Wednesday, 6 October 2021

(10.00 am)

Presentation by Counsel to The Inquiry on the Pharmaceutical Companies (continued)

MR HILL: Sir, we are continuing with the presentation on Alpha, Abbott, Grifols, turning to the Factor IX product, Profilnine, that was produced by Alpha and Abbott in the seventies and eighties. The Inquiry has not identified any documents to suggest that there was a product licence for this product during that time. But there is evidence that it was used in 1984 and 1985 in its heat-treated form, heated in the same way as the Factor VIII product, through the use of the heptane suspension.

In particular, the evidence suggests that that product was used by NHS clinicians because there wasn't an equivalent heat-treated NHS product at that time. The Krever Report at page 756 suggests that the heat-treated Factor IX product from Alpha was available from late October in 1984, at least in the States.

I won't go through this evidence in detail. We have already heard -- and I've given you the references to Dr Winter's evidence for this Inquiry -- which was that he was using heat-treated Factor VIII

and Factor IX for his patients in 1984. A memo from 7 May 1985 from Dr Lane noted that Dr Kernoff at the Royal Free was evaluating Alpha's heat-treated Factor IX at that stage the reference is CBLA0002159. So that's May 1985.

A later letter from Alpha to Professor Bloom recorded that the Cardiff centre had received batches of heat-treated Profilnine between June and October 1985, CVHB0000002_050. And Dr Jones at the Newcastle centre stated in a document from 1990 that he had used Profilnine and Konyne in 1985 as no heat-treated NHS product was available. That's PGON0000104_001.

In May 1982, Alpha applied for a product licence for a solvent detergent-treated Factor IX product, which was known as AlphaNine at that stage. I think it had previously been preferred to as Pure Nine. (?) **

The documents suggest that the licence was granted subject to some conditions. MHRA0007156 and MHRA0007149. I don't intend to say anything more about the Factor IX products, sir.

Turning to plasma sources and plasma donors. We have covered some of this ground as we went through the licensing and the viral inactivation documents

yesterday, for example the donor pool sizes and the introduction of some of the testing. There are some other documents to which I would like to draw your attention in terms of plasma sources and donors.

If we could begin with an article published in 1979 but looking back at what Alpha had done in the 1970s in terms of testing, in particular for hepatitis B surface antigen.

The reference is BAYP0000021_003.

The article comes from the publication Clinical Therapeutics, volume 2, number 5, from 1979. It is written by Clyde McAuley and Kay Noel of Alpha, and it is entitled "HBsAg Testing in Commercial Plasmapheresis".

The article details the different tests introduced by Alpha during the seventies. It notes that Alpha introduced screening for all plasma donations for hepatitis B surface antigen in January 1971. David Bell in his witness statement of 2 February 2021, to which we referred yesterday, said that this was done -- sorry, I said by Alpha but of course it was by Abbott at this time -- he says that this was done by Abbott a year before it was mandated by the FDA.

The article goes on to say -- I won't bring it

up, but it's page 4 -- that in April 1973 -- it says Alpha Therapeutic Corporation but I think we should understand that to mean Abbott at the time -- replaced the initial test, which was a counterimmunoelectropheresis test, with the first generation AusRIA-I test, so an RIA test, in April 1973.

Then a second generation test, AusRIA-II, was introduced in February 1975.

The article describes the effect that these tests had, and it does it both in prose and by reference to a figure, a graph.

I'm going to ask if we could have both of those on screen, please, Soumik. So if we could have page 5 on one side of the screen and page 6 of the article on the other side. We can see the graph there, or the figure. And on the left-hand margin, the left-hand axis, we can see it says, "Reactive Rates per 1,000 Donations", and then on the horizontal axis you have the different years starting from 1971 going up to 1979.

You can see how the years are split up according to the tests, so the first generation CEP test is the first block marked by diagonal lines. The AusRIA I first generation RIA test is marked by the

speckled dots, and the AusRIA-II test by the cross hatching.

If we could return that to its pane, thank you, Soumik, I will then read through what is said in the article, and people can perhaps look at the graph and see the particular spikes that it is referring to.

The second paragraph down of page 5, the authors write this and I quote:

"The first period of counterimmunoelectropheresis testing during 1971 and 1972 indicated a relatively stabilised donor population. Transition from the counterimmunoelectropheresis test to the radioimmunoassay technique, in April 1973, was marked by an enormous increase in the number of antigen-positive donations detected."

I pause there, sir. That is very visible in the figure, is that spike at the point of April 1973 in the graph.

"Consistent with increased sensitivity of the radioimmunoassay technique, a substantial number of donors were rejected in the ensuing five months. A subsequent slight rise in reactive rate during the first quarter of 1974 was attributed to the introduction of a modified version of the AusRIA test;

as noted previously, the test modification, involving shorter incubation periods at elevated temperature, greatly increased the test of specificity. Again, after the first few months of test introduction during which time previously unidentified HBsAg positive donors were excluded from the plasmapheresis program, the incidence of hepatitis B antigenemia in the donor population stabilised. The introduction of the AusRIA-II test, in February 1975, has allowed the most sensitive detection of antigen-positive donations."

Pausing there, sir, the story is one of the new test being introduced, there being an increase in the return of positive donations, because the new test is more sensitive, those donors being excluded, and therefore the figures becoming more stabilised as time went on.

SIR BRIAN LANGSTAFF: I don't quite understand the reference in the article to the introduction of the AusRIA-I having a greatly increased specificity. That wouldn't explain a higher reactive rate, would it? Because the reactive rate is sensitivity, isn't it?

MR HILL: The distinction, as I understand it, between sensitivity and specificity --

SIR BRIAN LANGSTAFF: Sensitivity may lead to a number of false positives. It eliminates false negatives.

Specificity is the other way around.

MR HILL: Yes, but as I understand it -- perhaps --

SIR BRIAN LANGSTAFF: You can come back to me on that.

MR HILL: I think that it may be that it -- the term "sensitivity" isn't necessarily being used in contradistinction to "specificity" in this article. It may be that it is -- (overspeaking) --

SIR BRIAN LANGSTAFF: So they're not using the lingo that we're used to from our experts?

MR HILL: I suspect that is right.

SIR BRIAN LANGSTAFF: Right.

MR HILL: And I think it should be read as meaning that this test is better at detecting hepatitis B surface antigen than the previous test.

SIR BRIAN LANGSTAFF: So it should be "sensitivity" rather than "specificity"?

MR HILL: Certainly that would be the --

SIR BRIAN LANGSTAFF: That seems to be the sense of it but it's just the word which puzzles me.

MR HILL: Yes. I haven't seen the word "specificity" used in this article.

SIR BRIAN LANGSTAFF: If, in the course of the next day or so, anyone gives you a better suggestion for what it means, then let me know.

MR HILL: I will do.

In the discussion section the authors go on to say -- this at the bottom of page 5:

"In reviewing the reactive donation rate [on to the next column], it is essential to take into account the test turn-around time. Until the use of the courier service was introduced in September 1975, there was a one-week turn-around time in the radioimmunoassay testing program. Because a plasmapheresis donor may contribute plasma twice weekly, the [hepatitis B surface antigen] reactive donor contributed an average of 1.7 donations before being excluded from the plasmapheresis program (as noted previously, all reactive donations are excluded from the manufacturing process)."

The authors, sir, are raising this to explain the statistical steps that they took in the article to account for this lag in time, but I flag it to you, sir, for the different purpose of indicating that, up until September 1975, when a donor was found to be hepatitis B surface antigen positive, on average that donor would have given 1.6 donations before being excluded from the programme. There is nothing in the article to suggest that retrospective steps were taken to remove that donor's previous donations from the plasma pool. It is prospective that the donor is

thereafter excluded.

From September 1975, there was a quicker turnaround.

If we could go down to about two-thirds of the way down that right-hand column, the sentence beginning "During the period", the final paragraph. Thank you.

So, second sentence into this paragraph:

"During the period of counterimmunoelectropheresis testing, the average annual reactive rates per 1,000 donations were 2.1 (January through December 1971) and 2.4 (January through March 1973). From April through December 1973, concomitant with the introduction of radioimmunoassay testing the reactive rate increased to an annual average of 9.0 per 1,000 donations, reflecting a peak of 31.7 per 1,000, stabilising to 4.0 per 1,000 by the last third of the year."

If we go over to page 6, please, on the left-hand screen -- I think actually we can take the graph down, and we can just, sorry, go to page 7. My error. Page 7:

"This marked increase represents the detection of formally unidentified [hepatitis B surface antigen] reactive donors ..."

SIR BRIAN LANGSTAFF: Thank you.

MR HILL: "... in addition to antigen reactive new donors."

So if I pause there, the RIA test, as one would expect, is picking up both new donors who are hepatitis B surface antigen and who will be excluded from the programme, and donors who had previously donated who were hepatitis B surface antigen positive but had not been detected by the previous test. Returning to the article, and I quote:

"Since the implementation of the modified AusRIA procedures, the corrected annual reactive rates per 1,000 donors have stabilised at 1.2 to 1.4.

"In good agreement with the new donor reactive rate observed in community service volunteer blood centres, nearly 90% of Alpha Therapeutic Corporation's reactive donations are attributed to new donors. These donations were never used in the manufacture of plasma products and, as mentioned previously, these donors were summarily excluded from the plasmapheresis program. Thus the reactive rate within Alpha Therapeutic Corporation's continually tested plasmapheresis donor population may be estimated as 0.12 to 0.14 per 1,000.

"The reactive donation rate of 1.2 to 1.4 per

1,000, which the Alpha Therapeutic Corporation's plasmapheresis program has maintained since April 1974 [and I pause to note this article is now 1979, so a 5-year period], is comparable to the rate of 1.5 per 1,000 reported for a volunteer whole blood donation program."

And it cites couple of sources in respect of that figure, and says:

"Thus the comparative reactive donor rates indicate that in a well-run commercial plasmapheresis program the incidence of HBsAg reactive donors is not significantly different from that reported in a volunteer whole blood donation program."

The reference to the volunteer program is to the US volunteer program.

The point made previously in that paragraph is that 90 per cent of the positive donations are for new donors who are excluded and therefore haven't entered into the Alpha or the Abbott process. But 10 per cent are previous donors.

That is all that I take from that article, sir, but you will be aware, of course, that you have heard considerable evidence from individuals about they were infected with hepatitis B and non-A, non-B hepatitis during the 1970s as a result of the use of blood

products.

A further point to be made about that article is that it concerns plasmapheresis centres that were run by Alpha and, as we have seen and will see, Alpha also used plasma that was obtained from contractors and also used plasma which was recovered from whole blood donations in the voluntary sector, although whether or not that plasma went into blood products that were used to treat Factor VIII patients in the UK is a different matter.

We don't have much further evidence about the available sources of Abbott's US plasma in the 1970s but there is one document which indicates that Abbott had received plasma from Central America, specifically Nicaragua, during that period. If we could have BAYP0003777, this is a letter dated 15 October 1975, and it comes from the plasmapheresis, the Centro Americana de Plasmapheresis company in Nicaragua and it's sent by Guillermo B Castro, his position title is "Responsible Head", and it is sent to the Director of the Bureau of Biologics in the United States. The letter states this:

"We hereby request authorization to ship 15,434 liters of Fresh Frozen (Human) Plasma, collected from normal donors to, Cutter Laboratories,

[in California].
"The use of this plasma will be for manufacturing purposes into Human Injectable Materials. The tentative point of entry of this product shall be San Francisco, California [through] (air freight)."
This is the paragraph for our purposes, and I quote:
"We already have been authorized by you to make this SAME SHIPMENT to Abbott Laboratories with tentative port of entry Los Angeles, California. (Kindly see attached copy of your letter of authorization dated July 31, 1975). We wish to inform you that such shipment did not take place as Abbott Laboratories informed us at the time, they were overstock."
The letter to which reference was made is at page 2 -- apologies, that is not the letter. But the point of this paragraph is that Abbott had made an arrangement to obtain blood -- or obtain plasma from Nicaragua. They hadn't, in the event, gone through with it on that instance because they were overstocked. We don't know whether or not a shipment was made at another time nor do we know to what purpose any plasma from Nicaragua was put.

As you will recall, sir, from the UK licences, the application of August 1974 expressly stated that the blood used was obtained from plasmapheresis of commercial donors at eight centres within the United States, and there was a variation application in January 1975, that added a further nine centres, all within the United States. Now, of those 17 centres it seems that 16 were identified as being part of the company that Alpha itself owned and ran but one centre was part of a different company and we don't know who had control of that company, or the extent of any influence that Alpha had over it.
Turning to the 1980s, the president of Alpha gave a speech or a talk in February 1980, a man called Thomas C Drees, and if we could have IPSN0000328_008, this -- we don't have much context for when this talk was given but the principal purpose of it was a discussion of the plasma industry worldwide and obtaining data about it. I won't go into that.
What I will draw your attention to is the second section of the speech on page 2, please, which talks about "Can the volunteer blood system replace the paid plasma system?" A series of calculations are given in the speech, the nub of which is that, in order to replace paid plasma in the United States, it would be

necessary to increase the proportion of the population voluntarily donating from 3 per cent to 19 per cent.
Mr Drees points out the difficulties that the US Red Cross have had in publicising and attracting donors, and goes on to say, this is at the top of page 3, the first full sentence there, please:
"I submit this is impossible, and the effort would not be worth the cost to the American public for a phony moral issue. A true moral issue in paid vs volunteer blood is simply: is there an adequate, safe, cost effective supply of blood and plasma? If the controversy reduces the supply, then the cause of the controversy is immoral."
That was the position put by Mr Drees. If we could turn to page 4 of this document, just on a slightly different point but one of interest, he addresses the suggestion which seems to have been made in the United States at the time that exporting anti-haemophilic factions caused high prices in the US, a source of concern for patients within the US. Mr Drees denies that this is the case and says actually the higher prices which were obtainable overseas, in effect, subsidised the cost in the United States.
He gives some prices, we can see that on the

second paragraph. He refers to the high prices in West Germany, 43 cents; Japan, 40 cents; it's written "US" but I think this must be a reference to the UK, UK, 17 cents; Sweden, 60 cents; Italy, 35 cents; and Spain, 43 cents. Those all subsidise the low prices in the US of 12 cents.
If I'm correct in thinking that there is a typographical error and the first reference to the US is to the UK, we can see that that figure is of course higher than the 12 cents of the United States but significantly lower than the prices in West Germany, Japan, Sweden, Italy and Spain.
I turn now to the subject of advertisements and efforts to recruit gay donors. We have discussed this over the last couple of weeks and the significance of gay donors for providing hepatitis B immune globulin, the question of whether or not plasma obtained from those donors was also used in the manufacture of Factor VIII.
If we could have on screen please UCSF0000058, please, Soumik. This the front cover of a magazine called Advocate, which describes itself as "the national gay news magazine". This, as we understand it, is an edition from 9 July 1981. If we could go, please, to page 4 of the document, on the left-hand

side the second entry down, headlined "Every healthy adult should be a plasma donor", we can see that this is an advert placed by Alpha Plasma Centers, you can see that at the bottom left-hand corner, and the advert says this, and I quote:

"Help us help people who need plasma.

"Every healthy adult should be a plasma donor.

"It's a two-way street. You help us meet the growing demand for plasma and we'll help you earn extra income.

"Join us ... Be a plasma donor.

"Did you know that plasma is desperately needed by the sick and injured every day?

"For burn, shock, and accident victims, haemophiliacs, and others, plasma can mean the difference between life and death."

The address of a plasma centre is given, 973 Mission, San Francisco. Then it says:

"Bring this add for new donor bonus!"

So plainly an advertisement directed at gay donors, from 1981.

If we could go over to page 6, please. Another advert which we understand to be from the same publication, and the advert this time reads -- it's the one in the top right-hand corner, this time it

reads:

"Chances are.

"You've got hepatitis

"Or were exposed to it.

"If you're an active Gay, you have an extremely high chance of getting Hepatitis. This disease can cripple you for months. It can hurt you, and everyone around you, for a lifetime. It might even kill you.

"Yes, Hepatitis is a serious disease. But now there is something you can do to stop it.

"Help develop the anti-hepatitis vaccine.

"At Alpha Plasma Centers we are collecting plasma for use in the development of a hepatitis vaccine, that may one day stop Hepatitis dead in its tracks.

"You, or anyone you know who's had Hepatitis, can help in our research by contacting an Alpha Plasma Center. At Alpha, giving this plasma is fast, easy and safe. We'll pay you cash if your plasma is acceptable. We will give you a free blood test to find out if you qualify.

"Please, consider the danger of Hepatitis in our community. Your blood may hold the factors we're searching for, so contact your Alpha Plasma Center today."

Then a list of Alpha Plasma Centers with contact details, including phone numbers, is given.

Finally, if we could have CGRA0000294_074. This advert reads as follows:

"Hepatitis 'B'

"Have you ever had Hepatitis 'B' or a positive test?

"Your blood may be valuable for making a new vaccine.

"Cash paid per donation.

"Free confidential testing available.

"For more information, contact the nearest Alpha Plasma Center."

Then five centres are listed there in different cities in Texas.

As we have previously seen and discussed, in August 1982, Dr Dennis Donohue, of the Office of Biologics of the FDA, approached commercial fractionators to seek a voluntary agreement to cease using plasma collected from the targeted gay donors in the production of Factor VIII concentrate.

If we could have BAUM0000008, please, on screen. This is a document that we have looked at before. It is dated 30 August 1982. It is a Cutter document, which is referring to Dr Donohue's requests to Cutter,

which has also been made to other pharmaceutical companies, and it is recording what appear to be discussions with others at other pharmaceutical companies about what their position is. So it is Cutter's understanding of what is happening at Hyland and at Alpha. We looked at the Hyland section before, and what the document records in the second paragraph is this:

"Hyland (Mike Rodell) has had a policy that any plasma collected from a donor having a history of hepatitis (the disease, [hepatitis B surface antigen] positive, or in close association with others having the disease) are excluded from use in the manufacture of [anti-haemophilic fraction]. Currently Hyland collects plasma from homosexuals for anti-HBs but does not use it in their fractionation, it is sold to Alpha. Mike has told Donohue that he thinks Hyland excludes homosexual plasma from AHF but he wanted to check their procedures before making a solid voluntary commitment. My guess is that Hyland will make the commitment."

The memorandum goes on:

"Alpha Therapeutics, (Penny Carr) has just returned from Washington and had not met with her management (Hartin and Drees). She will make the

recommendation that they voluntarily exclude all anti-HBs plasma (almost exclusively collected from homosexuals) from coagulation components. Penny believes that the commitment should be 'voluntary' rather than via a written request from BoB [Bureau of Biologics] because the latter, could have political repercussions, could be difficult to amend, and would ultimately create concerns and problems with both the homosexual and haemophilic populations."

So there is an expectation in that document that Alpha are going to give a voluntary commitment that the document doesn't necessarily address what Alpha was doing in the past, save that it notes that Hyland appear to be selling plasma from gay donors to Alpha. If we could now turn please to CGRA000027, this is a letter from Marietta Carr, Vice President of Regulatory Affairs, presumably the Penny Carr who was referred to in the previous document, which was sent to Harry M Meyer, the Director of the National Center for Drugs and Biologics in the FDA. The letter is dated 30 August 1982.

What it states is this, and I quote:

"The purpose of this letter is to inform you that until further notice Alpha Therapeutic Corporation will not be using the cryoprecipitated

material from plasma from hepatitis B surface antibody donors in the manufacture of Anti-haemophilic Factor (Human). Such plasma is used by Alpha in the manufacture of Hepatitis B Immune Globulin (Human)."

So a prospective commitment not to do it until further notice but no comment on what was done before.

If we could have CGRA0000657, please, it is a further letter from Marietta Carr, again to Mr Meyer, dated 7 September 1982. In this letter Marietta Carr states:

"We are in receipt of the Office of Biologics' August 20, 1982 letter approving our procedure for the immunization of donors with licensed hepatitis B vaccine. This letter stated that plasma obtained from donors with a history of hepatitis may be used only for the production of Hepatitis B Immune Globulin or in-vitro diagnostics."

So that's using it to diagnose infections in a laboratory setting. Going back to the letter, I quote:

"As we stated in an August 30, 1982 letter to you, we have voluntarily suspended until further notice the use of cryoprecipitated material from hepatitis B surface antibody donors in the manufacture of Anti-haemophilic Factor (Human). However, we know

of no reason why plasma from such donors should not continue to be [used] in the manufacture of Normal Serum Albumin (Human) or Plasma Protein Fraction (Human). Therefore, we will continue to utilize plasma from hepatitis B surface antigen donors in the manufacture of Normal Serum Albumin ... or Plasma Protein Fraction ..."

So the plasma from donors, particularly gay donors who have been targeted in order to make the hepatitis B immune globulin, will continue to be used, suggesting that it has been used before, in albumin and plasma protein fraction, presumably on the basis that there are viral inactivation techniques connected with those products. The use in anti-haemophilic factors, so Factor VIII and Factor IX, is stated to be suspended.

Can we have, please, CGRA0000262. This a letter from Thomas C Drees, the man whose speech we looked at a little while ago, and it was sent to the National Hemophilia Foundation, the -- at that time -- major haemophilia charity in the United States.

What Dr Drees says is this, and it is sent specifically to Mr Charles J Carman the Chairman of the Board, and Mr Louis Aledort, the Medical Co-Director of the National Hemophilia Foundation.

What the letter says is this, and I quote:

"Gentlemen:

"I was pleased to receive your recent letter of November 2, 1982, but was distressed with the bad news. Alpha has never used plasma from homosexuals, intravenous drug abusers or recent Haitian emigrees. We have no centers in Florida, New York, Los Angeles or San Francisco, and do not buy plasma from these areas. We have always avoided drug abusers, and while we have purchased some plasma collected from homosexuals for Hepatitis B Gamma and Vaccine, we have never used it to make [anti-haemophilic faction]. We also think that plasma from prisons should be avoided."

It goes on to say that they agree with the proposed restrictions that have been suggested by the National Hemophilia Foundation.

SIR BRIAN LANGSTAFF: If one just goes back for a moment, bearing in mind that it says, "We have no centers in Florida, New York, Los Angeles or San Francisco", to something you showed me a moment or two ago, UCSF0000058, page 4, the address says 973 Mission, San Francisco.

MR HILL: It does, sir. We understand that comes from July 1981.

SIR BRIAN LANGSTAFF: Yes, the centre may have closed in between, but this is certainly is targeting people in San Francisco to give their plasma, and it was a centre in San Francisco, just in case it might be thought that the letter was suggesting there never had been plasma in the system which came from those centres.

MR HILL: That's correct, sir. If we could go to page 6, I don't know -- my copy won't allow me to see where the listed centres are, but if you go to page 6 of that document --

SIR BRIAN LANGSTAFF: It refers to the 973 Mission, San Francisco. You can work it out looking at the fourth line up.

MR HILL: Yes, San Francisco.

SIR BRIAN LANGSTAFF: 973 Mission Street, San Francisco, CA.

MR HILL: I'm afraid my eyesight won't allow me to pick out --

SIR BRIAN LANGSTAFF: It's not very clear but that, I think, is what it says.

MR HILL: Yes, I'm very confident about that one because we have the previous address. I was just seeing, as I scanned down, whether or not there is any reference to centres in Florida, New York, or Los Angeles. I'm

afraid I can't make out clearly what the other centres are.

SIR BRIAN LANGSTAFF: It's very difficult to work that out. The head office was in Los Angeles, wasn't it?

MR HILL: Yes, but whether or not that also meant there was a plasma centre --

SIR BRIAN LANGSTAFF: It may not have been a collection centre but it certainly was the head office.

MR HILL: Yes. But certainly those two adverts demonstrate that, as of 1981, there was a centre that was in San Francisco.

SIR BRIAN LANGSTAFF: Yes. And that it was active or intended to be active at the time.

MR HILL: Yes, yes. The phrasing of Dr Drees' letters is "We have no centers in Florida, New York, Los Angeles or San Francisco" as of 9 November 1982.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: Trying to bring together those documents, it's not possible to give you a comprehensive picture, I'm afraid, but there does seem to be evidence of the following.

First, Alpha actively advertised for gay donors and, as we have seen, that included in the San Francisco area.

Second, plasma from those donors was used in the

products of hepatitis B immune globulin, and this was approved by the FDA.

Third, there is evidence that Alpha also purchased plasma from gay donors from Hyland.

Fourth, that as of August and September 1982, Alpha gave a prospective commitment not to use plasma in the manufacture of Factor VIII and Factor IX concentrates.

However, fifth, they reserved the right to use it an albumin or plasma protein fraction products.

And sixth, the president of the company informed the National Hemophilia Foundation in November 1982 that Alpha had never used such plasma in anti-haemophilia fractions.

That sir, I'm afraid, is as far as we are able to take it at this stage.

SIR BRIAN LANGSTAFF: Thank you.

MR HILL: Turning to prisons, the document that we have just looked at from Dr Drees contained the sentence:

"We also think that plasma from prisons should be avoided."

That is from 9 November 1982.

If we could have on screen, please, CGRA0000376. This is a document dated 15 December 1982, and it is directed from the sales department of Alpha to its

sales force regional managers, and it is a document which is about AIDS and gives some facts that the regional managers should know. We will be coming back, of course, to the question of how the company and other companies responded to the threat of AIDS in November.

For present purposes, the second point down in the "Some facts you should know" is the relevant one. It states:

"There is a large homosexual population in the penal institutions. Alpha does not collect plasma from penal institutions."

The present tense is used there, sir. I don't know if that has any significance, I'm afraid.

On 22 December 1982, Alpha's US medical director, Dr Clyde McAuley, wrote to US haemophilia centres regarding AIDS.

This is at CGRA0000265, please.

You can see the date there, 22 December 1982, and the addressees.

If we go down, please, to the third paragraph, the underlined section there. Dr McAuley said, and I quote:

"We do not operate prison donor centers which have a large high risk population, nor do we purchase

plasma from prisons."

Again, the present tense is used. I don't know if there is a significance to that.

While we are on this document, if we could just go to the previous paragraph, it gives us some insight into how Alpha had approached its donor checks before. Dr McAuley wrote, and I quote:

"Alpha has always checked potential donors for temperature, fever, weight loss and other physical signs which now are suspected of being symptomatic of AIDS. Wherever we find a potential risk factor, we will decline to accept plasma from that donor. This action is consistent with our policy to do all we can to ensure patient safety in using our plasma products."

That is the information that we have, sir, about the use of prison plasma.

In November, we will hear more about the steps that were taken by Alpha and other pharmaceutical companies in response to the threat of AIDS.

Alpha were one of the first companies to instigate a donor screening programme specifically addressing some of the risk factors of AIDS and seeking to exclude high-risk donors. They did that from December 1982. It may be that they were the

first company to do that.

Of interest for present purposes is the effect of that donor screening programme. On 14 January 1983 an Alpha representative, or several representatives, attended a large National Hemophilia Foundation meeting, alongside other pharmaceutical manufacturers. The note of this meeting -- I won't take you to it but the reference is CGRA0000327 -- recorded that in the first three weeks of Alpha's new screening process, 308 people had been excluded. That screening process was focused on male donors who had had sexual contact with a man, people from Haiti, and those who used intravenous drugs.

According to the Krever Report, those 308 Alpha donors who had been excluded as a result of the answers they had given to questions in the donor screening programme, came from a total of 6,000-7,000 donors who had been questioned during approximately three weeks about high risk behaviour. So 308 out of about 6,000-7,000.

Alpha published newsletters periodically, and the summer 1983 newsletter stated that in the first six months of the donor screening programme, 800 potential donors had voluntarily disqualified themselves from the donor pool. The reference to

that is CGRA0000665_001.

What those figures don't tell us is how many of those donors were first-time donors and how many had given previous donations.

If we could have on screen, please, CGRA0000241. This is on a slightly different but related point. This is an Alpha memorandum from 25 January 1983. It's entitled "AIDS - Plasma Risk". It's from Bob Rivett and sent to Dave Gury. It provides an overview of the sources of the company's expected plasma collection in 1983. It's helpful for our purposes to see where they were getting their plasma from. Although I stress that the fact that the company was obtaining plasma from a particular source does not mean that that plasma was necessarily being used in the production of Factor VIII products. Still less that it was being used in Factor VIII products that were all marketed in the United Kingdom. But it does help us to understand where the company was getting its plasma at that time.

What is recorded in this memorandum is this, at point 1:

"1. We will receive 900,000 Kgs of plasma from Alpha donor centres. At 666ml/donation this represents about 1,350,000 donations."

"2. We will receive 200,000 Kgs from contract centers or about 300,000 donations.

"3. In the above cases, the average donor donates 15 times per year.

"4. The annual donor population at Alpha is 89,000 individuals and in contract centers 20,000."

"5. We are planning to receive 100,000 Kgs of Recovered Fresh Frozen Plasma (RFFP) from Blood Banks. At 250ml per donation, this represents 400,000 individuals, since there are few repeat donations."

"This results in the following picture:

"Source."

And we can see the table here. "Source" is in the left-hand column, and then "Kgs" provided of plasma. The number of "Donations" in the next column, and the number of "Donors" in the column that follows, and the "[Percentage] of donors". So we can see that there are three sources: the Alpha centres, contract centres, and recovered fresh frozen plasma from blood banks.

The biggest per volume, by some distance, is the 900,000 kilograms obtained at Alpha centres compared to 200,000 in contract centres and 100,000 from recovered fresh frozen plasma. That was also reflected in the number of donations at the Alpha

centres, 1.35 million, compared to 300,000 and 400,000 from the contract and the recovered fresh frozen plasma.

But the "Donors" figure shows that 89,000 donors provided the 1.35 million donations at the Alpha centres, so that's 17.5 per cent of the donors. 3.5 per cent of the donors contributed to the contract plasma. 78.6 per cent of the donors contributed to the recovered fresh frozen plasma. The reasons for that are that the donations are smaller, 250 millilitres per donation, and there are few repeat donations, which I understand to mean that people who go to the blood banks tend to donate once per year, rather than the 15 times per year that those at the Alpha centre on average provide.

The final paragraph of the memorandum states this:

"It would appear that if the assumptions are correct, we will have 78.6% of our total donors contributing to only 10% of our plasma. One could conclude that it is important to take all steps possible to ensure that this large segment be carefully screened to avoid including plasma from 'high risk' individuals."

That is the end of the memorandum. It is

written of course at a time when Alpha had introduced its screening programmes within its own centres. The memorandum appears to be pointing out the danger, the risk involved in the fact that a large number of donors, the 78.6 per cent of the donors, weren't coming from Alpha centres but were coming from blood banks, and, in addition, 3.5 per cent were coming from contractors.

Could we have on screen, please, BPLL0001351_122. This document we believe dates from 31 May 1983, and it is from David J Gury, who was the recipient of the previous memorandum. And it is sent to Joe Kimoto, of the Green Cross Corporation in Osaka, Japan, the ultimate owner of Alpha. It is entitled "AIDS Report - For Discussion with the Japanese Ministry of Health June 6, 1983", which is why we believe it comes from May 1983. I won't take you through the whole document, maybe one that we will return to in November.

For present purposes, it's just page 4, item 3, to which I will draw your attention. What Mr Gury wrote there, and I quote, is:

"For plasma obtained from blood banks, Alpha's specifications were changed" --

SIR BRIAN LANGSTAFF: It is probably "requiring", is it?

MR HILL: I suspect it is "requiring":

"... [requiring] that plasma collected after January 1, 1983, be from donors screened in the [same] manner as those at Alpha's Plasma Centers. (At first this was applied to all plasma. Later in January, it was reduced to apply only to plasma to be used in the manufacturing of AHF since other products are subject to heat treatment."

"The result of this requirement was a severe reduction in plasma procurement from blood banks as blood banks, at this point in time, refused to follow Alpha's lead and would not follow the screening requirements until forced to by regulations from the Office of Biologics on March 24, 1983."

Recommendations we will come back to in due course. What can be taken from this in terms of what was done before January 1, 1983 would be -- or at least the inference that I take from it is that Alpha did not control the processes that were being used in the blood banks for donor screening before that time, and when they introduced or required that similar processes be introduced in January 1983, the contributions from blood banks dropped off.

SIR BRIAN LANGSTAFF: Just going back to the letter which Mr Drees wrote to the National Hemophilia Foundation

on 9 November 1982, CGRA0000262:

"Alpha has never used plasma from homosexuals, intravenous drug abusers or recent Haitian emigrees."

If at that time Alpha was receiving fresh frozen plasma from blood banks, recovered fresh frozen plasma, then they would have no way of knowing.

MR HILL: They would have no way of knowing, save for whatever information was provided by the blood banks to them, but the large scale of donations and donors --

SIR BRIAN LANGSTAFF: And if blood banks were supplying them then in the same manner as they had been applying in early January through to March of '83, the implication from the letter you've just shown me, at BPLL -- on the AIDS report, essentially -- is that there were a number of potentially high risk groups the blood banks weren't prepared to ask and find out.

MR HILL: Yes. I would point out that in his letter, Dr Drees says that the specific groups highlighted, the Haitians, gay donors, prison donors, weren't used in the production of anti-haemophilic fraction, but the letter that I have read says that first the requirements that were placed on the blood banks were applied to all plasma, but later in January it was reduced to apply only to plasma to be used in the

manufacturing of anti-haemophilic fraction. So it does appear that, as of January 1983, blood bank plasma was being used in the production of anti-haemophilic fraction.

SIR BRIAN LANGSTAFF: Yes, the result of this requirement was a severe reduction.

MR HILL: Yes. Yes.

SIR BRIAN LANGSTAFF: But what you don't have the documents to show me is the extent to which, prior to January 1, 1983, Alpha was taking from blood banks?

MR HILL: No. I would note that the previous document that I showed you, which showed the figures, the anticipated figures for 1983, made no reference to any dramatic changes that were anticipated in the supply at that time.

SIR BRIAN LANGSTAFF: Thank you.

MR HILL: The further point that I don't have information on, save for the documents were provided with the licence applications in 1974 and 1975, is whether the plasma that was obtained from blood banks was used in Factor VIII products that were provided to the UK market. Certainly the applications in 1974 and 1975 would indicate that it was not and, if the licence were granted on that basis, then, unless the licence was varied, it would not have been open to the

company to have used plasma from -- other than the 17 centres that were listed in such production.

But we don't have a full set of all of the licensing documentation regarding Profilate.

Sir, that is all I intend to say for now about the issue of donors. There may be -- I understand that a document has been forwarded to us while I have been speaking and I will look at that during the break to see if it sheds any more light, particularly on the San Francisco centres.

SIR BRIAN LANGSTAFF: Yes, I think there is a reference somewhere to the recently closed San Francisco centre.

MR HILL: That is the document which has been forwarded to me.

SIR BRIAN LANGSTAFF: That may be CGRA0000599.

MR HILL: 15 December 1982 from E Healey -- Mealey, perhaps -- PhD, an Alpha employee, sent to the Executive Committee. We can see Dr Drees' name there, copied to others including Mr Gury and Penny Carr, and it's "Re: AIDS Meeting December 15, 1982". So point 1.C:

"If plasma is on hand from our recently closed San Francisco center there is no reason it should not be used."

SIR BRIAN LANGSTAFF: Yes.

MR HILL: 15 December, 1982. Thank you, Soumik.

A few further references, sir, to give you about Alpha, Abbott. I won't bring any of these documents up. There is some evidence that Alpha and Green Cross expressed an interest in establishing a fractionation plant in the United Kingdom in circa 1979 to 1980. We have seen similar documents from other companies. The references are DHSC0002197_170, and the same stem _166, and _164, and we know, of course, that ultimately that wasn't pursued.

Then a couple of documents on financial donations to finish with. The minutes of 14 April 1986 Reference Centre Directors meeting note that Alpha had agreed to provide funds for the October 1986 annual general meeting of Haemophilia Centre Directors Organisation but no figure was given in those minutes. The reference is HCDO0000420.

We also have an undated letter regarding funding by pharmaceutical companies in the 1970s and 1980s which appears to relate to the Lothian Health Board. That records a donation of £6,500 from Alpha in 1986 to 1987 and another of £1,000 in 1987 to 1988. Those references are STHB0000220. Finally, from June 2002, Dr Hill wrote to Ian Marshall of Alpha UK on behalf of the UKHCDO, seeking a donation towards the

organisation's database and that reference is HCDO0000264_057.

That, sir, concludes the presentation on Alpha, Abbott and Grifols for the present time, and that concludes this round of presentations on pharmaceutical companies. As you know, we will be coming back in November to look at the response to risk of those companies and, in particular, the response to the risk of AIDS. There are, of course, many other issues arising from the pharmaceutical companies that we will keep in mind and may explore further as the Inquiry progresses.

SIR BRIAN LANGSTAFF: Thank you.

MR HILL: The next course is to turn to some presentations from Ms Richards on various haemophilia centres. I note the time, sir, and wonder whether --

SIR BRIAN LANGSTAFF: Well, we will do that after we've had a break, and starting at 20 to 12. 20 to 12.

(11.10 am)

(A short break)

(11.41 am)

Presentation by Counsel to The Inquiry on smaller haemophilia centres

MS RICHARDS: Good morning, sir. There are a number of centres that we'll be covering today tomorrow and

Friday.

I'm going to list them so that anyone listening can understand which centres will be covered this week. I am going to start with a brief update in relation to Alder Hey. I am then going to go today to a number of London centres, Great Ormond Street, Charing Cross, Westminster, St Mary's, UCH, Hammersmith, Middlesex, Northwick Park, Edgware, Hillingdon, Guy's, Lewisham and King's.

If time permits, I'm then going to deal with two Haemophilia Centres which we didn't manage to get to in June, and that's Southampton and Truro.

Then possibly late this afternoon but probably more realistically tomorrow morning, I'll then pick up on the south/south-west centres, and we'll be looking not necessarily in this precise order but at this cohort of centres: Bournemouth, Plymouth, Exeter, Taunton, Bath, Salisbury and Winchester.

There is then a number of East Anglian centres to consider: Norfolk and Norwich, and Cambridge -- both of which we had scheduled for the June hearing but didn't get to -- Ipswich, Bury St Edmunds and Peterborough.

Then the remaining centres that will be covered this week are Bangor, Derby, York, Coventry,

Wolverhampton, Stoke, Shrewsbury, Hereford and Worcester.

There will remain some individual Haemophilia Centres after that that we haven't looked at, but it is our intention to undertake the same exercise, in terms of looking at documents and seeing what questions we can answer, in relation to product usage, treatment policies, and so on, and we will be producing written presentations in relation to all the remaining Haemophilia Centres, which will be both disclosed to Core Participants and published on the Inquiry's website but that time hasn't permitted covering every single remaining Haemophilia Centre this week orally.

SIR BRIAN LANGSTAFF: With that number of Haemophilia Centres, plainly what you're going to have to do is highlight the main points.

MS RICHARDS: Yes, absolutely. So for some centres, there are almost no documents at all.

For some there are quite a lot, for most there are at the very least annual returns, which assist in understanding what products were being used, although not necessarily for which categories of patients or why.

We will be able to identify for the most part

who the relevant Centre Directors were at different points in time and so on. But I will be being selective in terms of the documents that we look at in the course of the hearing. The presentations notes themselves, both for the centres I cover this week and for the centres that won't get covered this week, are much more detailed than the oral presentation, so we will look at as much of the available documentation as we can uncover.

SIR BRIAN LANGSTAFF: So, in essence, what you'll be giving me in open session will be the highlights.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: And both myself and anyone else who wishes the detail will have to go and look at the presentation?

MS RICHARDS: Yes. And I think so far the presentation notes have been disclosed to Core Participants but haven't yet been published on the Inquiry's website, but the intention is, over the coming weeks, to publish all the presentation notes, including those delivered as long ago as last autumn, on the Inquiry's website, so that those who are not Core Participants can nonetheless see the material themselves.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Sir, as I said, I will just start with

a brief update in relation to Alder Hey. You will, I know, recall the evidence in relation to Alder Hey Hospital from the summer, and you will recall in particular that we had two medicolegal reports, a report from Dr Savidge and a report from Dr Ludlam, looking at aspects of the treatment given to various patients at Alder Hey, in terms that I think could uncontroversially be described as critical.

Reference was made to a witness statement from Dr John Martin, who was the relevant consultant and Centre Director at the most material time, and we now have that statement. We may always have had, it is possible, but the volume of material that the Inquiry has is such that certainly I didn't have it in the summer, but we have got it now and I just wanted to show the statement and just read aloud some parts of it to add to the picture in relation to Alder Hey.

Soumik, it's DHSC0043164_070.

Sir, you will see it is a statement from John Martin, Alder Hey Children's Hospital. He sets out his background and experience in paragraph 1, and you'll see he explains he came as a consultant paediatrician to Alder Hey in 1967 and he took over the care then of children with bleeding disorders.

If we pick it up in paragraph 2, about five

lines down, he says:

"In addition [so that's in addition to other work including paediatric oncology] I had responsibility for the Associate Haemophilia Centre at Alder Hey. There were no other consultants to assist me in this work. However, I received help from a Senior Registrar in Haematology. I also had a half share time of a Paediatric Registrar."

If we go over the page to paragraph 4, you will see he says:

"It was not my practice to give new members of my team a talk in relation to haemophilia care specifically. The Senior Registrars would have been reasonably knowledgeable in any event. Senior House Officers did receive some instruction from me, as necessary, and I was also able to rely upon the Senior Ward Sister, who was extremely knowledgeable on matters concerning haemophilia. However, I made sure that I was on call as much as possible so that I could advise, if necessary."

The next paragraph he says:

"5. Although at any one time we might have between 30 and 50 patients with blood coagulation disorders on our lists, we would treat in any one year no more than about 20 patients."

Then paragraph 6 -- and you may want to read this, sir, in light of paragraph 4, where he says it wasn't his practice to give new members of his team a talk in relation to haemophilia -- he says in the second sentence of paragraph 6:

"The day to day care of the haemophilia patients was delegated to my staff in accordance with their various experience. If the parents brought their child into the ward during the day, then it is likely that they would have been seen by a Medical Officer, from the Paediatric, Haematology and Oncology Unit but at night time, the treatment would have been given either by my [SHO] or by the [SHO] on duty. If they felt unable to deal with the problem they consulted me. As I have said, I made it my practice to be available for as much of the time as I reasonably could and although I would have seen the patients only occasionally, I obviously had overall clinical control of their care."

Then he continues:

"7. At no [time] did I lay down a particular treatment regime to the clinical staff. Clinical judgments were made depending on presentation. No one would treat any patient with any blood product unless it was deemed to be necessary but there was certainly

no instruction to use cryoprecipitate for mild haemophiliacs or that it should be the treatment of choice in particular circumstances, and as can be seen, cryoprecipitate had been phased out in the early 1980s and was not generally available in the hospital. Equally I placed no restrictions on my staff concerning the use of cryo. If any member of my staff wished to use cryo on any particular occasions, subject to its availability, I felt that that was a matter for his/her judgment and I would not make it my practice to interfere. However, I took the view that Factor VIII concentrate was a lot more acceptable to all concerned: staff, children and their families. My aim was to keep children out of hospital as much as possible.

"8. I was on the mailing list for Haemophilia Centre Director minutes and meetings and certainly received information supplied from the Oxford Secretariat and we filled in annual returns."

Paragraph 9:

"Because of my other clinical responsibilities in the Hospital I did not attend Haemophilia Directors' meetings. I tried to keep up with developments in the medical literature."

Then he deals with hepatitis in paragraph 10:

"I was aware of the risk of transmission of Hepatitis through blood products from a theoretical point of view during the 1970s, however from the clinical experience at this Hospital we had little or no problem with Hepatitis being transmitted through blood products and I did not regard Hepatitis as a reason to alter any treatment regime. I was aware that imported commercial concentrates would be regarded as carrying a higher risk of Hepatitis than NHS products but the supply of one product over the other was not within my control.

"At this time, we did not use DDAVP. I viewed this product as of limited value, and difficult to use with small children. In the early days of DDAVP usage, there was a certain amount of disquiet over its potential side-effects especially disturbance of fluid balance in young children.

"We did not have many older children who required haemophilia care and therefore I did not have to consider DDAVP for use in such cases. I made a conscious decision that it was not to be used for smaller children although it was available at the hospital since it is used to treat other disorders of fluid balance, eg some forms of diabetes. The reason for my decision is that we had an established form of

treatment in place which I felt, at the time, to be safe and there was no reason to change my treatment methods. Another reason for not using DDAVP was that most children were treated as out-patients and DDAVP requires in-patient admission, something neither the children nor their parents relished. I was however aware that DDAVP could be suitable in some cases for adults who had mild haemophilia."

He then, in paragraph 13, describes the treatment of haemophiliacs in 1967 -- which is when, as he said, he arrives at the hospital -- as relatively straightforward. He used cryoprecipitate, essentially.

In paragraph 14, he says this:

"The development and availability of freeze dried Factor VIII concentrate revolutionised the treatment of haemophilia patients. It enabled home treatment to become more widely available and also for surgery to be considered more readily.

"Cryoprecipitate was supplied direct from the BTS [the Blood Transfusion Service] and we always found this to be a good and reliable source of supply. However, it was largely phased out in 1980 and we went on to use concentrate."

Then he sets out over the next page information

from the annual returns, which we looked at last time and I don't propose to repeat.

If we then go to the bottom of the page, paragraph 16:

"Because of the considerable expense of Factor VIII concentrates, the Area and subsequently District Health Authority decided to purchase the commercial Factor VIII concentrate that was necessary via the Royal Liverpool Hospital (RLH). This made sense for a number of reasons. First, RLH was a Haemophilia Centre whilst Alder Hey was only an associate centre. They had greater medical expertise with a Consultant Haematologist. Indeed at the time, Alder Hey did not have the facilities to perform Factor VIII levels on our patients and we used to have these done at RLH. They were therefore in a better position to assess what products to purchase. I did not at any stage object to this system for the acquiring of Factor VIII concentrate for our needs. The RLH would then send the concentrate that we required to us.

"A further reason for obtaining concentrate through RLH is that a better price per unit was achieved by buying in bulk. Both hospitals were under the management of the same District Health Authority

and it therefore did not matter which hospital paid for the supplies."

If we then go to paragraph 19, please -- sorry, I should say in paragraph 18, he says that:

"... the specific commercial product that was bought was chosen by RLH. The commercial Factor VIII was normally Armour. During the whole of the relevant period there was never enough NHS/Elstree Factor VIII available."

Sir, just pausing there, the system he described, whereby products were purchased by RLH, which obviously was dealing predominantly with adult patients, and then those products were provided to Alder Hey, might suggest -- it'll be it a matter for you in due course, and indeed for submission -- that consideration was not given to what might be the different treatment needs or different appropriate policies for treatment of children rather than adults.

That's relevant when we look at the next paragraph, where he says:

"I cannot recall specifically receiving the letter from the Haemophilia Centre Directors Organisation dated 24th June 1983 with recommendations as to treatment of children and mild haemophiliacs because of the potential implications for AIDS. As

I was on the mailing list, I am sure that I would have received it. There was no alteration in the treatment regime at this time as a result of the letter. I understood the RLH was obtaining as much of the scarce NHS Factor VIII as possible."

Sir, I know we've looked at it on a number of occasions previously but if we can just put that 24 June letter up on screen. Soumik, I hope you have it. It's HCDO0000270_004.

Sir, you will recall the recommendations set out in the paragraphs numbered 1 and 2. 2 relates to the treatment of children, which would, of course, have to be of direct and immediate relevance to Alder Hey:

"For treatment of children and mildly affected patients or patients unexposed to imported concentrates, many Directors already reserve supplies of NHS concentrates (cryoprecipitate or freeze-dried) and it would be circumspect to continue this policy."

Reading that together with what we see Dr Martin says about the lack of any change in the approach to treatment at Alder Hey, following that letter, might give rise to two matters for your consideration and for submission in due course. The first is, would a more powerful and directive recommendation from UKHCDO, not something which has been described by more

than one witness as being a weak recommendation, potentially have had greater effect and led to clinicians, such as Dr Martin, taking more notice and changing the treatment plan?

Secondly, even with such a "weak" recommendation as we see set out in this letter, should Alder Hey nonetheless have been alerted to the need to consider changing its treatment plan on receipt of this letter? That same question would apply to any clinician treating children or treating mildly affected patients or treating patients previously unexposed to imported concentrates.

Soumik, if we can then go back to Dr Martin's statement, DHSC00 -- thank you, and go to page 6. Bottom of the page, he then deals with heat-treated products:

"I was aware in December 1984 of the development of heat treated products and that they should be used from this time onwards. However, I do not specifically recall receiving the December 1984 recommendation. Supplies of heat treated concentrate were inadequate initially and it was some time before we were able to obtain these easily. Heat treated products were sent to us by RLH. As I did not purchase the blood products I did not have any direct

control over the concentrates available to us."

So that is potentially consistent with what we saw from the material we examined in the summer in relation to Alder Hey, which suggested that children continued to be treated with unheated concentrates after December 1984.

He then goes on to deal with the question of information provided or not provided to patients and their families. He says this at paragraph 21:

"I did not make it my practice to raise the hepatitis issue with families since my experience of it as a problem at Alder Hey was limited. If the parents wanted their child to undergo elective or unnecessary surgery I would try to dissuade them. In those circumstances I would quite often raise the risks associated with the use of blood products, in terms of risk of infection, including hepatitis."

So it would appear from that that those who were routinely receiving blood products as part of treatment for their haemophilia care were not told of the risks of hepatitis, which is again consistent with the evidence the Inquiry has received from the families of those whose children were treated at Alder Hey. But in the circumstances then described by Dr Martin in paragraph 21, there were specific

occasions, dealing with contemplated surgery, where those risks might then be discussed.

Again, whether that was an adequate way of dealing with the matter is no doubt a matter you will wish to consider in due course. Then, in relation to AIDS, he says this:

"When I first became aware of the AIDS problem I did not wish to worry parents with what at first seemed to be a tenuous link. It was important that their children continued to receive treatment and I made a judgment based on what I felt to be in their best interests. If a parent, usually the mother, asked about AIDS, I said that there was a risk but that there were also risks associated with non treatment and that in my judgment the child should continue to receive treatment."

He then turns to the individual claims, which I'm not going to go through because, again, we looked at information in relation to those -- the treatment of those individual children in the medicolegal reports which we examined in the summer.

If we go to the top of the next page, however, we can pick up, by reference to what Dr Martin says about the treatment of one particular child, something about his general practice. He says -- sorry, the

very last word on the previous page -- we don't need to go back to the previous page, Soumik -- is "although". So:

"Although not recorded in the notes I suspect this treatment was with commercial Factor VIII because in the annual returns it is suggested that he was given commercial Factor VIII in 1983 only. His treatment was consistent with the standard treatment being given to patients at the time."

So children in 1983 treated with commercial concentrates.

Then if we go to the last paragraph, this is just in relation to how parents learnt that their children had been infected with HIV.

"In relation to both children, we arranged for HIV tests to be conducted on their blood samples in August 1985 and the samples were positive. I then sent out a letter ... explaining my current state of knowledge regarding the virus and arranging for counselling with the parents."

So it would appear there to be consistent again with the broader evidence the Inquiry received, that parents whose children had been found to be positive for HTLV-III were told that diagnosis by letter.

Sir, that is an additional document for you to

consider more broadly with the material relating to Alder Hey, which we looked at earlier in the year.

Sir, I'm going to turn now to the various London haemophilia centres and start with Great Ormond Street Hospital. There is comparatively little documentation available in relation to Great Ormond Street for reasons that I'll come to in a moment.

In terms of the directors of the Haemophilia Centre, the director during the 1970s through -- in fact, I think from 1968 through to 1987 was professor Roger Hardisty. He was then succeeded in 1987 by Professor Ian Hann, and you heard oral evidence from Professor Hann in December of last year. I am not going to go to his statement again, which for the most part, in fact, deals with his experiences in Scotland, rather than at Great Ormond Street, but the reference, for the benefit of the transcript, is, I think, WITN3497005.

We also have a statement from Dr Lynne Ball. Dr Ball's evidence largely pertains, in fact, to Alder Hey and I referred to that in the summer. Her statement is WITN -- again, we don't need to show it at the moment -- 4739001, but she was also Honorary Senior Registrar at the Great Ormond Street Hospital between March 1986 and March 1988, and she has

provided some background information in relation to Great Ormond Street at that time in her statement.

In terms of the paucity of documentation relating to Great Ormond Street, Soumik, could we have WITN3774003, please. This is a letter dated 10 September 2018 from Great Ormond Street, from its Chief Executive and from the Current Haemophilia Centre Director, in relation to documentation and the Inquiry's request that Great Ormond Street provide documentation that holds relevant to the Inquiry's terms of reference.

They say, in the third line:

"... we have been unable to locate any stored relevant documentation from the 1970s/80s except individual patient hospital records scanned onto our electronic database and handwritten treatment ledgers dated from November 1984 listing each treatment given to named patients including batch numbers of the products given. Since the 1980s the hospital has undergone many structural changes and the haemophilia centre and offices have moved location several times. The physician in charge of the haemophilia centre in the 1970s and 1980s -- Professor Roger Hardisty -- is deceased and there is no personal paperwork from that time to be found in storage."

Then there is reference in the next paragraph to holding one file of documentation relevant to the 2004 vCJD notification exercise.

So that's the position in relation to contemporaneous documentation from Great Ormond Street. There is comparatively little directly held by the Hospital Trust now, and we have received also -- I don't propose to display it -- but we have received a description from the Chief Executive of Great Ormond Street setting out what searches were undertaken, both, I think, physical and electronic, by Great Ormond Street in response to the Inquiry's request for data.

So we have had to piece together information from other sources and, as indeed with most of the centres, the picture is inevitably an incomplete one, looked at at this distance in time from the events with which we are most directly concerned.

We will see, from some of the documents, Great Ormond Street Hospital was formerly known as the Hospital for Sick Children. The haemophilia centre there was based at the Department of Haematology at Great Ormond Street Hospital, in Great Ormond Street in London.

If we go to -- forgive me for a moment whilst

I get the reference -- DHSC0100026_009. We see here a letter written by the DHSS in December 1969 in relation to Haemophilia Centres in London and it's a standard letter that went to the 13 then designated Haemophilia Centres in London and then we'll look -- as we look at the various centres, we'll look at the responses that were received.

Sir, this is from a medical officer, Mr Obank or Dr Obank, in the Department of Health and Social Security:

"As you will know there are 13 designated Haemophilia Centres in the London area dealing with the diagnosis and normal care of patients suffering from haemophilia and related conditions. In order to enable the Department to consider what provisions are required for the future development of this service I am writing to all the directors of centres in the area, in order to obtain an indication of the work which each centre has undertaken during the period since the issue of HM(68)8."

That was, I think, a department circular.

"I should therefore be obliged if you would let me have information on the following points for your own centre for the year ending 30 September 1969."

Then there are number of questions:

"The number of cases of registered with your centre as of 30 September 1969.

"The number of incidents of haemorrhage at which the patients have attended at the centre for treatment during the year ...

"The number of haemophiliac patients not registered with your centre who have attended there for treatment.

"The number of incidents of severe bleeding in patients attending your centre.

"The number of major surgical operations undertaken in patients registered with your centre during the year.

"The number of patients from categories 4 and 5 above who have been transferred to the Special Treatment Centre at Oxford (if patients have been referred to any of the other Special Treatment Centres please give a note of the circumstances)."

Then 7:

"Any general or specific comments on how the provisions of HM(68)8 are working out so far as they affect the London area."

The answers that were given in relation to the various of the 13 centres therefore provide a snapshot of the picture of haemophilia care and numbers of

haemophilia patients as at the very end of 1969.

If we turn to Professor Hardisty's response, it's DHSC0100026_011, we can see he explains 89 cases registered with the Centre; 527 incidents of haemorrhage; five is the number of patients who have attended there not registered with the Centre.

Then I don't think we need to go through the detail of his answer to 4, but he raises the question as to what is meant by severe bleeding.

Then you will see at paragraph 7, he refers to a joint memorandum from Dr Dormandy -- who you will recall was director of the Royal Free Haemophilia Centre -- Dr Ingram -- I think I'm right in saying who was at St Thomas's at the time, I'll double check my notes -- and himself.

If we go just to that memorandum, again it provides a picture of haemophilia care in London. DHSC0100026_026.

We will see that they explain that:

"This memorandum is intended as a basis for discussion of the need to improve existing facilities for the care of patients with haemophilia and related disorders in and around London."

Then says this in relation to cryoprecipitate:

"With the increasing availability of

cryoprecipitate, a much more active approach can and should be taken to the treatment of minor bleeding episodes."

Then goes on to talk about the functions of a Haemophilia Centre in the London area. I don't think we need to look at that.

But if we go to page 4, we can then pick up some data in relation to Great Ormond Street.

Sir, this is a table describing current workload at Great Ormond Street, the Royal Free, and St Thomas', and we are concerned only with Great Ormond Street for present purposes, so if we look at the right-hand column:

"No. of patients under supervision ... 90

"No. of patients treated ... 61"

Then we have numbers of treatments: 396 is inpatients, 498 is outpatients.

"Average no. of treatments per patient treated ... 14.6."

Then if we go to the next page, we can see the distribution of patients at Great Ormond Street. So, in terms of haemophilia -- and it doesn't here distinguish between mild, moderate and severe haemophilia, but I take that as a reference to haemophilia A -- we see 59 patients registered, 46

treated in that January-October period. Christmas Disease, so haemophilia B: 20 registered, 11 treated. Von Willebrand's: eight registered, two treated and then miscellaneous: two registered and two treated.

Then if we go to the next page, we can just pick up at the bottom of the page, under the heading "Great Ormond Street", it explains:

"The number of patients registered has increased from about 60 to 90 during the last 5 years, despite the referral of patients to adult hospitals ... on attaining the age of about 12-13 years. Although figures for the number of treatments in past years are not readily accessible, it can be confidently stated that the availability of cryoprecipitate has led to a very great increase in this respect during the last 2-3 years."

So that's the picture as at really the beginning of the 1970s.

Then if we go to DHSC0100026_084, this is, I think, a Department of Health note of a meeting held to discuss the organisation of haemophilia care in London.

Again, we don't need to look at much of the detail of it. You'll note Dr Yellowlees in attendance. At this point in time, February 1970, he

was, as I understand it, the Deputy Chief Medical Officer.

If we go over to the second page, paragraph 8, which is the bottom half of the page, we can pick up, in relation to Great Ormond Street, Professor Hardisty describing the approach there:

"Professor Hardisty explained that at Great Ormond Street the emphasis was on the early treatment of minor bleeds in children to prevent crippling. The increase in workload derived from the larger number of treatments being given per patients rather than increase in the number of patients. At his centre, some 50% of the 89 registered patients attended frequently or fairly often."

Then if we go to the next page, we can just see, under the heading "Availability of haemophiliac material", paragraph 12 -- I'm sorry, Soumik, I think -- yes, it's there.

"Dr Ingram stressed the need for additional material if therapeutic treatment of haemophiliacs was to continue and to expand. Dr Maycock outlined the measures which had been taken to increase production of this material; it was expected that in 3-4 years good supplies of cryoprecipitate etc would be available."

Then just picking up on "Conclusions" at the bottom of the page, you can see it says at paragraph 16:

"It seemed likely that St Thomas' and the Royal Free would in time naturally evolve as the main Haemophilia Centres [in relation to London, of course]. Great Ormond Street should also remain in view of its special nature and possibly Hammersmith."

And we will pick up the picture in relation to Hammersmith later in the course of the day.

If we then look at OXUH0003597, we can see a meeting later in 1970, so this is 15 October 1970, and there are now representatives more broadly from centres across London -- so not limited to Dr Dormandy, Professor Hardisty and Dr Ingram -- and we will see representatives there from various of the Haemophilia Centres, which we'll be exploring in the course of the day. I just want to pick up, towards the bottom of this page, what's said as the view of the department but also more broadly about the approach to haemophilia care, and this really has resonance not just for Great Ormond Street or London but more generally.

"Dr Lees [that's the chair of the meeting and a representative of the DHSS] said that the pattern of

treatment of haemophiliacs had changed quite markedly during the past 3-4 years due mainly to the increasing availability of cryoprecipitate."

Pausing there, sir, I draw these materials to your attention and the attention of those listening, because obviously we've heard a lot about what was said to be the revolutionary effect of factor concentrates, but it is perhaps important to understand what was said to be the very dramatic or significant effect of the availability and introduction of cryoprecipitate more widely in terms of improving the lives of people with bleeding disorders.

So the minute or the notes continue:

"This had allowed a much more active approach to be taken in the treatment of minor episodes of bleeding which in turn had encouraged the greater use of other facilities, (eg physiotherapy and orthopaedic surgery), in the prevention of crippling lesions from which haemophiliac patients had suffered in the past. The concept of an adequate therapeutic service had therefore altered radically and its provision demanded much greater resources of experienced staff as well as therapeutic materials. It had been suggested that a Haemophilia Centre should be able to provide skilled

treatment on demand at any time of day or night and this implied having staff always available who were experienced in treating these patients. The Centre should also provide cover for emergency surgery and should be able to undertake the assay of Factor VIII potency of cryoprecipitate made at the Regional Blood Transfusion Centre."

Then there were further discussions in the document relating to the organisation of haemophilia care in London more generally which I won't take time going to now.

We can take that document down, thank you.

Without then going through -- repetitively through lots of documents, in the course of around 1976 there were discussions about the organisation of haemophilia care within London, and indeed within the East Anglian region, as well. And this was part of what was called the south-east supra-region, and it was decided that overall responsibility would be split as between Dr Dormandy and Professor Ingram effectively along the Thames, so that for the most part Haemophilia Centres north of the Thames would be the overarching responsibility of Dr Dormandy and south of the Thames, the overarching responsibility of Professor Ingram, and Great Ormond Street appears to

have been regarded as part of the Northeast Thames region.

However, if we go to CBLA0000510, this is a document from December of 1976 and it's in relation to the allocation of NHS Factor VIII concentrate to regional blood transfusion centres. So the arrangement within this south-eastern supra-region was effectively that NHS concentrates would be distributed through the blood transfusion centres -- there were, I think, three blood transfusion centres within that region -- and then they would be distributed according to the 1974 annual returns. And we can see here now that the Hospital for Sick Children -- Great Ormond Street, as it became -- is regarded, for the purposes of the distribution of the NHS concentrate, as being within the North Thames Regional Health Authority, and you can see there a reference to a distribution of 62 bottles a month, or an allocation of 62 bottles a month of NHS factor concentrates.

If we then pick matters up at CBLA0000533, we can see this matter, this question of how NHS concentrates were going to be allocated within the region, was discussed at a meeting on 15 December 1976, and we can see the range of attendees. We will come back to some of these names

again when we look at some of the other London centres. But we can pick up what was happening in terms of the allocation of NHS Factor VIII concentrate at the bottom of the page.

"Dr Dormandy explained that as from December 1st, 1976, NHS F.VIII had been delivered to the Regional Blood Transfusion Centres ... and that the amount going to each was a proportion of the total availability based on the number of patients reported to have been treated at the Haemophilia Centres of that region in 1974."

Then there's a discussion about this distribution with the Thames as a dividing line between an area for which Dr Dormandy was responsible and an area for which Professor Ingram was responsible.

If we then go on to page 4, however, we can pick up the particular picture in relation to Great Ormond Street. Second paragraph:

"Professor Hardisty said that (a) all his patients on home treatment were on commercial F.VIII for which the Hospital for Sick Children had a special allocation from the DHSS ..."

That's the picture as at December 1976 with the children at Great Ormond Street. Pursuant to specific

arrangements with the Department of Health, home treatment using commercial concentrates.

Then:

"... (b) patients came from any of the 4 regions ... and that if a different system of allocating concentrate for each region had to be used, this would become very complicated and therefore dangerous. As far as he was concerned, it was only feasible to supply concentrate to the patient or his parents or to the hospital concerned with the care of the patient."

Then there's reference two paragraphs further down to the chair, who was Dr Donald Carmichael, I think, pointing out that:

"... the Hospital for Sick Children was in a unique situation because it was a supra-regional children's hospital. He asked if it could be accepted in principle that the Hospital for Sick Children should retain its individual status, and this was agreed."

There are various other meetings of this supra-regional entity. We'll look at them to the extent that they cast any light on the individual London haemophilia centres as we go through those centres in the course of the day.

If we just look at one further document from

this time period, it's at BART0000689.

This is a meeting again of the same, I think, group of individuals:

"... Second Meeting of Directors of Haemophilia, Associate Haemophilia Society and Blood Transfusion Centres, in [the Regional Health Authority areas] 04, 05 & 06, 23rd September 1977."

Professor Hardisty and -- I think it's Sieff -- Dr Sieff from the Hospital for Sick Children sent their apologies but if we go to the bottom of the second page we can see that Dr Seiff had provided a letter which was then read to the meeting by Dr Dormandy, and it is summarised as follows:

"Despite their allocation of 30 bottles NHS [concentrate per] month they had needed to buy more commercial [concentrate] from January to August 1977, (235,000 [units]) than over the same period in 1976 (185,000 [units])."

So we see a picture in 1977 or towards the autumn of 1977 of increased use of commercial concentrates at Great Ormond Street Hospital.

I won't go to it now, but there's a further meeting, the third meeting, I think, of this particular group, in September 1978. For the benefit of the transcript, the reference is CBLA0000838.

Again, Professor Hardisty sent his apologies and Dr Rankin attended in his stead, and again, the issue of shortage of concentrates was raised as a general issue.

We will look at the actual usage of concentrates at Great Ormond Street in a moment from the annual returns, but before we do so can I just then pick up a picture in relation to supply of NHS concentrates and heat-treated concentrates, now in December of 1984, at CBLA0001945. And again, it gives a snapshot in terms of the position by the end of '84.

It's a letter from Dr Evans, lecturer in haematology at the Great Ormond Hospital, to Mr Pettit at BPL. He says:

"... I am writing to you about supply of [NHS] factor VIII for the haemophilia children at [Great Ormond Street]. As you are aware my initial reason for contacting you was because of the difficulties in obtaining a sufficient amount of NHS concentrate to treat our patients this month.

"On reviewing the records of our patients we have four patients who have never received any commercial concentrate but who are currently receiving regular treatment with NHS factor VIII concentrate ..."

And then reference is made to those patients.

Then picking it up below the list of patients:

"We discussed the possibility of treating these patients with either a small pool plasmapheresis factor VIII concentrate or alternatively a small pool heat treated concentrate. We would be interested and willing to co-operate in a clinical trial of these products in these particular patients."

Then picking it up at the bottom of the page:

"As you are well aware, our reason for approaching you initially is that we would really like to treat all the children with NHS concentrate."

And then the last sentence of that page:

"I am sure it will come as no surprise to you that many of the parents of the children we treat here are very anxious about the use of commercial concentrate in use by their offspring."

That, of course, as at December 1984, will come as no surprise.

That Great Ormond Street continued to experience difficulties in terms of supply into 1985 appears from CBLA0002160. This is from May of 1985. It's from the haemophilia sister again to Mr Pettit at BPL. It refers to:

"... a lost of most of our severe haemophiliacs

requiring concentrate who we would like to have heat-treated Lister ...

"Our present supplies from Edgware and Brentwood certainly do not seem enough for our needs at the moment."

So those are snapshots at different points in time, but it would appear a common theme -- at least in relation to those periods for which we have documents -- a common theme in terms of insufficiency of NHS supply, and supplementing that by the use of commercial concentrates.

We can then pick that up by reference, in a moment, to the annual returns. Before we do that, however, I should just show you one letter, again from the early 1970s, which may assist in understanding Professor Hardisty's approach to treatment.

CBLA0008794.

Sir, we are now in November 1972. We looked at those materials from 1969 and 1970 which suggested an enthusiasm for cryoprecipitate. Here, in his letter to Dr Maycock, Professor Hardisty says in the second paragraph:

"Our present usage of cryoprecipitate is not restricted by shortage, but is undoubtedly excessive, since we have to compensate for the low potency of the

material we receive ... For this reason it would presumably be economical of material if we were to switch to Factor VIII concentrate, and I should certainly prefer to use the latter material ..."

"To use" is crossed out I think.

"... for its significantly greater reliability. On the other hand, since we treat most of our haemophiliacs as outpatients, it is important that we should be able to administer replacement therapy by syringe rather than by drip; for this reason cryoprecipitate of reliable potency would presumably be preferred to the Factor VIII concentrate supplied at present, since it could be given in a smaller volume. [However], I should certainly much prefer to be able to use concentrates with a higher potency than those at present made, and perhaps the yield in this case would not be significantly less than in the cryoprecipitate we are currently receiving."

So if we then look at the annual returns, and I won't go through all of them, we can get a sense of both product usage and numbers of patients treated if we look at some of them.

The annual return for 1976 is at HCDO0001077.

Sir, we can see for 1976 the total number of haemophilic patients treated during the year described

as 38, Christmas Disease patients, 12.

Then we can see the amount used. So cryoprecipitate still in 1976 in very considerable usage, 229,320 units; very, very modest amount of NHS Factor VIII concentrate; and then a range of different commercial concentrates used, predominantly the Armour product, Factorate, and the Immuno product, Kryobulin, but also some usage of Profilate, Koate to a very small extent, and Hemofil, and the NHS Factor IX concentrate for those treated for haemophilia B.

I won't go through the detail of the other documents supplied with the annual returns, but we see from them that there were 14 patients at that point in time on regular home therapy.

If we pick the picture up in 1977 at HCDO0001160, we can see a significant reduction in the usage of cryoprecipitate. So still used to a not insignificant extent, to approximately the same volume used as NHS Factor VIII concentrate, but rather less than the previous year, and then a significant increase in relation to some of the commercial concentrates with the largest share that year being the Cutter product Koate, at 223,000 odd.

Then -- sorry, I should say, just within that, if we go to page 3, please. Sir, we have seen these

kind of documents as part of the annual returns before and they show the individual treatment administered to individual patients, obviously the patient details are redacted. But what you'll see from the ticks on the right-hand side indicates that a number of patients at least, not all, received more than one, and indeed, in a number of cases, three different types of commercial concentrate in that year alone.

So it does not appear as though there was, at that point in time, any policy of restricting or trying to keep patients on one type of commercial concentrate, still less presumably one batch dedication at any particular point in time.

I won't then go through all of the remaining returns but we've set out in the presentation note in detail what the returns show.

Broadly speaking, 1978 shows an increase in the use of NHS concentrates but, again, the majority of concentrates in use being commercial concentrates, in particular for that year the Armour product Factorate.

There's a similar picture for 1979, and there's also there reference to use of the porcine product for an inhibitor patient. Then in 1980, again, it's a majority Factorate, the Armour product, that emerges from the annual returns with the next greatest in

volume being the NHS and then Kryobulin.

We don't have the annual return for 1981. If we pick the picture up then, in terms of looking at the documents, in 1982, at HCDO0001620, we can see there, if we look at the handwritten entries on the right-hand side of the table, very limited usage of cryoprecipitate. Some NHS factor concentrate in usage but, by far and away, the majority of treatment is with the Armour product Factorate. So it looks like nearly a million units for home treatment and over 400,000 units for hospital treatment of that Armour product.

Then the picture in 1983, HCDO0001717, does show increased use of NHS concentrate, and we have the figures there. We can still see the Armour product Factorate being used to a considerable extent for home treatment, albeit not in the same volume as previously.

Cryoprecipitate, again, is used only to a very limited extent.

The picture for 1984, HCDO0001812, is a little different. It's not entirely easy to work out what that handwriting for cryoprecipitate is intended to convey.

SIR BRIAN LANGSTAFF: Which?

MS RICHARDS: The cryoprecipitate -- obviously for von Willebrand's it's fairly straightforward with 39 bags, but in terms of haemophilia A patients, we've got a figure for bags which has been written over.

SIR BRIAN LANGSTAFF: Yes, that looks like 710 bags.

MS RICHARDS: It does. And then --

SIR BRIAN LANGSTAFF: That then would translate at roughly 70 units per bag to the figure which is above.

MS RICHARDS: Yes. That -- certainly, it's increased usage, albeit it's still not the majority, by any stretch of the imagination, but an increase on previous years.

Then we can see NHS concentrate being used, it would appear in 1984, as the main product for treatment, and a significant reduction in the use of commercial concentrates in terms of volume, and the note at the bottom seems to suggest that the Armour product that was being used was heat-treated, presumably towards the tail end of the year.

SIR BRIAN LANGSTAFF: One of the features of those last two years you've shown me may be the overall total used, by comparison with 1982. Can we just go back to HCDO0001620, and look at 1982. 43 haemophilia A patients, and it's well over 1 million units used for home treatment, and just over half or well over --

well, a bit over 500,000 in patient. Can we have a look again at 0001717?

MS RICHARDS: Slightly fewer patients but not a huge difference.

SIR BRIAN LANGSTAFF: No, seven less.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So roughly a fifth less. But the usage has drop off there. It may be down to one or two patients, of course, but it's repeated, I think in 1984, again.

MS RICHARDS: Yes. We don't have -- we do for 1983. If we go on to page 4, we do have these individual sheets. Of course, I don't think they tell us volumes but we can see there a number to patients being treated with Armour but we don't have the same widespread use of multiple commercial concentrates in a given year for an individual patient that we had previously.

SIR BRIAN LANGSTAFF: In due course, it may be that someone can have a quick look and just see if the total usage has dropped off or if there may be particular individual features that one can derive from the paperwork which shows that it might just be an individual moving on to some other hospital because of age, or other reasons.

MS RICHARDS: Yes. I'm not sure that we will know the answer to that. We have the data in relation to antibodies and that doesn't suggest that that is the cause. We've got the returns in relation obviously to Christmas Disease and haemophilia B. We see, as was the norm, I think, the sole usage being Factor IX concentrates. I don't think we have the individual patient data that will enable us to answer that question but we will have a look and see.

SIR BRIAN LANGSTAFF: But there is no -- or did you come across any reflection in the documents which might have suggested that a response to the possible threat of AIDS was to reduce the total amount of any product given?

MS RICHARDS: I'm afraid we just don't know because we don't have anything from Professor Hardisty, and we don't have any -- or we have very few internal Great Ormond Street documents. The documents we have, we have because they were correspondence to others or minutes kept by the Department of Health, rather than being Great Ormond Street documents. So there's nothing, I'm afraid, that I've seen that answers that question but, obviously, if we do find anything, we will let you know.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Again, I'm not going to take time now with referring to what was set out in individual statements that we have received from patients who were treated at Great Ormond Street or from the families of children who were treated at Great Ormond Street, but the Inquiry has received a range of statements, which I know you have read and indeed have heard oral evidence, and we have summarised some of that in the written presentation note.

If I turn then to the question of to what we can say was or might have been known about the risks of hepatitis and HIV, again, there's no real contemporaneous documentation that we can point to you to say this shows exactly what Professor Hardisty knew as at 1980 or 1983. What we can say is that Professor Hardisty was a regular attendee at UKHCDO meetings. We've listed in the presentation note the meetings at which we can identify him attending in person. On a number of other occasions, when he is not there, a colleague at Great Ormond Street attends on his behalf. So it can perhaps reasonably be assumed that he would be up to date at the very least with what was being discussed at the UKHCDO meetings.

Again, I'm not going to go to it but you'll recall, I am sure, the oral evidence of Della

Ryness-Hirsch recalling her discussions with Professor Hardisty at Great Ormond Street in the early 1980s about her concerns regarding the safety of imported factor concentrates and her sense that those concerns were not being taken seriously.

Again, we have set out those references in our written note but that's all evidence that you have heard.

Again, the evidence that the Inquiry has received from individuals paints a picture similar, I'm afraid, to the picture painted in relation to the other Haemophilia Centres, of patients not being given information, warnings, advice about the risks of viral infection associated either with the use of factor concentrates in general or with any enhanced risk arising from the use of imported concentrates. That's the picture that emerges fairly consistently from the individual accounts that the Inquiry has received.

Dr Ball and Professor Hann, in their statements, have described their knowledge of hepatitis risks, their knowledge in relation to HTLV-III, HIV, AIDS, and of course you had also the oral evidence of Professor Hann but, in relation to Great Ormond Street, they only arrive on the scene in the second half of the 1980s. So, again, that doesn't assist in

understanding or providing any direct evidence as to what was or might have been known by Professor Hardisty and his colleagues at Great Ormond Street in the 1970s and 1980s.

Again, there's an absence of documentation from the hospital on the question of the process of testing patients for HTLV-III and informing them of their diagnosis and so the best evidence you have, sir, in relation to that again are the individual accounts that you have received, either from patients or from families of patients, which certainly record patients being tested for HTLV-III, as far as they were concerned, without their knowledge, and therefore without their consent.

In terms of how patients were told of positive diagnoses or what information they were given, Dr Ball and Dr Hann again, by the time they came on the scene, their understanding was that that process had been undertaken and so they were not able to cast much light on it. Dr Hann said he had limited memories but he did say in his statement, and you may recall, that by the time he arrived at Great Ormond Street there had been a realisation that consent processes had not been adequately applied.

In terms of the numbers of patients of the

haemophilia centre at Great Ormond Street who were infected with HIV, Dr Ball couldn't recall. She had a clearer recollection in relation to Alder Hey. She had estimated six boys and she didn't recollect any attempt to document dates of seroconversion, and she was not aware of there being stored serum samples that would have allowed a retrospective analysis to be undertaken.

You will recall, sir, that UKHCDO has provided the Inquiry with a table setting out from its records the data it holds in relation to numbers of patients infected. That table, again, I'll give the reference, I'm not going to go to it now -- is INQY0000250. That table suggests 11 patients infected with HIV at Great Ormond Street and it suggests one testing positive in 1984, eight in 1985, two in 1987. That may reflect dates upon which patients arrived at the centre however, so isn't necessarily a completely reliable guide to the number of patients infected as a result of their treatment at the centre; but it's the best information we have.

In relation to hepatitis C, we don't have even that degree of information, I'm afraid. Dr Ball could not recall. Dr Hann recollected that some patients were indeed confirmed to have hepatitis C. He thought

that testing began soon after or, indeed, I think his statement says, immediately after validated tests became available. He says, in relation to hepatitis C and unlike his understanding of the position with HIV, patients were informed why the test was being done and that they would be called back to clinical daycare appointments to be provided with the test result rather than communicating it by letter or by telephone.

Of course, a number of patients -- because people transferred at a point in their teens from Great Ormond Street to the care of other hospitals, a number of patients who may have been infected with hepatitis C as a result of their treatment at Great Ormond Street may, because of the passage of time and having been transferred to an adult centre, learnt their diagnosis not from Great Ormond Street itself but from the adult centre to which they were transferred.

More broadly, in terms of the arrangements for care at Great Ormond Street for those infected with HIV and hepatitis C, we have some accounts from individuals in their statements, and we have referred to some of that in the written presentation note.

Dr Ball said this about the 1980s more

generally: there were no specialists in AIDS care for children with haemophilia. She says Great Ormond Street did have the advantage of the availability of other paediatric specialists, including immunologists, infectious disease specialists, and so on, and she would actively seek support from specialists caring for young adult HIV patients.

Dr Hann's recollection, again to similar effect, was that specialist counselling and diagnostic services became available at Great Ormond Street in due course, in collaboration with the infectious diseases and immunology teams.

He drew a contrast between what was available at Great Ormond Street, which had on-site access to this range of paediatric expertise, with what was available or might have been available at other centres.

Sir, that's an overview of the picture in relation to Great Ormond Street. As I say, notwithstanding its significance as a hospital and the relatively large number of patients it treated, we do have a paucity of documentation and limited information about the particular approach of its Haemophilia Centre Director in the 1970s and 1980s.

I'm going to turn next to Charing Cross Hospital. The documents that we have identify various

doctors associated with the Haemophilia Centre at Charing Cross Hospital during the 1970s and 1980s. We can see included on various annual returns the names of Dr Mitchell, Dr Haworth, Dr Ranasinghe and Dr Kendra.

We have a statement from Dr Samson, who was not a director of the Haemophilia Centre but a senior lecturer on haematology and worked at Charing Cross Hospital in the 1980s and 1990s, from I think autumn 1983 until 1995.

Charing Cross was one of three Haemophilia Centres under the umbrella of one the medical schools, the Charing Cross and Westminster Medical School, and the other two hospitals under that same umbrella was Westminster and Queen Mary's, which I'll come on to during the course of the day.

There were, according to Dr Samson, very limited facilities for haemophilia care at Charing Cross Hospital. She says it was a very small centre treating only a very few patients and there was no physical entity designated the Haemophilia Centre. The evidence we have suggests that Charing Cross treated both adults and children and, you may recall, sir, evidence heard early in the Inquiry's oral hearings from a witness, Mrs C, who had sons treated

at Charing Cross, and she described how there wasn't a haemophilia ward so you'd have to wait until the treatment was sent down to the ward, the general ward for the children.

In terms of its location, the Haemophilia Centre, such as it was, was based at Charing Cross Hospital on the Fulham Palace Road. It was formerly designated an associate Haemophilia Centre later in 1976, and we can pick that up if we go to CBLA0000533.

So these are the minutes of the meeting we looked at in relation to Great Ormond Street.

If we can pick the picture up insofar as Charing Cross is concerned at page 5, halfway down the page, under the heading "Organisation of Haemophilia Care ... Centres", it refers, at (iii):

"... that Dr Mitchell (Charing Cross Hospital) had asked if they could be an Associate Centre although they were only 2 miles from Hammersmith, as some of the consultants who looked after haemophiliacs attending Charing Cross were anxious to continue to look after them."

Again, I don't think we need to go to the documents, the underlying documents at the time. But we know from it that Charing Cross was part of the

Northwest Thames region, and it received its blood and its cryoprecipitate -- the picture is slightly less clear in relation to any commercial concentrates, but its blood, its cryoprecipitate and its NHS concentrates, from the North London blood transfusion centre in Edgware.

It also had links with St Thomas' and, later on in the course of the 1980s, it would appear that patients who were infected with HIV were transferred from Charing Cross to St Thomas'.

There were also links, and Dr Samson in her statement has described these -- again, from her perspective, from the eighties onwards -- links with the Royal Free Hospital.

The evidence we have from those treated at the hospital is limited, and our best evidence is indeed the written and oral account of Mrs C, who says that no warnings or advice or information about the risks of treatment with Factor VIII concentrates were provided to her. She told you, sir, that she was just told that Factor VIII was an amazing thing.

In terms of product usage and numbers of patients, we don't need to go to the document, but I will read it for the transcript. It is HCDO0000039_001. It's a note of a telephone call with

Dr Mitchell in 1977 which gives a flavour of the small size of the centre. It suggests one patient with haemophilia was treated with cryoprecipitate and one patient with von Willebrand's disease, who was a visitor to the United Kingdom, was treated with cryoprecipitate. So a very small centre indeed.

I won't, therefore, take you through most of the annual returns but we'll just summarise what they tell us.

The 1977 return shows the treatment of two patients with haemophilia A with cryoprecipitate, and one patient with haemophilia B with NHS Factor IX concentrate. There were no commercial concentrates used.

1978 shows five haemophilia A patients being treated, predominantly with cryoprecipitate, but we see the introduction of a commercial concentrate in that year. A small amount of the Hyland product, Hemofil, was used for treatment.

1979, cryoprecipitate still in use, six patients treated. There are just over 40,000 units of cryoprecipitate were used. A very small amount of the Abbott product, Profilate, but Hyland Hemofil again used, now to a greater extent, just under 35,000 units.

If we then, just in terms of looking at any returns, pick the picture up in 1981, at HCDO0001506, we can see this identifies the director in that year, Dr Ranasinghe. Total number of haemophilia A patients treated during the year: 7 and then, if we look at the figures, we can see cryoprecipitate in use only to a very limited extent, some use of NHS concentrates, some use of the Armour product Factorate, the Hyland product Hemofil, and the Immuno product Kryobulin.

There is, I think, a similar picture in 1982. Again, I won't go to it, but we set out the precise figures in the written note.

If we then just pick the picture up in 1983, at HCDO0001705, we see a slightly different picture emerging here for what's said to be the treatment of four patients during the year. It's NHS concentrates and the Armour product only, but a greater volume of Armour product being used, so just under 95,000 in hospital and just over 50,000 for home treatment.

And that, I think, is the first year for which we have data suggesting that a home treatment programme was under way.

In 1984 again, the picture is treatment with NHS concentrate and with Armour concentrate.

Then, in relation to 1985, there's just

a correction to our presentation note. We gave a figure for usage of cryoprecipitate of 71,000 units, that should be NHS concentrates.

So, again, in 1985, we see the mix of NHS concentrates and Armour concentrates being used. It may be, of course, by 1985 that the Armour concentrate may have been heat-treated concentrate, and we know the additional complications that arose in relation to the Armour heat-treated concentrates.

In terms of how the decisions were made as to what concentrates to treat individual patients with, I'm afraid we don't really have any information. Dr Samson, who, as I say, came on the scene in the autumn of 1983 at Charing Cross, couldn't recall how or on what basis decisions were made.

Her recollection was that DDAVP and cryoprecipitate were both available, although she expressed the view in her statement that cryoprecipitate wasn't really suitable for home treatment. Her recollection -- and this was based upon a recollection of an individual patient -- was that DDAVP came to be used in preference to anything else for patients with mild to moderate haemophilia after the problem of HIV became apparent in around, she says, 1984.

She couldn't recall any specific policies in relation to prophylactic treatment or any specific policies in relation to the treatment of children. But if we go to CBLA0002018, we can see this is a letter of February 1985. It's from the Charing Cross Hospital to Dr Snape at BPL and it's in relation to a request for heat-treated NHS concentrates to be supplied from BPL. We can see there it refers to three children, all of whom received prophylactic Factor VIII.

So there clearly was a prophylactic treatment policy in place at the time, and we see all three of those children were on home therapy.

Sir, if I may, I'll just finish the picture in relation to Charing Cross before we break for lunch, if people don't mind a further five minutes or so. There isn't an enormous amount of other documentation.

Again, we've no real direct information as to the particular knowledge of risk of infection of any of the doctors or directors at the Charing Cross Haemophilia Centre. We do know that Dr Mitchell attended, in the capacity of director of the Haemophilia Centre at Charing Cross, several UKHCDO meetings, including in 1978 and 1979. And on occasions others, including Dr Ranasinghe, attended in

his place.

Dr Samson attended a number of UKHCDO meetings on behalf of Northwick Park Hospital, where she worked at the time, and then, at a later stage, attended some UKHCDO meetings from the perspective of Charing Cross.

Then we can see others, Drs -- Dr Haworth for example, and Dr Desai attending on behalf of Charing Cross Hospital. So, although there doesn't appear to be a consistent picture of attendance by one clinician, it does appear that, for the most part, most UKHCDO annual meetings were attended by somebody on behalf of Charing Cross Hospital.

In terms of knowledge of risk of infection, I'll pick up what Dr Samson recalls about her state of knowledge when we look at Northwick Park this afternoon, but she does say that she didn't know in 1983 that HIV could be transmitted by blood and blood products. She says that really became apparent in 1984.

She does say, in relation to hepatitis, that it was known that both hepatitis B and non-A, non-B hepatitis could be transmitted by blood products when she was working at Charing Cross, but that it wasn't appreciated that non-A, non-B hepatitis could lead to chronic liver disease. She can't say with any

confidence when she became aware that there was a significant risk of serious liver disease.

Her recollection in relation to the process of testing the small number of patients at Charing Cross for HTLV-III was that patients wouldn't have been tested without their consent but she can't recall what the process was for obtaining consent.

Mrs C's evidence, as you'll recall, who had two children under the care of Charing Cross Hospital, was that she did not give her consent to treatment and wasn't aware of the children being test for HTLV-III.

In terms of hepatitis C, Dr Samson did not recall when testing began or whether any haemophilia patients were tested for hepatitis C. That may be a reflection of the very small numbers who were being treated under the auspices of the Haemophilia Centre.

We don't, I'm afraid, have, therefore, any clear picture as to the precise numbers of patients infected with hepatitis C or HIV in consequence of their treatment for their haemophilia care. The table we received from UKHCDO doesn't contain any information regarding Charing Cross Hospital, in terms of HIV. Dr Samson, however, recalled two children being infected with HIV at Charing Cross Hospital.

Their treatment was, as far as she recalls, then

transferred to the Haemophilia Centre at St Thomas's Hospital and there was no or little ongoing involvement from Charing Cross, and that's consistent with the individual evidence that we received. That's the extent of the picture we currently have, sir, in relation to Charing Cross Hospital .

We can pick up Westminster Hospital after the break.

SIR BRIAN LANGSTAFF: Very well. Well, let's take a break then now until 2.05. 2.05.

(1.05 pm)

(The luncheon adjournment)

(2.05 pm)

MS RICHARDS: Sir, before I turn to Westminster Hospital's Haemophilia Centre, this morning when I referred to the table of data which provides information about the numbers of cases of HIV associated with particular Haemophilia Centres, which was INQY0000250 -- we don't need to put it up, Soumik -- I think I said it was provided by UKHCDO. The table itself was not provided by UKHCDO, it was compiled by the Inquiry on the basis of the data supplied by UKHCDO. So I just wanted to make that clear.

So, I turn to consider now the Haemophilia Centre at the Westminster Hospital; Professor Humble

was the director in 1968 to 1979; succeeded by Dr Barrett, who was director from around 1979 to 1988; and then Dr Costello took over as director from, we understand, 1989.

Dr Giangrande, who, of course, you heard from in connection with his later work at the Oxford Haemophilia Centre, was a registrar at the Westminster Hospital under Professor Barrett for a period of time late 1983 to late 1984.

His recollection in terms of the staffing and facilities as at the autumn of 1983, in Westminster, was that there were two consultants, three junior doctors, a transfusion laboratory, a small research laboratory, and two clinic rooms where outpatients could be treated. That was in terms of a general haematology department, not specifically dedicated to the Haemophilia Centre.

It was based, the Westminster Hospital, in Dean Ryle Street in London, and it was one of the 13 designated Haemophilia Centres in the London area as at 1970.

Westminster fell within the Northwest Thames region, so in terms of Regional Health Authority responsibilities, that's region 5. In terms of distribution of NHS concentrates, we have seen

documents which suggest that, as at 1976, six bottles of NHS Factor VIII were allocated to Westminster Hospital.

But in fact, if we look at CBLA --

SIR BRIAN LANGSTAFF: Is that per month?

MS RICHARDS: Per month, sorry, yes.

If we look at CBLA0000657, this is one of the meetings of haemophilia directors, associate haemophilia directors, and directors of blood transfusion centres from the regional health authority areas, areas 4, 5 and 6. This meeting is 23 September 1977.

If we go to page 4, we can see towards the bottom of the page, there's a reference there to Professor Humble. So although Westminster, as I understand it, notionally fell within the Northwest Thames region, it actually received its allocation from the south London blood transfusion centre, and we can see that from:

"Professor Humble ..."

So two entries up from the bottom of the page:

"... (Westminster): NHS [concentrate] was supplied by Dr Rogers, South London BTC [so blood transfusion centre] and the allocation was satisfactory. No commercial [concentrate] had been

bought."

So that's the picture as at September 1977.

In terms of numbers of patients treated at the Centre, we don't need to go to the underlying documents but again we have a snapshot as at the end of 1969, beginning of 1970 in a letter from Professor Humble to the Department of Health.

I'll just give the reference for the benefit of the transcript. It's DHSC0100026_024. We don't need to go to it but it shows that at that point in time there were 13 registered patients at the Centre, there had been 14 incidences of haemorrhage for which patients had attended, and there were no patients who had attended for severe bleeding.

If we look at BPLL0008111, please, you'll see this was a survey undertaken by Dr Maycock at BPL in or around November 1972, and there are pages for a range of different Haemophilia Centres.

For present purposes, the relevant page is page 32. And we can see this is the letter that was addressed -- sorry, if we just look at the very top left-hand corner -- to Dr Humble, haematology department, Westminster Hospital. The letter is headed "Factor VIII Concentrate for treatment of Haemophilia", and it says:

"Factor VIII concentrate is supplied as a freeze-dried preparation in bottles containing from 400 to 600 units. At present the supply is insufficient for all needs."

Then Dr Maycock addressed a number of questions to a range of Haemophilia Centres which were the recipients of this letter:

"How many patients with haemophilia do you treat regularly?"

We will see the answer in relation to Westminster as at the end of 1972 was three.

Then there is a question:

"Would you prefer to use for the treatment of your patients

"(a) Cryoprecipitate?

"(b) Freeze-dried concentrate?"

Or:

"(c) Some cryoprecipitate and some freeze-dried concentrate?"

You can see that Dr Humble's preference was for freeze-dried concentrate. He answered "Yes," to question 2(b) and "No" to questions 2(a) and (c).

Then, if we go further down the page, Dr Maycock was asking for estimates in terms of how many bottles would be needed annually.

So that's Dr Humble's preference as at the end of 1972.

In terms, then, of what the returns show as to the numbers of patients treated, I won't go through all the returns. Broadly speaking, we have the returns from 1976 through to 1986, and we've summarised what they show in our written presentation note.

There are perhaps up to four patients with haemophilia A treated on an annual basis on average -- or, sorry, at a maximum. I think, some years it's one or two patients treated. Usually one patient with haemophilia B, one patient with von Willebrand's disease. That's the kind of figures that emerge from the annual returns.

If we then look at what the returns show in terms of the products that were used for the treatment of that small cohort of patients, 1976 shows cryoprecipitate being used to be for the treatment of haemophilia A, and NHS Factor IX concentrate for the treatment of haemophilia B. Plasma and cryoprecipitate for the treatment of von Willebrand's disease.

1977 shows cryoprecipitate and NHS concentrate being used for the treatment of haemophilia A and NHS

Factor IX concentrate for the treatment of haemophilia B. So there were no commercial concentrates in use in 1976 or 1977.

The first use of commercial concentrates emerges in 1979, when we see 40,000 units of the Immuno concentrate, Kryobulin, appearing for the first time on the annual return.

In 1980, we see, again, usage of Kryobulin, but also the Armour product, Factorate, and the NHS Factor VIII concentrate all being used for the treatment of patients with haemophilia A. Again, the pattern in relation to the haemophilia B patient is NHS Factor IX concentrate, and in relation to von Willebrand's, it's a mixed picture that emerges from the returns. In that particular year, Armour product is in fact used to treat the von Willebrand's patient.

1981 shows some cryoprecipitate being used but also NHS Factor VIII concentrate and the Armour product. Likewise, 1982, no cryoprecipitate in use but NHS Factor VIII concentrate and the Armour Factorate concentrate.

Again, the volumes for all these returns are relatively small, reflecting the small number of patients.

In relation to 1983, again we see a combination of NHS Factor VIII concentrates and Armour concentrate being used in relation to haemophilia A, the fairly usual picture of NHS Factor IX concentrate being used for the treatment of haemophilia B.

So it's a mix of NHS and commercial concentrates in relatively small volumes until 1984.

In 1984, six haemophilia A patients were treated. The only treatment identified in the annual returns in 1984 is NHS Factor VIII concentrate. And that's a similar picture for the patients with von Willebrand's who were treated that year with some cryoprecipitate and with some NHS Factor VIII concentrate.

In terms of knowledge of risk of hepatitis or knowledge of risk of HTLV-III/AIDS on the part of the clinicians at Westminster, there's no contemporaneous direct material that the Inquiry has, so again it may be a question of drawing inference from attendance at or receipt of UKHCDO minutes.

Professor Humble was not a regular attender at UKHCDO meetings, although the minutes do record his formal apologies on a number of occasions, and it may be a reasonable assumption that he would have received the minutes of the meetings.

From time to time other clinicians attend the meetings on his behalf. And that's true of a number of meetings in the course of the 1970s and the early 1980s, including, on occasion, Dr Giangrande, as you may recall from his oral evidence. But that, I'm afraid, is the limit of the direct evidence we have -- or, indeed, the indirect evidence we have in relation to developing knowledge of risk.

We don't have any information about, amongst the small cohort of patients, the number infected with hepatitis C. The data that we received from UKHCDO indicates one patient infected with HIV, testing positive in 1985.

And we don't, I'm afraid, have information about what the arrangements were for testing that small number of patients or how diagnosis/test results were communicated to patients or what the arrangements were for their treatment and care. So a relatively limited picture regarding Westminster, but perhaps unsurprising given the small size of the Haemophilia Centre there.

We turn then next to St Mary's Hospital, Paddington. In terms of the directors of the centre, Professor Mollison was director of the centre from 1986 (sic) or thereabouts until 1979. He was the lead

author of a textbook called Blood Transfusion in Clinical Medicine, and he was a member of a number of committees relating to blood products, blood and transfusions, and we will no doubt come across his name again when our hearings move to consider the role of the blood services and the --

SIR BRIAN LANGSTAFF: Just for the sake of the transcript, I think that was 1966, was it?

MS RICHARDS: From around 1968 to 1979.

SIR BRIAN LANGSTAFF: 1968?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Yes, because I think you may have said '86.

MS RICHARDS: Oh, I'm sorry.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: He was then succeeded by Professor Wickramesinghe and Dr Dodsworth, who were co-directors of the centre at St Mary's from 1979 and through into the 1980s.

We know from material that the Inquiry has that Dr Dodsworth was a member of a working group on trends in the demands for blood products in the course of 1977.

In terms of other personnel at St Mary's Hospital more broadly, Dr Anthony Pinching was an

immunologist at St Mary's who was heavily involved in early development in the course of the 1980s in relation to AIDS, and we've certainly seen his name more generally come up in a number of documents. So not based at the Haemophilia Centre, but a source of information in relation to AIDS potentially at the hospital more generally.

St Mary's Haemophilia Centre was based at St Mary's Hospital in Paddington in London. Again, it was one of the 13 designated Haemophilia Centres in the London area identified and listed in 1970.

It was part of the Northwest Thames region, region 5, but it received its Factor VIII concentrate, and no doubt presumably also its cryoprecipitate, from the North London blood transfusion centre in Edgware.

The allocation as at late 1976 within the Northwest Thames region of NHS concentrate provided for 15 bottles per month to be made available to St Mary's Hospital.

And we have the minutes of a meeting at CBLA0000657 -- we don't need to turn this up, Soumik, it is really just for the benefit of the transcript -- in September 1977. It is one of those meetings of directors of Haemophilia Centres, associate centres, and blood transfusion centres that we've already

looked at.

It records Dr Dodsworth at St Mary's saying that they wanted to start two patients on home therapy, and that they required for that purpose an allocation of NHS concentrate.

So that gives us a snapshot of the picture in terms of September 1977. It might suggest that home therapy had not been instituted before that.

If we then, again, just in terms of the relatively limited available information we have about St Mary's, turn to DHSC0100026_014.

This is a letter of 23 September 1969 from St Mary's department of haematology, to Dr Obank at the DHSS and you'll recall we looked this morning, in relation to Great Ormond Street, at the text of Dr Obank's letter asking a number of questions sent out to the various Haemophilia Centres, and the St Mary's response to that is set out here. It tells us that there were 16 cases registered at the centre, there were 84 incidents of haemorrhage for which patients attended the centre for treatment -- that's in the year ending 30 September 1969 -- two incidents of severe bleeding, no major surgical operations undertaken.

For the benefit of the transcript, that's

a response to the letter from Dr Obank that appears at DHSC0100026_009.

So not as small a Centre as some of the others that we have looked at but not a large centre.

If we look at BPLL0008111 -- again, this is the document we looked at a few minutes ago in relation to Westminster -- and we go to page 21 this time, we'll see here Professor Mollison's response on behalf of the Haemophilia Centre at St Mary's in November 1972 to Dr Maycock's questionnaire:

"How many patients with haemophilia do you treat regularly? 13."

Then, in answer to the question about preference for the treatment of patients, he says "No" to cryoprecipitate, "No" to a mix of cryoprecipitate and freeze-dried concentrate, and "Yes" to freeze-dried concentrate. So the preference there being expressed was for concentrates.

And if we just look further down the page, we can see the estimated usage there set out by Professor Mollison.

In terms of the information from the annual returns, we've summarised in the written note what the annual returns show for each year from 1976 through to 1988.

Sticking with the period from 1976 to 1986 for present purposes, what they show in terms of the number of patients treated are as follows: between five and twelve patients with haemophilia A -- so the figures range, depending on the particular year, but that's an indication of the magnitude; up to five haemophilia B patients; and occasionally one patient with von Willebrand's, treated on an annual basis.

We have no direct evidence in relation to treatment policies, again, and, sir we can look only at the annual returns and what they tell us about blood product usage.

1976, for example, shows cryoprecipitate and NHS concentrate in use. The first commercial concentrate appears to have been used in 1979 and, if we just look at that, it's HCDO0001373, please.

We can see this is the return completed for St Mary's by Dr Dodsworth, nine patients with haemophilia treated in that year -- with haemophilia A, I should say. Four patients with haemophilia B.

We can see there usage of cryoprecipitate, the estimate is 69,200 units of cryoprecipitate. Use of NHS factor concentrates just over 40,000. And then we can see some commercial products being used. So a relatively small amount of the Armour product,

Factorate, just over 7,000 units, and a larger volume of the Immuno product Kryobulin, 34,335 units.

So that's the beginning of the use of commercial concentrates at St Mary's.

There's a similar picture in 1980, I won't take you to that. It shows some use of cryoprecipitate still, usage of NHS factor concentrate, and then use of the Armour and the Immuno products.

The 1981 annual return again shows use of cryoprecipitate, NHS Factor VIII concentrate, Armour's Factorate and Immuno's Kryobulin. But the precise figures are too faint to read with any confidence.

Again, a similar picture emerging in 1982, in terms of the commercial concentrates used. Armour's product is used, Immuno's is used, NHS Factor VIII concentrate is used. No cryoprecipitate appears to be used in that year except for the treatment of patients with von Willebrand's and for the treatment of the patient with Factor VIII antibodies.

If then we pick the picture up in relation to 1983, and the reference there is HCDO0001766, please, Soumik. We can see there seven, and then it's crossed out, "?6" patients treated during the year with haemophilia A, one von Willebrand's.

Then if we look at the figures, what they appear

to indicate for that year is significantly more NHS concentrate used than commercial concentrate. Again, it's not possible -- because all we have are the returns -- not possible to know the reason for that and whether that reflects a conscious decision on grounds of safety or for some other reason, or whether it's simply reflective of what was made available to the Centre.

SIR BRIAN LANGSTAFF: So the -- one of the -- the one that you last showed me with Armour and Immuno and NHS concentrate, they were about 50 per cent each of the total concentrate. This is about 2:1.

MS RICHARDS: Yes.

Then there's a slight oddity with the annual return for 1984, which is probably easiest to explain by looking at it. So it's HCDO0001860.

If we just look at the top of the page, we can see we're talking about St Mary's, eight haemophilia A patients treated, one von Willebrand's patient, and someone's written at the top:

"It's very difficult to distinguish between in and outpatient use."

But if we then look at the figures, they appear to be implausibly high, given the number of patients treated. They bear no resemblance in terms of volume

to figures in previous years.

Figure for the use of NHS concentrate, for example, seems to be 1.8 million.

SIR BRIAN LANGSTAFF: Is that that's the -- is that the addition? It's the addition, I think, of the two. If you add --

MS RICHARDS: That looks about right, yes.

SIR BRIAN LANGSTAFF: -- 826 and 986 you get -- and 035, 650, you get 1,812,685. So I think it's using the total.

MS RICHARDS: I think that's right.

Again, it seems to bear no relationship with the number of patients treated or with the usage in previous years, where I haven't gone through each of the returns but the magnitude is in the tens of thousands rather than the hundreds of thousands.

SIR BRIAN LANGSTAFF: It's staggering higher than the commercial.

MS RICHARDS: Yes. So probably not a reliable piece of data but I wanted to display it on screen so you could see for yourself what was there set out. As I say, it seems implausibly high.

SIR BRIAN LANGSTAFF: Does it say "estimate" there?

MS RICHARDS: It does say "estimate" and it refers to a letter of 23 April 1985, but I don't think we have

traced that letter. In any event, as an estimate, it still wouldn't seem to make sense, because one would have thought if one was going to estimate one would estimate, in part, based on previous usage and conscious of the number of patients likely to be treated in the course of the year, which was always consistently a low number.

SIR BRIAN LANGSTAFF: Hmm.

MS RICHARDS: In any event, it is what it is. The 1985 annual return shows the use only of NHS concentrates, both Factor VIII for haemophilia A and Factor IX for haemophilia B.

In terms of --

SIR BRIAN LANGSTAFF: In 1985 they managed to get NHS Factor IX?

MS RICHARDS: Yes, I'm pretty sure that's right. Let me check, HCDO00001955. So that's haemophilia A. You'll see there only NHS concentrates. If we go over the page, haemophilia B, three patients treated, and you'll see it's home treatment, and it's entirely NHS Factor IX concentrate apparently.

Of course, that may mean that it was not heated.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: In terms then of knowledge of risk, again our only real guide is attendance at UKHCDO meetings,

receipt of UKHCDO minutes. So even prior to becoming director of the centre, Dr Dodsworth attended meetings on behalf of Professor Mollison on a number of occasions throughout the 1970s. There's no record of Professor Mollison himself attending in person the UKHCDO meetings.

Then Dr Dodsworth attends in her capacity as director, again on a fairly regular basis from 1979 onwards. There is one document with Dr Mollison that it may be worth looking at on this issue. It's PRSE0001960. These are the minutes of a meeting at the Medical Research Council on 12 February 1979. We've looked at the minutes of this meeting for different purposes on an earlier occasion, and we can see that the list of attendees identify there Professor Mollison as being the chair, and then there are a number of other, one might say, distinguished attendees so we've got Dr Craske, we've got Professor Sherlock, we've got Professor Zuckerman, we've got Sir William Maycock all in attendance.

We can see from the second paragraph that there is then a discussion initiated by the chair, so initiated by Professor Mollison, about non-A, non-B hepatitis.

Again, I won't go through it in detail because,

as I say, we've looked at it previously but, for present purposes, if we just go over the page, picking it up in the second line, we see there Professor Zuckerman pointing out that:

"... much non-A non-B associated [post-transfusion hepatitis, that's PTH] might be anicteric, and that the risk of progression to chronic liver disease remained, however mild the initial infection."

Then it records:

"Professor Sherlock, agreeing with Dr Cleghorn that PTH was rare in the [UK but] was nevertheless concerned about the continued use here of blood products of commercial origin. Many of these products were prepared in the United States, using blood from professional donors, and they carried a high risk of transmitting non-A, non-B hepatitis."

Then the discussion continues.

So, although Professor Mollison was not a regular attendee at UKHCDO meetings, he was a member of various committees in which issues such as non-A, non-B hepatitis and risks from transfusion were discussed, and we see there one such example.

Then just picking matters up with Dr Dodsworth's later reflections, this is on the question of supply

of concentrates more generally, if we go to RLIT0000022. This is a document we've looked at again on a number of occasions in relation to contributions from different clinicians. It was a seminar held at the Wellcome Institute in February 1988 -- sorry, 1998, and the topic was "Haemophilia: Recent History of Clinical Management".

Dr Dodsworth was one of the participants in the seminar. Although she doesn't say an awful lot in comparison to some of the other contributors, we don't have very much so it is worth looking at what she does say. If we go, first of all, to page 39, please.

We see there the entry "Dr Helen Dodsworth", she says:

"I used to work at St Mary's Hospital, London after working in Manchester, alongside Dr David Evans. May I say briefly something about the availability of factor VIII concentrate? Although the manufacturing process was discovered in the early 1950s, there was never adequate provision for manufacture of factor VIII concentrate in this country until the early 1970s."

Then she refers to the MRC unit on the Elstree site, in the early 1970s.

Then the next paragraph, she says this:

"In 1976 Pat Mollison, for whom I was working at the time, asked me to represent him on a committee convened to advise the Department of Health on how much factor VIII concentrate and albumin were needed to treat patients in the UK."

That's the Committee on Trends or the Working Group on Trends in Usage of Blood Products that I referred to a few minutes ago.

"Our spokesman, Dr Tovey, the director of the Bristol Transfusion Centre, had been through a similar exercise for the World Health Organisation in Geneva. He persuaded us that if we wanted to treat our patients adequately, it would be necessary to fractionate at least 80 per cent of the blood that was donated. At this point the Government decided that money was available for neither extending the fractionation unit at Elstree nor for equipping the transfusion centres to separate yet more plasma from donor units. So this is really why we found ourselves buying large quantities of factor VIII concentrate from America, and why we infected so many of our patients with HIV."

Then I won't take you to it, but her second contribution to the seminar is at page 71, and she talks there about there being insufficient plasma for

fractionation as a further problem.

In terms of numbers of patients treated at St Mary's at the Haemophilia Centre and infected with HIV, the data the Inquiry has received from UKHCDO suggests three patients testing positive for HIV: one recorded in 1984, that may be an indication of a relatively early testing or may be a test on stored sera, we don't know which; and two patients in 1985.

There are also documents which show Dr Dodsworth reporting to Ms Spooner at Oxford in 1990 and in 1993, cases of hepatitis. The 1990 case is described as a case of non-B hepatitis in a patient with von Willebrand's disease, who is recorded as having received buckets of cryo plus some Factor VIII concentrate, and the 1993 case is described as a case of hepatitis C in one of the patients of the Haemophilia Centre at St Mary's.

So that's the available information again in a snapshot, in relation to the Haemophilia Centre at St Mary's.

Sir, I'm going to turn next, sir, to consider University College Hospital, UCH. So the information that we have in relation to the identity of the directors of the Haemophilia Centre at UCH, during the 1970s and 1980s are Professor Prankerd, from around

1968 to 1977, and then Dr Richards from around 1977 to at least 1989.

We also have some evidence relevant to UCH from Dr Paula Bolton-Maggs, who was a registrar at UCH for periods in the 1980s. She describes the facilities in her statement and I won't put the statement up but let me just read the reference. It's WITN416001, and she describes the facilities at UCH as follows:

"The haemophilia patients would usually be seen as outpatients in the haematology department. As far as I recall, there was no formal Haemophilia Centre at UCH."

The haematology department at UCH was based at Gower Street in London and, again, UCH is one of those 13 Haemophilia Centres in the London area designated as such in or by 1970. It formed part of the Northeast Thames region, so that's region 6, as identified in various contemporaneous documents. If we look at CBLA0000533, we can see again, this is one of the sets of minutes of meetings of Directors of Haemophilia Centres and Blood Transfusion Centres for the Regional Health Authorities covering regions 4, 5 and 6, the date of this meeting is 15 December 1976.

If we go to the bottom of the second page, this is in the context of a discussion about allocation and

which blood transfusion centre would supply which Haemophilia Centres with NHS concentrates or cryoprecipitate. If we pick it up towards the bottom of the page, we can see there reference to "RHA 06 [North-East] Thames", and it says here:

"The distribution area of the Brentwood [Regional Blood Transfusion Centre], 'the Brentwood Parish', does not include the whole NET 'North East Thames' region. There are 3 Haemophilia Centres and 4 Associate Centres in RHA 06. Only one of these Haemophilia Centres (the London hospital) and all 4 Associate Centres are in the Brentwood Parish. The RFH [presumably the Royal Free Hospital] and UCH [University College Hospital] are both in the [North-East Thames Regional Health Authority] but outside the Brentwood Parish. Adjustments need to be made to the allocation of NHS [Factor] VIII concentrate to Brentwood and Edgware if each Director is to supply only his own 'parish'."

So you see there a parochial -- is probably precisely the accurate term -- a perhaps parochial attitude on the part of the directors of the Regional Blood Transfusion Centres, not wanting to be in a position of having to supply cryoprecipitate possibly or certainly NHS concentrates to areas that

might have fallen within a certain -- sorry, to centres that might have fallen within a certain Regional Health Authority area but didn't fall within what the blood transfusion centre regarded as its geographical or territorial remit.

Then we see at these regular meetings, or these annual meetings, attendance usually by somebody on behalf of University College Hospital. If we pick the picture up at the 1977 meeting CBLA0000657, this is the meeting on 23 September 1977.

If we go to the second page the list of attendees, the name is about 15 or 20 names down, shows Dr McVerry, who obviously we've come across in relation to other Haemophilia Centres later, attending for Professor Prankerd, representing University College Hospital. If we go to the bottom of the next page, we look at the last few lines, it records Dr McVerry saying this:

"UCH needed 40-45 bottles NHS [concentrate a month] as they now had 3 more patients on HT [home treatment]. They were currently purchasing 20-25 bottles ... of Hemofil [a month] to make good this shortfall. They wanted 20-25 extra bottles of NHS [concentrate a month]."

Then there's a response from Dr Dormandy which

says that the addresses of the patients should be taken into account in deciding whether Brentwood or Edgware should supply the extra needed.

So we can see there, in any event, UCH reporting a shortfall in NHS concentrates which they were making good through the purchase of commercial concentrates.

That issue of shortfall was raised again at the annual meeting the following year, of the same group of directors, in September 1978. We don't need to go to it, but the reference, for the transcript, is CBLA0000838.

Again, just looking at a snapshot, as at the beginning of the 1970s, if we go to DHSC0100026_014, we have ... I'm sorry, that's the wrong reference. That's the reference again to St Mary's.

I will try and find the correct reference for the transcript but I will just tell you what the answers were from Professor Prankerd.

Sorry, Soumik, we can take that down.

So the snapshot given by Professor Prankerd was 29 cases registered at the Centre. There had been in the year with which the request was concerned, 32 incidents of haemorrhage, four incidents of severe bleeding, four major surgical operations undertaken in patients registered with the centre. So that's the

picture as at the beginning of the 1970s.

If we then go to BPLL0008111, again this is Dr Maycock's questionnaire and the UCH response is at page 30. We can see, heading, top left of the page "Professor Prankerd ... University College Hospital". He responds as at late 1972, indicating that there are eight patients with haemophilia regularly treated. Again, you can see his expressed preference for the treatment of patients is freeze-dried concentrate, rather than cryo or a combination of cryo and concentrate.

In terms of the number of patients treated at UCH, in the 1970s and 1980s, this information is drawn from the annual returns. I think the return for 1978 might be missing. But what the returns for that period indicate is usually a relatively small number of patients treated, between three and 12 haemophilia A patients, up to four patients with haemophilia B, up to five patients with von Willebrand's, in some years rather less.

To get a sense of treatment policies, again, I'm afraid, it's really only the annual returns that provide any kind of guide. If we look at the 1976 return at HCDO0001124.

We've got the number of patients treated in that

particular year, 12. We can see there that cryoprecipitate is the main product in use for treatment but that, as early as 1976, a range of different concentrates were being used. So we've got NHS concentrate, Hyland's product Hemofil, Immuno's product Kryobulin, all in use, although in relatively small numbers.

There's again reasonably significant volume of cryoprecipitate used in 1977, approximately 105,000 units of cryoprecipitate, just under 68,000 units of NHS concentrate. But we then see by 1979 a significant decline in the usage of cryoprecipitate, so if we go to the 1979 return, at HCDO0001381, we can see by now cryoprecipitate is used only in the volume of 4,200 units. NHS concentrates used 60,000 units, and the product in greatest usage is the Hyland product Hemofil, at 126,000 units.

In 1980, again the main forms of treatment are with NHS concentrates and with Hyland but there is the introduction of the Immuno product, Kryobulin, used in very small amount in 1980.

In 1981, there is again usage of cryoprecipitate, and the usage has crept up slightly to around 67,000 units, NHS factor concentrates are used, and the main commercial concentrate used in 1981

was Kryobulin.

Again, a similar pattern in 1982: some cryoprecipitate but predominantly NHS Factor VIII concentrates and Kryobulin.

If we then pick the picture up in 1983 at HCDO0001775, we can see here that, in the course of 1983, we have five haemophilia A patients treated, one haemophilia A carrier, eight von Willebrand's patients treated. Then no cryoprecipitate in use for haemophilia A patients, it is used for the von Willebrand's patients, and then NHS concentrates in fairly substantial usage: 145,000 hospital, 125,000-odd home treatment. A small amount of the Armour product now, 2,000 in hospital, and then Immuno's Kryobulin, again relatively substantial use but not as much in that year as the NHS factor concentrates.

Then, just to complete the picture, 1984, is at HCDO0001869. We're told there seven haemophilia A patients treated, one carrier and then six von Willebrand's patients.

Then we can see there is some use of cryoprecipitate for haemophilia A patients. The main product, however, in use is the NHS Factor VIII concentrate for the haemophilia A patients. There's

a reference then towards the bottom -- in terms of the only commercial concentrate, there's reference to what's called "Kryoglobulin" there, "HT", presumably heat treated, and reference to the use of DDAVP, looks like that is for treatment of a carrier of haemophilia A, and that writing, I think, is the first reference in the returns to DDAVP.

SIR BRIAN LANGSTAFF: The use of cryo there, what is it, about 50,000 units roughly?

MS RICHARDS: Yes, it's relatively substantial.

SIR BRIAN LANGSTAFF: Yes. It's -- the NHS supplies, one way or the other, are -- hugely outnumber the commercial, and the commercial is heat-treated.

MS RICHARDS: Yes. Whether that reflects a conscious decision by this point in time to try to avoid the use of unheated commercial concentrates, and therefore we see, for example, the usage of DDAVP, or whether, again, it reflects what happened to be available, I'm afraid we've no way of knowing.

Without the need to go to it, the correct reference for the letter from Professor Prankerd from 1970 -- and this is just for the sake of the transcript -- is DHSC0100026_016.

Dr Bolton-Maggs in her statement provided some insight into products used at UCH where she first

began work as a part-time registrar in 1980. She referred to DDAVP being introduced in preference to concentrate for mild haemophilia and mild von Willebrand's. She also refers to recalling the use of cryoprecipitate but she doesn't recall the policy; in other words, she doesn't recall why particular products might be used for particular cohorts of patients. She says:

"Concentrates were introduced once they were available and this policy was not decided by me."

And as a part-time registrar at the time no doubt that's correct.

In terms of knowledge of risk of hepatitis or HIV, again, there's little by way of direct evidence. Professor Prankerd was often represented by a clinical colleague at UKHCDO meetings. And we see, for example, a number of names, including Dr Richards, who took over as director, or Dr McVerry attending from time to time, as well as others.

Then, once Dr Richards took over as director, we see him attending at various UKHCDO meetings in his own right as director, including in the early 1980s. Again, he didn't attend all of them and sent his apologies for some meetings, but it may be reasonable to assume he would have received the minutes of those

meetings and had some awareness of the discussions being undertaken.

Dr Bolton-Maggs has in her statement described her understanding of the nature and severity of different forms of hepatitis. She said in her statement the impact of non-A, non-B hepatitis was not fully appreciated for some time and that it became apparent that a number of patients with non-A, non-B hepatitis developed evidence of chronic liver damage.

In relation to HIV, she said this:

"It was known before the virus was identified that the condition could be transmitted by blood transfusion, so it was not surprising to find evidence of immune dysfunction and illness in haemophilia patients in the early 1980s before the virus was identified, in 1983-4, and the test developed, in 1984-86. Understanding and knowledge of HIV and AIDS evolved as further research was published and information shared at the UKHCDO and other meetings."

Dr Bolton-Maggs was not able to provide us with details of what information might have been given to patients regarding the risks of hepatitis or HIV. And she couldn't recall whether, for example, cryoprecipitate was used as an alternative to concentrates in response to the risk of infection.

In relation to the arrangements for testing for HIV, again, Dr Bolton-Maggs has endeavoured to assist. She indicated in her statement that testing became available at UCH in around 1984, using Dr Richard Tedder's laboratory. She could not remember herself the details of discussing AIDS with any patients, but again, that may be a reflection of the relatively junior position she held at the time.

She did say that she thought at UCH patients would have been told their test results in person. She did not have any information about the numbers of infected patients at UCH. The data which the UKHCDO has provided to the Inquiry suggests five patients positive for HIV: one patient identified as positive in 1982, that is presumably a reference to a retrospective testing of a stored sera example from 1982; one in 1984; and three testing positive in 1985.

Insofar as hepatitis C is concerned, Dr Bolton-Maggs believed that that would have become available in the early 1990s but she, by that time, had moved to a different hospital and so was not able to cast any further light upon what the position was in terms of the arrangements for either testing or for the treatment of patients with hepatitis C at UCH.

So that, sir, is the overview in relation to

UCH. If I can move to the Hammersmith Hospital, there are a number of names which appear in documents relating to the Hammersmith in terms of clinicians. It would appear Professor Dacie, D-A-C-I-E, may have been director of the centre from around 1968 to '70, that Dr Mibashan was director at Hammersmith from 1970 to 1976. He then moved to King's College.

Dr Crawford may have been director, or at least have acted in that capacity, in 1977, a Dr Hilgard, '78 to '79.

Dr Chipping, Dr Patricia Chipping, is identified as the clinician on annual returns in 1970 *(sic)*, '80 and '81, but she has provided the Inquiry with a statement that says she was not the director of the Haemophilia Centre, and her role at the Hammersmith, she says, was as a registrar and senior registrar in haematology, and then a locum consultant in blood transfusion from 1980 to 1982.

The statement we have from Dr Chipping, I'll just give the reference, is WITN4567001. We also have a statement from Dr Hows, who's identified as the director of the Centre '84 to '86 in the annual returns, and the reference for her statement is WITN3779001.

Then we have a statement from Dr Michael Laffan,

who took over as the director of the Hammersmith centre in 1992, and the reference for his statement is WITN37089003.

In terms of facilities at the Hammersmith Hospital, Dr Chipping describes them as follows:

"Haemophilia patients at the Hammersmith were treated in a side room adjacent to the blood transfusion department. This was essentially for ease of access as blood products were stored in the blood transfusion department. The coagulation department was housed in a separate building in the Royal Post-graduate Medical School."

Dr Laffan is then able to describe the arrangements for haemophilia care in the second half of the eighties, when he was a registrar. He says there was a treatment room, supplies of therapeutic products, staff of the haematology department. Then his statement relays a number of other changes to the way in which haemophilia care was delivered at the Hammersmith, culminating in there being a more structured approach in 1992.

Again, the Hammersmith was one of the 13 designated Haemophilia Centres in the London area as at 1970. It was part of the Northwest Thames region, so region 5., and was supplied by the North

London blood transfusion centre in Edgware, with blood and blood products.

The 1976 allocation identifies 55 bottles per month as the allocation for Hammersmith Hospital of NHS Factor VIII concentrate. I'm not going to go back to the various minutes of the meetings of directors of haemophilia centres and associate centres and blood transfusion centres, that we've now looked at on a number of occasions, which took place in 1976, 1977 and 1978. But the 1977 minutes record a Dr Bateman attending on behalf of the Hammersmith Hospital and reporting that there was a significant shortfall in NHS concentrate, and that a large amount of commercial concentrate was being purchased for patients on home therapy and for use in hospital and that's reported in the meeting on 23 September 1977 at BART0000689.

There is also some evidence to suggest that there may have been supplies of some products made available directly from BPL to the Hammersmith. But that may have been in relation to albumin rather than factor concentrates.

The snapshot from the end of 1969, end of 1970, that is provided by the Hammersmith's response to Dr Obank of the DHSS's letter, is at -- and I'm just going to read the transcript again -- read it for the

transcript, we don't need to go to it -- is at DHSC0100026_019. That indicates that there were 43 cases registered at the centre, 242 incidents of haemorrhage for which patients had attended the centre in the relevant year, four incidents of severe bleeding in patients attending the centre.

If we go, however, to BPLL0008111 -- so this is the response to Dr Maycock's questionnaire again -- and I'm afraid I've failed to mark which page it is, so if you just give me a moment I'll find the Hammersmith entry. Yes, it's page 24.

So this is Dr Mibashan's response, 30 patients treated with haemophilia regularly:

"Would you prefer to use for the patients of your patients

"... [Cryo]? No.

"... Freeze-dried concentrate? Yes.

"... Some [cryo] and some freeze-dried concentrate? No."

Again, an estimate is given as to what would ideally be needed in terms of supply.

In terms of the annual returns and numbers of patients treated, for the period 1976 to 1985, the returns suggest between about 28 patients and 36 patients with haemophilia A being treated on an

annual basis, up to eight von Willebrand's patients, between one and five haemophilia B patients, and in some years one or two carriers of haemophilia A.

So not a huge centre but a bigger centre than some of the other London centres that we have looked at.

There is also evidence to suggest, both from Dr Chipping but perhaps more pertinently directly from patients who were treated at the hospital, that children as well as adults were treated at the Hammersmith centre.

The Inquiry has received a number of statements from individuals treated with blood products at the centre or from their families. We referred to some of them in our presentation note and you, sir, have heard oral evidence from a number of them. I won't go through the details but again the themes that emerge are no advice or warnings or information about the risks of viral transmission in concentrates, a switch from cryoprecipitate to Factor VIII concentrates. Again, they are main issues that emerge in terms of product usage.

The annual returns, again, we'll just look at a handful of them, starting with 1976, HCDO0000088_002. If we go to page 4 we can see, in

1976, 30 haemophilia A patients treated, five haemophilia B patients treated and then, if we look at the products in use, cryoprecipitate used to a considerable extent, 392,000 units. Also, NHS factor concentrates, 206,000-odd. But a range, albeit in smaller volumes, of commercial concentrates being used, Koate, Hemofil, and Kryobulin, all in use in 1976.

1977, likewise shows continuing significant use of cryoprecipitate. The figure from the annual returns is just under 418,000 units for cryo. But also NHS concentrate, Koate and Hemofil all being used, with Hemofil being just under 200,000 units used in the course of 1977.

1978 also shows cryoprecipitate still being used in quite large measure, 338,000 odd units of cryoprecipitate used. But also Armour's product, Factorate, used, just 350,000 units, and some NHS concentrates being used.

1979, again, still shows cryoprecipitate in extensive use, but an increase in the usage of the Armour product, so over half a million units of Armour used in 1979, and approximately 325,000 units of cryoprecipitate, just over 100,000 units of NHS concentrates.

If we then pick the picture up in 1980, at HCDO0001423, we see a different picture emerging. So 33 patients of haemophilia A treated that year, five von Willebrand's.

Then if we look at the figures, we can see very small amounts of cryoprecipitate in use, reasonably significant volume of NHS concentrates being used, but by far and away the product in greatest use is the Armour product Factorate, over 700,000 units at hospital and just over 500,000 units for home treatment.

Although the figure for cryoprecipitate goes up in 1981, Armour was still the product in greatest use in 1981.

Then if we just go to 1982 -- and if I may, I will complete the position in relation to Hammersmith before we break -- it's HCDO0001624, we can see there a small amount of cryoprecipitate being used, just under 20,000, NHS concentrate being used, the Armour product again being used, and now Kryobulin also in fairly extensive usage.

And if we go to page 4 we see the entries per patient that you're very familiar with seeing now, and we can see from them that there isn't an obvious attempt to keep patients to one type of commercial

concentrate. So a significant number of the patients are shown as receiving, for example, both the Armour product and the Immuno product, and that pattern continues on the following page.

So that is the picture for 1982. 1983 shows little cryoprecipitate, an increase in NHS concentrate but, again, the main product in use in 1983 is the Armour product, and the same picture emerges in relation to 1984.

Dr Chipping, in her statement, recalls supplies to the Hammersmith Hospital coming from the North London Blood Transfusion Centre, and she says that:

"Decisions about ordering were made on the basis of clinical need but issue of product depended on their availability at the Regional Transfusion Centre."

She said this:

"Whilst we ordered British produced factor concentrates on the basis that we were aware the commercial products might contain plasma from paid donors, supplies of Factor VIII concentrate from BPL were limited and until well into the 1980s it was unusual to receive what we had ordered. Substitution being made with commercial Factor VIII, a supply was via the RTCs."

She says, however, that financial considerations were not a factor in decision making, so dictated, she suggests to some extent, by what was available. She doesn't recall DDAVP being available as an alternative treatment when she was at the Hammersmith Hospital and she doesn't recall cryoprecipitate in routine use for the treatment of haemophilia A.

Dr Laffan's statement talks about the centre's treatment policy but that, again, is in the second half of the 1980s, and specifically, in relation to the period from 1985 to 1987, he says patients were treated with non-concentrate therapies whenever possible and whenever it was judged safe from a haemostatic point of view.

He talks also about a preference for UK concentrate when it was thought essential to use a concentrate to achieve haemostasis.

In terms of knowledge of risk of hepatitis, response to risk, again we're dependent largely upon attendance at meetings. Dr Mibashan was a regular attender at UKHCDO meetings, or somebody attended from the Hammersmith on his behalf. We see, for example, also Dr Chipping attending, and others.

Dr Chipping has set out in her statement her general understanding in relation to hepatitis.

Dr Laffan has done likewise in his statement, picking up the picture from 1985 when he first started working at the Hammersmith. He says at that point in time the principal concern was the transmission of HIV. He says:

"There were no additional measures taken at that point in time for hepatitis."

In terms of testing, his recollection is, by the time he joined Hammersmith Hospital in 1985, most patients had been tested and already knew the results of their test. He describes it being routine practice for the virology laboratory to retain stored samples of sera.

Again, sir, you will wish to consider when you're looking at the Hammersmith the evidence you have heard from individuals who were treated there. You've heard accounts of patients not being told that they were being tested or HIV or indeed for hepatitis B, and having certainly no concerns about the way in which HIV test results were communicated.

The information that we have from UKHCDO as to the numbers of patients infected with HIV at the Hammersmith Hospital Haemophilia Centre suggests 26 patients, which obviously is a fairly high proportion of the number of patients who were treated.

In terms of hepatitis C, Dr Laffan's statement suggests that 64 patients at the centre were found to have evidence of hepatitis C infection. His recollection is that testing at the Hammersmith for hepatitis C began before 1992, and he says he would tell patients usually in clinic, and it wasn't the policy to inform patients by phone or by letter. He says this:

"[He] tried to ensure that all patients who had received blood or blood products were tested for hepatitis C antibodies. Later it became possible to test for hepatitis C virus by PCR and this was also done. However, this was not done systematically. A systematic review to ensure that all patients who received any blood products were tested was carried out in 2010 and followed up in 2017 under direction of UKHCDO."

Again, both Dr Laffan's statement and some of the evidence that you've received from witnesses provides, in broad terms, a description of the treatment arrangements for hepatitis and for HIV at the Hammersmith. Dr Laffan said he would refer patients with evidence of hepatitis C infection to the hepatology department for management and that, by the time he was director in 1992, patients with HIV

infection were referred to a dedicated HIV clinic.

So, sir, that's the position, then, again by way of overview and highlight of the documentation we have available relating to the Hammersmith Hospital, and that's probably a good point to break.

SIR BRIAN LANGSTAFF: Yes, well, we will take a break now until ten to four. Ten to four.

(3.20 pm)

(A short break)

(3.50 pm)

MS RICHARDS: Sir, I turn next to the Middlesex Hospital. The directors of the Haemophilia Centre at the Middlesex Hospital were Professor Stewart until 1984, when Dr Machin took over as director. Of course we will have seen numerous references to the Middlesex Hospital in a range of records to Dr Tedder, and to Dr Tedder's role, and in particular the role in relation to testing for HTLV-III is something we will explore perhaps in more detail in later hearings.

The Middlesex was also one of the 13 designated Haemophilia Centres in London as at 1970, and it fell within the North-West Thames region, and was supplied with products by the North London blood transfusion centre in Edgware. Its 1976 allocation of NHS Factor VIII concentrate was 22 bottles per month.

If we then go to BPLL0008111 and go to page 28, please -- and again these are the responses to Dr Maycock's questionnaire -- page 28 is the response on behalf of the Middlesex Hospital as at the beginning of 1973:

"How many patients with haemophilia do you treat regularly? 21."

Then, in terms of the preference for products, the preference expressed by Professor Stewart in his response was for some cryoprecipitate and some freeze-dried concentrate, so not just concentrate as the earlier responses we looked at were.

In terms of numbers of patients treated at the Middlesex Hospital, the annual returns for 1976 through to 1985 give a range of between eight and 22 patients with haemophilia A, between two and nine patients with von Willebrand's disease, and between one and five patients with haemophilia B.

The annual returns themselves, beginning in 1976, in terms of products show relatively early use of commercial concentrate, so both Hemofil and Kryobulin were used in 1976, albeit the main treatment in 1976, by some considerable margin, was cryoprecipitate. No NHS concentrates are recorded as used on the 1976 annual return.

1977, the pattern is similar, the main treatment is with cryoprecipitate. There's a small amount of NHS concentrate used and a small amount of Kryobulin used.

1978, again mainly cryoprecipitate, some NHS concentrate, and a small amount of the Hyland product Hemofil.

1979, still mostly cryoprecipitate, some NHS factor concentrates, some Hemofil and a very small amount of the Armour product Factorate introduced in 1979.

The picture then shifts a little in 1980, and so if we go to the annual return for 1980, which is HCDO0001450, this shows 16 haemophilia A patients treated during the year, seven von Willebrand's. Then if we look at the figures, we can see cryoprecipitate -- it looks like 4,000 bags. And then NHS concentrate, 2,000, and then 12,000 units. And then the Hemofil, 20,000 units and 14,700 units.

So that's the picture as of 1980.

SIR BRIAN LANGSTAFF: So that would equate, in the usual conversion, to 28,000 units of cryo?

MS RICHARDS: Yes, which is a significant reduction compared to the previous years. But still not cryoprecipitate as a marginal source of treatment,

which is what we've seen with some of the other centres.

SIR BRIAN LANGSTAFF: Well, it's the biggest product used per unit in hospital.

MS RICHARDS: Yes, not used for home treatment.

Then if we pick the picture up in 1981.

I'm sorry! HCDO0001551. It would help if I gave you the reference, Soumik.

We've got 18 haemophilia A patients treated and seven von Willebrand's, two carriers.

We can see there that bags of cryoprecipitate is now 759. I'm just looking, for present purposes, at the haemophilia A patients.

NHS concentrate used, 10,000, and then 16,500 units for home treatment.

Then we can see a range of commercial concentrates being used, Koate, Hemofil, Kryobulin and Humanate, in different proportions, but all four in use, as well as of the NHS concentrates.

Then if we go to 1982, which is HCDO0001650, we can see now cryoprecipitate is used to a lesser extent, the figure there given is roughly 10,500 units. Roughly 100,000 units of NHS concentrate. Koate is used, roughly 74,000 units. Then Kryobulin, around 11,000 units.

So that's the picture then for 1982, cryoprecipitate usage drops.

Then, if we pick it up in 1983, HCDO0001747, we see there the predominant picture is of treatment with NHS factor concentrates. So comparatively little commercial usage, although still 10,000-odd units of Koate. Cryoprecipitate usage just under 25,000. But roughly 250,000 units of NHS factor concentrates.

Again, whether that simply reflects issues of supply or whether it reflects conscious decision-making is not something we are able to detect from the returns.

Then I think finally, for present purposes, the 1984 return, which is HCDO0001841.

The figures for commercial concentrates have gone up, so we've got Profilate being used, just under 52,000. Factor VIII, 15,600. But again, the main product in use is NHS Factor VIII concentrate, and with some usage of cryoprecipitate.

Just in terms of relations with pharmaceutical companies, there is a document in relation to the Middlesex that may be worth looking at. It's BAYP0000009_603. It is a letter from Linda Frith, sales development manager with Cutter, and it's dated November '86. She refers to having met Dr Machin and

colleagues "at the Haemostasis and Thrombosis Club meeting". There's reference in the second paragraph to cheques being paid for travelling expenses and other expenses relating to a meeting. And then there's a discussion then, offers of selling Cutter's Gamimune product.

Then if we go over the page, there's a discussion in the top product about Koate-HT, so the heat-treated Koate product offered by Cutter's at the time, and then this in the last paragraph:

"I would like to confirm that Cutter will be able to provide funds to your department of £5,000. I would like to do this in one payment before the end of this year. Would you be able to provide me with a letter saying what the funds would be used for, eg to help support a research project or a researcher, etc."

I should perhaps, in fairness, indicate that the -- actually, I don't think we have the 1987 return, sir, sorry. The 1986 return doesn't show any purchases from Cutter, but I'm afraid I don't have the 1987 return to check.

Again, our information in relation to knowledge of risks of hepatitis or HIV really depends upon inferences to be drawn from attendance at meetings.

Professor Stewart was a regular attendee at UKHCDO meetings throughout the 1970s. Dr Machin would attend either in his own right or in place of Professor Stewart or sometimes in place of Dr Tedder at meetings in the course of the 1980s.

The evidence you've received from the patients who were treated at or family members of patients who were treated at the hospital indicate no information, advice or warnings being provided in relation to the risks of infection.

I should say that Dr Machin has provided a statement in response to specific criticisms contained in the statement of one patient's mother, in which he said it would be normal practice for patients in '84, '85, to have discussions about the dangers of infections, particularly hepatitis, HIV, and any other form of hepatitis from any blood products provided.

He says:

"I would expect for this to have occurred with the patient's mother although not necessarily directly with me."

Then he refers to the fact that the records don't show whether any such discussions took place or not.

The information the Inquiry has from UKHCDO in

terms of infections indicates one patient testing positive for HTLV-III from the Middlesex Haemophilia Centre in 1985.

Again, the evidence the Inquiry has received from a patient treated at of the hospital or the parent of a patient treated at the hospital gives an account of being tested for HIV without the knowledge or consent of the parent.

We've little information, I'm afraid, about HCV -- in fact I think no information about HCV, either in terms of numbers or in terms of what the arrangements were for treatment of any patients infected with hepatitis C.

Can I then turn to Northwick Park. The centre at Northwick Park again was a small centre in terms of the number of patients treated. Dr Chanarin was the director of the centre in the course of the 1970s. We then have two statements from doctors who were subsequently involved.

Dr Samson has provided a statement to the Inquiry. We don't need to put it up on the screen, but it's WITN4673001. She was a consultant haematologist at Northwick Park from 1977 to 1983 and she sometimes completed the centre's annual returns.

Then Dr Reid has also provided a statement to

the Inquiry. Again, for the benefit of the transcript it's WITN5248001. He was registrar and senior registrar in haematology at Northwick Park from 1977 to 1982 and then took over a consultant role in 1983 at Northwick Park, I think when Dr Samson moved on, and he remained at Northwick Park I think for the majority of the rest of his medical career.

In terms of facilities at Northwick Park, Dr Samson's description is that:

"There was no physical entity designated 'Haemophilia Centre' and [there were] no dedicated [haemophilia centre] staff."

Dr Reid's description is to similar effect. He says:

"[The centre] was comprised of myself and the other haematology consultants ... and junior staff ... at Northwick Park hospital. There were no dedicated nursing or other ancillary staff dedicated to these patients."

I should say Northwick Park Hospital was also the home to the Medical Research Council's Clinical Research Centre. Certainly I think Dr Samson I think was involved with the Clinical Research Centre at Northwick Park.

Northwick Park was designated a haemophilia

centre with associate status, so an associate haemophilia centre, in 1976. We have, I think, comparatively little information about the arrangements for the provision of supplies to it in terms of contemporaneous documentation.

I referred to it earlier as a very small centre, and that's borne out by the figures on the annual returns, which indicate in the period '76 to '86 up to five haemophilia A patients treated in a year, and then very occasionally a patient with von Willebrand's disease or a patient with haemophilia B.

In terms of product usage, most years show either -- or show a combination of cryoprecipitate and NHS factor concentrates.

So that's the position in 1976, cryo and NHS concentrates. In 1979, cryo and NHS concentrates. In 1980, cryo and NHS concentrates. Likewise in 1981 and in 1983, 4 and 5.

There are two years, 1978 and 1982, in which the annual returns show a relatively small amount of the Armour product Factorate in use. So in 1978, what's described as 11 bottles or 2,640 units of Armour was used, and in 1982, there's reference to I think 837 units of Armour Factorate.

So those are the years for which that commercial

concentrate is identified, and the significance of that will become apparent in a moment.

In terms of treatment policies and approach, we do, as I say, have a statement from Dr Reid, and he has said this: his recollection -- and I think it's fair to point out that he didn't, I think, have all the annual returns when he made his statement -- his recollection was that:

"Until the advent of the NHS 8Y product in 1985, cryoprecipitate was used in most or all cases."

His statement indicates that:

"Patients were not consulted over decisions as to which products to use but concerns may have been discussed with them."

And he says this in his statement:

"Our product policy was determined by what we perceived to be in the best interests of our patients. I do not recall consulting with them over our decisions but that does not mean that we did not discuss any of their concerns with them."

Then he says this:

"Until the NHS heat-treated products came along I was unhappy and did not consider using any other alternative except for DDAVP in mildly affected cases or in von Willebrand's disease."

Dr Reid also says this:

"I remember not being convinced of the safety of early commercial preparations because of their American provenance and what I understood about their donor pool. I was happier, therefore, to persist with cryoprecipitate until the UK product became available. Although I note we used Profilate in 1986, I cannot recall the reason for this at the time."

As I say, he did not, I think, have access to all the earlier annual returns when he gave his statement.

The Inquiry has evidence from or about two patients treated at Northwick Park, both anonymous, so I'm going to be careful in terms of what I say. We have evidence from an anonymous witness with severe haemophilia A treated at the haemophilia centre. He describes in his statement being treated initially with fresh frozen plasma and then cryoprecipitate. Then he describes a move towards treatment with factor concentrates and his statement says this:

"I was not comfortable changing my treatment from cryoprecipitate to Factor VIII and sat down with my doctors at Northwick Park Hospital in Harrow and told them that I did not want to be treated with Factor VIII. I felt relatively safe using

cryoprecipitate and unusually the doctors agreed to allow me to continue with the treatment, despite the fact it was uncommon for haemophilia patients to be allowed to elect their treatment. They were very helpful and, like all of us, uncertain of the scale and threat posed by HIV.

"My doctors provided me with a steady supply of circa 20 units of cryoprecipitate to keep in the freezer to treat bloods on demand."

That patient did, in fact, contract both HIV and HCV but the evidence suggests that that was because of treatment at a different hospital in London, out of hours treatment, in which he was treated with a commercial concentrate which infected him with HIV.

However, there's a different picture that emerges in the statement of, again an anonymous -- a parent whose son was treated at Northwick Park Hospital. She describes this:

"He was treated for the first 4 years of his life with cryoprecipitate but from 1978 onwards he was transferred to Factor VIII concentrate. I was advised by the hospital that the use of Factor VIII would be a great improvement in his care, allowing us to eventually go on home treatment. I was never asked if I was agreeable to the change and I was never informed

that there was a risk of viruses being carried in the blood product. The hospital said that the Factor VIII was purer. I was told it would make life simpler and easier for us and that the home treatment would reduce the number of hospital visits and this disruption to our home life."

You will recall, sir, that I mentioned those small amounts of Armour product appearing in the 1978 and 1982 returns.

Unhappily, the UKHCDO records in relation to the child treated at Northwick Park indicate that he was the recipient of Armour Factorate in 1978 and in 1982 from Northwick Park.

The patient's mother's statement to you, sir, continues:

"In 1983 HIV was a hot topic in the news and there were suggestions that haemophiliacs were susceptible."

She describes contacting Northwick Park, being told to carry on her son's home treatment as normal as the risk of him contracting an infection was minimal. She was not given an option for her son to revert to cryoprecipitate. She says in her statement:

"Mostly the treatment was NHS Factor VIII but if they were running low he would be given commercial

products."

As I say, the UKHCDO records confirm that.

I should also say that her statement describes being informed of her son's HIV positive test result by a letter from Northwick Park.

You will see, sir, the picture that emerges there, you may think, is somewhat different from the account in the witness statements from clinicians that the Inquiry has received.

I have referred in relation to an earlier centre to some of the evidence of Dr Samson and her recollection that it wasn't until a later stage that the severity of non-A, non-B hepatitis was appreciated. She says in her statement, and this is describing, I think, the position as at summer of 1983:

"We felt blood products were very safe."

She talks about becoming aware only of the risks in relation to HIV when she moved from Northwick Park to Charing Cross Hospital in 1984.

We don't know what the reasons were for there being some use of the commercial concentrate at Northwick Park in '78 and '82 as described. Dr Reid's recollection was that supply was not an issue and that they could get unlimited amounts of cryoprecipitate.

But, as I say, it's right to point out that he did not have either the information from the full returns or, indeed, the statement from the patient's mother, to which I've referred.

In terms of the arrangements for testing for HTLV-III, Dr Reid recalled arrangements being made to test for three haemophilia A patients in 1985 at the time of trying to make the arrangements to obtain heat treated concentrate.

We can see, if we go to -- forgive me while I check the reference. Yes, CBLA0002033. This is a letter that Dr Reid wrote to Dr Snape at BPL in February 1985 asking for heat-treated concentrates to be made available, and he identifies there three patients for whom heat-treated concentrates were being sought.

Sir, you may wish to ignore what's written in handwriting on the right-hand side because we know that that's not entirely accurate. So there's what's recorded there for the second identified patient as negative, we know that that's the child who, later in 1985, was found to be positive for HTLV-III. So we don't know who wrote that but that's not accurate.

But you will see that what's then said at the end of the letter is:

"... in the meantime we're conducting investigations to ascertain their HTLV-3 status."

Certainly, in relation to the child to whom I've referred, it was around September 1985 when the letter was sent communicating the HTLV-III positive test result.

The evidence that the Inquiry has then received in that regard from the parent of the patient treated there is consistent with the data that UKHCDO had supplied to the Inquiry, which suggested one patient testing positive for HIV at Northwick Park in 1985.

There is, I'm afraid, no real information in terms of hepatitis C. Dr Reid's recollection was that testing and monitoring for hepatitis C would have been undertaken at the Royal Free Hospital, which became the comprehensive treatment centre from the 1990s onwards, but he was unable to cast any further light on any issues relating to hepatitis C.

Sir, that is the picture in relation to Northwick Park. A small centre, a small number of patients, but perhaps really quite revealing in terms of what it tells us about relative risks and, indeed, practices in terms of the provision or non-provision of information and advice to patients.

Can I then turn to Edgware. The haemophilia

centre at Edgware Hospital was led in terms of directorship by Dr Ardeman from 1977, certainly until 1990, possibly later. Edgware was designated as an associate centre in later 1976, it was part of the North-West Thames region, so Region 05 and received, at least at that point in the 1970s, its NHS concentrates from the North London Blood Transfusion Centre in Edgware.

Dr Ardeman attended some of the meetings of directors of centres and blood transfusion centres that we have looked at, '76, '77 and '78. I am not going to go to those meetings again, largely because, although Dr Ardeman made contributions at the meetings they were contributions which related more generally to the supply arrangements in the Regional Health Authority area, rather than anything specific to the needs of or usage of products at the Edgware haemophilia centre.

Again, it was a very small centre. The number of the patients taken from the annual returns from 1976 to '86 suggests between one and four haemophilia A patients, two von Willebrand's and no haemophilia B patients treated.

The picture from the returns, in terms of the products that were used is as follows: only

cryoprecipitate in 1976 and 1977. In 1978, cryoprecipitate, NHS Factor VIII concentrate and the Hyland product Hemofil. The factor -- sorry, the product used most in that year was the NHS Factor VIII concentrate.

1979 shows usage of both the NHS Factor VIII concentrate and Kryobulin. That was for the treatment of a single patient in that year. In 1980, we can't discern the figures from the return, but the products that were used were cryoprecipitate, NHS concentrate and Hyland product, in relation to the treatment of haemophilia A.

1981 again shows continuing use of cryoprecipitate, the figures are all relatively small because of the small numbers of patients, but also use of NHS Factor VIII concentrate, Hemofil and Kryobulin. In 1982, again it's cryoprecipitate, NHS concentrate and Hemofil, no Kryobulin in that year.

In 1983, there's only one haemophilia A patient treated so it may be difficult to make any particular deductions, but it's treatment with cryoprecipitate only, and it looks like it's for home treatment. There doesn't appear to have been any Factor VIII concentrate whether NHS or commercial used in Edgware in 1983.

We don't, I think, have the return for 1984.

1985, again, shows the treatment of only one patient and that was with a commercial product, the Armour product, Factorate, and that's in hospital, no home treatment appears to have taken place in 1985.

1986, and this again shows the size of the centre, no patients treated and no blood products therefore used.

We've no direct information again about the knowledge of risks on the part of Dr Ardeman. He did attend UKHCDO meetings on occasions, so '77, '81 and '82, which are fairly important meetings, and he sent his apologies on a number of other occasions, and again it may be reasonable to assume that he would have received the minutes of those meetings.

The data that the Inquiry has received from UKHCDO suggests that there were no patients infected with HIV in the Edgware Hospital, but there's evidence to suggest two patients were tested to see whether they were HTLV-III positive but no positive test results. We have, I'm afraid, no information at all in relation to hepatitis C.

The next London centre that I wanted to look at is the haemophilia centre at the Hillingdon Hospital. The director there during the 1970s and 1980s was

Dr Britt. Again, it was an associate centre, designated as such in late 1976, and supplied with NHS concentrates by the North London Blood Transfusion Centre in Edgware.

You'll recall we looked this morning at a document which showed allocations as at 1976 of Factor VIII concentrate, numbers of bottles per month to certain centres. But the documents show no allocation to Edgware, presumably -- sorry, to Hillingdon, presumably because it was a newly designated associate centre so there was no established pattern of usage.

The annual returns show in terms of numbers of patients treated two patients with haemophilia A and one with Christmas Disease in 1976 and then, over the years that follow, the numbers remain small. I think the largest number treated in a given year with haemophilia A is six. Occasionally, a patient with von Willebrand's disease was treated and, occasionally, a patient with haemophilia B was treated.

I can again take the product usage from the annual returns, I think, by way of summary. Cryoprecipitate only in 1976 and 1977. In 1978, cryoprecipitate and NHS concentrates. In 1979,

cryoprecipitate and NHS concentrates but also Armour Factorate. Again, the volumes used are all small because the number of patients being treated was very small, but we see that commercial product being used in 1979.

1980, again, is a mixture of cryoprecipitate, NHS Factor VIII concentrates and Armour's Factorate, to treat two patients in hospital.

1981 seems to suggest no NHS concentrates used. There was a small amount of cryoprecipitate used, and then the treatment was with the Armour product and with Immuno's Kryobulin. Again, relatively small amounts in terms of overall usage.

1982 shows a slightly larger volume of concentrate being used, so roughly 70,000 units of Factorate, the Armour product, and just under 21,000 units of Kryobulin. Cryoprecipitate was used but only for the treatment of von Willebrand's disease in that year.

1983 shows cryoprecipitate being used in that year for the treatment of haemophilia A patients, but also NHS concentrates and just under 53,000 units of the Armour product used in 1983.

1984 shows cryoprecipitate and NHS concentrates. No commercial concentrates appear to have been used.

There's not much by way of evidence of Dr Britt himself attending UKHCDO meetings. He largely seemed to send his apologies, but there were clinicians from Hillingdon Hospital recorded as attending UKHCDO meetings on Dr Britt's behalf in 1977, '79, '81, '83 and '85. Again, it may be reasonable to infer that he would have been sent copies of the minutes and would have had available to him the discussions recorded in the minutes about hepatitis and HIV.

The data received by the Inquiry from UKHCDO suggests no patients at Hillingdon tested positive for HIV.

There's no information, I'm afraid, that we've unearthed from the hospital in relation to infection with hepatitis C for patients of the haemophilia centre. There is evidence in relation to patients infected with hepatitis C by way of transfusion, and of course those are issues that we will be exploring in more detail in later hearings.

I'm just going to read out the reference for a letter from a patient who was the subject of an operation at the Hillingdon Hospital in June 1991 -- and the significance of the date is apparent, it's shortly before the introduction of hepatitis C screening in the autumn of 1991 -- who was then

identified on a look-back exercise in late '95 early '96.

It's a very powerful and telling account in a letter he wrote to his local MP. And for the transcript, it's DHSC0004728_180.

There is some important information in relation to Hillingdon in relation to infection by way of transfusion with hepatitis C but nothing from the documentation in relation to the position of haemophilia patients and the extent to which they were infected with hepatitis C.

Sir, I note the time. I've got three more London hospitals to cover but I don't think I can do justice to them in the matter of a few minutes, so perhaps we could pick those up at 10 o'clock tomorrow morning.

SIR BRIAN LANGSTAFF: Yes, well, let's do that, then. Ten o'clock tomorrow morning to complete London, and then move into what, the south-west?

MS RICHARDS: South and south-west, and then East Anglia.

SIR BRIAN LANGSTAFF: Ten o'clock.

(4.29 pm)

(The hearing adjourned until 10.00 am the following day)

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