to necessary capital building work at the Blood Transfusion Centre.

Then there's reference to a table which we don't have showing cryoprecipitate supplies to hospitals. At this stage it said over 60 per cent was supplied to the QEH and Children's Hospital. So that's the Birmingham hospitals. Dr Bird's reported to have said that:

"... the requirement of the Queen Elizabeth Hospital was rising ... he stressed that if the present demand continued the supply of cryoprecipitate would soon be exhausted; there would not be enough for the Region, let alone the Lister Institute. He raised the question of centres buying commercially freeze-dried Factor VIII, and members then considered a paper by Dr Stuart on the availability

of freeze-dried Factor VIII or concentrate from the Lister Institute ..."

We don't, I'm afraid, have that paper.

Then if we go to the top of the next page it records that:

"Dr Stuart ..."

So the then director at Queen Elizabeth:

"... made the point that as the BTC was unable to meet all his requirements for cryoprecipitate it was necessary for him to purchase commercially manufactured concentrate."

If we go to then a few lines down:

"Following discussion, it was agreed:

"(1) to draw the attention of the Regional Medical Officer to the possibility of an acute shortage of cryoprecipitate over the next few weeks.

"(2) to draw the attention of the Regional Scientific Committee to the problem of the supply of cryoprecipitate and the cost consequences of buying commercial Factor VIII concentrate.

"(3) to recommend to the Regional Scientific Committee that all Directors of Associated Haemophilia Centres be allowed to purchase commercially prepared concentrate should the necessity arise. The recommended Factor VIII was Kryobulin."

Sir, you will see from that, and we see it from a number of meetings over the following years, at that point in time cryoprecipitate was the main form of treatment used in Birmingham and, indeed, at the other centres in the West Midlands but there was an issue in relation to the supply of cryoprecipitate, it was said, and Directors' response was to say they were going *to have to make that up* by buying commercial products, and we will certainly see from the annual returns that commercial products then started to be used to a considerable extent in the second half of the 1970s.

If we just go to the bottom of this page, there's a discussion on home treatment:

"Members reported that the number of haemophiliacs on home treatment was steadily increasing. It was agreed that this was the preferable form of treatment but there was discussion concerning the possible increased requirement of cryoprecipitate/Factor VIII concentrate in order to offer this more widely."

If we go to the next page, second paragraph:

"The Working Party agreed that home treatment should be instituted in suitable patients where possible."

We'll see in a little while some documents, sir, which show that home treatment was ongoing in Birmingham at this time and steadily increasing, and that the product used, at least to start with, was cryoprecipitate for home treatment.

That discussion about concerns in relation to supplies took place in 1975 against a background of national concerns about self-sufficiency, which we've obviously heard from other witnesses and in other documents, and also supra regional concerns. So there are a number of meetings that take place during this time of what's the snappily titled "Haemophilia Centre Directors, Regional Transfusion Directors and Regional Scientific Advisers from the Supra Regional Territory for which Oxford Haemophilia Reference Centre had responsibility". So this was a wider group than the West Midlands. I won't take time now going to the documents -- they are referenced in our written presentation -- but concerns about supplies, both nationally in terms of the failure to achieve self-sufficiency and within that broader region, were being voiced by Dr Rizza, Dr Biggs, Dr Maycock and others in the course of those meetings.

If we then move on to 1977, still now within the West Midlands region, could we have SHIN0000042,

please. So here we have a meeting of the Working Party on the Treatment of Haemophiliacs, as it's now termed, the West Midlands Regional Health Authority. This particular meeting is 23 May 1977 and we can see that Dr Hill is there in attendance from the Children's Hospital and Dr Stuart from the Queen Elizabeth Hospital.

If we go to the second page, we can see in the second paragraph, again, a discussion about supplies:

"Dr Bird said that the Blood Transfusion Centre's stocks of Factor VIII concentrates had been used up; the concentrate supplied by the Lister Institute was not being used at the rate which had been predicted, and the demand for cryoprecipitate was going down. He pointed out that there was no policy for the allocation of this material."

Then there are particular concerns expressed by Dr Shinton, who was the director of the Haemophilia Centre at Coventry, and there's a question as to why he was having to pay for concentrate where Stoke and Birmingham had a free allocation from Lister. This is presumably NHS concentrate. We see from the last sentence of this paragraph, it being pointed out that much of the Factor VIII used by the Queen Elizabeth Hospital was supplied direct by the Lister Institute.

So it appears that, at that time, the Queen Elizabeth was receiving at least some supplies of Lister Factor VIII directly from Elstree, not simply reliant upon supplies from the Blood Transfusion Centre.

If we just go to the next page, please, Henry.

This is in the context of a discussion about funding for a haemophilia nursing centre but if we just look at the third paragraph, we'll see again one of many expressions of concern about inadequate funding. Dr Shinton is recorded to have:

"... placed on record the fact that, in his view, the first essential was to ensure adequate central funding for the supply of commercial Factor VIII concentrate for issue by the BTS in the first instance ..."

It would appear he regarded that as more important than funding for the appointment of a haemophilia sister.

If we then move on a year to 1978, and go to SHIN0000040, please, Henry, this is a meeting of the same working party a year later, 15 May 1978, attended again by Dr Hill and Dr Stuart representing the two Birmingham hospitals.

If we go to the second page, please, there is

a long discussion -- I won't go through all of it -- about the availability of concentrate and freeze-dried Factor VIII concentrate. There's a discussion about the extent to which targets are being achieved. If we look at the fifth paragraph down under that heading, we'll see:

"Members then considered a paper by Dr Stuart, showing 'Actual and Estimated Consumptions of Factor VIII ...' Dr Stuart pointed out that it had been estimated that in 1977, 2,022,500 units of Factor VIII would be used ..."

The actual number was 2.197 million and then an estimate in relation to cryoprecipitate showing that the actual number of units of cryoprecipitate used was significantly less. So there's a reduction in the amount of cryoprecipitate from that which had been expected, it would appear.

Then if we go to the next paragraph, please, we see in the second sentence Dr Stuart explaining that the amount of cryoprecipitate had dropped from just over 2 million to just over 1.5 million between 1976 and 1977, while the amount of commercial Factor VIII used had doubled and that produced by Lister had remained the same. So the picture is of decreasing use of cryoprecipitate but still being used in not

insignificant quantities, significant increase in the amount of commercial Factor VIII used and a steady amount of Lister or NHS Factor VIII being used.

If we then, please, go to SHIN0000033, what we see -- and I'm obviously not going to go to all the minutes -- from the minutes throughout this period, that there is a regular discussion in the West Midlands region about supplies. I'll come on in a few minutes to the fact that by 1979/1980 a regional contract has been placed for the supply of commercial concentrates and there is a decreasing amount of use of cryoprecipitate. Concerns about shortfalls lead to increased production of commercial supplies and this is a meeting in which Professor Hill complained, for example, about the cost consequences of having to purchase commercial product. I'm afraid I haven't noted the precise reference. I will come back to that if necessary.

The idea of increasing the use of cryoprecipitate wasn't apparently discussed again until a meeting of the working party in June of 1982. If we have SHIN0000032 -- Henry, that's the reference I meant to give you -- and we go to the second page, this is a meeting of June 1982, if we go to the bottom of the second page to start with, "Supplies of

cryoprecipitate and freeze-dried Factor VIII Concentrate". So this is, again, a topic of regular discussion at these meetings. There's reference to an agreement having been reached between directors of Transfusion Centres and BPL about the pro rata return of BPL Factor VIII, and then if we go to the next page, we can see it's recorded that, in the fourth line down:

"In May 1982, the BPL had announced that due to impending alterations, Factor VIII production would diminish temporarily ..."

Then there's a discussion about solutions to meet this reduced availability of NHS Factor VIII. There's a recommendation that all centres should endeavour to cut down on the use of Factor VIII as far as possible, and increase their usage of cryoprecipitate but then what the agreement is: any shortfall would have to be met by increasing purchasing of commercial Factor VIII.

So although there is a reference to a suggestion or a recommendation that the way to deal with the shortfall of NHS Factor VIII is to use less and use more cryoprecipitate, in fact the solution that's reached upon is purchase more commercial Factor VIII concentrates.

As I mentioned a few moments ago, sir, what we see from the documents around this time is a move towards a regional contract with commercial suppliers, and if we pick that up in SHIN0000041, please, this is a meeting in November 1977. If we go please to the second page, we can see again the bottom half of the page there is a discussion about cryoprecipitate and freeze-dried Factor VIII concentrate supplies and there's a reference towards the bottom of the page to the possibility of central funding. If we go to the next page, please, towards the bottom of the page there, you'll see there's reference to DHSS central contracts, and this is the point at which there is discussed for the first time the possibility that the region might save money on purchase of commercial concentrates, with either central or regional contracts.

If we then go to SHIN0000040, please, Henry, we can see this is the meeting of May 1978, which we looked at a few minutes ago. If we go to the third page, we can see discussions about the contractual arrangements for purchasing commercial Factor VIII. So under the heading "DHSS Central Contracts" it said that:

"Dr Stuart said that the Queen Elizabeth

Hospital obtained its Commercial Factor VIII from two firms only. These firms had been changed in ... 1977. ... Members gave details of the costs of commercial Factor VIII from firms which they dealt with and agreed that it was a good principle to buy Factor VIII within the Region from at least two commercial firms."

The view then expressed by Dr Stewart -- that's a different Dr Stewart from the Stuart who is a director at the Queen Elizabeth:

"... explained that there would be no saving with a Regional Contract, as the amounts being purchased would not increase the discount" and talks about there being no financial gain, but then there is a suggestion that further consideration will be given to this at the next meeting.

If we then go to SHIN0000037, this is the working parties meeting from December 1979. If we go to the last page, please, we can see picking it up four paragraphs down that, by this time there is a regional contract in place. Other documentation suggests that there was a one-year regional contract for the West Midlands region that had been awarded to Armour alone, which ran from around the middle of 1979 to the middle of 1980. We'll see Professor Stuart

there raising a question of the rates for the purchase of Commercial Factor VIII. The terms were no better than if he'd purchased Factor VIII as an individual. He didn't want to participate in a further regional contract after the present two-year one expired. It doesn't appear that it was two year from other documents but it's not entirely clear.

Another regional contract then commenced, it would appear, on 1 August 1980. The reference -- but we don't need to go to it, Henry -- is SHIN0000035. Again, it's a regional contract with Armour. That appears to have been a two-year contract. The arrangements according to the various discussions in the minutes was that the commercial product would be delivered directly to the Children's Hospital in relation to Dr Hill's requirements for commercial product but other product was delivered to the transfusion centre and then called off by centres as and when required. So there appears to have been a difference in the practical arrangements for receipt of the supplies as between the Children's Hospital, where Dr Hill received what he requested directly from Armour, and the other centres in the West Midlands region including Queen Elizabeth, which appear to have called off the supplies from the regional transfusion

centre as and when they needed those supplies.

We don't have, I think, the contracts themselves, just the various references to them that we see in the minutes. We don't presently have the contracts themselves.

Those were the discussions and arrangements taking place in the second half of the 1970s, and we see there the increasing use of commercial concentrate. That emerges very starkly from the annual returns and we'll look at a handful of those returns over the second half of the 1970s and early part of the 1980s.

So if we start with the Children's Hospital annual return for 1975 that's at BWCT0000145_001, please, Henry. This is 1975. This is the Children's Hospital alone. The director is recorded as being Dr Jillian Mann. You will note there a reference to being "post vacant". I'm not sure what that's a reference to. We see the number of haemophiliac patients treated during the year, 48 plus 4 with Factor VIII antibodies and ten with Christmas disease. Then we can see from the return, if we go down to the table, the predominant usage is of cryoprecipitate, with a very small amount of NHS Factor VIII concentrate, no commercial concentrates being used in

1975, a small amount of NHS Factor IX concentrate for those with haemophilia B, and what looks like a tiny amount from the plasma fractionation laboratory in Oxford, but that last entry is not entirely clear.

That is 1975.

There are three documents that have been provided to the Inquiry by individual Core Participants that illuminate the use of cryoprecipitate at this time, both for surgery and for home treatment. We'll look at those documents, if we may.

Henry, could we please have, first of all, CWAL0000001. This is a circular letter from Dr Stuart, the director at the Queen Elizabeth Hospital, November 1975. We'll see it's a "Circular letter to all patients with a bleeding disorder who are registered at the Queen Elizabeth Hospital". He sets out the facilities at the QEH. If we go to the bottom of the page, he says that they are attempting to improve facilities along a number of lines and point 3 is:

"Provide home treatment facilities for severely affected patients who wish to have this. I have enclosed an instruction sheet which we issue to our own patients on home treatment to give you an idea of

what is required. All patients who start home treatment are, of course, given extensive training beforehand at the hospital and home treatment is not started until we are quite sure that the patient has become an expert.

"We normally restrict home treatment to those patients who suffer many bleeds per month and/or live a considerable distance from a haemophilia centre. Most patients so far on home treatment use cryoprecipitate but freeze-dried concentrate is likely to become available for a few patients who, for example, travel a great deal in the course of their work and are away from home for long intervals."

So that's the letter. The instruction sheet that he referred to is at CWAL0000002 and, if we zoom in on the first half of the page please, Henry, we can see it's headed "Notes on home treatment using cryoprecipitate", so again reflective of the fact that the practice at that time was to use cryo for home treatment. "The following items are necessary for home treatment", and then we see a list of items, "a deep freeze", so that's a domestic freezer, portable refrigeration box for transport, cryogel packs to keep the cryoprecipitate cool during transport, a thermometer -- that's for the thawing

process -- packs of cryoprecipitate, tourniquet and then home treatment pack. So a pack of what was required in terms of supplemental equipment was available from the blood bank, we don't need to look at the detail of those.

If we go to the next page please, Henry, we see then if we zoom in on the section under the heading "Procedure for infusion of cryoprecipitate", we'll see there that there are then some detailed instructions for those on home treatment who, as Dr Stuart's letter had said, would have been trained in the process. They assess the severity of bleed, decide whether you can treat it satisfactorily at home, whether you need advice from the QEH, or whether you require to come to ward E4B.

"3. Complete a home treatment record sheet.

"4. Select six donor packs of cryo ...

"5. Fill a basin with water until the temperature is 37 degrees Centigrade ..."

Hence the need for the thermometer, and then various equipment has to be selected.

If we go over the page, we go to the top part of the page, please, Henry, we can see point 7:

"When all the cryoprecipitate has melted and is free flowing (this usually requires 5 minutes at

37 degrees centigrade) ..."

So not a particularly long period of time, and then there are various practical instructions step-by-step. We don't need to go through all of it but it tells the patient exactly what to do, it identifies things that might go wrong and explains what the patient should do, and then essentially it explains that the patient will infuse the cryoprecipitate and then dispose of the equipment.

If we go to the next page, I should draw attention to paragraph -- sorry the next, please -- paragraph 15(c), which in the context of disposal of the equipment, refers to placing the needles in a brown bag and it says:

"Each brown bag should be kept in the orange-stripe 'hepatitis-risk' sack which must be kept in a safe place out of the reach of children."

There's also the practical advice of never allow children to have used syringes as a water pistol.

Then, bottom of the page:

"Telephone the Blood Bank at least 24 hours in advance ... before you call for a further supply of cryoprecipitate."

So there a really very revealing set of practical instructions which may help you, sir,

understand how, in practical terms, the patients on home treatment used cryoprecipitate for their bleeds. We heard, obviously, a lot of evidence last week about Dr Dormandy's use of cryoprecipitate at the Royal Free Hospital. It's clear from this that similar practices were in operation at the Queen Elizabeth Hospital in Birmingham in the mid-1970s.

The second document that I wanted to look at supplied by a Core Participant is JEVA0000012. This is a letter from Dr Jillian Mann, dated 19 June 1975. It's about a patient, Jonathan Evans, and you'll just see it's planning surgery but it's interesting to see how she describes how surgical cover will be provided. She says this:

"... we thought it wise to check Jonathan's blood for the presence of Factor VIII inhibitors before planning any surgical procedure, however minor. He does not have Factor VIII inhibitors, so it should be possible to carry out the procedure under cryoprecipitate cover in the usual way."

So you will see there a description of cryoprecipitate cover for surgery in the usual way. It appears, therefore, this wasn't a one-off but something that was something of a practice, and this is in the context of a patient who was a severe

haemophiliac.

If we return then to the annual returns and go to move on to the 1976 annual returns, if we could have, please, Henry, EWCT0000176. So this is the annual return for 1976 for the children's hospital. We've got the figures of patients treated that year, 46, three with inhibitors, five with Christmas disease, and we can see there, again, this is prior to the usage of commercial concentrate. The predominant treatment is with cryoprecipitate and then there is a smaller amount of NHS Factor VIII concentrate used and then, for those with Christmas disease, NHS Factor IX concentrate used.

If we then look at the Queen Elizabeth Hospital return for the same year, that's at HCDO0000028_002, please, Henry. If we go to page 8, we can see here the entry for 1976 Dr Stuart is director, 86 haemophiliac patients treated, 9 with antibodies, 7 with Christmas disease, and then if we go down the table we can see substantial amounts of cryoprecipitate used, reasonably substantial quantities of NHS Factor VIII concentrate but here at Queen Elizabeth Hospital we see that there are commercial concentrates that have been used, again in reasonably substantial quantities, in the course of

1976, Factor VIII produced by Armour and Kryobulin produced by Immuno. There is also usage of either bovine or porcine Factor VIII concentrates and then NHS Factor IX concentrate for those with Christmas disease.

SIR BRIAN LANGSTAFF: So one could sum that up by saying that, broadly speaking, the usage of NHS concentrate is equal to the use of commercial concentrate, a little bit higher, cryoprecipitate is higher than either the NHS concentrate or the commercial, viewed in isolation, but there is less cryoprecipitate used overall than there is commercial concentrate by a ratio of 5 to 4?

MS RICHARDS: That sounds about right, sir.

SIR BRIAN LANGSTAFF: Broadly.

MS RICHARDS: Around this time, 1976, we know from other documents that the home treatment numbers are given as follows: 30 patients on home treatment at Queen Elizabeth and 7 patients on home treatment at the Children's Hospital. That's as at May 1976 in one of the meeting minutes.

If we then move on to 1977 for the Children's Hospital, we have BWCT0000190, please. So by now Dr Hill is the director. Number of patients treated during the year -- haemophilic patients treated during

the year, 54, 6 with antibodies, 9 Christmas disease patients, 1 with Factor IX antibodies. Then if we look at the treatment we'll see still substantial volume of cryoprecipitate being used, apparently no NHS Factor VIII concentrate at all, and then Armour Factor VIII concentrate being used and a small amount of the Immuno Kryobulin product. Then for those with Christmas disease it's still the NHS Factor IX concentrate that's being used.

We don't, I think, have the annual return for 1977 for the Queen Elizabeth Hospital but if we go to CBLA0000940 this is a report that was prepared for a West Midlands working party meeting in 1979. If we go to page 5, please, Henry, we've got figures there for 1977, for the Queen Elizabeth Hospital. We've got the number of patients there recorded, 79 haemophilia, 6 Christmas disease, 12 von Willebrand's. Then we can see there cryoprecipitate in usage, Lister in usage and then commercial Factor VIII concentrates, the product which is used most, and then Oxford Factor IX, no doubt for the Christmas disease patients.

So that's 1977 for the Queen Elizabeth Hospital. If we then go to 1978, we start to see a different picture emerging. The Children's Hospital if we have BWCT0000189, this is the annual return completed by

Dr Hill for the year 1978, total number of haemophiliac patients treated during the year, 62, 4 with antibodies, 6 Christmas disease patients, one with Factor IX antibodies. Then if we look down, we'll see it would appear that cryoprecipitate is still in use, a number has been crossed out and the number of bottles used looks like 4,541. There is usage in this year of NHS Factor Concentrate. There is then substantial usage, comparatively speaking, of commercial concentrate and it's solely the Armour concentrate which may, no doubt, reflect the fact that, as we've seen, there was by this time, or around this time, a contemplation of a regional contract with Armour as the sole commercial supplier. So we see there the volume of Factor VIII units for that year 287,198 Armour Factor VIII units and then again the normal picture in relation to Factor IX, the use of NHS Factor IX concentrate and not commercial.

If we go back to CBLA0000940, please, Henry, this is the document we looked at a few moments ago and we go to the sixth page, we need to pick the picture for 1978 in relation to QEH from this document. So these are the statistics for 1978 and the Queen Elizabeth Hospital we see across the top line of the table, cryoprecipitate still in use,

Lister NHS concentrate in use but, again, the largest product used is the commercial concentrate, and then Oxford Factor IX concentrate for those with haemophilia B.

SIR BRIAN LANGSTAFF: Could you just go back for a moment. Just remove the flash across the page if you can, Henry. Thank you.

On the children's, it's now talking in units; so can we go back to the slide before, which is 0000189, BWCT.

MS RICHARDS: BWCT0000189.

SIR BRIAN LANGSTAFF: Because, unhelpfully, the number of bottles of cryoprecipitate, or it would have been bags presumably, has not been translated there into units.

MS RICHARDS: It hasn't, no.

SIR BRIAN LANGSTAFF: 317,870 if the second one's about right.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So it gives the impression here, for the first year, there have been more units of commercial concentrate used than cryoprecipitate for treating children at the Children's Hospital.

MS RICHARDS: Yes.

If, in fact, we go back to -- sorry, Henry -- CBLA0000940, page 6, if we look at the

Children's Hospital, the unit figures there are, as you said, sir, 317,870 for cryoprecipitate. The unit figure for commercial Factor VIII is less than that but the figure, if one adds together the Lister and commercial overall, shows that concentrates are being used significantly in excess of cryoprecipitate by that time.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: If we just go to SHIN0000036, please, Henry.

We're now at 1980, and these are minutes of the working party meeting on 19 May 1980. If we go to the bottom of page 2, please, this is describing the situation in the West Midlands region rather than simply looking at either the Children's Hospital in Birmingham or the Queen Elizabeth Hospital, but we'll see what's said there is the use of Factor VIII had been constant during the past four years.

"The use of commercial concentrate had increased from 21 per cent to 53 per cent during the same four-year period, and by a factor of 50 per cent between 1978-79. The use of cryoprecipitate had decreased ..."

And, you will see there, very substantially, sir: from just over 2 million units in 1976 to 443,400 units in 1979.

"... and this indicated that there had been a move from using cryoprecipitate to using Commercial Factor VIII which involved an increased cost to the Region."

Then the observation is made:

"This seemed to be an apparent change of policy to purchase commercial Factor VIII and was costing in excess of £100,000 per year, yet no positive decision to change to commercial supplies had actually been made."

If we go to the top of the next page, we'll see that:

"Dr O'Shea ..."

Who was, I think, the director at Shrewsbury.

"... said that he wished to continue to use cryoprecipitate ... but he had been unable to obtain the requested amounts ... from the BTS" and he asked if that could be increased.

Then Dr Bird is recorded as saying it wasn't possible to manufacture more cryo at the BTS because the plasma was needed to send to BPL. Then this, in the last sentence of that paragraph:

"The other members agreed that reversion to using cryoprecipitate would be a retrograde step but the financial implications were recognised."

It's not said there why it was regarded as a retrograde step.

SIR BRIAN LANGSTAFF: It may be the previous sentence.

MS RICHARDS: It may be, yes. Certainly the inconvenience maybe; that's been referred to by other witnesses.

SIR BRIAN LANGSTAFF: And the comparative lack of reactions.

MS RICHARDS: And there's reference then to there having been no official policy statement on the production of cryoprecipitate, but an encouragement to continue to send supplies of plasma to BPL for the manufacture of NHS Factor VIII.

So the plasma is being used essentially to manufacture the NHS plasma VIII as a priority over the manufacture of cryoprecipitate, appears to be the picture.

If we then look at the 1981 return for the Children's Hospital.

SIR BRIAN LANGSTAFF: It would follow, presumably, that the cryoprecipitate which was made was made locally.

MS RICHARDS: Yes. Yes, absolutely, from the local regional transfusion centre.

If we go then to the 1981 return for the Children's Hospital, which is BWCT0000137, please, Henry.

This is the page in relation to haemophilia A patients, haemophilia A carriers and von Willebrand's disease patients. We can see 55 haemophilia A patients, one carrier, 10 von Willebrand's disease patients treated during the year.

Then we can see in the table, cryoprecipitate still in usage. The volume now used in hospital recorded as being 159,900 units, but nothing used for home treatment for 1981.

There's NHS Factor VIII concentrate, but by far and away the main treatment now used at the Children's Hospital by 1981, as you'll see, is the Armour Factor VIII concentrate. Hospital usage is 751,139 units. Home treatment usage is 413,680 units.

So by 1981 it's very clear from the returns that the move to commercial products has effectively taken place and that the sole commercial product being used, at least at the Children's Hospital at that time, is the Armour product.

For the sake of completeness we have also within this the return in relation to patients with haemophilia B. That continues to show the sole treatment being with NHS Factor IX concentrate.

Then if we just complete the picture with 1982, '83 and '84, just so that we can see how the usage

continued, if we go please, Henry, to BWCT0000141.

This is 1982 at the Children's Hospital. Again, we've got the numbers of patients treated at the top. We can see a modest amount of cryoprecipitate used, some NHS factor concentrate used: 31,000-odd, hospital; 191,000 for home treatment. But the bulk of the treatment again is with the Armour product Factor VIII: 752,512 units for hospital treatment, 465,082 units for home treatment.

So the pattern established at least by 1981 continues.

If we then look at 1983, BWCT0000140, please.

We can see, again, in the course of 1983, some usage of cryoprecipitate in hospital only, some use of NHS Factor VIII concentrate both in hospital and for home treatment, but the bulk of the treatment, again, is with the Armour Factor VIII concentrate, both for hospital and home treatment, and the NHS Factor IX concentrate remains the sole treatment for those with haemophilia B.

That's 1983.

Then finally, for present purposes, 1984.

BWCT0000142 please, Henry.

This first page shows us treatment with Factor IX. If we go to the second page, please, this

is 1984 usage by Dr Hill in relation to haemophilia A patients, carriers and von Willebrand's disease, we can see again there's a relatively small amount of cryoprecipitate used, including a small amount of home treatment, 13,000-odd units, some NHS factor concentrate used both in hospital and at home, but throughout 1984 the vast majority of the treatment is with Armour Factor VIII. You see there the figure, sir: at hospital, 843,729 units; home treatment, 825,537 units.

SIR BRIAN LANGSTAFF: If you look at those last three years and look at the relative proportions of commercial concentrate compared to NHS concentrate, it presents a picture where, in 1981 -- or, 1982, rather, it's roughly 25 times as much commercial as NHS, 1983 is about 15 times as much, and here it's about 8 times as much.

So it's a reducing proportion of the commercial compared to the NHS for some reason. It's tempting to think it might have been influenced by events elsewhere.

MS RICHARDS: I can only say, sir, there's no evidence in any minutes that there is a change of policy in response to, for example, the risk of AIDS and, of course, throughout 1983 and 1984, which are key years

when one is considering the state of knowledge about the risk of AIDS from blood products, by far and away the main treatment continues to be with commercial concentrates from Armour. Of course, the second feature through those years is that there is only one commercial supplier providing concentrates to the Children's Hospital.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Which may reflect the regional contract but is nonetheless a noticeable fact.

Just one other document I should look at from 1984. It's at IPSN000036_012, please, Henry. IPSN -- sorry -- 0000036_012.

This is a document we've looked at in relation to other centres. It's an internal I think Speywood report about approaches to the treatment of inhibitor patients in the UK, looking at it particularly as to what their attitude -- clinician's attitude is towards the use of Hyate:C, which was the porcine product.

If we go to page 8, please, Henry, we will just see what's said about Dr Hill's approach under the heading "Current attitudes towards Hyate:C":

"Dr Hill has responsibility for the patients at both the Children's Hospital and the Queen Elizabeth Hospital and has about 12 inhibitor patients at the

former and 8 at the latter. This means that Birmingham have more patients than most of the reference centres ... Dr Hill treats all the patients with human Factor VIII in a similar way to Oxford. If that fails he uses [Factor IX] or FEIBA, but would use porcine [Factor VIII] if the cross-reactivity were favourable. He has FEIBA available in the pharmacy on a 'sale or return' basis and says he would be more inclined to use Hyate:C if that were similarly available."

Then this observation:

"He is extremely cost-conscious and would not use Hyate:C unless he thought there was a definite financial advantage in doing so."

So that's an observation from one of the pharmaceutical companies with whom he had dealings from time to time.

Sir, just perhaps to pick matters up in 1985, we know from documents that we'll look at with Professor Franklin this afternoon that in December 1984, following the Reference Centre Directors' meeting at BPL and the production of the UKHCDO AIDS advisory document, there was then a regional West Midlands meeting which looked at the move to heat-treated concentrates and, as I say,

I will explore that with Professor Franklin in the course of his evidence. But if we just pick up matters up in 1985 at SHIN0000024, we'll see that in the course of 1985 the move is made regionally to heat-treated products. If we go to the bottom half of the page, Dr Ala (who was by this time the director of the Regional Transfusion Centre, I think) informed the committee that supplies of heat-treated Armour Factor VIII was steady and there was no cause for concern.

Pausing there, sir, you will see that the region appears to have remained with Armour as its supplier following the switch to heat-treated product. There's then a reference to NHS supplies and it's said that:

"The majority of the supplies were being used for children and patients at the Queen Elizabeth Centre. A new NHS Factor VIII wet-heated preparation was awaited."

Then if we go to the bottom of that page -- sorry, Henry -- last few lines, it will see that what is contemplated is that when there is more NHS Factor VIII, i.e. heated NHS Factor VIII, treatment policy should perhaps be changed so that children and young adults should take precedence. Then at the top of the next page we can see the position in relation

to Factor IX: the use of unheated Factor IX was continuing.

That takes one up to 1989. We don't have, in fact the -- sorry, 1985. We don't have the annual returns for 1985 but a later working party discussion in 1987 records Professor Hill saying there was a fall in the use of Factor VIII in 1985 and a number of operations had been postponed, and then a catch-up in the course of 1986.

We do have the returns for the Queen Elizabeth Hospital for 1986 but, again, I can pick that up with Professor Franklin. If we get to then 1988 just to complete, as it were, what the returns show us, BWCT0000143, sir, this is Dr Hill's return for the Children's Hospital in 1988. We can see there no longer usage of cryoprecipitate; various Factor VIII product concentrates used (no doubt all heat-treated) including NHS product; no longer Armour in 1988, it's Alpha's Profilate and Cutter's Koate being used. Then you will see at the bottom reference to "other materials", DDAVP.

That is, I think, the first reference in the returns that we have detected to DDAVP but we don't have all the returns, I should say, but from those that we have that appears to be the first reference to

DDAVP.

I am proposing to turn next to what the documents tell us about Professor Hill's knowledge of the risks of hepatitis and HIV. I note the time. Could I perhaps do that after the break?

SIR BRIAN LANGSTAFF: Yes. Let's take a break now, our usual morning break, for three-quarters of an hour, and come back at 11.50, if you please.

(11.05 am)

(A short break)

(11.51 am)

MS RICHARDS: Sir, I turn to consider what the documents tell us about Professor Hill's knowledge of and response to the risks of hepatitis and HIV.

In the statement that Professor Hill made to the Inquiry in response to an individual patient's statement, he said this about non-A, non-B hepatitis:

"At the time that I was seeing the patient, late 1970s, non-A, non-B hepatitis was thought to be a minor self-limiting condition with no serious long-term consequences. Unfortunately, this did not turn out to be the case later on."

So that's what Professor Hill says. Obviously, sir, we've looked at a wide range of materials from the 1970s and 1980s, and indeed earlier, in relation

to that.

If we look then at the contemporaneous documents, if we could have first of all, Henry, SHIN0000043, please.

These are the minutes of a meeting of the West Midlands working party, attended by Dr Hill and, indeed, Dr Stuart from the Queen Elizabeth Hospital.

If we go to the second page, we'll see, just over halfway down the page, a paragraph beginning "Dr Hill referred":

"Dr Hill referred to the hepatitis risk in respect of freeze-dried Factor VIII concentrate obtained from commercial sources, and with this in mind he asked whether it might not be advantageous to reserve the supplies of concentrate obtained from the Lister Institute for children, leaving the concentrate obtained from commercial sources, largely of foreign origin, for adults. Dr Stuart agreed with Dr Hill as to the hepatitis risk and said that in case of doubt he would prefer to use cryoprecipitate for children rather than commercially obtained freeze-dried Factor VIII concentrate."

Sir, bearing in mind, of course, that all of Professor Hill's patients were children, at the Children's Hospital. The evidence that we have from

returns and from the working party minutes does not suggest that what is outlined here was implemented, rather we see, as we've seen from the returns, an ever-increasing use of commercial material and a decreasing use of cryoprecipitate.

We know that Professor Hill, as a member of UKHCDO, attended a number of UKHCDO meetings. If we pick the picture up in November of 1979 -- Henry, could we have PRSE0000150 -- we can see these are minutes of a meeting on 20 and 21 November 1979, and Dr Hill's name appears as attending both days on that page. Professor Stuart from the Queen Elizabeth Hospital also attended.

Henry, if we could go on, please, to page 18 -- I think the paper numbers are out of order. Can you go to the preceding page. Thank you.

So we can see that there was reported at that meeting the report of the Hepatitis Working Party by Dr Craske. Picking it up about two thirds of the way down that paragraph:

"The Working Party felt that it was important for the incidence of chronic hepatitis in haemophilic patients to be assessed. There was much discussion regarding the incidence of chronic hepatitis in haemophilic patients, the possible value of liver

biopsies and the type of information which Directors would be willing to give to the Working Party."

There was discussion about the completion of a form in which directors would submit information to Dr Craske in relation to signs of chronic hepatitis.

If we go to the bottom of the page, there's discussion about the relevance of age, and then:

"Dr Craske commented that most patients thought to have developed chronic liver disease had not previously had an overt attack of hepatitis."

A recognition there of the potential risk of chronic liver disease.

"There were various possible causes of hepatitis ..."

Henry, can we then skip on three pages, please, because the document pages are out of order. Thank you:

"... and one should keep an open mind [to] it."

Then Dr Craske is reported as going on to say there were two types of non-A, non-B hepatitis, and the agreement is that there be a new form for directors to report cases of chronic hepatitis.

The actual --

SIR BRIAN LANGSTAFF: The inference there that when he talks about hepatitis, he is talking about --

probably -- non-A, non-B?

MS RICHARDS: Yes. Yes, there are a number of discrete discussions about hepatitis B. They are normally, in UKHCDO materials, by this time referred to -- it's referred to as hepatitis B. That's not invariably the case but that is generally the position.

We can see the actual report that was being discussed at this meeting in November 1979 attended by Professor Hill at HCDO0000135_023.

You will see there it is the "Report of the Haemophilia Centre Directors' Working Party 1979". If we go on to the second page, there's a discussion, "Hepatitis surveillance - (Non-A, Non-B ...)", and reference to there being an increase in the proportion of cases of non-A, non-B hepatitis reported in patients with mild coagulation defects receiving concentrate for the first time to cover operations. Then there is reference there to certain data in that respect.

If we go over to page 5, please, Henry, you will see the heading "Mortality":

"No further fatalities directly due to acute hepatitis have been reported. One patient had acute [non-A, non-B hepatitis] followed by persistent raised enzyme levels in 1978."

That patient is recorded as having:

"... died of a ... haemorrhage ... possible that his hepatitis indirectly contributed to his death.

"A further patient at Oxford who died of causes unrelated to liver disease was found on post-mortem to have portal cirrhosis."

That person was hepatitis B negative.

The working party on hepatitis report their interest in further cases to collect further evidence of the prevalence of chronic liver disease. The preliminary results of the patients at Oxford so far studied for evidence of chronic liver disease are given in appendix 1. You will see there there's a summary:

"70 out of 174 patients ... had persistent transaminitis but only 20 per cent [sic]" --

SIR BRIAN LANGSTAFF: No, 20.

MS RICHARDS: "... only 20 of these so far ..."

So 20 out of 174, perhaps not an insignificant number.

"... have been found to have clinical evidence suggestive of chronic liver disease."

So that's part and parcel of the material that Dr Hill -- Professor Hill -- would have received, and was discussed at the annual UKHCDO meeting.

Professor Hill reported that back to the West Midlands region on 3 December.

If we could have SHIN0000037, please, Henry.

This is 3 December 1979. If we go to page 3, bottom half of the page:

"[Professor] Hill said that at the Oxford meeting referred to in Minute 79/15 above, the Hepatitis Working Party had reported that Commercial Factor VIII carried the risk of hepatitis, and he was concerned that some children at the Children's Hospital had become hepatitis carriers."

Then there's a reference to hepatitis B:

"Members echoed Dr Hill's concern regarding the risk of hepatitis B."

So it's unclear from what's reported by Dr Hill whether he is referring to just B, non-A non-B, or both.

"And Dr Stewart undertook to discuss the whole question of the availability of cryoprecipitate and Factor VIII with the Regional Medical Officer."

In between those two dates, so Professor Hill's attendance at the UKHCDO meeting and his reporting back to the West Midlands meeting, there's an interesting insight into Professor Hill's clinical practices from an individual witness. If we could

have up, please, Henry, WITN1103010, please. Thank you.

You will see this is an extract from a patient's treatment record. This is a patient with mild haemophilia. You'll see the date of birth is 1979. We've obviously concealed the precise date of birth. But this was the treatment of a baby with mild haemophilia.

If we look down to the bottom of the page, you will see there a number of dates from 28 November 1979 through to 2 December 1979, treatment given: Factor VIII. So that's commercial Factor VIII material given to a baby with mild haemophilia to cover surgery at the end of November and beginning of December 1979.

If we go to WITN1103011, please, this is a document relating to the same patient. If we zoom in on the bottom half of the page, please, Henry, you'll see there the first entry there:

"Relatives at Glasgow with mild haemophilia ..."

Is referred to. It's said in the second line:

"... likely he has mild haemophilia."

In fact, this particular patient, it turned out, the patient had been misdiagnosed and did not have mild haemophilia:

"Patients [sic] told diagnosis. He will need twice daily cover with Cryoprecipitate for at least 7 days to cover the operation."

Then you will see the words "or Factor VIII concentrates" have been added above "Cryoprecipitate".

Then if we look at the next entry, the 28th:

"Operation arranged ...

"Dr Hill has organised for Factor VIII infusion ..."

SIR BRIAN LANGSTAFF: So it would be open to the inference that cryoprecipitate was perfectly acceptable as cover?

MS RICHARDS: Yes, and for reasons that we do not know, Factor VIII concentrates were used instead, commercial Factor VIII concentrates, in this very young baby with mild haemophilia.

SIR BRIAN LANGSTAFF: Who didn't actually have it, but they didn't know that at the time?

MS RICHARDS: No. Who did contract hepatitis C, probably as a result of this infusion.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: You'll see how that -- you'll see the coincidence of timing, if I can put it that way, in terms of that treatment following on from the

discussions at the UKHCDO meeting.

There were, unsurprisingly, further discussions at the following year's meeting of UKHCDO, in September of 1980. I won't go to those documents but there was the routine update for the Hepatitis Working Party which Professor Hill also fed back to the regional working party in December of 1980.

If we could then go please, Henry, to BAYP0000019_024, please.

This is an internal Cutter document 27 February 1981. It's a discussion or a report of a visit made by the Cutter sales representative to Birmingham Children's Hospital on 9 February. It says:

"Most of the West Midlands Regional Health Authority have been firm Armour accounts for about four years. Dr Hill's attitude was therefore one of friendly hostility."

There's then a discussion about usage. Then if we go down we can see:

"Choice of product. Dictated by three parameters: price ..."

There's a reference to the Regional Health Authority being contracted to Armour until October 1981. Then this:

"Hepatitis risk. He [Professor Hill] stated that some commercial products have a higher rate of infectivity than others. I questioned this closely -- no names were given -- the inference was that Armour's product is the cleanest. Supposedly info from UK directors. I have no evidence of this at all (and frankly don't believe it!)

"We discussed the general concern of altered liver architecture in haemophiliacs and the possibility that some of this could be caused by the high protein levels of some Factor VIII preparations. He thought that the Armour high potency product was a step in the right direction."

Then you will just see the third factor that fed into choice of product was packaging and the availability of particular home treatment packs. I draw attention to it for the purposes of the discussion in relation to hepatitis and the risk of hepatitis from commercial concentrates.

If we then go, please, to SHIN0000034, this is the West Midlands Working Party meeting that followed on a few months after the interaction with Cutter that we have looked at and if we go to the bottom of page 2, please, there's no reference to hepatitis at all. What we do see is the reasoning for the award of

the regional contract. So:

"Mr Edwards [who's from the regional supplies department] laid on the table details of tenders received for the Regional Contract for the supply of Commercial Factor VIII ... tenders invited from 6 firms and 5 had replied ...

"Members considered the information before them and recommended that the contract made by Armour should be accepted. It was agreed that the home treatment pack supplied by Armour was superior to that of Cutter ... It was also felt that there were advantages in remaining with the existing supplier and thus avoiding the complexities of change over."

Then there was a discussion about the period of the contract and a suggestion that a period of one year was appropriate. So no discussion there of any issue about relative risks of infectivity informing the decision as to which firm's tender to accept.

We then, in terms of documents that refer to hepatitis discussions, move on to January 1983. This is the meeting at a London airport hotel with Immuno we've looked at on a number of occasions. I'll come back to it in a moment when we look at AIDS but Professor Hill was one of the attendees at that meeting and we know that there was a prolonged

discussion about this possibility of hepatitis-reduced factor commercial concentrates.

If we then look at SHIN0000030, this is a meeting in June 1983, again attended by Dr Hill and Professor Stuart from the Queen Elizabeth. If we go to the second page, under the heading "Regional Contract", there's a further discussion about the tendering process:

"It was agreed Mr Stanton should invite tenders on the basis of £3.5 million worth of units of commercial Factor VIII. Dr Shinton, Dr Hill and Mr Stanton would meet to adjudicate when the tenders had been received."

So Dr Hill had a decision-making role in relation to which tender to accept. Unfortunately there are no minutes of those discussions:

"It was agreed that the following points should be taken into consideration at the adjudication meeting:

"The amount of effort involved in changing supplier.

"Where firms have their donor facilities in the US.

"Any public pressure for a change of products (eg to heat-treated Factor VIII) should be resisted

until another product have been proved to be more satisfactory."

So those are said to be the criteria or some of the criteria for considering which tender to award. I draw attention to (2) "Where firms have their donor facilities in the US". The relevance of that is not explained but an inference at least would be because of the concerns about paid commercial donors and the risk of hepatitis and/or transmission of AIDS.

Just to complete that picture, if we then look at the following working party meeting, that's SHIN0000029 please, Henry, December 1983 if we look towards the bottom half of that page under the heading "Regional Contract", it just says:

"Dr Ala informed the committee that the lowest tender was forwarded by the present supplier -- Armour, and no change was envisaged."

So there's no apparent consideration to that issue about location of donor facilities or any other factors going to infection risk. Price appears to be the key factor there.

That's the material such as it is in relation to how the risk of hepatitis was or was not being considered at the Birmingham Children's Hospital in the second half of the 1970s/beginning of the 1980s.

Turn to consider the position in relation to AIDS. We will just go briefly to that January 1983 meeting with Immuno at the London airport hotel, PRSE0002647. If we go to the last page please, Henry, we can see from the list of attendees that Dr Hill was there is. Sir, whilst we've obviously looked at this document on a number of occasions there maybe those who have a particular interest in the children Birmingham Children's Hospital who have not heard the evidence in relation to this document, so I think it is important to show, first of all, Dr Hill was there. Then if we go to the previous page please, Henry, the bottom half of the page under the heading "Acquired Immunodeficiency Syndrome", we can see that in this January 1983 meeting there was a detailed update given, and possibly by Dr Craske, about the position in relation to the developing knowledge of AIDS, but reference is made to:

"Up to 10 December ... some 800 people had been reported as suffering from AIDS ... 45 per cent mortality."

Then up-to-date figures given in relation to the haemophiliacs in the States affected -- 10 affected, five died, youngest 7 -- and to the cases of blood transfusion or platelets transfusion, including the

San Francisco baby case.

So that would all have come to Professor Hill's attention on 24 January, if it wasn't already known to him. If we just continue over the page, we see then the discussion continuing in relation to the incubation period appearing to be six months to two years, and then the meeting's attention being expressly drawn to the New England Journal of Medicine Articles on 13 January. So, again, if Professor Hill had not read those articles on 13 January in the New England Journal of Medicine, he would have learnt about them within the space of a couple of weeks through this meeting.

We know that in June of 1983 Professor Bloom and Dr Rizza on behalf of UKHCDO --

SIR BRIAN LANGSTAFF: Just before you leave that, the very last paragraph beginning "Final comments", this is looking to see what the infectious agent might be, assuming there is one, and it might be not just one but a mixture and the supposition there is that that might include non-A, non-B.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So if that is so, then non-A, non-B would give rise not only to a risk of hepatitis but also to a risk of giving rise to, in due course, the

AIDS syndrome.

MS RICHARDS: Yes, and obviously whilst we know that not to be the case, that was being advanced as one possible matter to be considered.

SIR BRIAN LANGSTAFF: So it is regarded as a risk?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: We have not seen any document to show any change of approach on the part of Professor Hill in terms of treatment of his child patients in the months that followed. If we go to HCDO0000270_004, please, this is the letter that we have seen before, June 1983, sent out by Professor Bloom and Dr Rizza. I think in our presentation we say this would have been received by Professor Hill and Professor Franklin in fact Professor Stuart was still the Queen Elizabeth Hospital director, I think, at this point.

But, in any event, it would have been received by Professor Hill. This made the treatment recommendations that we see, if we just go down to the paragraphs numbered 1 and 2. So the suggestion that DDAVP should be considered for mildly affected patients with haemophilia A or von Willebrand's and minor lesions and reference there made to the increased risk of transmitting hepatitis by means of

large pool concentrates in such patients. Then point 2, the idea that it would be circumspect to continue a policy for the treatment of children and mildly affected patients or previously unexposed patients with NHS concentrates cryo or freeze-dried.

That wasn't, of course, as far as we can tell by this stage, the policy at Birmingham Children's Hospital. Most children were receiving commercial concentrates, although some received NHS or cryoprecipitate. So we don't know whether this led to any change of approach on the part of Professor Hill, these recommendations, such as they were. We've seen no positive evidence of any change of approach in the second half of 1983 following receipt of this letter.

SIR BRIAN LANGSTAFF: In terms of what it says, it says continue doing what you are doing.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: It doesn't say change it.

MS RICHARDS: No. So perhaps not surprising that the evidence doesn't establish a change of approach.

There is some discussion at around this time in the West Midlands working party of the risks of AIDS and if we could go then to SHIN0000030, this is 27 June 1983, West Midlands Working Party meeting. We looked at it a few moments ago for a different

purpose. So it's three days after that letter. If we turn on to the second page and go this time to the bottom half of the page, the penultimate paragraph says:

"Dr Shinton referred to a letter he had received from Dr Ala, who made the point that cryoprecipitate was probably a safer product than Factor VIII concentrate in respect of transmission of Acquired Immune Deficiency Syndrome (AIDS)."

Then Dr Ala asks the working party to advise on the purchase of heat treated Factor VIII. So no suggestion there that the cause of AIDS is something other than, for haemophiliacs at least, use of blood products. If we go to the next paragraph please, Henry, we can see:

"After a lengthy discussion, it was agreed that more information was required before a decision could be made."

So apparently no positive decision made for any change of approach. It's agreed instead two papers should be produced during the next year, so not even quickly. Top of the next page, the two papers are to be:

"A discussion paper indicating the type of product that would be delivered to each hospital and

the change in treatment policy that this would involve."

And:

"An economic appraisal of this development stating the amount of Factor VIII that would be saved per annum [et cetera, et cetera]. Would there be a substantial benefit to patients or considerable savings?"

We don't have, at least not at the moment, these discussion papers. We don't know if, I think, with any confidence, whether they were produced or not but that's the response to Dr Ala's observation that cryoprecipitate would be safer.

If we go over the page, the other reference to AIDS in this meeting is -- so next page, apologies, Henry -- top of the page under the heading "AIDS":

"Dr Shinton reported that the Regional Blood Transfusion Service was issuing a pamphlet to all donors in the hope they would voluntarily withdraw if they were likely to have AIDS."

Then there's a reference to interviewing as a way of screening donors:

"It was agreed that the situation should be reviewed constantly and treatment revised accordingly."

There's no documentary evidence of any kind of constant review or revision of treatment policies.

Also, around this time, TREL0000335_020, please, Henry, this is a letter that Dr Hill dated 29 June 1983 from Treloar College from Dr Wassef at Treloar. We can see it is about a particular patient, bottom of the page:

"AIDS Related Investigations:

"Clinically he exhibits some of the stigmata of AIDS."

Those are then described. Then we go over the page:

"For your information, we have undertaken the enclosed AIDS-related tests. We are repeating these before the end of term and will let you have the results when they are available."

So, again, we've seen from earlier presentations the invitation sent out by UKHCDO in March 1983 to directors to monitor their patients for signs of AIDS and report back to UKHCDO. We can see here evidence of that being undertaken at Treloar and the results of that being fed back to Professor Hill. We don't know what, if any, observations Professor Hill was undertaking in that regard at the Birmingham Children's Hospital in relation to the patients who

remained full time under his care.

SIR BRIAN LANGSTAFF: So it would follow that whatever was thought at the time of the risk that blood products might transmit the cause of AIDS, they were actually taking significant measures involving a fair bit of time and clinical investigation to discover if any person taking blood products had actually got any signs?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Yes. So it appears they were taking at least the risk very seriously to that extent.

MS RICHARDS: Yes. In terms of examination of patients, the translation of that into any action in terms of changes of treatment policies is what one looks for but doesn't find.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: In relation to the Birmingham Children's Hospital, at least.

We know that Professor Hill attended the October 1983 UKHCDO annual meeting. I won't go to that but you'll recall, sir, that's the meeting at which Dr Chisholm raises the possibility of returning to the use of cryoprecipitate and Professor Bloom says there's no proof that commercial concentrates were the cause of AIDS.

If we then move on to the next West Midlands working party meeting, that's at SHIN0000029, this is December 1983, 5 December 1983. We've already looked at it in terms of the tender award. If we go over to the second page, this is the extent of the discussion in relation to AIDS:

"Dr Ala informed the committee that a blood transfusion handout was now available at donor sessions. It was agreed that if any case of AIDS was suspected, then the Regional Public Relations Office should be informed in case their help was required."

That is the only minuted reference to the risk of AIDS or any action in relation to it in this meeting in December 1983: contact the public relations office if required.

If we move to March of 1984, sir, if we could have, please, Henry BSHA0000119 we know that Professor Hill attended and presented a paper at the conference of the British Society for Haematology and Netherlands Society of Haematology joint meeting in late Marchof 1984, held in Exeter.

If we go to page 6, I think, Henry, we can see that there was a session on haemophilia chaired by Professor Bloom. We can see reference, if we go down the page, to there being a page presented by

Dr Kernoff and Professor Lee about the high risk of non-A, non-B hepatitis. We know, obviously, that translated into a paper that we heard about from Professor Lee last week.

Then there's reference to "Immune Function in Haemophiliacs", a paper presented by a number of representatives, including Professor Ludlam. Then we'll see two papers presented by Dr Hill, Professor Hill, one, referred to at the bottom of the page, about von Willebrand's, and, top of the next page, this was a paper about "Altered T-Cell Lymphocyte Populations in Haemophiliac Boys", co-presented by Professor Hill. If we go on, please, to -- I think it's page 37, Henry. Yes.

So here's a summary of the paper presented by Professor Ludlam and others, and the second paragraph tells us that:

"Haemophiliacs are at risk of developing the acquired immunodeficiency syndrome possibly due to contamination of commercial Factor VIII concentrates by a causative virus."

Then if we go on two pages, please, we see a summary of the paper presented by Professor Hill and others relating to observations of haematological and immunological abnormalities, particularly in relation

to the T4:T8 ratios associated with high usage of Factor VIII products.

Still in March 1984, Professor Hill would no doubt, as a director, have received a further document from UKHCDO -- we don't need to go to it, we've looked at it a number of times -- which was concerned with hepatitis-reduced Factor VIII trials, clinical trials, but said in terms:

"All products except those derived from NHS Factor VIII are made from plasma imported from the USA and therefore they carry a putative risk of transmission of AIDS."

We then come to the working party meeting, the West Midlands working party meeting, 14 May 1984. That's SHIN0000028.

This is May 1984. If we look halfway down the page, under the heading "AIDS", Dr Ala refers to, when an appropriate screening test for HTLV was available, it would be essential for this to be introduced for blood donors.

Then bottom of the page refers to "Annual Statistics" compiled by Dr Hill:

"They showed an increase in usage of BPL Factor VIII supply with an appropriate decrease in Commercial Factor VIII purchase."

That is I think a regional -- it looks like those would be regional statistics rather than just the Children's Hospital, but we don't have the appendix to the meeting.

Then over the next page we can see there's a discussion of the likely shortfall of 3.5 million units -- this is in terms of factor concentrate -- to be made up from commercial sources. Then there's going to be consideration of tenders and an adjudication by Dr Franklin, Dr Ibbotson and others, and I can no doubt ask Professor Franklin about that this afternoon or tomorrow.

We then get to December of 1984, and we see an emergency general meeting being held by -- or, an extraordinary general meeting being held by the West Midlands working party on 17 December 1984, and that is SHIN0000026_002.

It's not that. It's SHIN0000026_002. Thank you.

So it's the West Midlands working party again, an extraordinary meeting held on 17 December -- this is 1984 -- to discuss the implication of AIDS on the provision of concentrate for the treatment of the haemophiliacs.

So this would appear to be the first detailed

discussion that the working party has held on the implications of AIDS for treatment, and it follows that meeting of Reference Centre Directors on 10 December and the production by reference centres of their AIDS advisory document, although the latter may not have reached the working party by then.

We can see it refers to:

"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. Dr Hill informed the committee that following an outbreak of TB at the Children's Hospital, the incidence in haemophiliacs was similar to that in immunocompromised leukemic children."

There's a discussion in relation to that, and:

"A research product is now underway at the Children's to investigate immune states (T4 T8 sub-sets) antibodies to HTLV-III and other findings associated with the AIDS syndrome. The committee agreed with Dr Hill that seroconversion to HTLV-III antibody positivity was linked with Factor VIII concentrate which was more likely to be imported rather than NHS.

"The committee accepted that the use of Factor VIII concentrate was associated with the risk

of transfusing the AIDS virus."

Then if we go down a few lines:

"Dr Hill informed the committee that the statistics regarding the incidence of AIDS in HTLV-III positive patients had risen to 1 in 50. It was considered imperative that heat-treated Factor VIII should ... be made available to haemophiliacs as a matter of urgency. Unfortunately, the Chairman [that was Professor Shinton] informed the committee that this was unlikely to occur with NHS Factor VIII until 1 April, 1985, but that Armour heat-treated material would be available in January 1985. Following discussion, a treatment policy to cover the interim period was agreed upon ..."

Here we finally reach a change of treatment policy:

"1. Mildly affected patients - Haemophilia A, and von Willebrand's ... to be treated with DDAVP or cryoprecipitate.

"2. Newly diagnosed severe haemophiliacs to be managed wholly on cryoprecipitate."

So no suggestion that that was impossible to achieve, either clinically in terms of efficacy or in terms of supply:

"3. a) Patients with no previous exposure to

commercial Factor VIII should continue on NHS Factor VIII."

Over the page:

"b) Patients with previous exposure to commercial Factor VIII should continue on NHS Factor VIII if available and heat-treated commercial Factor VIII when not.

"It was stressed that full discussion should take place with the recipients regarding use of therapeutic material, as the availability and speed of HTLV-III screening precluded its use for treatment guidance."

Then there's discussion about the financial implications and then, under the heading "General Advice":

"This was left to the discretion of the individual centre directors. The views of the meeting were that all haemophiliacs and parents of children affected, should be appraised of the action being taken locally. It was stressed that spouses of haemophiliacs should cease to be blood donors and that sexual activity should be regularised and a sheath used.

"Medical staff - that haemophiliacs should be treated as a high risk group from the point of view of

transmission of AIDS. Management as for Hepatitis B positive would be acceptable."

So that's the discussion that then took place in December of 1984, and obviously one issue for you, sir, will be whether those kind of discussions could or should have taken place earlier, and whether there should have been any changes in treatment, practice or approach at an earlier stage.

If we then just go to SHIN0000026_001, Henry. We can see this is the letter as sent to Professor Shinton, but it was sent to all members of the West Midlands working party, 19 December. It refers to the extraordinary meeting. Then says:

"Armour have agreed to heat all material which is returned to them at a cost of 4p per unit. I would be grateful if you could send any material back to the Regional Blood Transfusion Centre."

Sir, there are then further meetings in 1985 of the working party. I will just give the dates rather than go to the documents. On 15 February 1985 the West Midlands working party met again. On this occasion they noted that their interim guidance drawn up in the minutes we've just looked at was at odds, in some respects, with the UKHCDO's AIDS advisory document, and so there was an adjustment of treatment

strategy to reflect the UKHCDO's AIDS advisory document.

There was a further revision of the treatment guidelines on 29 July 1985 following Professor Bloom's letter to the BMJ about the safety of unheated cryoprecipitate.

In the meantime, it would appear that efforts were made to obtain heat-treated Factor VIII supplies for patients at the Children's Hospital, and we can see two letters, CBLA0002092. This was from Dr Hill to Dr Snape, 18 March 1985. He says:

"I am anxious to receive sufficient Factor VIII concentrate of the heated type for the following patients with severe haemophilia."

And then lists nine patients. Then he says:

"I wish if possible to maintain all these patients on NHS concentrates either because they are allergic to other concentrates, or because they would be useful to include in a study of the use of heat-treated NHS Factor VIII concentrate and because this product is potentially safer. The other fifty severe haemophiliac boys under my care are all receiving Armour heat-treated Factor VIII."

So that seems to be the position as at March 1985: 50 boys with severe haemophilia receiving

Armour heat-treated product, a request for NHS product on a named patient basis for these nine patients.

Then if we just go to BPLL0006105, please, there's a slightly curious letter. This is a later letter. It's from Dr Smith at BPL, dated 18 March 1991. It talks about 8Y transfer charges to Children's Hospital, and says this:

"In 1985, BPL adopted (without publicising it) the policy of ensuring that the limited supply of 8Y would go first to HIV negative and previously untreated patients. Many of these were children attending Haemophilia Centres at Great Ormond Street and Birmingham Children's Hospital. These children were invaluable to BPL's clinical proof that 8Y does not transmit HIV or hepatitis, but their value can be extended further because they have never had anything except 8Y. This may hold the key to other eg immunological questions which cannot be answered any other way.

"Supplies to these two hospitals, and to other centres with patients in the first trial, were guaranteed by delivery via PFL, which was given this allocation 'for support of clinical trial'. When it became clear that someone would have to pay for the product, both centres (Dr Hann and Dr Hill) wished to

continue the arrangement, on the understanding that BPL would 'transfer charge' their RHA. That is what my 'Transfer' stamp means."

So there appears to have been some debate in 1991 about a stamp that had appeared on some documentation.

Then Dr Smith continues:

"When supplies of 8Y became adequate about 1990, I asked again whether they wished to revert to assured direct supplies from BPL, and they preferred that the existing system should not be disturbed until they let me know positively. If there is any difficulty in Birmingham, Dr Lane should be invited to assess the value of Dr Hill's several very productive clinical trials before any abrupt decision is taken.

"As you will appreciate, these understandings have not been documented but I will do my best to recall distant events if controversy threatens."

So there appears to have been some arrangement as between BPL and, amongst others, Birmingham Children's Hospital and Dr Hill for receipt of 8Y, and usage of 8Y in certain clinical trials.

Just picking up then events after 1985 relatively briefly, if we go, please, to ARMO0000519, please.

This is a document dated March 26, 1986. It's an internal pharmaceutical rep memo. The author is a Loftus S Lucas, and it's describing what is called a "Satellite Meeting, Haemophiliac Centre Directors Meeting, St Thomas's Hospital, London, 17 March 1986".

We can't be certain that this meeting was attended by Professor Hill, but it looks likely as though he did because he did attend the Haemophilia Centre Directors' meeting at St Thomas' that day.

What is said by the author of this memo:

"I estimate that approximately 150 people attended this meeting chaired by Dr Savidge. The purpose of the meeting was to look at the viral safety of AHF concentrates.

"There was little discussion about HTLV-III inactivation, and most people assumed that all heat-treating was sufficient."

Then there's some reference to some presentations about hepatitis. Dr Preston did a presentation on liver cirrhosis in which he concluded that hepatitis leads to progressive liver disease, and it records Dr Preston taking issue with the published work of Professor Mannucci and reference to biopsies taken by Professor Preston, with:

"Seven out of ten patients [progressing] from

chronic persistent hepatitis to either chronic active hepatitis or full cirrhosis."

So I think probably reasonable to infer that that material was known to Dr Hill.

Over the top of the next page we can see a presentation by Dr Kernoff, described as "another of our MONOCLATE investigators", saying:

"... from the platform that liver disease is a very serious problem resulting from AHF concentrates and acute [non-A, non-B] hepatitis."

Then there are various figures given by Dr Kernoff including the following:

"... estimated attack rates from pooled plasma produced AHF to be as follows:

"US Commercial: 100 per cent attack rate.

"UK Volunteer: 33 per cent [attack rate]."

SIR BRIAN LANGSTAFF: Now this is Dr Kernoff?

MS RICHARDS: This is.

SIR BRIAN LANGSTAFF: In 1986.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: In March, quoting from the published work of prospective virgin patient studies which he had been conducting himself, I think. Professor Lee understood that the result of the study was that there was essentially little difference between NHS

concentrate and commercial concentrate in terms of causing hepatitis for those patients who had not been treated with any form of concentrate previously.

This, from Dr Kernoff, suggests that there is a huge difference. Both will cause it but it's three times as likely in the US commercial as it is in the NHS.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: That's what it seems to say.

MS RICHARDS: That's what it seems to say.

SIR BRIAN LANGSTAFF: And it is said by one of the authors of a paper which has been taken at any rate to say the opposite.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: That's the paper which you -- Professor Lee referred to published in the British Journal of Haematology in 1985.

MS RICHARDS: That's right, sir, and clearly a matter that will warrant further enquiry by the Inquiry.

SIR BRIAN LANGSTAFF: The question is really how one reconciles those two.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Yes, it might involve, I suppose, in due course, seeing what the actual raw data said.

MS RICHARDS: If we are able to obtain it, then yes.

SIR BRIAN LANGSTAFF: Plainly there is a difference of -- if it is the same data -- and there's a reference in this to prospective study which he'd been conducting, so he is talking about unheat-treated Factor VIII product, as it would seem -- you would expect the raw data at least to be open to interpretation and it's been interpreted in two different ways by the same author.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: It's curious.

MS RICHARDS: It curious, sir, and a matter that we will need to investigate further.

Just still with this document, if we go to the last page, we just see a reference to some research by Dr Hill. Paragraph numbered 2 under the heading "Conclusions":

"C Bishop is pursuing a study with Dr Hill (Birmingham), who believes that the protein load is perhaps as important as viral transmission. I believe that we should support this study with Monoclate."

So we don't, I think, at the moment know more about that particular study but it's one of a number of studies that Dr Hill appears to have been involved with around this time.

Sir, we know also -- I don't need, I think, to

take you to any documents in relation to this -- that in the autumn of 1986 Professor Hill discovered that some of his patients had seroconverted following their use of the Armour heat-treated Factor VIII product and that was reported to, again, a working party extraordinary meeting on 13 October 1986.

There are a number of documents that make reference to that, and indeed, sir, I think you have heard from at least one patient who was in that unfortunate position.

Moving on then --

SIR BRIAN LANGSTAFF: I think in the paper which you have prepared there's a reference to some correspondence between himself and the pharmaceutical company concerned.

MS RICHARDS: Yes.

Are you referring to paragraph 97, sir? No, that's a different document.

SIR BRIAN LANGSTAFF: No, that's not what I had in mind. I had in mind that there was a question of to whom the outbreak was first reported.

MS RICHARDS: Yes. I will see if I can find the references. They are later in the paper.

I am conscious of time, sir, so I am moving relatively quickly through the documentary material,

but we will find that and come back to it if we can.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: The issue I was proposing to move on to is what information was or may have been provided by Professor Hill to his patients or their parents.

Dr Hill's statement to the Inquiry, if we just have it up on screen, WITN3087001, please. Go to the next page, next page.

He says in paragraph 5 this:

"... when a child was first diagnosed with haemophilia I, or sometimes a member of my team, had a discussion with the parents about treatment with blood products and the risk of potential infection with certain viruses."

So that's his evidence about the discussion that might take place when a child was first diagnosed with haemophilia. The evidence that the Inquiry has received from patients paints a different picture. I am not going to go to any of the underlying documents but we have sought to summarise some of the evidence that you have heard so far on this issue.

So we had evidence from Andrew Evans of his parents being called to a meeting at the Children's Hospital not long after February 1983 -- that was when a New Scientist article was published, you may recall,

dealing with AIDS -- at which Professor Hill told Mr Evans' parents, in response to a direct question as to the chances of Mr Evans being infected with AIDS, that he had more chance of getting arthritis through a lack of treatment than getting AIDS through having treatment.

We heard evidence from Mr O, an anonymous witness, that his parents were not consulted when there was a change of treatment from cryoprecipitate to factor concentrate and that they were given no warnings of the risks of infection from some products.

You heard from Mr AI, whose understanding was that his parents had not been told there was any risk of factor concentrates and then, when he moved on to heat-treated factor concentrates, was told that the products were safe and free from viruses so he couldn't become infected and, in fact, was.

You heard from Elizabeth Hooper about her late husband Paul, treated at the Children's Hospital, who wasn't, as far as she was aware, ever warned of the risks involved in receiving Factor VIII.

You heard the evidence of Stuart Gregg, that his mother was never told of the risk of infection from a Factor VIII concentrates, and the evidence of Mr AN that neither he nor his parents were informed of any

risks from factor products and were told it was a wonder product.

There is documentary evidence of Professor Hill providing written information to parents in January of 1987. There's a letter informing them that the Factor VIII supply was changing.

There is no documentary evidence that we've found from any earlier date providing any equivalent information.

So that's in terms of risks of treatment.

You can take that down, thanks, Henry.

In terms of the rates of HIV infection at the Birmingham Children's Hospital, a report from April of 1986 identified 60 per cent of the patients at the Children's Hospital being positive to HIV.

In a report in March of 1987, Professor Hill reported five haemophiliac AIDS deaths in the region, four patients with AIDS symptoms, 140 haemophiliac HIV carriers in the West Midlands region.

At a further working party meeting in November 1987 it was reported that the number of HIV patients was continuing to rise.

A 1990 UKHCDO return records that there were 23 patients at the Children's Hospital with HIV in 1989 and 38 negative patients. There would, of

course, have been some new patients by then.

In terms of the arrangements that were made for testing children at the Children's Hospital for HIV, Professor Hill's statement, that we had on screen a moment ago, suggests that when HTLV-III testing came in he tested his patients from stored samples. We don't know precisely when testing was undertaken but if we go, please, to ARMO0000375, this is, again, an internal pharmaceutical sales rep document reporting a visit to Dr Hill on 29 April 1985:

"The objective of the visit was to discuss Dr Hill's research on AIDS and haemophiliacs and his recent hepatitis B problem."

You will see there there's a reference to nine children having been shown to be positive for hepatitis B.

Then if we go over the page we will see under the heading "AIDS Research":

"Dr Hill's original project involving the children exposed to tuberculosis has been written up for publication. He will send me a transcript.

"Dr Hill continues to screen haemophiliac children for HTLV-III antibodies. Just over 50 per cent are positive."

Then it is recorded that:

"Dr Hill suspects that all children who have had a long exposure to concentrate may well be infected!"

Further down the page it is recorded that Dr Hill is now testing parents and siblings of haemophilia patients.

Then if we go to ARNO0000391, there's again an internal Armour update and it said:

"The situation now known to me at the present is Birmingham Children's Hospital 32 patients, 52 per cent of those tested HTLV-III antibody positive."

There is identification of specific batches said to be involved. A very significant proportion of the children treated at the Birmingham Children's Hospital were infected with HIV.

If we go to DHSC0039636. This is a letter from Dr Hill to the regional virus lab, 17 February 1986. If we go to the text of the letter there's reference to a particular haemophiliac and to there having been samples sent to the lab in July and October 1984 and it said:

"... I wonder if it's possible for you to get them out and test them for HTLV-III antibody ..."

So there seems to be subsequent testing of stored samples. The extent to which that was known to

the patients or their parents is unclear.

Well, Sir, then in terms of what information we have about how patients were told of their diagnosis of HIV, Professor Hill's statement says that on receipt of the test results he called in the parents of the children and asked them if they wanted to know the results and if they did he would explain them and discuss whether the child should be told. Again, Sir, you have heard a range of evidence from individuals which conflicts in a number of respects with that account.

So again Andrew Evans' recollection, or his mother's recollection, was Professor Hill informed her at a routine appointment with no further information being given. Mr O's evidence was that neither he nor his parents were informed that he was being tested for HTLV-III. His records show he was tested on a number of occasions. They suggest a delay, or his records and his evidence suggested a delay, between the date of his test and his parents being informed.

There was evidence from Mr Al that his mother was told he was HIV positive over the phone and then, Sir, you will recall, no doubt, the evidence we heard from Martin Beard and the correspondence we looked at -- I won't go into it again -- at least one

inference that you could draw from it is that there was a deliberate decision not to inform Martin of his infection.

SIR BRIAN LANGSTAFF: That is what the letter appears to say --

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: -- or at least to record the writer having been told by Professor Hill.

MS RICHARDS: Yes. Another witness, Mr Gregg, said that neither he nor his mother were ever told in terms of his diagnosis, it just became apparent over the years and another witness has told the Inquiry in her written statement that she found out her son was HIV positive by reading it in his medical records and when she raised that with her son she was informed that Professor Hill had already told him, at the age of about 12, of his diagnosis without his parents being present and she hadn't known.

So that's some of the information that the Inquiry's received. I should say that when I refer in the presentations to statements received or oral evidence received from the Inquiry, we are referring to only part of the evidence received by the Inquiry to those statements which have so far been disclosed. There are, of course, other statements that the

Inquiry has both from Children's Hospital patients and other centres which the Inquiry has read and analysed, and which will be disclosed in due course, but which I can't yet refer to by name for the purpose of the presentation.

One of the themes of the documents relating to the position in Birmingham, both at the Children's Hospital and the Queen Elizabeth Hospital in the latter part of the 1980s, are difficulties in terms of obtaining funding to ensure appropriate treatment and facilities for patients who were infected with HIV, but that is an issue I can explore with Professor Franklin in his evidence because that's information that he was privy to and part of attempts to obtain further funding.

On the issue of hepatitis C testing, there are, I think, just two documents that it would be worth looking at. These are general observations by Professor Hill after the event. DHSC0004003_038, please. This is Professor Hill, I think, having a conversation in his capacity as UKHCDO Chair with Mr Charles Lister at the Department of Health. So it doesn't necessarily follow that he's talking about his own practice within the Children's Hospital but it says this:

"I've been talking to Professor Frank Hill about allegations that the patients were tested for Hep C without their knowledge and that some found positive were not told until years later. He thinks that this is quite likely to be true."

Then there's a discussion of various possible explanations for that: some patients included without their knowledge in blind trials, there might have been a concern about telling people the bad news, especially if they already had HIV, concern that no-one knew exactly what a positive antibody test actually meant, some may have been children so that their parents were told but not them.

There's one further letter in which this is alluded to, HCDO0000254_644. This is a letter from Professor Hill, October 2004, to The Haemophilia Society, so again it's a number of years later. Bottom of the page, he says:

"It's difficult to comment further other than to say some clinicians may have considered they were acting in the best interest of their patients. When HCV antibody tests were introduced there were difficulties in interpretation. The test indicated past infection but until there was a PCR test, ongoing infection could not be excluded and then there was the

issue of treatment and how it would be funded. Many of the patients with HCV were already coping with advancing HIV and some clinicians may have been concerned with presenting them with further uncertainty."

Top of the next page:

"Since early 1990, medicine and its practice has evolved from what could be described as a paternalistic approach to a doctor patient partnership."

So those are his reflections or contributions after the event. We don't have any evidence from Professor Hill directly in relation to what his practice was in terms of either screening patients for hepatitis C once the test was available or his practice in terms of informing them but, there again, you have a range of evidence from Professor Hill's patients and we summarised some of the evidence received so far in the note. So, again, Mr Evans, for example, neither he nor his parents were informed by Professor Hill that he had been infected with hepatitis C. This only became apparent later, he said, in a clinic appointment with Dr Wilde. Evidence of Mr O that he wasn't told until 1995, again once he transferred to the Queen Elizabeth Hospital, that he

had hepatitis C. The evidence of Mr Gregg's mother was that she was told that her son had non-A, non-B hepatitis, but it was so poorly explained she thought it meant he didn't have hepatitis A or hepatitis B and so was free from viral hepatitis.

Sir, I am conscious of the time and there are just two further documents I wanted to refer to. The first may be the document you were referring to earlier, Sir, ARMO0000510. This is the minutes of a meeting between representatives of Rorer Health Care and the Department of Health, and you will see from the first paragraph it's a discussion about seroconversion in response to Armour's heat-treated Factor VIII, and reference to a case reported by Dr Hill of the Birmingham Children's Hospital. If we go to the next page, we'll see, second paragraph -- zoom in on the second paragraph, please -- Mr Jeffreys is said to have asked how Rorer were proposing to handle the current situation:

"It was inevitable that news of this additional seroconversion and its circumstances would be in the public domain fairly shortly, possibly by the end of the next week, as there was a meeting of all Haemophilia Centre directors in Edinburgh. Mr Christie mentioned that Dr Hill did not intend to

disclose the details of his case to the Haemophilia Centre Directors' meeting until (sic) it was absolutely essential" --

SIR BRIAN LANGSTAFF: "Unless it was absolutely".

MS RICHARDS: Sorry:

"... unless it was absolutely essential to do so. He had only discussed it with Dr Rizza and the area supplies clinician apart from ourselves and the DHSS. If this was the case then it might be possible to hold the information from breaking into the public domain for a little longer, although Dr Hill would have to inform the parents of the children who had seroconverted ..."

So it would appear from this, at this stage, that the pharmaceutical company, the Department of Health, Dr Rizza and the Area Supplies Commission had been told this information by Dr Hill but not yet the parents of the children who had seroconverted and it wasn't information Dr Hill was planning to disclose to his fellow directors at the next meeting.

SIR BRIAN LANGSTAFF: It was a document associated with that but it was earlier in time, I think. It was a report from the -- I think correspondence of some sort between Armour, or considering it in Armour, the response which they had had from the then Dr Hill

about the seroconversion of people on heat-treated Armour concentrate.

MS RICHARDS: Sir, there are a number of documents associated with that issue, so we can find it at a later stage if need be. There is just one further document I wanted to refer to before we end the presentation.

That is at -- I think it is ARMO0000370. Yes. We have set out in our notes some documentary evidence of interactions between pharmaceutical companies and Professor Hill. This is one of the more striking examples. It's from Armour dated March 27, 1985, to Dr Hill:

"Dear Frank, you will note from the enclosed copy letter that I have paid our first 1985 donation to your research fund to the Finance Department of the Central Birmingham Health Authority. We continue to be very interested in the progress of this project, and of course its extension into HTLV-III screening of children who have been treated with non-treated and latterly heat-treated Factor VIII."

It would appear that, as at 1985, Professor Hill had a research fund to which Armour (who had, for many years, been the sole commercial supplier to the region) was making donations. At present, we don't

have any more information about this particular issue than as set out in that document.

SIR BRIAN LANGSTAFF: The document which I had in mind was ARMO0000585.

MS RICHARDS: Yes, if we zoom in on that, please. Ah yes. September 1986, again an internal memo:

"Dr Hill rang me this morning to report two haemophiliac children who had seroconverted to HIV antibody positive following a long course of Armour heat-treated Factorate."

Then reference to the incident needing to be reported to the DHSS and he also believed that a publication describing his experience should be prepared.

SIR BRIAN LANGSTAFF: So the course of events, according to this, if it's right, is that Dr Hill discovers that there are two children in his care who have now tested positive for HTLV-III. The first person he tells of this is the maker of the product before he tells the DHSS. He then has in mind telling who?

MS RICHARDS: Well, the evidence suggests that it was reported to the DHSS, that earlier document we looked at; that it was reported to Dr Rizza, presumably in his capacity as someone effectively maintaining the database at Oxford at that stage; it was reported to

the Area Regional Supplies Officer, that's presumably the West Midlands Area Regional Supplies Officer, responsible for the contracting, and then an inference, at least from the documents, that only then is it reported to the parents.

SIR BRIAN LANGSTAFF: Is there any reason anywhere in the documentation why he should tell the producer of the product before he tells the DHSS?

MS RICHARDS: No, I don't think so, sir.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: There was then, as I think I mentioned, discussion of this at an extraordinary meeting of the working party on 13 October 1986 at SHIN0000019.

If we go down the page, we'll see Dr Hill outlined the events culminating in the calling of the emergency meeting of the working party and reference to seroconversion. It's said:

"He passed his findings to Armour Pharmaceuticals whose representatives met with members of the DHSS and jointly decided to withdraw all Armour Factor XIII."

I'm not sure whether there's any reference in here to telling parents. If we can just look at the rest of the document, Henry -- if we keep on going. No. I'll double-check, sir, but I don't recall there

being any particular reference. The discussion in this meeting, perhaps understandably, is more general.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Obviously, there is more in the presentation I haven't covered, in particular in relation to the issue of vCJD but that's detailed in some considerable detail in our written presentation, which has already been provided to recognised legal representatives of Core Participants, and will be published on the Inquiry's website in due course, so I don't propose to say any more today about the Birmingham presentation. But we'll obviously continue our consideration of Birmingham with Professor Franklin this afternoon.

SIR BRIAN LANGSTAFF: Yes. Well, we will do that at 2.00, shall we?

(1.07 pm)

(Luncheon Adjournment)

(2.00 pm)

SIR BRIAN LANGSTAFF: Professor Franklin, you don't need to wear a mask when you are giving evidence. It might help in fact if you don't. May you be sworn.

PROFESSOR IAN MAXWELL FRANKLIN (affirmed)

Questioned by MS RICHARDS

MS RICHARDS: Professor Franklin, I'm going to ask you first for an overview of your career. You undertook,

I think, various house officer and senior house officer roles in Leeds between 1974 and 1976?

A. Yes, I did.

Q. And then between I think 1977 and 1980 you were a research training fellow for the Medical Research Council?

A. Yes.

Q. Your work then, I think, was predominantly related to sickle cell anaemia?

A. Yes, the research was, yes.

Q. Did you undertake any clinical work during that period?

A. I did nothing for the first year and then I used to attend a sickle cell anaemia clinic at The London School of Hygiene and at University College about a couple of times a month, and that carried on for those -- the last two years, and in the final year I used to go and help a general haematology clinic at the now defunct Royal Northern Hospital.

Q. Then from 1980 to 1982, you were a senior registrar in haematology at University College Hospital?

A. Yes, based there, yes.

Q. That was your specialist haematology training to achieve membership of the Royal College of Pathologists?

A. Yes.
Q. Your statement and your CV tells us that between October 1980 and February 1981, you worked for approximately three months at Great Ormond Street Hospital under Professor Hardisty?
A. That's right, yes.
Q. So you would, in the course of that period, have seen children with bleeding disorders. You said you didn't have a decision-making role in terms of what treatment to provide to them?
A. No, I didn't. It was observational, I would say.
Q. Can you recall anything about what the treatment policies were at Great Ormond Street at that stage?
A. I can't really. I remember they had Lister Factor VIII. I think that was the first time I had heard of Lister Factor VIII. I don't remember whether they had commercial product and I don't remember seeing cryoprecipitate used either.
Q. Then from March to September 1981 you were training in blood transfusion medicine under Dr Barbara at the North London Regional Transfusion Centre in Edgware?
A. Well, I didn't work with him. He taught me about transfusion virology but also Dr Marcela, now Dame -- Professor Dame Marcela Contreras was the haematologist who was actually leading my training.

Q. You said in your statement that the focus in terms of what you recall learning there was on hepatitis B. It would seem likely that there must have been some discussion of non-A, non-B hepatitis and its risks at that time. Can you --
A. I think there was some. I mean, I have to say outside the world of haemophilia, I would say even in general haematology, there was probably a lack of appreciation of the level to which blood transfusion red cells and so on could transmit non-A, non-B hepatitis. I mean, I think there was -- I'd heard of it. I think there was -- generally there was a feeling that it was something that largely happened in the United States because of paid donors and that the volunteer donor base in the UK was much safer.

So from that point of view there wasn't a lot of exposure to knowledge of it.
Q. Then you moved to St Albans City Hospital, where you spent, I think, around three months doing general haematology work?
A. Yes, yes.
Q. Then January to August 1982 you were at UCH. You've said in your statement you were mainly concerned with the development of a bone marrow transplant programme?
A. Well, my boss, Professor Tony Goldstone, was setting

out the programme there. He had been doing that for a year or so. I was involved to a very small degree while I was still a research fellow but then, yes, I was quite involved with the early transplant patients that were starting off what is now a very big unit.
Q. You have said there was no involvement with the care of those with bleeding disorders, save for the odd patient?
A. Well, yes. I mean, I remember seeing the occasional person with haemophilia on the wards but, really, it was a haemophilia centre but couldn't have had many patients, I think.
Q. Did you have any involvement in decisions as to how to treat those occasional patients?
A. Don't remember having any such role, no.
Q. Do you have any recollection of what treatment was routinely provided?
A. No, I'm afraid not, no.
Q. Then on completion of that specialist training you gained membership of the Royal College of Pathologists?
A. Yes.
Q. Then in September 1982, you took up your post as a consultant at the Queen Elizabeth Hospital in

Birmingham?
A. Yes.
Q. You were around 33 years old at the time?
A. Just about, yes.
Q. Your statement suggests that your appointment was principally to develop a bone marrow programme because of your sickle cell experience; is that correct?
A. Yes. I mean, they had quite a large sickle cell population, which I think made me attractive but they particularly wanted to start doing -- we call them now stem cell transplants, bone marrow transplants, yes.
Q. So in terms of haemophilia care, Professor Stuart was still the director of the haemophilia centre at that point?
A. He was.
Q. For that first 12 months, your statement describes you only dealing with the care of patients with bleeding disorders when you were on call?
A. Yes, so if we had haemophilia patients in the ward, you would see them on the ward, the ward round, during the day and then if there were any issues deal with them at weekends or at night and, as you are fully aware, the haemophilia care was a 24-hour service. Men could come up for treatment to be seen on the ward -- the treatment room was next to the ward --

pretty much any time of the day or night. So I'd get involved, to some extent, in those episodes.

Q. I will ask you a little more about that in a few minutes.

You then took over as the director of the haemophilia centre after approximately a year, so September 1983 or thereabouts?

A. Yes.

Q. Did Professor Stuart continue as a consultant or did he retire completely?

A. No, he -- obviously, he was a professor. He had a research interest and he continued to provide out-of-hours cover on a one-in-three rota and at weekends, but he largely retained responsibility for the laboratory and the clinical -- the hospital laboratory and his research.

Q. So is it fair to say that at the point at which you became a director of the Haemophilia Centre at the Queen Elizabeth Hospital your direct experience relating to the treatment of patients with bleeding disorders had been largely limited to those three months at Great Ormond Street and then the first 12 months at QEH, working with --

A. Yes, I was quite inexperienced really.

Q. You remained consultant haematologist and director of

the Haemophilia Centre at the Queen Elizabeth Hospital until the end of July 1992 --

A. Yes.

Q. -- and then moved to Glasgow --

A. Yes.

Q. -- to take up a role as a consultant focusing on bone marrow transplantation?

A. Yes.

Q. You then worked for a number of years thereafter in the Blood Transfusion Service, initially locally and then as SNBTS's National Medical and Scientific Director?

A. Yes, I started as National Medical and Scientific Director in early 1997.

Q. I think you remained a professor of transfusion medicine throughout that period as well.

A. Yes, and I continued to work on the transplant units as well.

Q. Then 2011 to 2014, you had a similar role at the Irish Blood Transfusion Service?

A. Yes, that was just solely the medical and scientific director, with no other hospital role.

Q. As I think you know, the questions I ask you today are going to be focused upon your work at Birmingham.

A. Yes.

Q. I'm not going to be asking you about your work in Scotland, although that may be something that the Inquiry will need to ask you about at a later stage of its hearings.

In terms of working parties or organisations you belonged to, you were, once you became director of the Queen Elizabeth Hospital Centre, a member of UKHCDO?

A. Yes. I think that sort of went with the territory.

Q. I think we've only got a record of you attending two meetings, one in 1983 and one in 1984. Does that sound about right?

A. Yes, I don't remember -- well, it was a long time ago. I didn't actually remember many of the West Midlands working parties either, other than the early ones but I don't think I did go to them after that.

Q. As you just alluded to, you were a member of the Working Party On the Treatment of Haemophiliacs for the West Midlands Regional Health Authority, and we'll look at some of the minutes of that in the course of your evidence.

You gave evidence to the Archer Inquiry?

A. I did.

Q. You, I think, had some involvement in some litigation against the West Midlands Health Authority. You had to provide some schedules, I think you said, in

relation to patients. Without, obviously, discussing any individual case, can you recall the nature of your involvement?

A. There were four legal cases, I remember. Two of them related to areas of relevance to this Inquiry but none of those -- I don't think any of the cases got to court. I think those two were both -- well, they didn't proceed.

The other two related to issues with care of haemophiliac -- people with haemophilia and I believe, but I'm not sure, that they were settled out of court.

Q. Can I ask you just to give us an overview of what the facilities were at the Haemophilia Centre at QEH when you took up your post as director in 1983?

A. Well, first of all, I had a co-director, Dr Frank Hill, who came to the hospital once a week to do the clinic, as I remember, in the morning, and then we would meet through the afternoon to discuss problems with particular patients and strategy, I suppose. We had a single room which was like a large office, which was a treatment room with a treatment couch, where patients could have their treatment administered, whether that was Factor VIII, those not on home treatment.

I remember us giving FEIBA in there as well. It

was just one room. We had patient records in there. Definitely patient records of home treatment, so that would be sheets that the patients themselves had filled in.

I don't remember whether we had all of the patient records in there. I don't believe we could have done. I think they must have been stored somewhere else, in medical records, but we certainly had quite a lot of filing cabinets with records.

We stored working stock of Factor VIII concentrate. It was quite a busy room. I think cryo was stored down in the blood bank, not in that room.

We only had facilities in there to treat one patient at a time -- for reasons of confidentiality. So that was a bit limiting. We had one nurse, of sister grade, who was full time for haemophilia care, and she would see patients who attended whether for home therapy advice or supplies or people not on home therapy with a bleed. She may be able to manage a lot of those, otherwise she would then refer to doctors, which would depend on who was around really on the main team.

Medical support, in addition to myself and Dr Hill were provided by a senior registrar, one registrar and a couple of senior house officers, about

four junior level doctors.

We had quite a good coagulation laboratory, which was down in the hospital laboratory, but that was about it really. There was no -- well, I suppose we had a room -- two rooms and an out-patient clinic, but that was part of the general out-patient facilities. So really, in terms of special facilities, there was really just this one room and one person, one nurse.

Q. In terms of doctors -- we'll come back to your role and Professor Hill's -- you've mentioned in your statement already, and your evidence relating to Professor Stuart, but there was a Dr Brian Borton ...?

A. Boughton.

Q. Boughton. Did he --

A. I do know he was a senior lecturer. He really only was doing the same as I was doing in the first year, which was one in three nights and one in three weekends covering.

Q. Were there registrars, senior registrars, who participated in the work of the clinic over the years that followed?

A. Yes, yes, depending on -- they, a bit like me in my training, would rotate through the department. There were other hospitals in the area, Coventry, the

Children's -- Birmingham Children's Hospital, General Hospital. So they all had junior doctors who would then rotate, move round, to ensure that their training was -- covered all the specialties.

Q. So Professor Hill would come and do clinics jointly with you at the Queen Elizabeth. Did you have any involvement in clinics at the Children's Hospital?

A. No, never.

Q. Can you recall when you started at Queen Elizabeth Hospital? So first appointed as a consultant but before you took over as director a year later, was there any particular guidance or training that you recall being given by Professor Stuart?

A. You know, I don't remember, to be honest.

Q. How did the relationship with Professor Hill, and the fact that you were co-directors, how did that work in practice?

A. I think it worked pretty well. I mean, I had a bit more time to spend than him, but he was a trained and experienced haemophilia -- well, I would say, haemophilia expert. He'd trained at Great Ormond Street, he'd trained in Oxford, and the systems, although barely sufficient for the management of the bleeds in the men with haemophilia, I thought it was actually quite well organised in terms of managing the

treatment.

Q. You said in your statement that you were, to some extent, guided by Professor Hill because he was more experienced. You also told the Archer Inquiry that because you were -- I'm not directly quoting from you, but you were relatively inexperienced --

A. Yes, I accept that.

Q. -- you needed guidance from more haemophilia experts and tried to follow a consensus opinion. Is that correct?

A. Yes.

Q. Let's have a look in terms of a rough idea of numbers of patients, Professor Franklin.

Could we have UBFT0000252, please, Henry.

This is a report prepared jointly by you and Professor Hill in April 1986. It was a request for further resources, and we'll come on to that at a later stage of your evidence, about funding problems for the care of those with HIV.

But if we just look at the second paragraph on this page, please, Henry, we can see it said:

"The haemophiliac population within the West Midlands represents 11 per cent of all the haemophiliacs in the [UK]. The majority (about 75 per cent) are registered with the

Queen Elizabeth Hospital or Birmingham Children's Hospital ... At the Queen Elizabeth there are 423 patients registered as having a bleeding disorder ... of these approximately 90 attend regularly for therapy or use Factor VIII concentrate at home."

So that's an accurate snapshot, is it, of the numbers?

A. I think so, yes.

Q. I don't think we need to go to it but in a report the following year you described Queen Elizabeth Hospital as effectively the fifth largest haemophilia centre in England and the largest not to receive any bespoke funding as a reference centre?

A. Yes. I don't particularly remember that. In fact, I only really realised how large we were until I was preparing for this inquiry. But yes, it was clearly quite a big centre.

Q. I think it's right that during the time you were director, the QEH didn't have the status of a reference centre?

A. No, I think they changed -- they seemed to be quite obsessed with the rules around what a reference centre was, the UK Haemophilia Centre Doctors' Organisation. I think the Children's Hospital became a comprehensive care centre.

Then we can see the products being used: cryoprecipitate, 97,090 units, and that's just for hospital treatment.

So no cryoprecipitate for home therapy by that time. Does that accord with your recollection?

A. Yes, I don't remember any patients still -- if they ever were, still being on cryoprecipitate at home.

Q. Then NHS factor concentrate we can see being used both in hospital and for home treatment?

A. Yes.

Q. 338,000-odd in hospital, 569,000-odd for home treatment. But then the predominant product is the Armour Factor VIII, so the commercial product, a smaller amount used in hospital but 1.2 million used for home treatment?

A. Yes.

Q. We will look at some of the contracting arrangements in a little while.

So that's haemophilia A patients. Von Willebrand's we can see treated solely with cryoprecipitate.

And then if we go to the document I had been looking at -- sorry, Henry, HCDO0000206_004 -- we can see there nine patients with haemophilia B, no carriers, and the sole product used both in hospital

Q. Yes, in 1989.

A. Yes. So I think they changed the nomenclature, but no, I think the adult centre remained the same status.

Q. Can we look at the annual return for 1983. Again, just to get an idea of what treatments were being used at that stage.

Henry, it is HCDO0000206_002.

So this is for the treatment of patients with haemophilia B, and we can see it's a 1983 return. Director: yourself and Dr Hill. Nine patients with haemophilia B and the sole treatment there, NHS Factor IX concentrate, and we can see both hospital and home treatment.

A. I think I have a different one --

MS RICHARDS: I'm so sorry --

SIR BRIAN LANGSTAFF: We're looking at the wrong page. We're looking at page 1 --

MS RICHARDS: I am looking at the wrong paper document. I am so sorry.

Yes, sorry, this is the 1983 return for haemophilia A patients, carriers and von Willebrand's disease. So we can see 83 patients treated during the year with haemophilia A, three carriers of haemophilia A treated during the year, and 13 with von Willebrand's disease treated during the year.

and for home treatment is the NHS Factor IX concentrate?

A. Yes, I think we always -- as far as I remember, we always had enough NHS Factor IX.

Q. You've said in your statement that the home treatment programme was established before you took up your post.

A. Yes.

Q. You didn't remember actually starting anyone on home treatment yourself; is that correct?

A. No, I don't remember doing that, no.

Q. Was there any programme of prophylactic treatment at the time?

A. No, I don't -- well, I don't remember that, and certainly I don't think there was in the adults. Prophylaxis was still -- was talked about and considered to be beyond our ability to afford it, I think, probably.

Q. One of the treatment policies in operation when you joined was a policy of trying to keep patients on the same product. Can you explain how that worked.

A. Yes. Well, as taught to me, and I think it does make sense, the idea was that once you were exposed to one batch of product, it would be best if you continued to use that and not be given either different batches of

the same product or lots of different product.

And the idea there, I think, is to -- well, is to try to restrict the number of donors to which a particular person is exposed. You are still going to be exposed to a lot of donors but if you had -- say you had three treatments from the same batch of a US product, that might be a 20,000 donor exposure, which sounds a huge number, but if you have one treatment from one company, one from another and one from another company, that could be 60,000 donors. So the chances of becoming infected with something would have been much greater.

I think it did make a bit of a difference in terms of HIV but I don't think it made much difference for hepatitis.

Q. First of all, it was a policy you inherited?

A. Oh, yes. It wasn't my idea, no.

Q. The rationale was to reduce the risk of infection?

A. Reduce donor exposures and therefore, hopefully, reduce the risk of infection.

Q. How did that work in practice? How was a particular batch secured for a particular patient?

A. I can't actually remember exactly how. I mean, I think once a person was on a particular batch, that would be on their record in the treatment room. So if

they were not on home treatment and were coming up for *ad hoc* treatment, the same batch would be given if available. And if they were on home treatment and coming up to replenish their home stock, they would be given the same batch if at all possible.

Q. We'll just look at a couple of documents about this. So could we have UBFT0000156, please.

This is a later letter, written in the context of HIV haemophilia litigation, but it's referring to an earlier letter from March 1984, and we don't have the earlier letter, Professor Franklin, which is why we are having to look at this as our best evidence of it. You refer to a letter you had sent to Dr Ala, the regional director of the transfusion centre, in March 1984, outlining reasons for seeking continuity in Factor VIII supply.

Then you talk about:

"... supplies of material NHS material had been very limited and both myself and my colleague ..."

Presumably that would have been Dr Hill?

A. Yes.

Q. "... were of the opinion that it was better to make a gradual change to NHS products that could be sustained rather than a sudden switch in times of glut and then a sudden transfer back of all patients to

commercial material. This was the sort of thing that had been happening at that time."

Then you refer to there having been a meeting of Haemophilia Centre Directors in which it was considered advisable that patients remain on the Factor VIII product they had been regularly using. So that's the approach you were just describing, Professor Franklin?

A. Yes.

Q. "Therefore it did not appear unreasonable at that time to propose that patients who had been using Armour for several years should continue to do so. There was never at any time sufficient NHS Factor VIII available to treat all patients and the decision of Dr Hill and myself was that patients should receive a regular supply of a one or other product and not a mixture of both."

So pausing there, the aim was if someone was receiving Armour they'd carry on receiving Armour. If someone was receiving NHS concentrate they would carry on receiving NHS concentrate, as much as you could?

A. Not only that they would stay on that same batch until that batch was exhausted, yes.

Q. You referred there to limited supplies of NHS material, and then times of glut, and having to

transfer patients between different products. What, if anything, can you recall about that?

A. Well, I don't think we ever had a glut, actually, but we did -- there was -- there were times when the supply of NHS product increased, and so we -- I think there is some correspondence that you have between myself and the director of BPL, which made the NHS product. In light of that, I think we did transfer some people from commercial onto NHS, in the hope that that would be sustained. In the end, it turned out not to be sustained and, I presume, though I don't have any records, I presume we had to move them back. I wasn't very happy about that at the time.

Q. We might sense that from the tone of your letter to Dr Lane, Professor Franklin. If we have a look at it, BPLL0000853_002, please, Henry. So this is your letter, 24 May 1984, so a couple of months after the letter that we don't have but we have seen described in your letter to Dr Ala, and you are saying here:

"As co-director of the Haemophilia Centre at this hospital, I have been most disturbed at the sudden fall in supplies of NHS material for our patients. It is only a month or so ago that I was requested to change some patients to NHS from commercial material because of a glut of the former at

the Regional Transfusion Centre."

So it appears there had been at least temporary glut of NHS material?

A. Yes.

Q. "It appears that we will now be in the position of having to treat patients with commercial material who may never have been exposed to this in the past. This situation is particularly regrettable given the current interest amongst haemophiliacs in the acquired immune deficiency syndrome."

Obviously, we will come on to that later, Professor Franklin. You go on to say:

"Our efforts to reassure patients have included maintaining them on a single product so as to limit the pool of donors to which they are exposed as much as possible. Not only will this sudden and unexpected shortfall in NHS material mean that we will have to change this policy but it will also make epidemiological studies of hepatitis and AIDS meaningless."

What did you mean by the reference to epidemiological studies? Was that something you were involved with?

A. Not particularly as a study. I imagine that was just -- as we'll come on, you know, we knew -- we came

to know how many people had -- were HTLV-III positive and I suppose it would have been perhaps helpful to know whether any of those had been from people who'd only ever had NHS material.

Q. Then if we just --

A. It wasn't a trial or formal --

Q. Not as far as your involvement's concerned?

A. No.

Q. Then if we look at the next paragraph:

"Could you perhaps let me know of the likely future supplies of NHS material so that I may plan the treatment strategy for my patients."

You go on to say that you find:

"... the sudden swings in supplies with no due notice to clinicians involved in the treatment of patients to be unacceptable."

I think it's fair to say that Dr Lane's response, which we have at BPLL0000853_001, suggests that this is an issue that you would need to take up with the Regional Transfusion Centre rather than BPL?

A. Yes, it was a fairly robust rebuttal, I suppose.

Q. We see that in his second paragraph:

"... Regional Transfusion Centres, and not the Blood Products Laboratory, determine the issuing policy within individual regions."

If we skip down to the fourth paragraph of the letter he says, in relation to the sudden and unexpected shortfall:

"Regional Transfusion Centres have monthly issue reports and six-monthly updates at the time of Pro-rata. Your RTC must have been aware of their Pro-rata issue of Factor VIII as far as back as December 1983 and known that this period would be affected by the yield and plasma supply ..."

I mean, whatever the precise cause of the fluctuation, was that a situation that persisted, as far as you can recall, in those first two or three years that you were there? Was this a perennial problem?

A. To be quite honest, until I saw these I had rather forgotten. I did know that I had some correspondence with Dr Lane. This change in treatment obviously came at a really critical period, sort of '84, and I think that was why I was concerned about it. I'm not sure. I think, thereafter -- after this, most of the major changes came about when the issue around requiring heat treatment came in and that sort of disrupted a lot of the regular supply issues. So I think after that, there was hardly any such thing as routine supplies for a couple of years.

Q. Okay. It would seem that you received your supply of NHS Factor concentrate from the Regional Transfusion Centre?

A. Yes, I think we got all the supplies from there but I'm sure -- well, you were speaking this morning about the contracts, and so on but -- I think it was all stored over there, yes.

Q. So the cryoprecipitate was from the Regional Transfusion Centre?

A. Yes, that would have been made locally.

Q. The NHS Factor concentrate was made by BPL at Elstree but supplied to the Regional Transfusion Centre and then to you?

A. Yes.

Q. Then the commercial products, we'll look at the contracting arrangements in a few minutes, but your recollection is they were delivered to the RTC and then hospitals would call them off --

A. I think we called them off as we needed but it's a long time ago. I'm not 100 per cent sure.

Q. If it assists you, Professor Franklin, the documentation suggests that for Queen Elizabeth, although not the children's hospital, that that was probably the case.

A. Yes.

Q. Just generally, in terms of the treatment policies, what use was there in this period 1982, 1983, 1984, of cryoprecipitate?
A. Well, there was use. I remember doing it. I think your previous chart suggested that we were using it for von Willebrand's disease. I would have thought we were using it for mild cases. It really depended on the severity of the problem that was required but we were definitely using it. In the absence of any more, sort of, figures, I can't remember.
Q. What about DDAVP?
A. We certainly did use that. It was very useful, but it was really good for things like dentistry in less severe patients. As I'm sure you know -- I mean, DDAVP works by releasing Factor VIII from the body from the blood vessels. So if you are a very severe -- a person with very severe haemophilia 0 to 1 per cent, you don't have Factor VIII to be released from the blood vessels, but if your normal Factor VIII level is between 5 and 10 per cent, say, you actually have quite a bit and the DDAVP would release that and then you would be able to give it, perhaps, for a couple of days to tide you over. But it was very short-lived. So it was something we used -- I mean, I remember using it.

Q. We saw reference this morning in the 1970s to cryoprecipitate being used to provide cover for surgery. Was that something which was still happening when you joined QEH?
A. Yes, I think it was, yes.
Q. Then, in terms of NHS product, as opposed to commercial, how were decisions taken as to which patients would receive NHS product and which would receive commercial; can you recall?
A. Yes, difficult. To be quite honest, I can't remember. I'm sure that if we had a young man transferring from the children's unit who had only been on NHS we would have done everything possible we could to try and keep them on that. But, at times, we had very little NHS and so, apart from that sort of more general comment, I don't remember specifics.
Q. Presumably your product and batch policy would mean the converse as well: if you had a patient transferred from the Children's Hospital who had been receiving commercial concentrate, as we know many of the children did, you would have been likely to keep them on that?
A. Probably. It's unlikely it would have been the same batch, perhaps, but yes.
Q. Was there any specific policy or approach or practice

in relation to patients who were previously untreated patients?
A. Well, I don't remember ever treating -- well, other than possibly some with DDAVP, who were very mild, I don't remember treating any totally new patients.
Q. The arrangements for obtaining the commercial product, we know that there was a regional contract in place, and it appears to have been with Armour at the time at which we're talking when you arrived in 1982. As far as you can recall, was all your commercial product at QEH obtained pursuant to that contract or did you ever make any separate arrangements yourself for the procurement of commercial concentrates?
A. In normal times, it was always off that contract. The period of time when the -- I think, maybe the BPL but certainly the commercial unheated products were recalled, we went through a period of having very little and, although I have a vague memory of it, but you have provided papers to show that I actually made a personal plea to Armour for some extra supplies, which they did provide us with, which was -- it was commented by my colleagues was outside the spirit of the agreement but it was a difficult time.
Q. The criteria for awarding the regional contract for commercial product, before we look at any of the

documents, your statement refers to Professor Hill suggesting that one might question suppliers of Factor concentrates about their donor pools. If we just look at your statement, I think it is your paragraph 11.
A. Yes, I remember him doing that.
Q. What you say is, you talk about -- in the early years of your time working at QEH you recall there being a committee of doctors in the region which determined which clotting factors were to be bought, and we will look at the documents in a moment.

What is it you can recall about Professor Hill talking to you about donor pools and you asking for --

A. He would ask about whether they were collecting blood from prisons, skid row locale -- I mean, this was after the 1975 bad blood -- I can't remember the name of the programme now, but the World in Action programme and there was, you know, great concern about the quality of product. I know he had certain views about certain companies but -- and I think it was really a combination, I think, of trying to reassure himself and myself that we were hopefully getting the best product, and also perhaps send a message back the other way that this was an important issue that companies should address.
Q. You say he had certain views about certain companies.

What can you recall about his views about particular companies?

A. Well, there is a letter in the papers from a surgeon in Stanford University to the then head of BPL, Dr Maycock, being really quite damning about one company's product, and that company was one that Dr Hill was never very keen on.

Q. That's the letter from Dr Garrott Allen --

A. It is.

Q. -- to Dr Maycock, 1975?

A. Yes.

Q. Can you recall any other particular discussions you had with Professor Hill about specific companies?

A. No. None beyond that, no.

Q. If we could just look at three meetings, one before you arrived -- well, one whilst you were there but before you took over as director, and then two after you became director, just to get a sense of how decisions were taken.

Could we please have? Henry, FHIN0000030.

This is a meeting of the West Midlands Regional Health Authority's working party on the treatment of haemophiliacs. We looked at it this morning during the presentation, Professor Franklin.

It's dated 27 June 1983. We can see Dr Hill was

there, and then representing QEH would have been Professor Stuart.

So this is the time that you were a consultant at the hospital but not yet director?

A. Yes.

Q. If we go to the second page, we can see under the heading "Regional Contract":

"It was agreed that Mr Stanton should invite tenders ..."

And then:

"Mr Shinton, Dr Hill and Mr Stanton would meet to adjudicate when the tenders had been received."

So the process appears to have been, and we see it later involving you, that Mr Stanton, from the regional supplies department, would -- was that something from the Regional Health Authority?

A. I would have thought so, yes.

Q. Would invite the tenders from a range of commercial companies, and then there would be involvement of two of the Haemophilia Centre Directors here, Dr Shinton, who was Coventry, Dr Hill, the Children's Hospital, and Mr Stanton adjudicating.

Then we can see three criteria there set out, or points to be taken into consideration:

"The amount of effort involved in changing

supplier."

What, if anything, can you tell us about why that was regarded as important?

A. Not really. It seems a strange thing to say, really. I would have thought you would want the best product, but -- I think, I mean, to be -- there were differences, which I've only been reminded about in the last week by reading a lot of the correspondence and meeting papers, that the different companies prepared different packs. Some of these were perceived to be easier to use by patients at home than others. I can't see what other amount of effort was relevant really.

Q. Then the second point:

"Where firms have their donor facilities in the United States."

So that goes back to the issue that you were discussing a few moments ago.

A. Well, I did think they all did. Maybe Immuno didn't. I know possibly Bayer didn't, but Bayer I think never made a lot of product, and it was very expensive. But as far as I knew they were all American products.

Q. This appears to be looking at where in the United States the donor facilities were.

A. I see, I'm sorry. Different meaning of "where", I beg

your pardon.

Yes, where in the United States they had their collection facilities, yes, which would be away from major conurbations and places where ...

SIR BRIAN LANGSTAFF: You may not remember this but was there any appreciation that a number of the commercial firms may have got their plasma supplies not from their own donor facilities but from plasma brokers?

A. I certainly didn't have any awareness of that at the time. I think I became aware when I was more involved in plasma fractionation in Scotland but not -- not at that time. No, I think it was an assumption they were going -- we knew there were paid donors but I think the assumption was that they were going out and collecting their own plasma.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Then we see the third point that's identified to be taken into consideration is:

"Any public pressure for a change of products (eg to heat-treated Factor VIII) should be resisted until another product had been proved to be more satisfactory."

Do you know what the reference to "public pressure" refers to?

A. No.

Q. We can see that as at June 1983 there's a reference to heat-treated Factor VIII. We'll come on to how and when QEH moved to using heat-treated products, which was either at the very end of 1984 or the beginning of 1985 as far as we can tell. Do you recall any consideration being given in the course of '83 or '84 to starting to use heat-treated products earlier?

A. No. I think my only awareness of the heat-treated product was the Bayer product, which was, as I say, very expensive and beyond our budget. No.

Q. If we go to the next page, please, Henry -- sorry, actually we'll go back to the previous page. My apologies, Henry.

If we just look at the bottom part of the page, Professor Franklin, under "Supplies of Cryoprecipitate and Freeze-dried Factor VIII", we can see there there's a discussion about the -- well, what is described as "Receipts and Purchases", so presumably who is using what in terms of Factor VIII.

There's a reference to a letter from Dr Shinton about the risk of AIDS, and we'll come back on to the question of AIDS. But then there's a reference to asking the working party to advise on the purchase of heat-dried Factor VIII. So that appears to be something that at least Dr Ala was raising in June of

1983. Was that something that you recall becoming involved with advising?

A. No. As you point out, I wasn't at this meeting. It was quite prescient of him. But I don't remember any particular fall-out or progression of that idea.

Q. Then the next page, please, Henry, if you go to the heading "Funding of Commercial Factor VIII".

I don't know whether you can assist, Professor Franklin, in understanding what's being discussed here. In the second paragraph it's referred to -- or, there's an issue about deducting from districts with haemophilia centres in order to "top-slice", and the possibility of applying for RCCD funds. Do you know what any of that refers to?

A. RCCD is the revenue -- no, wait, revenue consequences of ... I think it might mean revenue consequences of some sort of development -- capital development. The West Midlands Regional Health Authority had these sort of arcane phrases, I don't know whether they were common across the NHS, but -- so we were often applying for money to support the haemophilia patients from something called the regional consequences of services capital development, RCDRS. So they had -- basically these are systems which the region divvied up the money that they presumably had from central

Government and -- probably in 1984 I would have been able to work my way round this but I'm afraid I can't anymore.

Q. Don't worry. We will move on then to the first of these meetings that you did attend.

SHIN0000029, please, Henry.

So we can see this is a meeting on 5 December 1983. You had taken over as director by this time, although Professor Stuart was there, you were there, Dr Hill was there.

A. Yes.

Q. And a number of others. If we look down the page towards the second half of the page, we can see under the heading "Regional Contract" that:

"Dr Ala informed the committee that the lowest tender was forwarded by the present supplier - Armour Pharmaceutical Corporation, and no change was envisaged."

So it doesn't appear that there's any discussion, at least here, of those points that we saw referred to in the previous document. It just seems to be here the contract's been awarded on the basis of price. Do you have any recollection or understanding of that?

A. I don't, but I would perhaps suggest that that might

still have been going on in the background. Obviously, the tendering process was developed to separate us as the users from the spending of the money. I would have still thought that those requirements, even if they were slightly strange, the three requirements, would have still been informing the decision as to which companies to ask to tender. But obviously that's a very brief limit so it's not explicit, is it?

Q. No. If we go to the next page, just two further points to pick up, we can see that under "Any Other Business", Professor Stuart informing the committee that this would be his last attendance and in future you would attend as sole representative. Just go down the page. So we see that under "Any Other Business".

A. Yes.

Q. Then just going up from that, the paragraph headed "AIDS" -- so this is now December 1983, there's reference to there being a handout at donor sessions at the blood transfusion centre, and then it says this:

"It was agreed that if any case of AIDS was suspected, then the Regional Public Relations Office should be informed in case their help was required."

Are you able to cast any light on that because,

at first blush, it seems a bit odd to see the public relations office being involved?

A. Well, tragically we did ultimately have men who developed AIDS, and I don't ever remember talking to the Regional Public Relations Office about it.

Q. Then if we go on to the next meeting, which is SHIN0000028, so we're now in May of 1984, you weren't in fact at that meeting. You sent your apologies. But if we go over the page, we can see in the top section of the minutes it says:

"From the annual statistics and supply of BPL expected, there could be a shortfall of 3.5 million units to be made up from Commercial sources. The Working Party agreed that Mr Stanton ... should, in due course, invite tenders and subsequently meet with Drs I Franklin and RM Ibbotson to adjudicate."

Just pausing there, on this occasion it appears that the assessment of tenders is going to be by Mr Stanton, Dr Ibbotson -- where was Dr Ibbotson from?

A. Stoke-on-Trent. I know him well.

Q. And Dr Franklin, so yourself?

A. Yes.

Q. And then:

"It was agreed that the following points should be taken into consideration ..."

And then we see the same three points there articulated. So this is for the next round of the contract?

A. Yes.

Q. Can you recall anything about that subsequent adjudication process?

A. I'm afraid I can't. I don't remember that at all.

Q. So you don't know whether it would have been an informal or formal process or records kept of it?

A. Well, ideally they would have been kept but I don't recollect any such meeting.

Q. Do you know what, if any, steps were taken to get the information that would help you consider point 2, the point about donor facilities, what questions were asked or when enquiries were undertaken?

A. Well, the only enquiries I remember were those that I think I also did ask in -- having been trained by Dr Hill as to what questions to ask, I probably asked myself, but I don't know whether the supplies department asked those questions in a formal way and required anything in writing. I don't know.

Q. Okay. I think we can see some evidence, when we get to about 1986, of perhaps a more structured approach, but we don't have anything very clear in this stage.

Apart from the reference to donor facilities, we

can see that there is no express reference to any other aspect of safety or risk. Can you recall whether that factored into the decision-making process at all?

A. Well, knowing what I know now, I suspect that it was accepted that all these products had non-A, non-B hepatitis in them, and that the issue of where the plasma came from was our only lever, if you like, of trying to manage that risk in any way?

Q. In your witness statement at -- let me just find the paragraph -- yes, so two passages I wanted to ask you about. Paragraph 13. Do you have a copy of your statement?

A. Yes, I do.

Q. We can put it up on screen, Henry.

It's WITN4032001, please.

If we go to page 14. So paragraph 13, this is now talking about the particular products for treating patients. You say this:

"The particular products used for treating patients at the Centre depended on availability - which changed over time ..."

And we've touched on that.

"... previous treatment history ..."

Is that a reference to they have already been on

this product --

A. Yes, whether they were always on NHS or commercial or vice versa.

Q. Then you say:

"... and also the specific reason for treatment being needed."

What does that refer to?

A. Well, I would think if you had someone who may have been a less severe haemophiliac who you might try to use DDAVP for tooth extraction or possibly cryo for, I don't know, a hernia operation, and if they had perhaps bowel cancer and needed a major resection, you might feel you had to use concentrate.

Q. Then if we go, please, to page 22, paragraph 18, you say in the first sentence:

"Decisions were taken on the basis of an assessment of risk and availability."

We have covered availability. What did you mean by an assessment of risk?

A. Sorry can you just run back up to the precise question?

Q. Yes, of course.

A. Right, there we are.

Well, I think probably I've kind of explained that. If the risk was relatively low, tooth

extraction something like that, then you might -- you definitely try to use DDAVP if you could, and then so on down to some sort of major cancer operation.

I think I mentioned somewhere else in my statement one patient had a large bladder tumour that needed quite a big operation and that really had to be done under concentrate cover.

I think they're the risks. That's the risk strategy, isn't it, really?

Q. What role did patients have in decisions about what treatment to have at this time '83, '84, '85?

A. Well, any patient is at liberty to refuse any treatment at any time. I realise that might sound a bit glib but it's true. Beyond that, probably not a lot. I mean, we would have recommended what we thought was appropriate for the particular procedure they had.

Q. Can you recall whether patients were ever offered any kind of choice of treatment? So you correctly observed there's obviously an entitlement and principle to refuse?

A. Yes.

Q. Were they ever given a choice between, for example, NHS concentrate and commercial concentrate?

A. To be honest, I'm not sure I ever had that choice to

offer them. The supply of the NHS product was insufficient, so I think possibly not, really.

Q. What about a choice between concentrates and cryoprecipitate; was that a choice that was offered?

A. I don't remember offering that as a choice, no.

Q. You talked about assessment of risk and much might depend upon the circumstances of the patient and the risk of, for example, the bleed. Could we just look at your evidence, your written evidence, to the Archer Inquiry. There's just one point I wanted to pick up with you. Henry, it's ARCH0000443. Could we go, please, to page -- I'm sorry we've only got this annotated version of your statement.

A. Yes, I couldn't find a clean version for you.

Q. Are these your annotations?

A. I don't think so. It's not my writing, no.

Q. We didn't think so either. If you could go to page 5, please, it's the top paragraph. I'm going to come back at a later stage in your evidence and ask you about the precautionary principle, Professor Franklin, but you say this about six lines down:

"... the regular use of Factor VIII as a home therapy was a quality of life, rather than a life saving, approach. Most home therapy was for incipient joint or soft tissue bleeds. These are not trivial,

they are very unpleasant. But in the main they are not life-threatening."

Do you see that? Because some of the evidence the Inquiry's heard has posed this choice between life-saving treatment to prevent, say, a cerebral haemorrhage, on the one hand, and the risk of treatments with concentrates. But, as I understand the evidence you were giving there, you were making the observation that most treatment for haemophiliacs is of the life-enhancing, rather than life-saving, nature.

A. Well, I did think that and I'm not sure I've changed my view. I mean, I'd have to preface that by saying I was not one of the long-standing haemophilia doctors who had seen haemophilia care before decent treatment was available and the long-term effect of even these bleeds in some of the survivors that we did have was pretty devastating in terms of arthritis, employment prospects, personal relations, education. But I was always slightly suspicious about the idea that if we didn't carry on using concentrate -- and I did carry on using concentrate -- that if that was stopped then suddenly many, many, many, many people with haemophilia would have died.

I mean, if you develop cerebral haemorrhage when

you are at home, you need an ambulance. You don't need someone to put cryo -- to get cryo out of the freezer, I think that was my feeling. So I was always a bit sceptical about this but, I have to confess, you know, I went with the -- I was at the meeting when Professor Bloom said you should carry on with concentrate and that's what I did, so --

MS RICHARDS: Yes, and we will come on to that.

Sir, I note the time. I think I'm about to move on to a topic which will require looking at quite a lot of documents, so would this be a convenient point to take a half-hour break?

SIR BRIAN LANGSTAFF: Yes, let us take a break until 3.30 pm.

(The witness was reminded not to discuss his evidence during the break)

(3.03 pm)

(A short break)

(3.30 pm)

MS RICHARDS: Professor Franklin, I'm going to ask you to consider now your knowledge of the risks of hepatitis and, in due course, AIDS.

Before we look at any specific documents, what, if anything, can you recall being taught in your general medical training and then your haematology

training about the risks of viral transmission from blood and blood products?

A. Well, when I was in Leeds my main mentor, a chap called Brian Roberts, Dr Roberts, did say that, you know, blood transfusion was one of the more dangerous treatments in a way. It sounds a bit dramatic, and I think he was largely thinking of cross-match mistakes, blood group errors, but I think it did extend into concerns about hepatitis.

He did, however, sort of temper that by saying it seemed to be mainly a problem in the USA rather than in the UK. I mean, I think relatively speaking that may be true but I think we now know that there was a lot of hepatitis risk in the UK. So that was there.

As I say, when I was at the Blood Transfusion Centre, most of the experience or the training was in hepatitis B, and I think there was a sense of denial about non-A, non B in the UK. There was a meeting in -- Medical Research Council meeting about non-A, non-B hepatitis in 1979 when the then director of the Regional Transfusion Centre where I was training, in Edgware, Tom Cleghorn, said that he thought there was very little post-transfusion hepatitis in the UK at the time and quoted the fact that they were

transplanting one and three quarters of a million units of red cells at that time, which is a huge amount.

His colleague Dr Maycock, from BPL, agreed with that, that there wasn't much post-transfusion hepatitis, and even Dame Sheila Sherlock agreed, although she did caution about the use of commercial concentrates in that.

So I think there is a sort of sense that the UK was protected by its non-remunerated volunteer donor population from this. So I didn't have a lot of awareness of understanding about it other than that -- you know, what one got from textbooks or things like that.

Q. Just before we look at some of the materials that you have referred to in your statement, what kind of journals, medical journals or other sources of information did you routinely have access to and would read?

A. Well, it varied a little over time. I mean, throughout my career that would be the British Medical Journal, The Lancet and the New England Journal of Medicine. During my research it would have been papers about sickle cell disease, the journal Blood, which is probably the most prestigious haematology

journal. Various other journals over time. Online papers now, really, in the last 15 years. You're more likely to look for specific papers rather than open a magazine.

Q. In your evidence to the Archer Inquiry -- which we'll look at, ARCH0000008.

If we go to page 27, I think it should be -- next page, please -- you say this about non-A, non-B hepatitis, picking it up four lines down:

"Certainly to my mind it was not taken that seriously until a publication from the Sheffield group was published in 1985 with the lead author of Dr Hay, who showed quite clearly that quite a lot of patients with these liver abnormalities actually had significant liver damage."

Then you refer to a 1983 publication from Manchester.

So your recollection at the time you were giving your evidence to Archer was that it was this publication in 1985 which was significant in your own understanding of non-A, non-B; is that right?

A. Well, yes. I think, though -- I don't know, you will be talking to both of the key workers on this paper, Charles Hay and Eric Preston, and I would be interested to hear what they say. I think when you

look back now, I would say there's a high risk that a lot of this was damage due to a combination of hepatitis C and HIV.

Professor Lee's evidence last week suggested that hepatitis C on its own, while certainly not being benign, was certainly consistent with long-term survival in most cases.

Q. In your witness statement, if we go, please, to WITN4032001, and we go to page 26, picking it up in the last two paragraphs you talk about non-A, non-B hepatitis being considered "mild and relatively benign", and say that:

"Unfortunately this reflected a lack of knowledge of the full long-term history of non-A, non-B..."

Then you refer again to the Manchester paper and then the Sheffield paper.

A. Yes.

Q. We'll just look at those briefly, and then the textbook you refer to, as I think those are the particular documents you suggest that you were influenced by.

Before we do that, you say you would have learnt more about non-A, non-B hepatitis from the reports by Dr Craske at the UKHCDO. Would you have seen those

before becoming a director?
A. No.
Q. So only from 1983 onwards?
A. Yes.
Q. Then we'll just look at the other documents that you refer to. So the Manchester paper is WITN4032009 I hope, Henry. No.
A. That's the Manchester paper.
Q. It's certainly not the report I've got.
Do you have PRSE0002564, Henry?
So this is a full copy of the Manchester paper?
A. Yes.
Q. This I think is the paper you're referring to, "Liver disease in haemophiliacs: an overstated problem?" 1983. We can see it refers to:
"... biopsy ... on 12 multi-transfused haemophiliacs from the Manchester area with persistently abnormal liver function tests."
If we go please, Henry, to -- it's page number 654 of the report, Henry. I think it's probably the sixth page of the electronic document. That's it.
Go to the last paragraph on that page, we can see it says in this study:
"Only one patient was found to have CAH ..."

That's chronic active hepatitis?
A. Yes.
Q. "... with progression to micronodular cirrhosis. Four other patients had only mild chronic active hepatitis. We suggest that the true incidence of it severe histological liver abnormality in multi-transfused haemophiliacs may be less than previously reported but similar to the more recent results of 115 liver biopsies carried out worldwide (Aledort ... 1981) where the incidence of [chronic active hepatitis] and cirrhosis was 16 per cent."
Then it goes on to say that liver biopsies may not be indicated, perhaps for self-evident reasons.
Was this study which you recall reading at the time?
A. Yes.
Q. Do you recall any discussions with Professor Hill about non-A, non-B hepatitis or the risks of liver disease?
A. Well, I think we did. I mean, can I remember a particular moment? I mean, no, I can't. I think my knowledge of non-A, non-B hepatitis was quite limited until I started looking after the men with haemophilia, and that's interesting because I was doing bone marrow transplants in patients with sickle

cell disease, some of those were multi-transfused and yet it didn't seem to be something that was appearing in them, and for that reason it wasn't something that was foremost in my concern until I began to look after the haemophilia patients and it was obvious that all of them or virtually all of them had abnormal liver in function tests.
So when this paper came along about that, about the time I began -- either just about the time I started or maybe it was a bit before but it was certainly around that time, it seemed to be -- it's not actually that reassuring when you read it again.
Q. What I was going to ask you about, Professor Franklin, it's a study of 12 patients, I think.
A. It is -- the only thing I would say, it's a very small study we're looking at.
Q. As indeed many of them are.
A. Yes.
Q. Then if we look at the reference to Aledort, which was a slightly bigger study --
A. Yes.
Q. -- 16 per cent CAH and cirrhosis, it's not a small figure, it's still a significant figure?
A. Yes.
Q. Do you recall whether either you or Dr Hill at the

time had any opportunity to discuss this issue with liver specialists in Birmingham?
A. Well, we did have liver specialists there. I don't remember discussing this -- discussing that, sorry.
I do remember Frank Hill and myself talking about whether we should be doing liver biopsies, and we decided against. I think -- to be quite honest, I think by the time the Hay and Preston study came out, the issue was largely resolved, and I think we felt: what was the point? It's risky. You are well aware that there was a death at the Royal Free Hospital?
Q. Yes.
A. The -- not that money was the issue, but you need a lot of Factor VIII to safely do this. So we decided we wouldn't do that. 1983, the liver unit was only just starting at the Queen Elizabeth Hospital. There was a liver expert there, a guy called Elias, very good. He used to come and see my other haematology patients. There's no reason why we wouldn't have discussed these with him, but no, I don't think we had any systematic approach with the liver unit, no.
Q. Then the 1985 Hay and Preston paper -- Henry, I'm hoping I've got the right reference here, PRSE0004229. Do you have that? Thank you.

So this is the 1985 study that you referred to in The Lancet, and we can see there it refers to there being:

"... an eight-year study of 79 unselected patients with haemophilia ... [and] evidence of chronic progressive liver disease in at least 17 (21 per cent). 8 patients had chronic active hepatitis and 9 had cirrhosis ..."

What, if anything, can you recall your reaction to this paper being?

A. Well, concern. It's quite, you know, serious, serious data. I mean, I think as a pure study in hepatitis, then I think the difficulty is that these were probably taken from many patients who also had HIV; so that affects its value as a pure study on non-A, non-B hepatitis. But in terms of the seriousness to people with haemophilia, it's obviously pretty bad news.

The only problem is and was -- certainly was -- was there wasn't really any treatment. So in terms of what we discussed, it was -- what we discussed with individual people was that this may not be good and we probably reinforced avoiding alcohol, not a lot else you can do. It also, of course, was published at the height of the worry about HIV. So I think a lot of the discussions in my clinic were dominated by worries

about HIV and AIDS.

Q. You've also referred in your statement to the publication by Sheila Sherlock and, again, I think in fairness to your evidence, we should probably look at that because you say you did recall consulting this textbook?

A. Yes. I mean, I did. That was my source of knowledge about liver disease, really.

Q. You have referred in your statement to two passages. Sorry, you referred in your statement to one passage then more recently another?

A. I've since realised there are two passages relevant to non-A, non-B in this book, yes.

Q. So we will look at the passage you refer to expressly in your statement, first of all. Henry, it is WITN4032021, please. So this is page 290 of the book. We can pick it up at the bottom of the page, "Chronic non-A, non-B hepatitis":

"Serial studies have shown that patients with acute non-A, non-B hepatitis progress to chronic liver disease. This applies to the blood transfusion-related, the blood factor-related and the sporadic disease. The incidence of chronicity seems to be about 30 to 40 per cent."

That would suggest a significant number of

patients, a very significant number of patients, proceeding to a chronic liver disease.

A. Well, it's probably actually an underestimate.

Q. Then, if we just look at the next page, which was the second -- I'm sorry, Henry, it's a different reference: WITN4032022.

Then we can see the clinical features set out:

"Chronic hepatitis can follow both the long and short incubation types."

It says:

"Chronicity ... may develop insidiously and the acute episode would not have been recognised if the patient had not been under medical observation ...

"A characteristic feature is the marked fluctuation in serum transaminase levels, extending over many months."

Then:

"Liver histology shows the general features of chronic hepatitis, usually of persistent or mild chronic active type."

Then we see the next column "Prognosis and course", it says:

"Clinical progress is toward improvement, but cirrhosis has been reported."

Then "Treatment":

"Reassurance and regular supervision at approximately three to six-month intervals."

So this is 1981, this publication?

A. Yes.

Q. So that was the part you refer to in your statement --

SIR BRIAN LANGSTAFF: Just one moment before you go further, can you help me to understand the expression "clinical progress is towards improvement", because this is looking at a chronic disease, which is measurable only by transaminase values but otherwise one assumes is progressive in its natural way. We know now, as a matter of fact or at least matter of expert report to the Inquiry, it is progressive.

A. Yes.

SIR BRIAN LANGSTAFF: So "clinical progress", does that mean that the transaminase values tend to not be as bad later on or what does it mean?

A. Well, I can only speculate that it reflects uncertainties at the time because there are parts of this that seem to be suggesting one thing and parts that seem to be suggesting something else.

SIR BRIAN LANGSTAFF: Yes.

A. So, on the one hand, they go on -- people go on to get cirrhosis, on the other hand most people improve. Also, we are supposed to be reassuring people. That

word crops up on quite a number of occasions.
SIR BRIAN LANGSTAFF: But reassuring may mean telling people what isn't the case --
A. Well, I would hope not but it could, yes.
SIR BRIAN LANGSTAFF: Yes --
A. That would be inappropriate reassurance, wouldn't it. I think -- I think it reflects the fact that even Dame Sheila Sherlock didn't really know what was going to be happening.
SIR BRIAN LANGSTAFF: Do you happen to know if she actually wrote this chapter?
A. I think this volume she wrote herself, solely, this whole book. I think later volumes she had co-authors. Maybe you --
MS RICHARDS: I am just checking.
A. Counsel has the volume but I think it is a single-author text -- only her name on the --
Q. It's certainly only her name. I can look in more detail, sir, at the preface and acknowledgements but there isn't another author whose name is given on the text.

You have also drawn the Inquiry's attention to an earlier passage in the book pages 257 to 259. Henry, those are at WITN4032023. Is there another page? Keep going.

The end of that paragraph says "Cirrhosis can develop."

Then it talks about liver biopsies if you go to the next page. There's a description there of what might be seen in liver biopsies.

Then it says:

"Non-A, non-B hepatitis often progresses to a mild chronic hepatitis. The prognosis of this is, at the moment, uncertain but probably benign."

Unfortunately, there is no reference that is one way or the other in relation to that last section.
A. No. I mean, I think I wrote somewhere else in my statement that when it became clear that a lot of the men that I was looking after had got HIV, that I looked back at their notes from the period when I wasn't there and I was quite shocked to discover that virtually on the first injection of concentrate, regardless of type, they developed abnormal liver function tests. I like to think that, had I been there at that time, I might have been more concerned to not carry on but, I'm ashamed to say, I'm not sure I would have had that strength of character to go against the prevailing view.

I think this is sort of showing that -- to be honest, I would interpret this as uncertainty from

A. I'm fairly sure it's only her that wrote the whole book from that plate.
Q. Yes, certainly the plate only contains her name, you are right, Professor. So we see here, this is the other passage that you have drawn attention to, pages 257 onwards "Non-A, non-B hepatitis":

"The elimination of hepatitis A and hepatitis B from transfused blood did not eliminate post-transfusion hepatitis. Some of the cases were due to cytomegala infection, but the majority were due to another virus or viruses termed non-A, non-B. This infection now accounts for about 75 per cent of post-transfusion hepatitis ..."

It goes on to say:

"Haemophiliacs receiving factor concentrates obtained from commercial sources are particularly at risk. Non-A, non-B hepatitis is largely blood spread."

Then if we go over the page, I can see it says:

"The agent has not been conclusively identified. It has been transmitted to chimpanzees."

Then the clinical course is then described, an incubation period:

"The acute episode is usually mild and often anicteric ... Fulminant hepatitis is rare."

someone who is the world expert not really knowing what's going to happen, to be honest, and I think also when we look back she hadn't -- even she hadn't got a long enough longitudinal experience of a disease that can take 15/20/30 years to destroy someone's liver.
Q. In terms of the materials that you recall seeing at the time, bearing in mind that you were assuming responsibility for people with bleeding disorders in 1982/1983, other documents that we have looked at, you recall looking at this book, you recall the Manchester report, you recall the Hay/Preston 1985 study?
A. Yes.
Q. The Inquiry sent you some earlier and other materials from the second half of the 1970s through to 1980. I am very happy to go through them with you if it would assist, Professor Franklin, but they include publications in The Lancet from Prince and then in 1978 an earlier study from Professor Preston which, if I can put it this way, is not inconsistent with the 1985 study; would you agree with that?
A. Yes, it's quite small but absolutely, yes.
Q. We have sent you also some material from Dr Craske from 1978 reporting some American information about liver biopsies with 50 per cent showing changes

compatible with cirrhosis. I think we sent you a letter, which we've looked at with a number of witnesses, from Dr Kernoff to Dr Colvin, describing non-A, non-B hepatitis as a serious disease with long-term consequences.

You wouldn't, I imagine, have seen that letter at the time. Do you recall whether, in the second half of the 1970s, you came across any of the materials that we've provided you with?

A. Well, if I did they didn't impact that well. You showed a number of papers from Harvey Alter and colleagues. I don't remember those. It's quite likely I read the Prince paper but it didn't impact on me, I'm ashamed to say, no. I don't remember it.

Q. As I say, I'm happy to go to each of those materials if it would assist Professor Franklin but, in an attempt to short-cut it, would you agree that, looking at that material, which you may not have seen at the time, that paints a rather different picture of non-A, non-B. It doesn't suggest it is necessarily going to be a mild or benign infection, it suggests it may be something rather more serious?

A. It does. I'd still stick to my statement that I felt there was a bit of an atmosphere of denial in the UK over the risks of non-A, non-B hepatitis from UK blood

transfusion and that was the area in which I had experience at that time. I did not have experience of treatment with concentrates, particularly not concentrates from America until through towards the end of '82 -- no, I started in '82. Towards the middle and end of '83 probably.

Q. I think one of our witnesses used a term that there may have been a degree of wishful thinking on the part of haemophilia clinicians not wanting to think of non-A, non-B hepatitis as something serious, because of what was seen as the very great benefits that factor concentrates had brought. Do you feel able to comment on that from your own experience and perspective?

A. I think there was definitely wishful thinking about HIV AIDS in some of the papers I've seen. I think there was in 1995, if you allow me to sort of -- there was an Institute of Medicine book from the United States that looked back at the disaster in relation to hepatitis and HIV, and it came up with a hypothesis that there wasn't enough effort made to introduce heat-treated safe products because there was a feeling that hepatitis was -- if you let me look at -- I scribbled this down.

Hepatitis was viewed as an acceptable risk --

this is not me saying this -- by governmental regulatory advisory agencies responsible for the safety of blood and blood products, by the plasma fractionation industry and by the physicians looking after haemophiliacs. It also says, and I don't agree with this, by individuals with haemophilia. But I do think that hepatitis at that time does appear to have been viewed as an acceptable risk.

I mean, it was -- surely it must have gone to the Committee on Safety of Medicines, all these people getting hepatitis. I don't know.

Q. Can I just see whether we're looking at the same document. Is that the "HIV in the blood supply and analysis of crisis decision-making"?

A. Yes.

Q. Sir, we've got that, I hope, at WITN4032024.

Is that the right document, Professor Franklin?

A. Yes, I think so. Yes, it is.

Q. What was the page you were referring to?

A. That's a good question. If you could run down. It's not far from the front. It should be four bullet points, I think. Two hypotheses. A bit further please, next page.

Q. Ah, yes. I think it is your second point.

A. Here we are.

Q. "Hepatitis was viewed as an acceptable risk by the Government regulatory agencies responsible for the safety of blood and blood products, the plasma fractionation industry, the physicians who treated the individuals with haemophilia ..."

Pausing there. That, I think, is the bit you are associating yourself with --

A. Well, I think it looks as if that was the case, yes. In terms of wishful thinking, I suppose the hope was it wasn't very serious.

Q. In terms of the 1985 Hay/Preston research, would you accept that that wasn't something which showed something radically new or different, it was rather perhaps confirmatory of earlier fears; would that be a fair way of putting it?

A. Yes. Well, I think it was the final -- yes, the final sort of straw that, as it turned out, maybe it wasn't all hepatitis C, but what it definitely meant was that we were going to see a lot of bad liver disease in that group of men who were having those concentrates before effective heat treatment, yes.

Q. Move on to HIV/AIDS.

I think I understand from your statement you think you would have seen the MMWR report in 1982?

A. I started looking at them. They weren't easy to find

but yes, I did, because that was where -- I think I mention in my report that the pre-internet era, the -- actually knowledge was quite powerful, when I think about it, because not everybody had it. Now everybody has knowledge.

So we all knew that AIDS was happening in the gay men in America. The journals were months out of date, so you really relied on things like MMWR, because it was a weekly report, and also word of mouth by experts. Reading journals was -- you had to read the journals but it was insufficient.

Q. So the July 1982 report we know is the report about PCP being observed in some haemophiliacs in the States?

A. Yes.

Q. You also, I think, read the New England Journal of Medicine January 1983 Desforges article, and you noted there the recommendation to switch back to cryoprecipitate.

A. Yes, I wasn't responsible -- I was looking after people with haemophilia, that was on my rota, but I wasn't responsible for it at that time.

Yes, that was quite a prescient article.

Q. Then if we have up on screen, please, PRSE0002647.

This is the note of a meeting on

24 January 1983. It was with Immuno, to look at hepatitis-reduced Factor VIII.

We know -- if we go to the last page please, Henry -- from the list of attendees that Professor Hill attended, Professor Stuart did not. This is before you took over as director at Queen Elizabeth. But there's what appears to be, from the minutes, quite a lengthy discussion about AIDS. There's a report about the San Francisco baby case that had been reported in --

A. Yes, that must have been very shortly before this.

Q. Yes, that's absolutely --

A. And it wasn't yet published. But that goes to show the importance of bush telegraph-type communications.

SIR BRIAN LANGSTAFF: I think it had actually been published in the MMWR for the December, but it hadn't yet got to The Lancet, which came later.

A. Yes.

MS RICHARDS: And there's a discussion about the New England Journal of Medicine report.

Now, do you know whether this meeting, these updates, were something that -- did Dr Hill come back and discuss them with Professor Stuart, to your knowledge, or with you?

A. I don't remember. This is Frank Boulton's note, isn't

it?

Q. Yes.

A. No, I don't even remember being -- anyone talking about this meeting. No.

Q. What about the issues that were raised? So the case of the San Francisco baby which, as the Chair points out, was reported in December of 1982 in the MMWRs and the issues flagged up by Jane Desforges in her article, do you recall any conversation about those issues if not about the meeting?

A. I remember conversations about the doctors in Birmingham, my colleagues being very concerned that AIDS was going to be a problem in patients in the UK, not necessarily only men with haemophilia but -- you know, we transfused a lot of blood into people with leukaemia. We were worried about them as well.

Yes, there was a big -- well, it was huge issue.

Q. Was it -- when was it reasonably clear to you that AIDS was probably being transmitted by blood and blood products? Was it from these January 1983 reports?

A. Yeah, difficult. Well, I suppose it was actually from -- I mean, Chairman put me right on the MMWR. I don't know whether I read that one. I read some of them. But certainly by the time that -- the case of the baby came out, then that was pretty clear. There

was still other theories around but I think they began to fall away.

Q. In your statement, you say that when HIV/AIDS became a clinical issue, as co-directors we discussed our approach and reached agreement. I'll try to find the reference to that in your statement. But what I wanted to ask you was what did you mean by that? Co-directors is you and Dr Hill, so this is presumably after you have taken over in September of 1983 as director. What was the approach and the agreement that was reached?

A. Sorry, that was from Archer or my current --

Q. That was from your current statement. Forgive me, I'll find the reference.

A. Is that in relation to whether the men should be looked after in the infectious diseases unit or --

Q. I don't think so but let me find it, Professor Franklin, rather than asking you in the abstract.

A. I think that would have been later, wouldn't it?

Q. There are a few references I haven't noted down. I may have to come back to that tomorrow morning, Professor Franklin, when I have found the reference to the specific discussions you had with Dr Hill.

Can I ask you about the other materials which

your statement suggests or your Archer evidence suggests was influential on your approach and on your thinking.

You have referred in your statement to being guided by the advice of others, in particular UKHCDO and The Haemophilia Society, in terms of how to respond to the AIDS crisis.

A. I now know that wasn't The Haemophilia Society but, yes, I mean, absolutely. It was late '83, wasn't it, the meeting we went to when Morag Chisholm raised the issue of cryo? Yes.

Q. Yes, so 17 October 1983 was that meeting.

A. Yes. I mean, I think that was when I came away and thought, well, that's -- I can't remember -- I can't remember the discussion but I think that was -- we came away with a view to carry on. And then there was the next May, wasn't it, the letter from Professor Bloom to -- on The Haemophilia Society notepaper -- saying "carry on"?

So I think all the advice that I was getting from people who I would have looked up to and expected to give me definitive advice, that was where it came from.

Q. We'll take it in chronological stages. There's not too much we need to look at.

"... whilst it would be wrong to be complacent it would equally be counter-productive to alter our treatment programmes radically. We should avoid precipitate action and give those experts who are responsible a chance continually to assess the situation."

Was this, to some extent at least, influential on your thinking?

A. It sounds like wishful thinking now, doesn't it, but I think it was, yes. I mean, the advice of the experts -- I wasn't an expert. I wasn't an expert at bone marrow transplants and I would have taken advice from world experts in that as well. So yes, I mean I think that seemed to be the advice. Well, it was the advice -- clear, wasn't it?

Q. There's reference there to being "unaware of any proven case in our own haemophiliac population". We know from other materials that there was in fact a case --

A. That seems an economy of the truth, I would have said.

Q. Do you recall when you first became aware of the Cardiff case?

A. Well, I think it was around about the same time as this. I think it was quite well known. Wasn't there a Bristol one?

The May '83 Haemophilia Society publication, that was actually in '83.

A. Oh, was it? Okay.

Q. That's WITN4032008.

A. I think I was aware of that at the time, even though I wasn't the co-director, because I think -- I mean, we had weekly meetings of everybody -- or maybe not -- maybe Frank wasn't there at every one of those because he was mainly at the Children's Hospital, but I do remember this.

Q. This, as we know, was authored by -- as it says, it was authored by Professor Bloom.

If we just go a little further down, please, Henry, if we pick it up about halfway down, it says:

"Bearing this in mind [that's the investment in BPL] it is important to consider the facts concerning AIDS and haemophilia. The cause of AIDS is quite unknown and it has not been proven to result from transmission of a specific infective agent in blood products."

Then it goes on to talk about the number of cases being small:

"... we are unaware of any proven case in our own haemophilia population."

And then towards the bottom of that paragraph:

Q. Yes.

A. Was that before or after? I don't -- I have to say I'm not sure.

Q. The Bristol case was certainly the first death, in the summer of 1983.

SIR BRIAN LANGSTAFF: Just on the same vein, I heard this morning from what counsel was saying that in June Frank Hill was told that one of the patients of his who was at Treloars had been reported to show the stigmata of AIDS.

A. Yes.

SIR BRIAN LANGSTAFF: Is that the sort of thing which you would have expected generally to have been mentioned in the UKHCDO discussions?

A. Well, I would have expected it to have been mentioned within the department, yes.

I mean, I did -- I think I may have put in my statement that I didn't recall any of the men in my clinic having stigmata of AIDS before we began testing. So if that had been the case with someone from the children's side, I would have -- well, I would have expected to know that.

SIR BRIAN LANGSTAFF: Yes. Thank you.

A. I mean, I think these are -- absolutely vital information to have.

SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: Then if we go from May 1983, this publication, to the UKHCDO meeting that you've referred to -- Henry, it's PRSE004440, please.
Let me check that. PRSE0004440. I think I omitted a zero.
We can see your name appearing. This is 17 October 1983. This would presumably have been your first meeting that you attended as director?
A. Yes.
Q. If we go, please, to page 10, this is the discussion that you've referred to already, Professor Franklin. So Dr Morag Chisholm raising the question of reverting to cryoprecipitate. Professor Bloom's response:
"... no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS."
It might be said that's a somewhat surprising statement. Do you recall whether there was any challenge to that by anybody?
A. To be frank, I don't even know if I was in the room at the time.
No, I don't have any recollection of this. I mean, I've looked at it many times since. I think

you first showed it to Mark Winter. I remember going to the meeting and I think I said in my statement that I remembered going, because it was the first time I had been to a meeting where people with the condition that the meeting was about (i.e. people with haemophilia) were actually present and I think that was a good thing, but also it was a novel thing, and I remember that. But no, I don't remember this.
Q. The observation you make about it in your witness statement, if we just go back to that, it's WITN4032001, and it's page 72 of your statement, it's a sub-paragraph D in the first half of the page you say:
"They recommended at the end of the 1983 meeting~...
That's the meeting we have just been looking at:
"... that patients did not switch from concentrates to cryo."
Then you say this:
"I suspect that was taken not by vote but by the sapiential authority of the senior figures and a lack of organised alternative opinion."
Can I ask you to elaborate on what you meant by that?
A. Well, sapiential authority is the authority that

vested in someone by their experience or knowledge, I suppose, and I think, from reading the minute, it just seemed to move effortlessly on to the -- the senior figures in the UKHCDO decided that that wasn't the right thing. And there was -- if Dr Chisholm disagreed, there's no evidence in the minute that anyone else sided with her. I think that's what I mean.
Q. It may be difficult for you to answer this, Professor Franklin, as I think you only attended this and then the 1984 AGM, but I do not know whether from your discussions with Dr Hill or any other colleagues you have a view on the organisation of UKHCDO at the time. Was it effectively being -- were policies and recommendations being set by Professor Bloom and the other older, more experienced figures? Was there too much deference?
A. I think Mark Winter alluded to the fact that it would have been good to have had some more direct -- well, instruction or central advice rather than -- there's a lot of discussion in all of these notes about, you know, individual directors should decide. Well, I was an individual director but I wasn't very experienced, and actually neither was Mark at that time, and I think we both would have benefited from something

a bit more forthright as to what to do. Even whether it was right or wrong, that would have been helpful.
I think I've come to be not that happy about the UKHCDO, to be blunt, as someone who was in a very large haemophilia centre that was not a reference centre and a lot of the minutes and the notes that you and your colleagues have provided come from subgroups of the reference centres' directors. They contained far more useful information than the annual meeting of the UKHCDO. I don't remember seeing those minutes. I don't think those minutes were circulated to the rank and file, if I can say. I think that was a shame because they are far more useful than the two meetings I went to.
I don't remember why I only went to the first two. It's unlikely that I found them so unhelpful that I didn't want to go, but the fact is I didn't go and usually, if there was something really good and valuable in meetings, I would have attended. The meeting of the AIDS group for the HCDO was again reference centres' doctors, very interesting minutes. They would have been very helpful. So I'm sorry we didn't get to see them or the hepatitis ones, we didn't get to see those.
So I do feel a bit sad on behalf of the patients

at the Queen Elizabeth Hospital that we didn't get enough advice. You know, there was more to be had, I think, and I think it would have been -- it was never going to be easy but it would have been better. So definitely -- sorry, to cut things short. If there'd have been more advice, Mark Winter mentioned the CMO -- pretty silent in all this. I don't think it necessarily had to be the CMO but something definitive as to what we should do.

MS RICHARDS: Sir, I note the time. I am going to move on to look at again some of the local West Midlands meetings and the response to the HIV AIDS crisis. I'm fairly confident we can finish Professor Franklin's evident in the course of tomorrow morning by lunchtime; so would that be a convenient point to stop for today?

SIR BRIAN LANGSTAFF: Yes, it would. I'm sorry, professor, I think, as you knew, but I'm sorry anyway, that you have to come back and spread your evidence over two days rather than one.

A. No, that's -- I'm here to help.

SIR BRIAN LANGSTAFF: Thank you very much for that. There's just one thing I want to ask before you finish for the day and it goes back to a question which counsel asked you when she said in respect of the risk

of AIDS from blood products: when were you first clear that the blood products carried AIDS?

Can I just alter the question a bit and say: when were you first clear that there was a real risk that they might?

A. Well, I suppose we were afraid they might, all increasing through 1982.

SIR BRIAN LANGSTAFF: Thank you.

A. I don't think I can give you even the baby date, but I think that was always the worry, that that was going to happen.

SIR BRIAN LANGSTAFF: Thank you very much.

We will take a break then until 10 o'clock tomorrow. So 10 o'clock tomorrow.

(4.23 pm)

(Adjourned until 10.00 am the following day)

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