Wednesday, 31 March 2021

(10.00 am)

MS RICHARDS: Sir, just two matters I'm going to pick up from yesterday. Firstly, you asked the question when we looked at the annual returns as to whether there was any apparent correlation between the severity of haemophilia, mild, moderate or severe, and the receipt of more than one type of concentrate or treatment. The answer is, Ms Fraser Butlin having analysed the return data for 1978, 1979, 1980 and 1984, that there's no apparent correlation.

The second point arises out of the documents I referred to yesterday in relation to the proposed exchange in around 1988/1989 between Northern Ireland and Scotland at the time of Z8 usage. The later evidence -- I'm not going to put the documents up on screen -- suggests that that exchange did take place and that there was an exchange of Z8 allocated to Northern Ireland with commercial products supplied by Scotland.

We looked yesterday afternoon at documents relevant to what was or should have been known and understood by those working in clinical roles at the centre about risks of hepatitis. Before I move to do a similar exercise in relation to HIV and AIDS, I just

want to refer to Dr Mayne's most recent statement, and what she says about the information she says was provided to patients. Soumik could we have WITN0736009. Could we go to page 46, please.

This part of the statement is in relation to a series of questions posed by the Inquiry about the process of consent. If we pick it up at paragraph 69.1, Dr Mayne says this:

"The customary practice of the [Northern Ireland] Haemophilia Centre was to check patients' blood at every visit. I must stress that many patients attended at widely spaced intervals, at times six months to a year apart for those that were mildly or moderately affected. Those that were severely affected or were involved in the programme of home treatment were seen and checked more frequently."

And then she refers to forms which those on home treatment completed.

Then at 69.2 she says:

"Thereafter, they" -- I take it those are the home treatment patients -- "were seen at monthly intervals. It was in my view imperative that their bloods were checked to ensure that they had not developed any haematological problems such as anaemia, unduly excessive bleeding or the development of

inhibitor that would negate the efficacy of their concentrate and finally, to check on their liver function tests and hepatitis status."

So part of the monthly testing for those on home treatment appears to have been according to Dr Mayne not just to look at liver function tests but to expressly consider the question of hepatitis.

Then in 69.3 she says:

"Patients were well versed in this practice and accepted the information given to them about the blood testing and the purposes for which they were being taken. They seemed happy to consent to these arrangements."

What that paragraph doesn't do is spell out what information it is Dr Mayne says was routinely given to patients about blood testing and the purposes for which tests were being undertaken.

If we then go to the --

SIR BRIAN LANGSTAFF: It would imply that what they were told was the checks were for their hepatitis status.

MS RICHARDS: It might well imply that.

SIR BRIAN LANGSTAFF: And the expression "they seemed happy to consent" suggests that there was no active consent. It was an assumption by her that they were happy.

MS RICHARDS: Yes.

We'll see similar expression when we look at the question of consent to treatment on the next page. So those questions concerned consent in relation to blood testing. These questions concern consent in relation to treatment. At 70.1 she says this:

"All patients attending the Centre were happy to receive treatment with factor concentrates.

"70.2 In the early days of treatment with concentrates, it was not the practice at the time to obtain written informed consent. Patients, to put it mildly, were overjoyed at receiving concentrate treatment. As the [home treatment] programme progressed, some severally affected patients felt left out and contacted the Centre to request the opportunity of participating in the [home treatment] programme."

And then this:

"Everyone was told of the risk of viral infections associated with all blood and blood products."

Again, what that doesn't identify is what actual information was provided to patients about the risk of viral infections. I should add, sir, having reread every statement received by the Inquiry by or

about a patient treated at the Belfast Haemophilia Centre, that does not accord -- what Dr Mayne says here -- does not accord with any of the evidence that the Inquiry has received from patients or their family members.

If we then just go down the page, just to complete what Dr Mayne says, she says at 71.1:

"For the purpose of clarification, at the instigation of concentrate therapy, all matters pertaining at that time in respect of risk were conveyed to patients before they commenced on [home treatment]. Discussions included comparison of treatment with cryoprecipitate and treatment with concentrates. No figures were mentioned but patients understood that concentrates came from a large number of donors in comparison to cryoprecipitate."

Of course, if that's right, it doesn't follow that they understood and were informed about the relative risks or potential consequences as a result of those risks:

"However, the prospect of their lives being revolutionised, the ease of injection, and the ability to undertake reliable dose calculations precluded any obvious reservations about the treatment. No patient favour expressed any reservation to myself or

any other member of staff in respect of their treatment."

Again, just picking up on some of the evidence from patients and relatives that the Inquiry's received, there are patients who recall, indeed, recall being delighted about factor concentrates. There are patients who describe being left with the impression that these were pioneering treatments is a phrase used in one statement, miracle treatments, wonder drug, although I should say in relation to the latter Dr Mayne has said that's not a phrase she would have used. But those are the recollections of patients. None recount a recollection of being advised of risks of significant health consequences as a potential result of receipt of factor concentrates.

Sorry, I should just complete the series of answers by going over the page to the top of the next page. This is in relation to testing and whether patients were tested without their express consent. I'll come on to that later on this morning also but whilst we're in this statement Dr Mayne's answer is:

"Absolutely not."

That's to the question of were patients tested for HIV or hepatitis or for any other purpose without their express consent. She says she obtained verbal

consent from the patient in all cases and, again, there is evidence that the Inquiry holds from patients which is to the opposite affected and I will refer to that a little later.

SIR BRIAN LANGSTAFF: If we just go back a page, and 71.1 she is speaking in the first sentence of when concentrate therapy on home treatment was begun. It may but probably isn't talking about treatment not at home but in hospital because it refers to "HT".

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: But it doesn't say that there was any further discussion in respect of the risks as they became better known in the case of hepatitis non-A, non-B or as they were becoming known in respect of the risks of whatever it was that caused AIDS later identified.

Is there anything in her witness statement which deals with what she says about the continued conversations that might have been expected in the light of the changed and developing perception of risks?

MS RICHARDS: I don't think so, sir. I am going to show you in the course of the morning some other parts of her statement where she talks about the provision of information to patients and what she says in

particular in relation to the question of providing information about HIV and AIDS.

I don't think we have any form of narrative about as things became clearer this is what I explained. We do when we get to the mid-1990s, 1995 specifically, of course by which time infections will already have occurred. We do have a more detailed account of the weekend that was organised in around 1995 to provide information, it was said, about hepatitis C. But I can't recall any account which picks up upon the point that you have just made, but I will check that both so that I can be confident I've given you an accurate answer and, of course, out of fairness to Dr Mayne.

Sir, I'm going to move next to documentation and evidence relevant to what was as a matter of fact known in Belfast or what should have been known in Belfast by the clinicians I hasten to add, not patients, about the risk of AIDS and HTLV-III.

So if we start if we go back to that same document please, Soumik, WITN0736009 we start with Dr Mayne's witness statement and go to page 25, please. We can see at the top of the page, Dr Mayne says this:

"The immune deficiency syndrome which later

became known as HIV/AIDS first came to my notice during an informal lunchtime discussion with three colleagues. They were the late Arthur Bloom, Virologist John Craske and the late Peter Kernoff.

"30.2. John Craske was describing the content of a paper just published, to the best of my recollection in the Lancet, but with the passage of time I cannot be more specific. It described an account of an immune condition which had occurred in homosexual males in San Francisco. I enquired as to the relevance to haemophilia. He reminded us that the individuals cited in the paper were known to maintain their lifestyle by being paid blood donors, as was documented in the World in Action (1975) programme. Whilst the revelations of that were horrific, I was unprepared for the shock of the news of a possible future infection which could affect those in receipt of plasma derived concentrates, namely, the Haemophiliac population."

Dr Mayne, perhaps unsurprisingly can't recall when this conversation took place. There is The Lancet article that might be the article that's described at PRSE0004476. I'm not going to go through the detail of it. You'll see it's a letter to the editor about something then referred to as "Gay

Compromise Syndrome", and it refers to:

"A remarkable outbreak of opportunistic lung infections and/or Kaposi's sarcoma in homosexual men has been reported this year in the United States."

And if so, that's an article in The Lancet, 12 December 1981. So that might fit the bill in terms of it helping us to date the discussion to which Dr Mayne refers.

If we go next to Dr Mayne's HIV litigation report CBLA0000072_024. If we turn to page 32, Soumik.

So under the heading "The Development of the AIDS Epidemic", if we go to the bottom of the page, Dr Mayne says this:

"Early publications during 1981 (62) and 1982 (63) ..."

And the footnoted publications there are -- footnote 62 is a publication in the New England Journal of Medicine by Gottlieb, Schroff, Schanker and others about PCP pneumonia, evidence of a new acquired cellular immunodeficiency. It's a 1981 New England Journal of Medicine. I don't have the precise date but we can check that.

The 1982 publication to which she is referring is in the Annals of Internal Medicine 1982, an article

by Friedman-Kien and others, "Disseminated Kaposi's sarcoma in homosexual men".

In any event, she says:

"Early publications during 1981 (62) and 1982 (63), describing the unexpected outbreaks of the rare disorders [PCP] and Kaposi's sarcoma in homosexuals provoked discussion amongst Haemophilia Centre Directors as early as September 1982."

We'll look at that in a moment.

"At that time particular relevance to haemophilia care was not yet evident. In July 1982 MMWR ... reported that three haemophiliacs had developed AIDS, but little evidence had accumulated to suggest that haemophiliacs of themselves constituted a special risk group for AIDS."

And then she says at the top of the next page:

"The situation changed with increasing haemophiliac involvement and towards the end of the year ..."

So that's towards the end of 1982.

"... they were categorised as a separate 'at risk' population."

And then she goes on to refer to some UKHCDO interactions which I'll deal with separately.

So, again, there's nothing in Dr Mayne's

HIV litigation report to suggest that these developments were unknown to her or unknown to the Haemophilia Centre Directors members, organisation members. On the contrary, the implication might be thought to be she's setting this out precisely because they were known and were a subject of discussion.

So that's what she says in the litigation report about the knowledge in 1982. I should just remind you, sir, although we've looked at it on a number of occasions, of the UKHCDO records of discussions in 1982.

We start with HCDO0000410. You will recall this is the Reference Centre Directors' meeting on 6 September 1982 attended by Dr Mayne and by Dr Craske as well and by a number of others.

If we go to page 8 we see towards the bottom of the page the beginning of a verbal report from Dr Craske about the work of the Hepatitis Working Party.

Then if we go on to page 11, in the paragraph halfway down the page beginning, "Professor Bloom asked":

"Professor Bloom asked Dr Craske if he had any information about the acquired immune-deficiency syndrome following reports from the United States and

the possible relationship of the syndrome with blood products and hepatitis. Dr Craske said that he would find out more about this and agreed to try to have some information available for the Haemophilia Centre Directors at the Manchester meeting."

Then if we go to the Haemophilia Centre Directors' meeting the following week at CBLA0001619, so this is the Manchester meeting of the bigger group of Haemophilia Centre Directors, 13 September 1982. The list of attendees on the second page tells us that Dr Mayne was present and there is a short discussion about AIDS on page 10. Bottom of the page:

"The acquired immune deficiency syndrome. The Reference Centre Directors had asked Dr Craske to look into the report from the United States of this syndrome mainly in homosexuals but including three haemophiliacs. It appeared that there was a remote possibility that commercial blood products had been involved."

And we considered in earlier hearings the question which will ultimately be for you to resolve, sir, of whether that was a fair or accurate statement given the state of knowledge already by that time.

Dr Craske asked the directors to let him know if they had any cases of the syndrome. The working

party was considering the implications of the reports from the USA. So those are the minutes of the September 1982 meetings. Obviously, we don't have a more detailed account of the underlying discussions because the minutes are only, on any view, a summary.

What we do know is that in November 1982 Dr Craske produced the first version of a report about AIDS.

If we go to HCDO0000557, we see a letter from Dr Craske dated 11 November 1982. This letter is addressed to Ms Spooner. We do have copies of this letter addressed to others, including I think Dr Kernoff and at least one other Reference Centre Director.

What's not clear from what we have been able to analyse is whether this letter was being sent solely to members of the Hepatitis Working Party, which would not have included Dr Mayne, or whether it was being sent, at this point in time, to the Reference Centre Directors as well, which would have included Dr Mayne. So I'm afraid at the moment we simply don't know the answer to that question.

But, in any event, we have over the page the first version of a report prepared by Dr Craske. It's dated 5 November 1982 on its third page, and if we

look at the second page -- sorry, the next page, my apologies, Soumik. Bottom half of the page, we see the passage we've explored before under the heading, "Aetiology":

"Several theories have been advanced. It seems likely that this is a 'new' syndrome."

And then he sets out the three theories. "Effect of drugs", and says this is not a factor. A second theory is "the immuno-suppressive effect of cytomegalovirus infection", and he says this seems unlikely.

Then over the page the third possible cause, "the association with sexual promiscuity, intravenous drug use and possibly the transfusion of commercial blood concentrates", and then he says just below that:

"If (3) is the most likely cause, then it seems possible that such an agent might be present in the plasma of hepatitis B carriers used to prepare hepatitis B vaccines."

The relevance of that was this was a paper Dr Craske had prepared at that stage for the Medical Research Council's hepatitis vaccine working group.

So that's November 1982.

If we then go to PRSE0002647, this again is a document that we have looked at on a number of

occasions. It's one of the records of the meeting with Immuno at London Airport or at a London airport hotel on 24 January 1983.

If we go to the last page, please, we see in the bottom half of the page the list of attendees and we'll see that they include Dr Mayne.

If we go to the page before that, we can see the heading almost halfway down the page, "Acquired immunodeficiency Syndrome", and we see there set out the discussion about AIDS, Dr Craske summarising the current position, giving a clinical description of the AIDS syndrome, and then picking it up towards the bottom of the page reference to the mortality rate, 45 per cent mortality, and then in the last paragraph a description of haemophiliacs in the United States affected:

"Ten ... affected ... five have died. The youngest was aged 7. All cases have had prolonged treatment with factor VIII but there is no specific implication of one particular product or batch. Other cases involving blood and blood product transmission have included platelets transfused in three cases. In one of these cases, one of the donors was a young New York man in his twenties. A second case was a 20 month old child with rhesus HDN who had received

several units, including platelets known to have come from a homosexual donor who was asymptomatic at the time, but who later died."

That's the San Francisco baby case.

If we go over the page, the discussion continues with reference to the incubation period:

"In the UK, so far only one or two cases have been reported from the communicable diseases centre."

There's then reference to, "protocols from the United States [that] are being considered by the Hepatitis Working Party", and a reference to American fractionation companies being "very aware of the problem".

Then in the next paragraph a discussion of the editorial, that's the Desforges editorial, in the New England Journal of Medicine, 13 January 1983.

So that, it's a matter for you, sir, but may be taken as a guide to what by 24 January 1983 would have been known to Dr Mayne about the latest developments in the state of knowledge in relation to AIDS risk for haemophiliacs.

There was then, again in terms of the chronology in early 1983, which is of some particular significance for Belfast patients because of the dates of seroconversion for most of them, which I'll come on

to later. So continuing with the chronology, there's then a Reference Centre Directors' meeting in February 1983. That's at HCDO0000411.

It's right I should note the covering letter which sends out the draft minutes is 9 May 1983, so it's several months after the meeting on 14 February 1983.

I mention that because if we look at the next page, we can see that Dr Mayne did not attend this particular Reference Centre Directors' meeting on 14 February 1983. We see apologies for absence were received from her.

If we go to page 5, Soumik, we can see the discussion about the AIDS syndrome. Professor Bloom reporting it:

"... would be discussed at the Stockholm meeting at the World Federation of Haemophilia. Reports from the United States indicated that the incidence of AIDS was higher than at first thought and there was some concern that the haemophilic population of the UK who had received American concentrates might be at risk."

Then there is a discussion of a form being prepared for the reporting of cases and Dr Craske was going to draw that up and it would be circulated to

all Haemophilia Centre Directors with appropriate notes regarding the criteria on which a diagnosis should be based.

I should note although Dr Mayne wasn't present at that meeting, her HIV litigation report does refer to that meeting, so it may be something that she was aware of, and aware of the discussion, but we can't say that for certain.

We do know however that as agreed at that meeting Drs Craske, Rizza and Bloom did write to all centre directors, so that would have included Dr Mayne, in March of 1983. And we can see the letter at HCDO0000517_001. This is the letter of 22 March 1983. Again, we've looked at it before but not, as it were, through the prism of the Belfast Haemophilia Centre:

"Dear Director,

"Re: Acquired Immune Deficiency Syndrome ..."

And then there's reference to:

"Recent discussions in both the Hepatitis Working Party and a recent meeting of the Reference Centre Directors ..."

And the system being set up:

"... for the reporting of possible cases of [AIDS] ..."

Then the letter continues, this is the second paragraph:

"The criteria for reporting cases are given in the accompanying paper AIDS/2."

And a request is made to use the form AIDS/3.

If we look at the enclosed documents themselves, they are, first of all, we start with the AIDS/1 report. That is HCDO0000517_002.

So this is an updated version of Dr Craske's November 1982 report. It's dated at the end of the paper, 1 March 1983. Again, it sets out the growing knowledge at the Communicable Disease Centre in Atlanta of infections.

Then if we go towards the bottom of the page we see reference in the last paragraph to delay between initial symptoms and diagnosis.

If we go over the page, we see reference, just towards the middle of the page, to mortality rate. And then if we go to the next page, the bottom half of the page -- sorry, I should start with the top half of the page, my apologies. There's reference in the third line:

"Since then reported cases of a similar syndrome have been noted in ..."

And then there are various now very familiar

categories, including the following:

"... recently in 7 haemophiliacs, 6 of whom also have no association with drugs or sexual promiscuity. Three cases have been described in the UK and one in Spain. All probably acquired their disease in the USA. However, 4 cases were recently observed in Denmark ..."

Then if we go further down the page we have the discussion of aetiology, again in similar terms to the discussion in the November 1982-version of Dr Craske's paper. So he discounts effect of drugs in paragraph 1. He suggests that cytomegalovirus as a cause is unlikely in paragraph 2. And then if we go over the page he alights upon (3) as the most likely cause, so "sexual promiscuity, intravenous blood abuse and possibly the transfusion of commercial blood concentrates". This time, below paragraph 3, rather than referring to the issue of hepatitis vaccines he says this:

"If (3) is the most likely cause, then it is possible that such an agent might be present in the plasma pools used to prepare commercial factor VIII and IX concentrate manufactured from donor plasma collected in the USA."

He refers in the next paragraph, if we go

further down the page, to three patients having, acquired the disease where the most likely mode of transmission was blood or platelet transfusions. He refers then to the incubation period. He says:

"The most recent information ... suggests that at least ten haemophilia A patients have been reported with clinical features of the syndrome."

And at the end of that paragraph that five of those have since died.

There's reference to possibility of sexual transmission at the bottom of the page.

Then if we go to the next page and we look at the last -- the first paragraph, the last two sentences, where he says:

"All the epidemiological evidence is consistent with the existence of a transmissible agent whose mode of spread is remarkably similar to that of hepatitis B."

Then he refers to precautions against cross-infection and then says:

"It is thought likely that batches of factor VIII concentrate which might contain the AIDS agent came into use since January 1st 1980 in the USA. The Communicable Disease Centre of the US Public Health Service at Atlanta, Georgia, therefore has

requested the UK Haemophilia Centre Directors to co-operate with them in a survey by reporting cases of AIDS possibly associated with transfusion of US commercial factor VIII concentrate."

He says:

"Cases will also be notified to the Communicable Disease Surveillance Centre in the UK at the Central Public Health Laboratory, Colindale, London."

SIR BRIAN LANGSTAFF: Could you just go back a couple of pages. It says there, six lines down:

"... recently in 7 haemophiliacs, 6 of whom also have no association with drugs or sexual promiscuity."

Then if we go over a couple of pages, back a page, and again I think.

MS RICHARDS: There's a reference to ten patients.

SIR BRIAN LANGSTAFF: Yes, that's it, it's the reference to ten.

MS RICHARDS: The reason for the difference, sir, is this -- it only becomes apparent if we look at the footnotes. So if we go on two pages please, Soumik, footnote 4 is the source of the seven haemophiliacs. So that's public reporting and that's in MMWR. I don't know which without checking. That might be

the December MMWR.

SIR BRIAN LANGSTAFF: I think December was more than seven.

MS RICHARDS: I think it may well have been an earlier MMWR. The ten patients -- so Dr Craske goes:

"The most recent information ... suggests at least ten ..."

That's footnote 8, and he says it's a personal communication from Dr Dale Lawrence, CDC Task Force on AIDS.

SIR BRIAN LANGSTAFF: Yes, what Dr Mayne has picked up on in her statement I think is the lower figure.

MS RICHARDS: Yes, that might be right. The ten figure is the figure discussed I think in the January Immuno meeting at London Airport.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: We'll check the MMWRs for December. I think you are right, sir. It may be the ten figure and the seven figure is earlier.

SIR BRIAN LANGSTAFF: I think then it was eight confirmed cases and -- seven or eight anyway.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: And then by some time between January and May it grew to 11, I think, in the States.

MS RICHARDS: In the States, yes. Those are cases all in

the States.

So we know Dr Mayne is present at that meeting at the Excelsior Hotel, Heathrow Airport, 24 January, and we know that this letter and its attachments were sent to all Haemophilia Centre Directors.

For the sake of completeness I'll just -- as well as looking at the form, we'll just look at the other two documents.

So if we go to the other two documents that accompanied the letter. If we go to HCDO0000273_078, that's, as it were, a note for directors as to conditions, symptoms and findings to look out for and report, and we can see from the third page that's also dated 1 March 1983.

Then if we go to HCDO0000517_004, that's the form that directors were asked to complete in relation to possible cases and, of course, we've looked by way of example at the actual form completed by Professor Bloom in relation to the Cardiff case.

Those are the communications from Haemophilia Centre Directors -- sorry, to Haemophilia Centre Directors in March of 1983.

If we then go to HCDO0000003_008, this is the special meeting of Reference Centre Directors held on 13 May 1983, and it's right to note that Dr Mayne was

not in attendance at that meeting. It was, however, obviously a very significant meeting. How the discussion was communicated to Dr Mayne and when it was communicated to Dr Mayne, we don't know.

Again, we've looked at this on a number of occasions. If we just go briefly down the page we'll see Professor Bloom outlined the background to the meeting and its purpose:

"The recent publicity ... had caused considerable anxiety to haemophiliacs and their medical attendants as well as to the Department of Health."

If we go over the page -- sorry, it was the previous page. My apologies. Yes, if we go down. It says -- this is halfway down this long paragraph:

"To date in the [UK] one haemophiliac is suspected of suffering from AIDS."

So that is again, we anticipate, the Cardiff case that Professor Bloom is there referring to. And again, Dr Mayne in her litigation report refers to a knowledge of there being that case.

Following that meeting, recommendations were sent to all centre directors, so that would have included Dr Mayne, in June of 1983 and the reference for that is HCDO0000270_004. It's the letter of

24 June 1983. It refers to the special meeting of the reference centre directors in the opening paragraph and then says this:

"At the above mentioned meeting on May 13th the following general recommendations were agreed.

"1. For mildly affected patients with haemophilia A or von Willebrand's disease and minor lesions, treatment with DDAVP should be considered. Because of the increased risk of transmitting hepatitis by means of large pool concentrates in such patients, this is in any case the usual practice of many Directors.

"2. 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."

And then it goes on to say that:

"It was agreed [at the 13 May meeting] that there [was] as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy ..."

Although Dr Mayne was not present at that meeting it's clear from her evidence that that

accorded with her own view. She talks on multiple occasions throughout her various statements of what she regarded as the immense benefits of treatment with factor concentrates.

In relation to this letter, Dr Mayne's evidence is this essentially reflected existing practice at the Belfast Haemophilia Centre. We've looked already at the position of children and seen that those who were being treated at the Royal Belfast Hospital for Sick Children were treated with cryoprecipitates but that there were two severely affected children treated with factor concentrate, so I think not entirely correct to say that it was the policy across the board for all children.

In terms of paragraph 1, suggestion there of treatment with DDAVP, we've seen from the annual returns comparatively infrequent reference to DDAVP, albeit it's right that I note we don't have every return for the early part of the 1980s.

We do see von Willebrand's patients, apparently, being treated largely with cryoprecipitate.

In terms of mildly affected patients or patients previously unexposed to imported concentrates, the position is less clear in relation

to Belfast. I don't think we have any specific evidence about a particular treatment policy in relation to previously untreated patients.

In relation to those who were mildly affected haemophiliacs or those whose haemophilia was of moderate severity, Dr Mayne addresses this in her witness statement at WITN0736009. We pick it up at the bottom of page 17, bottom half of the page.

You'll see reference in the bold print to the question posed by the Inquiry which refers to the June 1983 UKHCDO recommendations and she's asked what the Belfast Centre's policy is, and her answer is as follows:

"As described above, the policy of using cryoprecipitate for treating mildly affected patients and children was adhered to but, at times, proved in practice to be much more complex than expected."

She then says that:

"Cryoprecipitate, DDAVP and antifibrinolytic agents were, and are, used for the management of von Willebrand's syndrome."

Then over the page she sets out in paragraph 19.1, and we looked at this or a similar passage yesterday, at the position in relation to children, but then in relation to people with mild or

moderate bleeding disorder she deals with that in the bottom half of this page and says this in 20.1:

"... effective treatment of bleeding disorders is patient specific and needs to take account of individual circumstances. Occasionally, it was necessary to use concentrates for patients whose bleeding disorders were classified as mild or moderate. I can best illustrate circumstances in which this situation arose by reference to specific examples."

Then she sets out in her next paragraph an example of two brothers who had what might be described as a typical level for a mildly affected patient but asserts that clinically they were much more severely affected and that appropriate doses of cryoprecipitate proved totally ineffective.

If we go over the page, paragraph 20.4 suggests that in relation to those patients they resorted to concentrates, and then she gives another example in 20.5 and 20.6 of other patients, and in paragraph 20.6 talks about then the use of concentrate and says this:

"Theoretically, I would have advocated the use of much larger doses of cryoprecipitate, but by the time these results were available ..."

She gives a description of the tests that were

undertaken in the above paragraph.

"... the patients had become used to concentrate and rejected cryoprecipitate."

She doesn't say what information was given to the patients to enable them to make an informed decision as between concentrates and cryoprecipitate. And then says:

"I have gone into these cases in some detail to explain that classification of bleeding disorders as 'mild' or 'moderate' in vivo activity is not always straightforward nor is it a reliable indication of patients' clotting Factor VIII. Limiting treatment to, for example, cryoprecipitate is in practice not always its easy as it might seem in theory."

So it would appear that whilst Dr Mayne is saying that her general policy in relation to those who were mildly affected was to treat with cryoprecipitate and not concentrate. There were cases of those who were not severely affected who were treated with factor concentrates.

So that's the position as at June 1983. We then in terms of Haemophilia Centre Directors' meetings move to the meeting on 17 October 1983 which is at PRSE0004440, so the Haemophilia Centre Directors' meeting 7 October 1983. Dr Mayne is listed

as present on the second page of attendees, and if we go to page 10 under the heading "Any Other Business", this is the meeting at which Dr Chisholm raised the question of reversion to cryoprecipitate for home therapy and Professor Bloom is reported as expressing the view that there was no need for patients to stop using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. We've again canvassed in a number of previous hearings the significance or otherwise of the phrase "no proof".

You will recall, sir, that the discussion goes on to talk about ease of access to cryoprecipitate as opposed to difficulty in getting large amounts of commercial concentrates. In relation to the Belfast Centre, it doesn't appear there was any lack of access to commercial concentrates and we've seen them being used in large measure during the early 1980s, but it also doesn't appear that there was any lack of access to cryoprecipitate. You will recall yesterday Dr Mayne saying that there was a sufficient supply of cryoprecipitate from the Regional Transfusion Centre itself in Northern Ireland.

I should then go to the next page, which is an update from Dr Craske, under the heading, "Current

situation regarding AIDS", and that sets out the work he's proposing to do. Then we'll see halfway down the page -- halfway down that paragraph, sorry:

"There was some discussion regarding the two cases of AIDS in haemophiliacs in the [UK] ..."

So that by this time is the Cardiff case and the Bristol case.

"... and Dr Scott gave details about his case."

And that's a reference, we understand, to the Bristol case.

So that's the position as at 17 October 1983. If we go back to Dr Mayne's litigation report at CBLA0000072_024 and we pick it up at page 33 -- sorry, I have already referred to -- that's it, if we go to the top half of the page -- I've already referred to the first sentence which was looking at 1982, and then we can see Dr Mayne referring to the March 1983 paper. That's Dr Craske's paper that we looked at a few minutes ago. You are right, sir, she refers to the seven haemophiliacs there, rather than the figure of ten, and if we look towards the bottom of this paragraph she says:

"The Directors considered it possible that an infectious agent could be present in blood and present, in particular in the Factor concentrates used

to treat haemophilia."

So that's Dr Mayne's articulation of what her understanding was of the views of haemophilia centre -- Reference Centre Directors, which was the small cohort of which she was a number at that time.

SIR BRIAN LANGSTAFF: So what she's describing is that giving people who suffer from haemophilia commercial concentrate was recognised before the end of 1982 as being -- making them an at-risk group, that the risk was one which was recognised by her colleagues as Reference Centre Directors and was known as a realistic possibility in very early 1983.

MS RICHARDS: Yes, precisely. If we pick it up in the next paragraph, we see Dr Mayne saying this:

"Throughout 1983 publications occurred with increasing frequency confirming the presence of some, if not all, the preceding immune abnormalities to be present in homosexuals, in multi-transfused adults, children and in some haemophiliac patients."

Then we see she refers to some publications, so a January 1983 publication by Jones.

Then if we go over the page -- and that's Dr Peter Jones' publication in The Lancet, "Altered immunity in haemophilia". If we go over the page, we see at the top of the page she's referring to the

Desforges article in the New England Journal of Medicine in January 1983. The White article is a 1983 editorial in the Annals of Internal Medicine. I don't have the precise date in 1983 but it sounds like it's early 1983 because she then goes on to say this, after referring to the White Article:

"Such publications, plus the media coverage of the syndrome in the press, on radio and television, caused great anxiety to patients and their haemophilia centre physicians. Therefore, in February 1983 a special meeting of the Reference Centres was convened to plan measures which might be undertaken regarding surveillance of patients and their treatment."

I've already referred to that meeting. She describes it in further detail further down. It may be that she's conflating the February and May 1983 meetings to some extent in her narrative here but she then talks, bottom of the page, about the recommendation sent to centre directors in June 1983.

If we go to the top of the next page she refers to a discussion about AIDS at the World Haemophilia Federation Congress in Stockholm and says this:

"There was great awareness of the AIDS problem amongst both the 'users' and the 'treaters' ..."

And she records that:

"Further reports of immunological abnormalities in Haemophilia were presented. Patients attending the meeting expressed worry regarding the possible curtailment of their treatment."

A theme which, sir, you might wish to consider whether it arises from this part of her litigation report appears to be a theme of saying this was or may have been known to patients because of what was being reported in the media and/or through attendance at the World Haemophilia Federation Congress.

There's no narrative in the litigation report of discussions with patients specifically. I'll come on to what Dr Mayne says on that subject in her witness statements in a little while.

Then if we go to the bottom of this page she refers to:

"By September 1983 two haemophiliacs in the [UK] were suspected of contracting AIDS following treatment with commercial concentrates."

She suggests that:

"... Haemophilia Centres were circularised informing them of the batch numbers of the suspected infected Factor VIII concentrates."

It's not currently clear to me what that's

a reference to at that point in time. But we do know that investigative work was being undertaken by Dr Craske looking at batches, so it may be that's what she's referring to.

"Surveillance and collation of data was undertaken by the Hepatitis Working Party."

Then she refers to the report by Dr Daly and Dr Scott which was in The Lancet in late 1983, November 1983, the first death of a UK haemophiliac from PCP, and she records that:

"At that time the world statistics indicated that some 26 Haemophilia A patients and two Haemophilia B patients had been reported to CDC as having AIDS."

She then goes on over the page -- I'm not going to go through this part in detail -- to talk about the identification of HTLV-III and various publications in that regard in the course of 1984.

At the bottom of the page she reports -- she refers to an article about patients having antibodies to HTLV-III and then says:

"During the same month" -- I need to check which month that is, sir, because I don't think --

SIR BRIAN LANGSTAFF: Well, that's the article in I think September in The Lancet, isn't it, Popovic et al,

which talks -- it's Cheingsong-Popov, I think it is.

MS RICHARDS: The Popovic article that she refers to is a publication in Science in 1984 and without checking I can't recall, I'm afraid, the month, and then the editorial in the BMJ that she says accepted that AIDS was transmitted by blood products is an editorial entitled, "Infection, immunity and blood transfusion", the author being given as Bruce-Chwatt, which again I will need to check the month.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: And then reference to the Danish study that was in The Lancet. Again, without checking I can't recall off the top of my head which month it was.

Well, in fact, so that I needn't go back to it if we go to the next page and look at the bottom half of the page she says this -- this is obviously looking generally in the United Kingdom and not specifically at Belfast because this was a report for the HIV litigation to the Department of Health, but she says this:

"The results of antibody testing of the UK haemophiliacs accumulated during 1985, it was found that 44 per cent were positive. 1983 was found to be the major year of infection, established from the availability of retrospective testing for some but not

all patients."

And then she says this:

"Thus, the recommendations to revert to cryoprecipitate unfortunately would have been too late to prevent infection."

Given that those recommendations appeared in amongst other things the New England Journal of Medicine in January of 1983, how logically it could be said that that recommendation would have been too late to prevent infection if 1983 is the major year of infection, well it simply doesn't follow chronologically.

Then it's perhaps worth reading Dr Mayne's observations in the following paragraph. She says this:

"The foregoing paragraphs indicate that the growing awareness of the grave threat of infection to haemophiliac patients through AIDS."

I think there must be a verb missing there. She refers to:

"... during these years 1982-85 dramatic developments in medicine received worldwide publicity. Medicine is both a science and an art. Scientific research forms the basis for advances in treatment. The art is the appropriate application of the science.

Members of the medical profession and laymen are entitled to express public opinions regarding the state of the art at any time. Media reporters are particularly adept in this respect. However, in the light of subsequent scientific knowledge the expressed opinions may require revision."

Then she says:

"Such opinions are documented in paragraph 63."

To understand that we need to look at which version of HIV litigation Statement of Claim she's referring to. But she says this:

"Their expression was based on the then available evidence and reflected the element of doubt which existed regarding the magnitude of the AIDS problem in haemophilia and its causation. They did not unduly underestimate or understate the position during the year 1983, a feeling which now might be construed by the aid of the retrospectoscope."

So it's not entirely clear what is being said in that. It appears to be suggesting that there should be the avoidance of retrospective reflection or any application of hindsight possibly.

SIR BRIAN LANGSTAFF: At the moment what I'm inclined to do, but obviously it's subject to any submissions I may later receive at the end of the Inquiry, that

what she appears to be saying is that the position during the year 1983 was indeed understated and underestimated. However, that is what appears now looking back. At the time, the science had not advanced sufficiently to allow for those conclusions properly to be drawn.

MS RICHARDS: That may be what she is saying and, of course, you have the benefit of being able to look yourself at the contemporaneous materials from 1982 and 1983 to assess that claim.

SIR BRIAN LANGSTAFF: It's not a question of what was the cause, what was the problem, was it understated. It's a question of whether it should have been stated in a different way is the question I think she's addressing.

MS RICHARDS: Yes, what was understood as a risk, what action could and should have been taken, what information could and should have been provided to patients to enable informed judgments to be made by those whose health and lives were potentially being placed at risk.

Going to then, just in terms of UKHCDO meetings, refer to one further meeting on this topic. It's the December 1984 meeting at Elstree, at HCDO0000394_117.

Again, we've looked at this on a number of occasions but not for the purpose of highlighting Dr Mayne's attendance. So it was the haemophilia Reference Centre Directors' meeting held at BPL 10 December 1984 to discuss what should by now be done, and we can see from the list of attendees Dr Mayne there along with a range of other representatives.

I'm not going to go through the detail of the meeting. There is no particular contribution to the meeting from Dr Mayne that's identified in the minutes. You will recall, sir, it records the Reference Centre Directors' discussion about what should now be done both in terms of testing patients and in terms of ceasing to use commercial concentrates.

We can see Dr Mayne writing about the meeting in brief terms at BPLL0010480. She writes to Dr Lane at BPL on 12 December 1984 thanking him and his staff for the hospitality at the meeting and says this:

"The meeting was certainly beneficial if indeed somewhat depressing."

Just perhaps picking up on the issue of reflection as set out at the end of that section of Dr Mayne's litigation report, if we go to

LOTH0000080_007. This is a rather later letter. It's August 1993, so it's three years on from the production of the litigation report and obviously a decade on from the key events in 1983 but it's a letter Dr Mayne wrote to the editor of The Lancet about what had happened in relation to Professor Allain in France, and she says this in the -- picking it up in the second sentence:

"This action [that's the imprisonment of Professor Allain] instilled a feeling of dismay and grave concern over the fate of such a respected colleague; one who I know personally and for whom I have the highest regard for his scientific contributions to the field of Haemophilia and for his humanitarian attitude to the entire problem of HIV infection contracted by Haemophiliac patients through the receipt of blood products."

Then she says this:

"The evolvement of the HIV problem within the haemophilia population has caused immeasurable distress to patients and to all physicians treating them. The doctors concerned were guilty of one fault, namely that of ignorance. The imposition of a prison sentence in these circumstances seems illogical."

Now I draw attention to that not particularly

because of Dr Mayne's views in relation to the fate of Professor Allain but because of what she suggests as a more general point, "the doctors concerned", which would encompass presumably not only those in the position of Professor Allain but all those involved with treating haemophiliac patients with blood products, so all Haemophilia Centre Directors, including herself, guilty only of ignorance she says. No doubt for you to decide whether that is an accurate characterisation of the position.

If we turn next, on the issue of the extent of HIV infection in the Northern Ireland haemophilia community, to one of Dr Mayne's witness statements. It's at WITN0736006, so it's one of her statements from last year. If we pick it up at the bottom of the page, "Statistics", she says this:

"... it is not difficult to recall the data for the overall UK percentage of treated Haemophilia patients who became infected with HIV. I believe it to be 44.5 per cent. Some regions in England and Wales attained figures greater than 70 per cent. The comparable figure for Northern Ireland (NI) was 14.5 per cent, clearly anomalous. I well recall presenting the [Northern Ireland] data to a meeting of the [UK] Haemophilia Directors Organisation (UKHCDO)

in Autumn 1985. Some colleagues, not unsurprisingly, were politely sceptical about the veracity of the results. Further testing was carried out by all centres. In [Northern Ireland] I organised for all samples to be tested in duplicate and simultaneously in the Belfast Virology Laboratory and in the Middlesex Hospital (London). The [Northern Ireland] results were unchanged."

If we go to, I think it's the next page -- yes, if we pick it up in paragraphs 8 and 9, this is where she derives her figures from:

"Of the 110 annually treated patients, 43 were on Home Treatment. Of this group 15 became HIV positive. The patients had received comparable amounts of Factor Concentrate to those in the rest of the UK. The 16th positive HIV patient was a spouse within the [home treatment] group. There were no positive patients in the [non-home treatment] group and no children seroconverted. The number 16 is accurate however, the final number included in the [home treatment] group may be 43 or 47, my memory eludes me."

SIR BRIAN LANGSTAFF: Just pausing there, of those who were on home treatment, which one -- would tend to be, one would expect, serious, severe haemophilia A

patients, largely, it's just over a third.

MS RICHARDS: Yes, it is. So, as always with statistics, it depends what you are presenting and what you are looking as your overall group. But that's absolutely right, sir. A third of those on home treatment became HIV positive with one infection from a spouse or partner as well.

There is then what Dr Mayne in fairness characterises as conjecture in the following paragraph. She says:

"A conjectural conclusion may be appropriate; I speculate that repeated injections of treatment regardless of plasma source may induce a degree of immune tolerance, perhaps mediated through alteration within the Complement system? It does not seem to matter whether the treatment is Cryoprecipitate, or Concentrate sourced in Scotland, Europe or the USA."

Not entirely clear what is meant by that.

"Figures from Scotland and NI would indicate the Cryoprecipitate may well have been the safest product available at that time. However, it was cumbersome to use, accurate dosage was impossible ..."

Whether that puts it too high, given what else we've seen about cryoprecipitate usage, is a matter for your judgment, sir.

"... and home treatment impracticable."

Again, whether it's correct to characterise it as "impracticable" as opposed to "less practicable" is a matter for you.

"The advent of Factor VIII Concentrate in small vials and with accurate dosage revolutionised life for the Haemophilic patient.

"Furthermore, an alternative explanation might have a straightforward numerical basis. Each company utilised approximately 25,000 donors. If, due to large patients numbers, financial constraints or problems relating to product availability any one patient could be treated with 2, 4 or even up to 6 different products, thus their exposure could be increased even to 125,000 donors, leading to the possibility of increased viral conversion.

"Regardless of underlying reason, there seems to be a definite pointer to the fact that patients do better on one product."

Just picking it up over the page, she refers to, paragraph 10:

"... one severely affected patient was treated with a batch of a new concentrate which was contaminated by HIV. ... Armour ... informed me after it had been used. The patient was in the [home

treatment] group and thankfully did not seroconvert."

So we don't, I'm afraid, sir, I think have sufficient data in relation to every year throughout the first part of the 1980s to look at the individuals who were infected with HIV and to trace whether they were treated with more than one product, and if so which products, and that's because we don't have the returns data for some of the key years. So in relation to the -- we've got the Bull returns for example for 1983 but not the detailed breakdown of individual patients that we have, for example, for 1984.

So I'm afraid we can't, at least on the information currently available, verify the correctness or otherwise or the plausibility or otherwise of Dr Mayne's conjecture.

That's what she says in her statement in relation to rates of infection. Sir, perhaps given the time -- I'll just show you one more document which just picks up on her last point about the communication she received about an HTLV-III contaminated batch. That's at ARMO0000382, so it's a letter 10 May 1985 from Armour to Dr Mayne. She refers to -- sorry, the letter refers to:

"... one donor, whose plasma was incorporated

into pools from which our [Factor VIII] was produced, has developed [AIDS]."

And then in the third paragraph:

"Only one batch in the [UK] is implicated. Fortunately this is a heat-treated batch ..."

And he gives the batch number.

"This small heat-treated batch was distributed in December 1984 in January 1985 to a few centres only, of which yours is one, and we anticipate the product has already been used."

And then a suggestion that if it hasn't been, it should be returned and there will be reimbursement or replacement. So that's, I think, the communication to which Dr Mayne was referring in her statement.

Sir, there's some more to say in relation to HIV and AIDS, so perhaps we could pick that up after the break.

SIR BRIAN LANGSTAFF: Yes. Let's take a break now until 11.45.

MS RICHARDS: Thank you.

(11.15 am)

(A short break)

(11.45 am)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Sir, I'm going to refer now to various parts

treatment available to the physicians in charge of the patient: the personal in possession of all the information regarding the patient's needs."

Now, I emphasise those sentences because they may be relevant to any assessment you make, sir, about Dr Mayne's views as to the patient-physician relationship.

SIR BRIAN LANGSTAFF: It is not, as I read it, consistent with the view which was clearly expressed to us by the expert ethicists who emphasised, I think, the person in possession of all the information regarding the patient's needs, in the broad sense, is usually the patient.

MS RICHARDS: Precisely.

SIR BRIAN LANGSTAFF: Although how best medically to resolve the needs is a matter upon which the doctor has very valuable information to give in the light of what he understands the individual patient's needs to be.

MS RICHARDS: Precisely.

SIR BRIAN LANGSTAFF: Have I summarised their view properly?

MS RICHARDS: Absolutely, and this appears to show a different concept of characterisation of the patient-physician relationship, with the physician

in documents authored by Dr Mayne relevant to issues relating to what action was or was not taken in response to the risk of AIDS reflection or absence of reflection and what information was or wasn't provided to patients.

If we can start with the litigation report at CBLA0000072_024 and if we go to page 40, this is the last substantive page of the report. What follows is simply the footnoted or end note references. This is under a heading "The duties of care and breaches of the duties of care", and then there are some observations from Dr Mayne in relation to hepatitis risk and then AIDS risk and she says this:

"The earlier sections of the report affirm that haemophiliacs were at risk from hepatitis through the medium of their treatment ..."

She then refers again to what must be matters set out in one of the versions of the HIV litigation Statement of Claim about alternative measures and she says:

"In general, they are impractical but in particular [she refers to one of them] denies the goal of haemophilia treatment, namely to minimise pain and disability and to prolong life. Its conjectural implementation would have restricted the choice of

essentially being the person in charge.

SIR BRIAN LANGSTAFF: This is a justification of paternalism I think.

MS RICHARDS: Yes. Then she continues:

"The alternative treatments; cryoprecipitate, Desmopressin and animal concentrates have already been discussed and found wanting for the universal treatment of severe haemophilia."

Again pausing there, it may be that those are treatments that would not suffice for universal treatment. It doesn't necessarily follow they couldn't be used for treatment for some at least severe haemophiliacs. Then she says this:

"The risk/benefit ratio of non-treatment versus treatment could not be upheld" -- and I guess that begs the question of by whom -- "in the light of the plight of haemophiliacs in the era before infusion treatment became available. A return to bed rest, immobilisation and analgesia for joint bleeds would have been untenable."

So strong terms there used by Dr Mayne to characterise what she says was the option, treatment versus non-treatment, and her identification and characterisation of the risk benefit ratio predicated, it would seem, upon at least on one reading of this

document an assumption that that's ultimately a balancing exercise for the physician rather than the patient.

In relation to AIDS she then deals with it shortly by saying:

"Comments of a similar nature apply to the paragraphs ... relating to AIDS."

So that's the HIV report.

If we then go to Dr Mayne's main witness statement, at WITN0736009, and if we turn, please, to page 30, we look at the question at the bottom of the page, and it's a question that the Inquiry has posed to most of the clinicians from whom it's requested statements, who were haemophilia clinicians practising at the relevant time:

"Do you consider that your decisions and actions, and those of the Centre in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently."

Then Dr Mayne's response at the top of the page:

"The two words 'could' and 'should' often suggest that today, with the benefit of hindsight, it

may cause alteration of decisions or changed actions. Like everyone else, I wish that none of my patients had been infected as a result of blood products. However, after careful appraisal I remain convinced that the course of action pursued by both myself and my colleagues was measured and appropriate for that time in light of the information and the state of knowledge at the time."

So that is Dr Mayne's response. Then in answer to the next question, "What decisions or actions by you and/or by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?", she refers to that answer.

In terms of the question of whether it patients were warned or provided with information or advice about the risks of HIV so that the patients could make an informed decision, that's obviously a matter for you to determine. You will recall the evidence that the Inquiry has already received and heard from patients themselves or from their relatives, which is, I think I'm right in saying, universally to the effect that they were not provided with specific advice, warnings or information about risks of AIDS from factor concentrates prior to the group meetings that took place probably in January 1985 and which I'll

come on to.

So that's the evidence for you to assess from patients -- from people who were infected or from their family members.

In terms of Dr Mayne's witness statement, if we stick with the document on screen but go first of all, please, to page 28, bottom of the page is the question:

"Did you take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

"[Answer] I do not think I can expand usefully to answer this question other than as already answered previously."

In terms of what is previously set out it's not clear what Dr Mayne is there referring to in the statement. There's little that I can see which talks about the provision of information to patients in the earlier part of her statement. There is a discussion which I'm going to come on to about what was done in response to the risk of AIDS, but that all appears to be at a later stage but be that as it may that's Dr Mayne's answer to that question?

SIR BRIAN LANGSTAFF: Is she possible referring to other witness statements which she gave earlier?

MS RICHARDS: It is possible and I'm going to go through where I can find reference in her statements to this issue. I can't guarantee that I necessarily refer to every single statement that she refers to it and no doubt you will be reading them all again in due course, sir. But it is absolutely possible that she may be referring to earlier statements.

In relation to this statement, if we go to paragraph 43.1, I'm looking here for passages which deal with information provided to or discussions held with patients, so it's page 31. She was asked about reversion to treatment with cryoprecipitate and her answer is this:

"Theoretically a return to using cryoprecipitate would have been appropriate for some patients. However, it was neither a practical nor realistic option. Following lengthy explanatory discussions, during which the possibility of reverting to cryo was raised, I was greeted by an emphatic refusal from the patients concerned. Patients had become used to carrying their concentrate/pack with them to school, to college or their workplace. The presence of that pack had become life changing. A return to being dependent on the availability of a fridge freezer and to the lengthy process of thawing

and preparing cryoprecipitate was just not acceptable to them."

Unfortunately, what that paragraph doesn't tell us is when it is said such conversations took place or what information was provided about risks to enable a judgment to be made by the patient.

I should say I don't think we've seen anything in individual statements from people who were infected or their relatives which reports any such conversations but assuming for the purposes of debate in Dr Mayne's favour she had them, it doesn't tell us when she had them and whether it was at any stage prior to the group meetings in January 1985.

If we then turn over the page and go to the bottom half of the page, so this is under a series of questions relating to the provision of information to patients, she's asked the general question:

"What information did you provide or cause to be provided to patients with a bleeding disorder ... about the risks of infection in consequence of treatment with blood products ... prior to such treatment commencing?"

The answer is:

"No local leaflets/printouts were available. Discussions with patients were held if and when

possible. Each patient was provided with information provided by the national Haemophilic Society. There were few occasions when concentrate was given to patients other than those with haemophilia or allied disorders. I recall rare incidents when concentrates were given to counteract the excessive effects of Warfarin anti-coagulation. It was also used for patients with advanced liver disease."

She refers, top of the next page, to instances where concentrates were used erroneously on an emergency basis within the ICU.

So, again, that doesn't actually tell us what information was provided. It merely says leaflets or information from The Haemophilia Society was provided and discussions were held with patients, but the content of that information remains unclear.

If we go to the next page -- sorry, stick where we are, Soumik. Paragraph 47.1, you'll see the question that's been posed of her, and by reference to the HIV litigation expert report, was picking up on her assertion that patients became aware of the risks of hepatitis during the mid-1970s.

She's asked what the factual basis for that is and what discussions she had with patients in the mid-'70s.

What she says by way of response is:

"An annual meeting for patients, relatives and members of staff was held as part and parcel of the activities of the Northern Ireland Group of the National Haemophilia Society. Over time, a multiplicity of experts was invited to be speakers. Each gave an opening talk on aspects of haemophilia and then the afternoon was open to patients and their relatives to ask questions of the experts - questions about treatments, about the risks, about advances in therapy, changes in scientific research etc."

And then she gives a list of some of those who spoke over the years.

So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than the fact of them.

If we go to the next paragraph, Dr Mayne says:

"Patients also had their own magazine/journal originally started by me but then passed on to the patients. ... entitled 'CLOTT'."

Again, it doesn't provide us with any

information -- I don't say this in pejorative terms, just as a matter of fact -- it doesn't provide us with information about what the content of any such articles might be.

If we go over the page we then see the assertion at 47.4:

"Therefore, the patients in the 1970s onwards would have been aware of all aspects of haemophilia treatment and research, if they attended their local society and read its magazine."

That's, well, sir, a matter for you as to whether that's an adequate substitute for information being provided directly to patients by their physician.

If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy.

In terms of risks of infection, what we see is at the bottom of the page, it's just said in last sentence on the page:

"At all times patients were advised regarding the risks of disease, any then-known risk of using concentrate and were encouraged to have discussions

any time they had a problem."

Again, there's a sharp contrast between what Dr Mayne says and what those who have provided statements to the Inquiry say in relation to being warned of risks.

Then we have the question at 50.1:

"When did you first discuss AIDS or HIV ... with any of your patients?

"50.1 At this distance in time, I cannot recall the details but I have no doubt I had informal discussions with the patients at clinical appointments. The minutes of the UKHCDO meeting in December 1984 have been brought to my attention. I note that I attended; however, I cannot recall attending or the meeting itself. I assume that the decision to hold the 1985 meetings ..."

So those are the group meetings held for patients in January or thereabouts.

"... was influenced by this meeting. It was then decided to have formal meetings. I arranged for three meetings to take place in early 1985."

And she refers to those being described in her earlier witness statement.

So in terms of any dates, we have the January 1985 meetings, which obviously is too late in

terms of providing information in advance of treatment or in the course of treatment programmes, and then we have the general statement that she has no doubt she had informal discussions with patients at clinical appointments but we're not told what the content of those discussions were. And, again, the evidence from individual patients or their family members is to the effect that information about the risks was not communicated to them.

So that's what she says in her statement about information provided to -- in that statement about information provided to patients.

If we go back in this statement then to page 28, she's asked the question, so this is now "What actions did you take in response to the risk of AIDS", she's asked the question in 35:

"What, if any, actions did you take to reduce the risk to your patients of being infected with HIV?"

She says:

"[She] followed the recommendations issued by UKHCDO in June 1983 which reflected my existing practice in any event."

We've already explored that. That's the June '83 letter and the UKHCDO recommendations in relation to children, mildly affected patients and

previously untreated patients.

Then she's asked the question:

"Did you continue to use blood products to treat patients, after becoming aware of the possible risks of infected with HIV? Why?"

And she says this:

"Within my response to [question] 33 I have indicated that I continued to use concentrates. Even with the benefit of hindsight, I cannot envisage otherwise. In reality, the choice was stark -- stop treatment with concentrates with all the risks and disruption that would entail for patients or continue with treatment in light of the information then available."

In common with some others who have provided evidence to the Inquiry from a clinical perspective or from some of the material we've seen in contemporaneous documentation, the choice is posed as this stark choice between essentially no treatment or continuation of treatment rather than a potential spectrum of choices.

She refers in the next paragraph to the special meeting of Reference Centre Directors, and that's I think an accurate reflection of what -- the outcome of the Reference Centre Directors' meeting in May

of 1983.

I should draw your attention to a previous set of answers on page 26, where Dr Mayne is asked the question:

"What, if any, enquiries and/or investigations did you carry out or cause to be carried out in respect of the risks of transmission of HIV or AIDS? What information was obtained as a result?"

The way in which Dr Mayne has answered that is to look at the process of testing patients for HTLV-III and what happened thereafter, so there's not a suggestion in her answer of enquiries or investigations prior to the actual point of testing which seems to have commenced at the beginning of 1985. We can see that because she -- that talks in paragraph 33.3 about what her expectation was as to how many patients would be HTLV-III positive. She poses a rhetorical question about immunity in paragraph 33.4.

If we go down the page, she says that -- this may be in relation to an earlier period in fairness -- she says:

"The treatment policy was kept under review. Discussions and many conversations took place with the patients."

Again, that doesn't reflect the evidence that individuals who were infected or their family members has provided to the Inquiry so those are factual issues that will be for you, sir, to consider.

She says a return to cryoprecipitate was offered and was turned down. Again, there's no information as to when she says that offer was made or to whom and she says patients were asked to reduce their usage if possible.

There's certainly a later letter, from the late 1980s when there's a request for reasons of financial constraint, for patients to reduce their usage. There's no documentary evidence of patients being asked to reduce usage that the Inquiry has found in the first half of the 1980s; so relevant to the risk of AIDS.

She then refers to offering testing to staff. That again puts this into the either very end of 1984 or 1985 period. She refers then in the next paragraph to regular patient testing continuing and where appropriate testing of partners being carried out. Again, that puts what she's talking about squarely into 1985 or thereafter.

If we go to the next page, the measures she then sets out I think on a fair reading of the

statement all relate to the period from 1985 onwards, at least that seems the likeliest reading. So she talks out paragraph 33.8 about needing to disseminate information because of misconceptions relating to stigma. She talks in paragraph 33.9 about speaking on the radio/TV, attending a range of meetings to offset and counteract incorrect rumours regarding infection with HIV.

She then talks about increasing staffing levels in 33.10, and in 33.11 liaising with colleagues from other disciplines. So that's looking I think then at how to treat and care for those infected with HTLV-III HIV rather than the prior question of what steps were taken to consider and the best response to the risks in advance of those risks actually being fulfilled.

Sir, that's I think the most relevant part of Dr Mayne's main witness statement. If we then look again at information about the circumstances of infection and dates of seroconversion, we pick it up at BHCT0000484. This is a letter dated 15 October 1985. It's from the Regional Virus Laboratory at the Royal Victoria Hospital to Dr Mayne and it says:

"We have completed the retrospective study on our stored sera from your patients. The results of

the anti-HTLV-III seroconversions from negative to positive are as follows."

Sir, I should say what flows from this and is acknowledged by Dr Mayne in her statements is that, in common with some other haemophilia centres, samples of sera were stored I think in the Regional Virus Laboratory primarily, possibly exclusively. To what extent that was with the knowledge or informed consent of patients I think is probably unclear on the state of the evidence but, as a matter of fact, there were stored sera samples and that enabled this exercise to be undertaken for a number of those who had been found to be positive for HIV and the dates are significant.

First one, last negative result January '84, first positive result July '84, so seroconversion within the first half of 1984. Second one is last negative result October '84, first positive result April '85, so seroconversion in the last months of '84 or the first months of 1985. The third suggests seroconversion in the period between February and October of 1983; the next August 1983 and January 1984; then January '83 and January '84; then November '83 and June '84; September '83 and February '84; February '83 and November '83; September '83 and March '84; September '84 and July '85; August '83 and

March 1984.

Then there are four patients listed for whom we have a first positive result, the earliest of those dates being February 1983 and one being February 1984, but no earlier stored serum samples. So what we can see from that list is no apparent seroconversions prior to 1983. The earliest date of a last negative result is January 1983 and the majority of the last negative results are later than that. That obviously raises the question of whether, given what was known in late 1982 and by the beginning of 1983, these were avoidable seroconversions.

So that's information about the patients who were found to be HIV positive. As Dr Mayne's statement says there is also one spouse or partner who was infected with HTLV-III.

You will recall Dr Mayne's statement saying that there were no children who seroconverted. However, that might depend upon one's definition of a child. If we go to BHCT0000846_004, if we go to the next page, so this is a letter from Dr Mayne to Dr Machin in the Haematology Department of the Middlesex Hospital, 18 October 1985. Obviously, the patient details are redacted but you can see -- sorry, if we go up the page -- the date of birth is 1971.

This is a letter written in 1985 so it refers to a 14-year old. For the avoidance of doubt I confirm it does refer to one of the patients listed in that letter we looked at a few moments ago.

We can see from this it refers to a "moderately severe haemophiliac", so not severe, moderate severity, and if we go to the bottom of the page we can see this paragraph:

"The most significant problem with [him] is the fact that the human material given in January [so it would seem that's January 1985, given what's set out in the rest of the letter] produced seroconversion on 10 July 1985 with a positive HTLV-III result confirmed. I have not told the patient this result, nor his family, at the present time ..."

Again, the letter is October 1985, so three months further on:

"... the reasons are due to the precarious family base of the patient."

The letter continues over the page but there's nothing material for present purposes in that letter.

So that would suggest that a 14-year old was infected, and infected at a late stage, and the fact of his infection with withheld from him and his family for a period of time.

If we go to BHCT0000860 and go to the next page. Again, this is picking up upon the suggestion in Dr Mayne's statement that no child was infected. This says "Surveillance of paediatric HIV infection and AIDS follow-up", and if we look further down the page we can see:

"Has the child received treatment for HIV?

"Yes", and we can see that the child has received AZT. If we go over the page -- sorry, we're back to the first page, I should say. We see there reference to this patient having HIV-related symptoms and details are there given.

Sir, again, obviously patient identifying details are redacted by the Inquiry but it appears from the information we have that relates to the same person, that same patient as we looked at in relation to the previous letter.

If we then go to one of the other documents authored by Dr Mayne, again looking at seroconversion rates, it's RHSC0000067_002. We've looked at this previously. It's Dr Mayne's March 1988 report. If we just pick up on something she says on page 4, under the heading "HIV Positivity", at the bottom of the page, she says:

"The HIV antibody positive rate for severely

affected patients in the UK is 54 per cent, with some centres having ratings of 75 to 80 per cent."

I think we have seen 44 per cent cited elsewhere, but in any event.

"In Northern Ireland only 16 patients have been shown to be antibody positive. This is equivalent to 25 per cent of the most severely affected patients and 16.5 per cent of all treated patients in the Province."

Then she goes on, and we looked at this yesterday, to suggest that that may be explicable upon the basis of the policy of using a single concentrate and I've explored the extent to which that was in fact adhered to in practical terms yesterday.

If we go to HCDO0000 --

SIR BRIAN LANGSTAFF: Just before you leave this, if we can just go back to page 1. It is a completely different point. No, sorry, forget that.

Forget that.

MS RICHARDS: If we go to HCDO0000524, these are the minutes of a meeting of the AIDS Group of Haemophilia Centre Directors. That was a group established I think at the beginning of 1985. This is the sixth meeting, October 1985, and Dr Mayne was a member of that group.

If we just go to page 4, we can see at the bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her patients was low probably because all her home therapy patients were kept on one product and, as I say, that doesn't appear to be correct, although the individual patient data we have doesn't clearly distinguish home therapy and hospital therapy. Some had only received one product for ten years and then there's a discussion amongst directors of the variable incidence of positivity between centres.

It's not, I think, clear that it's accurate to say that the patients -- if this is what Dr Mayne was saying, that the patients who seroconverted were all severely affected patients. We've looked at one example already of someone who was described as moderately severe.

If we then go to BHCT0000612, this is a letter from Dr Mayne dated 23 August 1994 to Ms Spooner in Oxford and she says this:

"Further to your query regarding [patient] there has been no documentation of his receiving treatment since 1974 because that is the state of his hospital records both here and in a peripheral hospital. Agatha Christie or otherwise known as

Dr Elizabeth Mayne found out that he had been given two bottles of Edinburgh Factor IX on the day his niece was born. It was never written down by the kind Doctor who administered the dose and it led to much consternation for the patient, his family and myself. The sad and ironic aspect of the whole performance was that the patient did not need the Factor IX. He has mild Christmas Disease and does not suffer from Haemarthrosis. The Doctor who saw him either forgot or did not realise these facts and [he] now sadly has full-blown AIDS."

Again, the patient cross-referencing between the documents available to the Inquiry identified there is, it would appear, one of the patients listed in that letter, that list of seroconversions. So there we have an account of a patient with mild haemophilia B, even on Dr Mayne's account, having been given Factor IX, not I should say according to this letter by Dr Mayne but elsewhere, completely unnecessarily. It's not clear from this or from the other material the Inquiry has I think which hospital that treatment was administered at.

That obviously raises an issue that we've seen explored elsewhere in relation to other centres within the United Kingdom of systemic problems with hospitals

which were not full haemophilia centres or doctors who were not knowledgeable about risks providing treatment where it wasn't required.

If we then look at the question of the meetings that were held in January 1985 and -- we can take that down, Soumik -- I'm sure you will recall, sir, from the Belfast hearings some very vivid testimony about those meetings at the hospital. I'll have to dart between different statements I think in order to see what's said about those meetings by Dr Mayne.

So if we start with WITN0736001 and we go to page 7, so this is Dr Mayne's statement in response to a number of individual statements from people who were infected, a number of whom were giving evidence at the oral hearings in Belfast, and in paragraph 2.6 she says:

"... categorically, there was no HIV testing carried out before the meetings that were convened in January to March 1985 at the Royal Victoria Hospital."

So that assists, if that's correct, in telling us that there was no HIV testing in the course of 1984. We know of course that there were HIV tests or HTLV-III tests carried out in relation to samples from 1983 and 1984 and possibly earlier, but she says there was no HIV testing and she gives that window of

January to March 1984 as the dates --

SIR BRIAN LANGSTAFF: 1985.

MS RICHARDS: 1985, sorry -- when these meetings occurred.

If we then go to WITN2658002, go to the second page, we see that this is the report entitled "A synopsis of haemophilia re Mr Malachy Devlin", and we explored the evidence relating to Mr Devlin in the oral hearings in Belfast.

If we go to page 12 and we pick it up at the bottom of the page, bottom half, we can see Dr Mayne saying this under the heading "December 1984":

"During December 1984 plans were laid to interview all of the patients attending the Northern Ireland Haemophilia Centre. It was felt that the opportunity should be afforded to all to have frank discussions regarding the possibilities of becoming infected or already being infected by the AIDS virus."

There's no reference to any earlier meetings in this document as I recall.

"At that time a test was available to measure antibody to the HIV virus. There was no test available to test for the presence of the actual virus i.e. there was no antigen test available. Therefore, it was not possible to predict the consequences of finding a positive result. The arrangements took

several months to complete, as patients were requested to come to the Centre in small groups to allow sufficient time for discussion and debate. Actual testing of samples commenced on 2 January 1985. Each sample was coded. The prefix was BV (Belfast virus) and each patient's sample was allocated a sequential number commencing at BV1 up to and including BV396. When the results were available, they were entered into a confidential notebook retained by Dr Mayne and kept in a locked filing cabinet drawer in her office. Access was permitted only to two other people, the Chief MLSO in the Haemophilia Laboratory and Dr Mayne's personal and confidential secretary."

Then although --

SIR BRIAN LANGSTAFF: Just pausing there, this is not consistent with what you've just referred me to at page 7 of WITN0736001 where she said no testing was carried out before the meetings in January to March of '85. Here it's saying testing did begin, isn't it, upon the previous page?

MS RICHARDS: She's saying the actual testing began on 2 January.

SIR BRIAN LANGSTAFF: Yes. How does that fit with what she said at page 7?

MS RICHARDS: So that's WITN0736001.

SIR BRIAN LANGSTAFF: Page 7.
MS RICHARDS: Sir, unless there was a meeting --
SIR BRIAN LANGSTAFF: It may just be relating to Mr Kilpatrick, but it seemed to be more generally expressed --
MS RICHARDS: Yes.
SIR BRIAN LANGSTAFF: -- because it's talking about meetings, so it looks as though it's wider: no HIV testing carried out before the meetings in January to March '85, i.e. none before March 1985 meeting.
MS RICHARDS: Yes. Well, that's obviously not consistent with saying that the actual testing commenced on 2 January 1985.
SIR BRIAN LANGSTAFF: I just wanted to confirm that was so.
MS RICHARDS: Yes.
SIR BRIAN LANGSTAFF: Thank you.
MS RICHARDS: Then in terms of the meetings themselves, it seems from trying to piece together the evidence that there were a series possibly of three meetings. You'll recall I'm sure, and I'll just put it up on screen briefly, one of the oral accounts you have heard from an attendee at the meeting WITN1371001. This is from the statement of Louise Marsden. If we go to the fifth page, bottom of the page, the date

that's given for the open meeting is 1983, which appears to be unlikely to be correct but it's the characterisation of the meeting that's of value here. So it refers to the open meeting where Dr Mayne announced everyone would be tested for HIV.

"She gave the Haemophiliacs present the choice of whether they wanted to know the result of their HIV test."

And she says:

"I found that bizarre."

If we look at one of Dr Mayne's responses at WITN0736005, and if we go to -- this is in response to the Marsden statements. If we go to page 10 I think it is, you'll see Dr Mayne giving this description in this statement. She says:

"Three open meetings were held regarding the problems of HIV infections. Two were held within the confines of Ward 37, [Royal Victoria Hospital]. In addition to patients attending the meetings, RVH members of portering, catering and cleaning staff were all invited to attend and express their worries and queries about HIV infection. The staff expressed much gratitude at having all their problems aired and clarified. Unfortunately, the meeting to which the witness and his wife attended had per force, to be

held in an alternative venue. This was because a terrorist episode had necessitated the occupation of all bed space in the hospital.

"The alternative venue was unsuitable for severely affected patients as the seating was not appropriate for patients with severe joint disabilities. Therefore, proceedings were foreshortened and perhaps not as much information as previously was presented. I seem to recall that on this occasion Professor John Bridges, Head of Academic Haematology and Consultant Clinical Haematologist attended as a support for myself as I had been up all the previous night on emergency hospital business. It was neither practical nor possible to carry out long consultations on an individual basis but the situation was addressed as far as possible when the person was having the test carried out."

So that's Dr Mayne's account of the meetings in this statement and obviously raises a question about the appropriateness of having both patients and members of portering, catering and cleaning staff all in attendance together.

If we then go to WITN0736006, this is another of Dr Mayne's witness statements, and if we go to the last page, please, Soumik, Dr Mayne says this:

"Later within the deposition of Louise Marsden she referred to the 1985 HIV meeting as bizarre. She was completely correct in her description. I agree. The explanation is as follows. I had been up all the previous night dealing with the unclottable blood of a patient in the Intensive Care Unit. The hospital was full to capacity. Therefore, the normal venue for the meeting was unavailable. It had been commandeered for emergency bed space. I think the full capacity was related to an increased incidence of influenza and pneumonia."

That's a different reason. It may be nothing turns on it but, in any event, I just observe that.

"However, the only available space for the meeting was the historic Old Surgical Extern Theatre. It was unsuitable in every respect. The space was confined; the seating was unsuitable for disabled patients and the general impression inhibitory. It was not possible to cancel the meeting as transport had been arranged for the disabled patients and others were coming from far afield ..."

And she gives some examples.

"Professor John Bridges attended as support. He was concerned that I might pass out from fatigue. I have not discussed this aspect of the meeting

previously as it seemed irrelevant. However, in view of Louise Marsden's apposite description I thought I should enlarge on the detail to the Inquiry."

Then if we go to WITN0736001, again this is another of Dr Mayne's statements and if we look at page 11, please, bottom half of the page, this is in response to a recollection of the meeting described by Mr Hamilton, and Dr Mayne says this:

"... when the possibilities of viral infection became known, in 1984, towards the end of that year, meetings were planned to meet with all patients who had received treatment. They began in January 1985. Routinely, they were scheduled to take place in Ward 37, block A, [Royal Victoria Hospital]. Initially, Mr Hamilton's description of a hexagonal room caused bewilderment. After two weeks consideration, I remembered that Ward 37 was not available for one of the scheduled meetings due to an influx of emergency admissions the previous evening. The only hospital venue available, therefore, was the Sir Ian Fraser Lecture Theatre which was located off the main hospital corridor. It was a historical venue as it was the old anatomy and surgical theatre for teaching medical students. It was in the form of a rotunda, with a glass ceiling and tiered seats which

were very uncomfortable. It had old fashioned heavy wooden doors which clanged shut when closed. It had been refurbished and was used for weekly physicians meetings and post graduate seminars. Sadly there was no facility for tea and coffee."

I refer to that because this meeting was obviously a very significant event in the memory of a lot of individuals and it seemed important to draw out what information we have from Dr Mayne about it. She then continues:

"I cannot recall how the subsequent blood testing was [arranged]."

So it sounds as though there was testing undertaken on this account immediately following the meeting:

"It may have been necessary for the attendees to walk to a nearby ward. I do not remember. I can certainly remember that the room was not locked. There was absolutely no justification or reason to take such a step."

Then perhaps in contrast to the other accounts she says here:

"As much time and space was given for discussion as was necessary."

That may, of course, be a reference to

individual taking of samples rather than the group meeting; I don't know:

"All samples were tested and labelled anonymously by a code."

And then -- well, I might as well read this so I don't have to come back to it. I'm going to look at the process for giving patients their diagnosis in a moment. She says:

"Patients plus relatives were invited to come back to receive their results. If negative, at first, it was thought a letter might be a good idea but this was rapidly rejected. All but two families returned for results and both received a home visit. The situation was dire and all members of the Centre's staff did the best they possibly could. Only 16 adults tested positive but for each and every one of them it was then a disaster. All patients accepted the invitation to be tested, but some deferred the appointment to a more convenient time."

So that's the further description we have from Dr Mayne of the group meetings and the arrangements for testing. I should say that in the evidence the Inquiry has received from individuals, whilst it's absolutely right that there is evidence of patients being informed of their diagnosis in person, there is

also evidence of patients being informed of their diagnosis, both negative and positive in some cases, by letter. So that again may be an area where there is a factual conflict that you, sir, may wish to consider in due course.

One of the themes that has emerged from the statements of those who were infected or from their family members is as to the adequacy of the information that was provided when patients were told their HIV diagnosis and again you'll recall, sir, it's a theme that the Inquiry has heard both in relation to evidence relating to Belfast and in relation to evidence relating to a number of other centres, criticisms or concerns expressed about the adequacy of the information that was provided. It has been to some extent, perhaps, a fairly typical clinician response to say much was uncertain and the information that was provided was the information that was known at the time.

There is some evidence from individuals suggesting that their impression was that they were given no choice about whether to be tested for HIV, only as to whether they wished to know the results.

If we look at WITN2658009, these are the terms of a letter written to one patient, Mr Devlin, and

again we looked at a lot of the material relating to his tragic case in the oral hearings in Belfast, but this is a letter 25 March 1985. It helps gives some context as well and a chronology to the period of time over which testing was being undertaken. This is late March and Dr Mayne is writing saying:

"... we ... have serum for the antibody to the virus. A positive test does not mean that the person will be developing AIDS but it is important to carry out this test ..."

And she says:

"... I want to know the antibody status of all patients before receiving heat-treated material."

So that would suggest that as at 25 March 1985 patients were still receiving unheated concentrates and the change had not taken place or at least not taken place for all patients. Then it's a "please come for a simple straightforward blood test". So it could I think in fairness to Dr Mayne be said there's no compulsion there, but equally it could be said in fairness to some of the criticisms that have been expressed that there's no statement there that it's a choice for the patient to make.

SIR BRIAN LANGSTAFF: It sounds a bit like rationing the heat-treated material, presumably because of

a shortage, I do not know, but -- yes, as to the question of were people -- did think they were obliged to have a test or not, does she ever deal with the question of why would you give people a choice as to whether they wanted to know the results if they had had a choice as to whether they should be tested in the first place?

MS RICHARDS: I'm going to check that because I'm confident Dr Mayne does deal with it somewhere.

This might be one of the places, WITN0736005. If we go to page 5 and we look at the bottom of the page, you'll see this is in response to an individual witness statement, and reference is made to the witness W1371's statement describing the meeting and the witness saying that Dr Mayne said all haemophiliacs in the room would be tested for HIV because she was erring on the side of caution, and so Dr Mayne is invited to comment on the patients only being given the option to choose whether or not they wanted to know the results of the testing. This is Dr Mayne's response:

"HIV testing was offered to all those who had been in receipt of blood factor concentrates. The witness is correct, because in carrying out such a widespread testing it probably was 'erring on the

side of caution'. However at the time of actually testing, the patient was invited to give consent and if they had any difficulty in doing it the test was easily postponed until a future date or not carried out at all in accordance with the patient's wishes. Several patients postponed testing but none refused. It seemed only right and proper that they should be given the opportunity to know or not know the results. One of the secretaries took a note of the names of patients who did not wish to know the result."

And then she deals with the individual patients in question, or the individual patient and his spouse in question.

Then I should I think perhaps point out the next answer. This is dealing with the more general question about the suggestion that not sufficient information was provided about HIV at 2.10.1 Dr Mayne's response is:

"... each patient when tested received the maximum amount of knowledge available and was offered appointments at any time to discuss important issues relating to HIV."

So again it doesn't really tell us what information was routinely provided to patients at this point in time. I can check whether any more detail is

given elsewhere but that's Dr Mayne's response in this statement to the question that you raised, sir.

SIR BRIAN LANGSTAFF: Yes, it doesn't really deal with the point at all, which is really a question of argument, I suspect, and it may simply be she was offering people not only a test but if they didn't want to know the result, they didn't want to know the result, but it seems rather curious that you would expect people to go for a test without wanting to know the result one way or the other.

MS RICHARDS: Yes. I can't --

SIR BRIAN LANGSTAFF: It's just an observation and it may simply be misplaced because of the nature of the times and the difficulties that she was facing. But I can be addressed on that in due course if it's regarded as important.

MS RICHARDS: Yes, I should I think probably just refer you to two other passages in Dr Mayne's other statements that deal with this issue. I don't think they cast any further or additional light on the matter but for the sake of completeness if we go to WITN0736001, page 13, top paragraph, and again this is in response to the statement of Mr Simon Hamilton, she says:

"... it was decided that all patients who had

received Factor treatment whether in the form of cryoprecipitate or freeze-dried concentrate should be offered testing for HIV. Patients and their relatives were invited to a succession of meetings to update them on all known risks and information about the virus."

Again, that still doesn't tell us what the information was that was provided.

"The meetings took place between January and March of 1985 at the Royal Victoria Hospital. Patients were invited to be tested; it was a matter of choice whether they wished to do so. No-one was compelled to participate."

Then she says -- I'll just find the reference WITN0736009, page 35, paragraph, 51.1, so bottom half of the page:

"I have set out previously that I arranged a number of special meetings in 1985 with the patients. At that meeting they were invited to be tested. Their express consent was invited for that testing and prior to such testing had no knowledge of whether a patient was infected with HIV. I only became aware after the test results were received."

What's not clear, and we saw the date of the letter inviting Mr Devlin to come and be tested, which

was late March 1985, what's not clear is why it took a period of time for the testing to be undertaken. There may be plenty of explanations as to why but obviously every day, week or month that goes past potentially puts patients or their relatives at risk and so we've seen example in another case of a patient being tested for example in July 1985, so the testing process seems to have taken a period of months. That may simply be a reflection of what the facilities were that were available and the numbers that had to be tested.

It's not clear whether there was any particular sequence chosen in terms of testing first particular cohorts of patients and then testing other cohorts of patients at later stage. We don't know one way or another those kind of details.

SIR BRIAN LANGSTAFF: I thought you made a suggestion a few minutes ago that at at least one of the meetings those who were there understood they were to go down the corridor and have a test, unless they wanted to defer it.

MS RICHARDS: That's certainly what Dr Mayne says about one of the meetings. I don't think we have the same detail about the other two meetings and we know from other references that certainly not all testing was

undertaken then. That may of course be a reflection of not all patients attending the meetings. Again, that remains unclear.

In terms of the process then for telling patients their results, I've indicated that there's some evidence of patients saying in their statements or their relative's statements to the Inquiry that they were told the results by letter. There isn't evidence to suggest that that was a universal practice I should make clear.

If we look at WITN0736005, and we go to page 10, please, if we look at the bottom half of the page, paragraph 3.10.1, now this is in relation to relaying a negative test result:

"There was no intention to" -- so the question is -- the criticism that Dr Mayne is being asked to respond to is the appropriateness of informing a witness of their test result by letter. Dr Mayne's response is:

"There was no intention to relay this information but the secretarial staff had a difficult job to complete and they would have assumed despite the clipboard entry [I think that's a reference to where they've taken information about how people wanted to be told their results, but that may be

wrong] that you would be pleased to know the negativity of the result. It was the policy of the Centre not to send positive information via a letter. Either patients were told when they came to the Department or else I myself visited them to discuss the positive results."

You will recall again we looked at this during the Belfast hearing but I think it's probably worth referring to again in the context of the issues we are currently exploring. It was a letter BHCT0000896. This is October 1985 and I'm sure you will recall this letter, sir, because of the evidence you heard about the relative's concern about the language in which it was expressed. So this is not a communication of the outcome of the first test. It's a communication of the outcome of the investigations into dates of seroconversion:

"You will be glad to know that you became positive some time between February 1983 and October 1983. We have no sample between those two dates but I imagine that you became positive some time during the summer of 1983. Therefore you have more than passed the two-year point."

I should then show you what Dr Mayne said in response, because she accepted that the use of the

word "glad" would seem to be appalling. If we look at WITN0736001 and we go to page 10, paragraph 4.2, this was Dr Mayne's account of telling this particular patient how she communicated the result to him and that she did so in person by visiting his house and then she explains towards the end of the paragraph the context of the letter and what she says the seemingly appalling use of the word "glad", because she says it was in response to him asking if she could find out exactly when he was infected and him saying he would be glad if she could find and let him know.

So that's communication by letter of seroconversion dates. It's obviously not the same as communication by letter of the positive result itself but, as I say, there is some evidence the Inquiry has received which suggests that that was the position.

We've already looked at a letter in relation to one patient, the patient who was 14 or thereabouts, and the fact that that patient and the patient's family had not yet been told the positive HTLV-III result.

If we look at BHCT0000846_003, you'll see this is a letter of 18 October 1985 to a school. Before we look at what's there set out it's a letter of the same date of the letter that was being written to a doctor

in London, so a doctor in London is being told the positive result for a particular patient in October '85 in circumstances where the patient and their family has not been told. What we see here appears to be, or hints at, Dr Mayne wanting to let the school know. That's an inference that you could draw from the letter. It's not clear. She asks for a personal conversation with the person to whom the letter's addressed at the school by telephone in the second letter. So it raises the possibility that others were being told of diagnosis but not the patients themselves or their record. We can take that down.

Again, there are a number of different accounts the Inquiry's received. There are patients who have no recollection. There's a patient who has no recollection of being tested or being told of the test result, which was negative, only discovering being tested on receipt of their medical records. Again, to try and get some understanding of the dates when testing was being undertaken, if we look at WITN2607004, this is a letter 12 February 1985 and it says:

"I'm sure that, by now, you have heard that [X]'s blood sample was positive for the AIDS related virus."

Then it refers in the next paragraph to retrospective samples being sent off and then a suggestion that other family contacts come in to be tested. Now, again, it's unclear I think from the information we have as to whether the communication of that information by letter to family members was done with the patient's consent or not.

Then in terms of just a further example on the issue of communication of test results, go to WITN0265001. This is -- if we go to page 14, I think, and pick it up in paragraph 50, it says this:

"In 1985, prior to telling me that I was HIV positive, Dr Mayne had come to the house when I wasn't there and told my parents that me and my two brothers had HIV. When I went to see her, I told her that I had not wanted my parents to be informed but she said it was better for them to know."

So obviously highly material evidence there in relation to HIV diagnosis.

SIR BRIAN LANGSTAFF: How old was that patient?

MS RICHARDS: They were an adult -- in 1985 would have been in their 20s. I'm afraid I don't know the brothers' ages.

Then if we go to WITN2658008, again, I think we probably looked at this when we heard the testimony

relating to Mr Devlin at the oral hearings in Belfast but, again, it just provides a little further light on the process of telling patients their results. So this is August 1985 to a GP:

"The problem of testing for response to the AIDS virus is well-known throughout the media and my policy has been to ask each patient when they are being tested if each individual wishes to know the result or not. At the meeting, Malachy himself declared that he did not wish to know the result, therefore I have respected his wishes and have not informed him."

But then Dr Mayne says that she's written to the patient's spouse and, of course, that in itself may ultimately give rise to the inference of the patient themselves being infected.

Again, these are bits and pieces of jigsaw information relating to individual patients which may assist you in forming an overall view, sir.

Dr Mayne has responded to that in her statement. I'm sorry, I don't have the reference noted down but I note the time and I can pick that up perhaps at 2 o'clock. There are a handful of further references and documents to look at on this issue but they will take longer than minute or so, so perhaps we

could adjourn for lunch now.

SIR BRIAN LANGSTAFF: Very well. 2 o'clock.

MS RICHARDS: Thank you, sir.

SIR BRIAN LANGSTAFF: 2 o'clock.

(1.01 pm)

(Luncheon Adjournment)

(2.00 pm)

MS RICHARDS: Sir, if I can just go back to the documents we were looking at before lunch, Soumik, WITN2658008, I had been about to say before lunch that there was a response from Dr Mayne to this letter. That's incorrect. What I had in mind was Dr Mayne's explanation within the letter.

She describes her policy about asking patients if they want to know the result, and then a reference to her practice in relation to spouses being tested.

Then she says in the last paragraph:

"I have been trying to keep the panic situation at the minimal level throughout the Province's haemophilic population, hence this practice."

Quite how that's an explanation of the policy or practice is unclear but I just wanted to make clear that's what Dr Mayne says in the letter itself as opposed to any particular statement.

More generally, it is apparent from materials

that the Inquiry has examined that Dr Mayne was alive to the issues relating to confidentiality and stigma, and we can see that, for example, from BHCT0000981.

This is a letter from January 1986 to a GP about an individual infected with HTLV-III, but if we just look at the bottom of the page and what she's written in handwriting at the very bottom:

"Phone call to GP re extreme need [of] confidentiality."

We can see that also in RHSC0000040_050. This is the meeting of something called the HIV Advisory Group of the Eastern Health and Social Services Board. It's their second meeting, in October 1986, and we can see that Dr Mayne is one of the attendees.

If we go to page 3, picking it up in the fourth and fifth paragraphs, we can see the discussion refers to:

"The confidentiality of information on AIDS patients is an important matter ... the media are only entitled to historic information, eg at six-monthly intervals about the number of cases and the number of deaths ..."

And then in the next paragraph Dr Mayne is recorded as:

"... [raising] the possibility of telephonists

being able to listen to conversations and that we should be careful about what we say over the telephone ..."

And a suggestion of staff education also being directed toward telephonists so they are aware of the importance of confidentiality.

More generally in her witness statement, at WITN0736009, at paragraph -- sorry, page 36 she talks at the bottom of the page, last paragraph:

"Lack of knowledge within the general population and the limited experience of many individuals led me to suggest that patients should not publicise their results unnecessarily."

Again, that chimes with some of the oral and written testimony the Inquiry has received. I should also note, if we look at the next page, I omitted to take you earlier to a rather more detailed explanation or account of the January 1985 onwards meetings from Dr Mayne in this statement. So I will, if I may, just invite you to look at the bottom half of this page and then over the page. She says this at paragraph 54.1:

"When the HIV/AIDS tragedy was evolving in the 1980s, to be told of a positive HIV test was in essence a death sentence. There was no treatment. Patients were terrified. Likewise, relatives and

friends were bewildered and frightened. I gave much thought to the planning of how to achieve the essential HIV testing. Finally, I agreed to have group meetings, three in total. All patients who had been treated were invited to attend with the exception of the paediatric patients who were looked after by their haematologist.

"The prime aim of the meetings was to provide information about the global situation, and secondly, to inform patients of the local situation. In particular, the mode of transmission from person to person and its effect on the day-to-day living of those concerned, information about care about was given to friends and relations. It was suggested to be careful as the general public was not well informed about modes of transmission and infectivity."

So, again, that's the suggestion of keeping these matters confidential. And then she says in terms:

"Finally, there was a need to address confidentiality, lack of which gave great concern to patients.

"The format of the meetings was that I gave an introduction. Thereafter, there was time for an informal chat over a cup of tea ..."

Again, that's not consistent, I think, with some of the accounts we have of at least -- including Dr Mayne's own account, of at least one of the meetings.

SIR BRIAN LANGSTAFF: That was the third meeting in the old lecture theatre.

MS RICHARDS: Precisely:

"... and finally the testing would take place."

So that again suggests that the expectation was that those who were present at the meeting would immediately be tested:

"My sources of information regarding HIV infection were multiple; the UKHCDO AIDS working party, chaired by Dr Rizza, provided copies of all publications as and when they appeared. This information was invaluable."

Now, I will need to double-check, sir, but my recollection is that the UKHCDO's AIDS group was set up for the first time or met for the first time in January 1985, so it's unlikely that there had been much produced by that stage. Of course, as the months went on, the AIDS group did meet on several occasions during 1985 so more might have been produced. She says:

"This information was invaluable. Secondly,

information gained through combined monthly meetings with colleagues in Scotland and, thirdly, in an informal manner through conversations with my colleagues with whom I had worked in the USA, Australia and Europe. In a different context, I also had regular discussions with my STD colleagues."

She then refers in the next paragraph to going from time to time to London for meetings. Again, I think that's potentially looking forward in time.

Then in paragraph 54.5 she returns to the format of the group meetings at the hospital. She says:

"... I presented and explained to patients and relatives the characteristics of the HIV virus. Inside the body cavity in the blood stream, it was lethal. However, outside the body the virus was extremely vulnerable. It could be destroyed by a simple wipe of bleach and certainly, heat treatment removed its activity ... Therefore, apart from IV, i.e. through treatment, blood transfusion, dirty needles between drug users, there was no way that it could be transmitted except by sexual intercourse. It was easier to transmit it by what could be described as vigorous sexual intercourse.

"After my introduction, the patients were

offered testing. At this point in time, testing was not mandatory. Patients could say yes or no. I had anticipated that most people would accept the opportunity to be tested. They all did. The reason for couching the invitation for testing in this manner was to permit patients to be in full control of their lives - circumstances which, sadly, would change radically if the tests proved to be positive. They were told that no names would be used, that a coding system would be applied and that for confidentiality purposes the results would be logged into a confidential notebook. They were asked if they wished to know their result. Contrary to my expectations one patient declined to hear the result. His response posed a problem. Rapidly, I had to consider the action I would take if this particular patient tested positive. It was recognised that all patients who tested positive would require a confirmatory test. Apart from taking his routine treatment, sexual transmission was the only other means of transmission. Therefore, a short delay before his confirmatory test would not constitute a public health issue.

"After the testing was completed, I then had a concluding address with the patients. I was acutely

aware of the difficulty of imparting unpleasant news to patients. I had been much involved in telling individuals that either they, or their close relative was suffering from acute leukaemia and all the problems associated with chemotherapy. I well knew from experience that the audience for this type of introductory session would perhaps remember as much as 25 per cent of what they were told and it was unlikely that they would remember more than 50 per cent. Therefore, it seemed important to me to reiterate to them exactly how their lifestyle might change in the future if they had experienced transmission of the virus. I also asked them to refrain from sexual activity before they came back for their results. They were aghast, and there was some laughter at this, but the purpose was to protect spouses and partners and the general public."

So that's Dr Mayne's more detailed account of her recollection in her most recent witness statement and then over the page -- so questions were asked about why she -- about her decision to tell patients their test results only if they wished to be told, and she refers back to the answer above.

She's then asked in question 56 about the policy in relation to testing partners and family

members and she says there:

"Following the confirmation of a positive result spouses/partners were tested by mutual agreement."

Then she's asked about what, if any, information or advice was provided to partners or family members and the response is to say that all relevant information was relayed, either in the centre or at home during home visits but it doesn't tell us what information or advice was, as a matter of fact, relayed. That's, as I say, to complete the picture in terms of Dr Mayne's evidence on that issue.

I've referred to Dr Mayne's statement that 15 patients were infected with HIV as a result of treatment. In fact, if we go back to BHCT0000484, there are 16 patients listed, and then of course there is the one additional case of a partner who became infected, so 16 cases of direct infection and one of infection via sexual transmission presumably, or indirect infection, however one wants to term it. So a total of 17 cases in that regard.

Just then two further documents in relation to the testing process. If we look at BHCT0000158, this is a communication, 21 August 1985:

"The results of our latest test for

anti-HTLV-III in your patients are as follows ..."

And then there are two identified as positive and then a series identified as not positive and then down the bottom of the page is:

"We have no sera in store from ..."

And then there are two patients there identified. So it would appear that the testing process was ongoing for a period of time.

If we look over the page -- sorry, not over the page. If we look at BHCT0000161, there's a later letter, 12 September 1985. Again, it provides results of anti-HTLV-III tests in the centre's haemophiliac patients. The first three, who are listed as positive, two of those are identified as having already been tested, one by the regional virology lab, which is where this letter emanates from, one by Dr Tedder, but the second of the three is what appears to be a new result. So again, it would appear that the testing process was still ongoing as at September 1985. And then there's a whole list of patients who are anti-HTLV-III negative.

If we can then -- just turning to the question of how those patients with HIV were treated, it would appear as though the process for treatment for their HIV was that they were treated by Dr Mayne.

There is reference in later statements to arrangements being made for some form of joint clinic or joint arrangement with an infectious diseases specialist, but that looks to be from around 1999 onwards or indeed a little later than that during Dr Anderson's tenure.

If we go to WITN3082020, we can see an article in the Ulster Medical Journal. We looked at one yesterday which was about hepatitis B infection in Northern Ireland. This is "[HIV] infection in Northern Ireland 1980-1989", and it's published in the Ulster Medical Journal in April 1991.

If we go to the second page -- I should say, Dr Mayne is identified as one of the authors -- under the heading "Methods", the second paragraph tells us that:

"The Regional Virus Laboratory began anti-HIV testing in May 1983 *(sic)* and the Northern Ireland" --

SIR BRIAN LANGSTAFF: '85.

MS RICHARDS: I'm so sorry:

"... 1985 and the Northern Ireland Blood Transfusion Service in October 1985."

So there is evidence of some test results earlier in 1985 and it may be that those were tests that were undertaken elsewhere. We've seen one

reference to a test, for example, by Dr Tedder. So it may be that sera were sent off to be tested elsewhere. It's not clear. But, in any event, in terms of the Regional Virus Laboratory there's no reason to doubt what's said here, that their process began in May of 1985.

We can also see from the next paragraph that it says that:

"Retrospective testing of haemophiliacs was done on available sera which had been stored at minus 20 degrees centigrade in the Regional Virus Laboratory and fresh sera were obtained from the Department of Haematology, Royal Victoria Hospital."

Then if we go to the next page, and we look at the third paragraph it says:

"The 16 haemophiliacs ... identified as infected with the virus in 1985 ..."

So that doesn't include the one partner.

"... when HIV antibody testing became available have been cared for by the Northern Ireland Haemophilia Service. Of the 55 remaining persons 49 ... have been cared for by the genito-urinary services. The remaining six ... have been cared for by other agencies."

So that would appear to confirm that the

responsibility for the consequences of their HIV infection was retained within the haemophilia centre.

If we go two pages further on under the heading "Testing", the second paragraph refers to testing of patients with coagulation defects, so it says:

"One hundred and twenty-three patients with coagulation defects who had received treatment with blood products were tested and 16 were positive (13.8 per cent). If only severely affected patients ... are included this rises to 25 per cent."

It's not entirely clear why you would include only severely affected patients in one sense because we have seen two examples of patients who were not severely affected who were infected with HIV.

"Stored sera were available on 11 of the 16 positive patients and when tested showed that seroconversion occurred between 1983 and 1985. The source of seroconversion in one patient in 1985 was traced to a batch of heat-treated factor VIII which was found retrospectively to be contaminated with HIV."

SIR BRIAN LANGSTAFF: Do we know if that's the same as we looked at earlier on today, where there had been heat-treated Factor VIII, it had been reported as a batch from Armour where there had been a contributor

who subsequently developed AIDS and the comment made by I think Dr Mayne was that thankfully there had been no seroconversion?

MS RICHARDS: The comment made by Dr Mayne, as I understand the position, relates to a patient whose identity I think is known to the Inquiry who was not as the matter of fact infected with HIV. I think that's right.

SIR BRIAN LANGSTAFF: So this is another episode where --

MS RICHARDS: It may be the same batch --

SIR BRIAN LANGSTAFF: -- *(unclear: multiple speakers)* product might have been -- well, was in this case implicated?

MS RICHARDS: Yes, I don't think we've seen anything other than that single letter from Armour so it may be that it was a batch used for more than one patient. I don't know. But there is some evidence -- Dr Mayne's evidence, as I recall, relates to a particular patient who was not infected with HIV. This is I think no reason to doubt what is said here in a journal co-authored -- article co-authored by Dr Mayne in 1991, so only a few years after the event, which tells us that there was one heat-treated seroconversion.

Who that was, we don't know. We have looked as

you will recall in the course of today at a letter which refers to an identification of a patient seroconverting in 1985. Whether it's that patient or a different patient, given that we also know there wasn't an immediate switchover, it would appear, to heat-treated products, is unclear.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: But in any event, as we see there, evidence that one seroconversion was from heat-treated Factor VIII.

If we turn over then to page 9 please, Soumik, and look at the second paragraph, this is the position set out in the second paragraph as at the date of this report:

"Of the 16 haemophiliac patients infected, three have died, one by suicide, one from liver failure unrelated to HIV infection, and one in whom HIV infection was contributory."

Then if we go over the page and look at the heading "Management", we'll see how patients other than haemophiliacs with HIV infection, how their care was managed:

"... mostly been managed as outpatients by the Genitourinary Medicine Service at the Royal Victoria Hospital ..."

Some are recorded as attending clinics elsewhere:

"These patients have open access to the clinics and the counselling and social services provided at these centres. A designated HIV clinic is in operation at the Royal Victoria Hospital. In-patient management has mostly been handled by the genitourinary medicine physicians, with close co-operation with relevant specialists, mostly gastroenterology, immunology, neurology and respiratory medicine."

So there would appear to be a contrast between the multidisciplinary care that appears to have been available to patients other than haemophiliacs with HIV infection in contrast with those who were haemophiliacs whose care was retained within the haemophilia centre.

If we go next to WITN0736010, again we've looked at this yesterday for different purposes. It's a 1991 report of activity of the Northern Ireland Regional Centre.

If we go to the second page, this is authored by Dr Mayne and we look at the bottom of the page, Dr Mayne says this:

"It is noteworthy that the visits of HIV

positive patients for counselling by the director of the Centre averages ten visits per month and many of these visits last up to two hours in duration."

So a description there of Dr Mayne undertaking counselling, but what she means by "counselling" and what might be meant more generally by "counselling" may be different matters.

"Initially there were 16 HIV positive Haemophilic patients in Northern Ireland. They were all adults."

I have already drawn attention to the fact that one at least seems to have been 14 at the date of testing.

"By 1991 three had already died."

We have seen that picked up in the Ulster Medical Journal. Go to the top the next page:

"During that year [so 1991] a fourth patient died of salmonella septicaemia directly related to his HIV condition."

That is an update as at 1991 that four of the 16 had already died.

In terms of what Dr Mayne says about the arrangements for the care of those with HIV, if we turn to WITN0736009, this is her main statement again, and we go to page 27, if we look at the third and

fourth paragraphs she says:

"The staffing levels in the Centre were augmented by an E grade nurse, a full-time secretary and a scientific officer. The letter was to help with the laboratory side of the situation and possible future research."

It's not entirely clear how that assisted with HIV care but this her answer in response to a series of questions -- a question about what enquiries or investigations were undertaken in respect of the risks of transmission of HIV.

Then paragraph 33.11:

"Measures were taken to liaise with colleagues from other disciplines as and when necessary. A Dermatologist, a Neurologist, and an Infectious Disease expert were all briefed, and were willing to and did attend patients in the Centre. In respect of general assistance, a liaison was also formed with the Sexually Transmitted Disease Department. They had many more HIV patients."

Then if we turn to BHCT0000609, go to the next page. This is a letter in relation to one patient. It's from June of 1994. I'm not proposing to go through the detail of it.

We can see in the first paragraph, just over

halfway down, she talks about -- sorry, Dr Mayne talks about her next visit to London hoping to:

"... have some further consultations with experts there in the dermatological manifestations of HIV infection."

And then there's a discussion about what treatment the patient should receive. We see that continuing in the next paragraph, discussion about what treatment the patient should be on.

So, again, it's one example. There are other examples in the bundle of Dr Mayne essentially being the primary clinician in relation to the haemophiliac HIV patients.

If we go to HSOC0010892 and we go to the third page, there's a letter from Dr Mayne dated March 2, 1994, which contains her comments on AZT. She says:

"The advent of AZT was a therapeutic advance in the management of HIV. At the time of granting of its licence, I remember being particularly concerned about its side effects."

She sets out what she thought those would be, and then says:

"Despite these reservations, I have found it to be effective in treating HIV positive patients whose CD4 counts were falling. I would admit, however, that

I have never utilised the maximum recommended dose. Most patients in this Centre have been treated intermittently, rather than with permanent prophylaxis.

"I think patients can be reassured that the drug has a well established role in treating certain aspects of HIV and AIDS."

And she carries on.

So again it would appear decisions relating to use of AZT from a clinical perspective were taken by Dr Mayne. There is a description by Dr Anderson picking up the picture a little later on in her witness statement, as I indicated a few minutes ago, of care being shared with an infectious diseases consultant and, again, Dr Benson I think will be able to assist tomorrow in relation to the position as at 2008 and since in that regard.

Turn then to the information that the Inquiry has about the process of testing for hepatitis C and informing patients of their diagnosis. The themes which emerge from the evidence which the Inquiry have received from people who were infected with hepatitis C or their relatives has a number of common themes. Some, not all but some, describe being unaware of being tested for hepatitis C. A number of

them draw attention to there being an apparently significant delay between date of testing, whether with the first test or a second generation test, and the patient themselves being informed of their diagnosis. Some recount an experience of only being told effectively when there's a significant event going on and they are attending the Haemophilia Centre and then, as it were, are told almost as an afterthought about the hepatitis C diagnosis.

A further theme that emerges from this statement is of insufficient information being provided in terms of the nature of the virus, its likely consequences, treatment options and the like, and a final theme which emerges from the witness statements, some of the witness statements, is of a degree of false reassurance or perhaps I should say over-optimistic reassurance about the nature of the condition.

I want to start then, if I may, with looking at Dr Mayne's various accounts of the position in relation to hepatitis C testing. So if we go, first of all, to WITN0736001 and if we go, first of all, to -- in fact, if we go first of all to page 6, if we look at paragraph 2.2, this is in fact on a slightly different point but whilst we are looking at this

statement I should have drawn attention to it. So I referred earlier to the individual statements giving a near-universal account of not being told about the risks of viral infection from their treatment, and to some recalling receiving the impression of it being a wonder drug or pioneering or a miracle treatment.

You will see here Dr Mayne responds to one individual witness statement. She says this:

"... no warnings, apart from vein care and aseptic techniques, were given because at that time ..."

And we will have to look back at Mr Kirkpatrick's statement to check the particular time.

"... I believed the treatment was both effective and safe. I certainly do not recall being asked about risks. The words 'wonder drug' may have emanated from others but not me. I doubt if I would have dared to utter such words."

So I should have referred to that. Then returning then to the issue of hepatitis C testing, if we go on two pages, Soumik, we look at paragraph 3.2, I should refer probably back to 3.1. This is in response to an account of a patient being -- having their hepatitis C diagnosis communicated to them in

a corridor. She says she doesn't recall:

"It would not be my clinical practice to discuss patients' health in a corridor."

Then more generally in relation to hepatitis C testing she says this:

"Precise laboratory testing for Hepatitis C became the norm in 1992-1993, the virus having been identified in 1991."

That latter date, obviously, is not correct.

SIR BRIAN LANGSTAFF: No, it was 1988 but not published I think in detail until 1989.

MS RICHARDS: Yes. And there is evidence of testing having been undertaken at the Centre in 1991 as well as 1992 to '93.

SIR BRIAN LANGSTAFF: Yes. This talks about the norm, but it was introduced across the board apparently from 1 September 1991.

MS RICHARDS: Yes. She says:

"It was not my clinical practice to test patients for Hepatitis C without their consent. All patients attending the centre, after receiving blood products, were checked physically and had laboratory investigations."

Then she goes on to talk about liver function tests but, in any event, that's the general statement

in relation to the testing process.

I should also draw attention to paragraph 3.4. Dr Mayne says in the first sentence:

"... there was no specific test for Hepatitis C available in 1987."

That obviously is correct, and then she describes hepatitis C as not a prevalent concept in '87:

"It merely referred to the existence of abnormal liver function tests designated by the UKHCDO Hepatitis Working Party as non-A, non-B hepatitis."

Well, I think the term "non-A, non-B hepatitis" is not attributable to UKHCDO's hepatitis C working party but had been in common usage since at least the mid-1970s. But in any event, we see then she says -- in response to the patient saying she was not advised until 1993 of her hepatitis C diagnosis, Dr Mayne says:

"Precise laboratory testing for Hepatitis C [only became available] in 1992-1993."

If we then turn on four pages, I think, Soumik, to paragraph 5.4, this is part of Dr Mayne's response here to an individual witness, here to the statement of Mr Nigel Hamilton. Dr Mayne says:

"... the diagnosis of hepatitis C was difficult

as nearly all patients had evidence of abnormal liver function tests ..."

She refers again to it being given the title non-A, non-B hepatitis, and then says:

"Definitive tests for Hepatitis C were not available until 1992-1993 ..."

It may of course turn on the use of the word "definitive", but obviously there were tests available prior to that.

So that's that witness statement. If we then go to WITN0736005, if we go to the bottom of the second page we can see in paragraph 2.1.1 there's a description in the second half of that paragraph to what was said to be the practice of the virology laboratory to keep a sample of serum to be retested in the future.

She then, in paragraph 2.1.2, says:

"The Hepatitis C virus became isolated in 1991."

We've already dealt with the incorrectness of that date.

"Tests became available to detect HCV antibody around that time but tests for active HCV infection were not available until 1993. As far as I can recall, I believe the original 1976 sample was

re-tested in 1991. In 1991 a further sample was taken and tested and a further sample was taken and tested in 1993, making three tests in all. The customary length of time elapsed between testing and results becoming available. Patients were seen as soon as possible after their results were received for consultation and discussion.

"Present day practice would require oral or written permission to carry out viral blood tests. At the time in question, locally, nationally and internationally, expediency seemed paramount and specific consent was often not obtained. Quite unlike the situation relating to HIV testing, when no test was ever carried out without consent of the patient. Refusal to have any test was acceptable at all times."

Again, there may potentially be much to unpick in that paragraph. Specific consent often not obtained, but it's then said refusal to have any test was acceptable at all times. Of course, if a patient doesn't know what they are being tested for it may be a little difficult for them to exercise a right of refusal to the test.

Picking up upon the dates given at the top of the page, you will no doubt recall, sir, from the hearing in Belfast and from the oral and written

testimony overall from patients treated at this centre, there is evidence in medical records of tests being undertaken in 1991 but of patients not learning the results until some considerable time later, sometimes in 1992 or 1993 but sometimes much later. We've given a number of examples in the written note and I'll refer to a handful of them.

If we look at the bottom of this page, we can see confirmation by Dr Mayne of there being testing in 1991 because in relation to again another individual witness's account she says:

"The test in 1991 demonstrated that the witness had 'met' the Hepatitis C Virus at some time. It showed that he had antibody but not active infection at the time of testing. He was clinically well."

Top of the next page:

"Therefore he was not informed about this particular result. It was thought it might cause undue anxiety and worry. At that time, it was unclear what the future would hold for someone with such a result. By 1993, a test became available which could detect active Hepatitis C infection. It took time before the test came into routine use. The witness' definitive result of active infection was obtained in March 1996 and confirmed in August 1996.

It was now felt important that he should know the findings hence the invitation to come and meet with the staff."

So there is an example, but a fairly striking example in terms of the dates, of a patient tested in 1991, using the tests then available, a positive result, but the patient learning for the first time about a positive result following further testing five years later, in 1996. That's, as I say, one of a number of examples.

Whilst we're looking at this witness statement, if we go to the paragraph a little further down, 2.4.1, again a theme from the -- a theme from the evidence has been Dr Mayne's manner in providing information and diagnoses, and she responds here to a statement that described her as patronising and as not providing answers or the information that the patient was requesting. She says:

"There was a considerable degree of confusion at this time caused by lack of precise knowledge as to how HCV would ultimately affect patients. I was fully aware of the situation, as I travelled on a monthly basis to meetings in Scotland and also to other meetings in the UK and Europe. Specifically, I tried to bring back knowledge to Northern Ireland and relay

it to the patients. It was not always easy to answer the patients' questions. It was felt better not to speculate about what might or might not happen in the future. It is regrettable that the witness found the presentation of the paucity of information patronising."

SIR BRIAN LANGSTAFF: When she says "it was felt better not to speculate", is she describing there her understanding of general practice derived from Scotland, Europe, et cetera, or is she describing her own practice by adopting the third person?

MS RICHARDS: Grammatically, it could be either. I don't think we've heard evidence more generally to suggest it would be the former and there's no particular material relating to Scotland, UK or Europe which she refers to. You obviously, sir, have encountered evidence of a range of different practices and approaches taken by clinicians at this time.

SIR BRIAN LANGSTAFF: Do I have to take into account in looking at this my understanding of what was generally known about the prospects for those who had chronic infection?

MS RICHARDS: Yes, absolutely.

SIR BRIAN LANGSTAFF: As they were understood, at any rate, at the start of the '90s?

MS RICHARDS: Yes. Well, at the start of in the course of the 90s because I don't --

SIR BRIAN LANGSTAFF: That's why I said the start of the '90s. It covers the whole period.

MS RICHARDS: Yes. I don't know without checking witness 1371's statement what the particular date was of this consultation.

Then if we go a little further down the page we just see the issue being raised at 2.6 and 2.61 about risks of HCV transmission during sexual intercourse. The witness records Dr Mayne saying that there was no risk of HCV transmission during unprotected sexual intercourse. Dr Mayne's response is to say:

"I do not recall this part of our conversation but the witness is probably correct that at that time I did not feel it was likely that HCV would be transmitted through unexpected intercourse."

Again, there may be a difference between saying no risk and the question of whether it's likely or not.

Then if we go to the top of the next page, this is again in response to a witness expressing concern about an absence of openness and transparency in the information provided about hepatitis C.

Dr Mayne's response is to say:

"This paragraph underlines the need for the witness and her husband to have discussed these matters with experts. During the early 1990s, concerns regarding the implications of having HCV infection grew by leaps and bounds. Clinical symptoms were developing and the most common complaint was of extreme lethargy, therefore, in 1995 a residential weekend for all patients and Centre staff was arranged."

Then she provides details of the location, says it was fully sponsored by nine international pharmaceutical companies and she describes a number of experts, including virologists, coming to address the conference and they made themselves available to individuals.

She says in the next paragraph:

"I do not remember the witnesses being present at the residential weekend, at least I do not remember seeing or speaking with them on that occasion. If they were not present it was sad as they might have received much help and advice."

There's no evidence that we've thus far uncovered of any -- for those potentially majority of patients who didn't attend this particular conference, and there may of course be multiple reasons why

patients would either not want to or not be able to, we've seen no evidence of the material from that conference being gathered and disseminated to a non-attendees.

Then if we go to -- go on another three pages, Soumik. Sorry, back one page. My fault. Bottom of this page, this is in response to a witness saying that they were not told about their HCV infection for five years and a reference to blood samples being regularly taken in visits to hospital. Dr Mayne says:

"Regular blood samples were taken from patients at all visits to the Centre. This was to ensure that they had not developed an inhibitor to their own specific clotting factor as this would alter their future management to a significant degree. As previously stated in earlier responses, samples from the 1970s were retained as was customary in the protocols of the Northern Ireland Virus Laboratory."

Then this:

"The patient's final diagnosis of active HCV was not made until after the 1993 test was in routine use, i.e. in 1996. Prior to that time he was designated as having Non-A, Non-B hepatitis."

Now, it's not clear why a test which Dr Mayne describes as being available from 1993 was not

seemingly in routine use, to use her phrase, in the Belfast Centre until 1996.

Then if we go -- no, we've looked at the next passage I was going to refer to already today. If we then turn to WITN0736007 this is a further statement from Dr Mayne in response to individual witness statements. If we go to the second page, paragraph 5, so again Dr Mayne repeats the error about when HCV was identified. Then she says:

"Tests for antibody were available in 1993 [again, that doesn't appear to be right], but not indicative of active clinical infection. Tests for RNA viral load were available in 1994/95. The patient visited in 1995 and therefore was not involved in any particular delay. He was seen as soon as possible in rotation with his fellow patients."

She says he was informed that the source of infection was his treatment. The evidence more generally suggests that there was no programme for calling patients in to be tested specifically for hepatitis C or calling them back in to be informed of their test results as soon as those test results were available or as soon as practicable after those test results became available.

The evidence suggests that once hepatitis C

testing was in use it would be when the patient attended for a routine appointment that they might be tested. Again, there is some evidence from individuals of them being -- occasional evidence of being called in when there was special -- in some individual special circumstances, but more generally that appears to have been the case and then not being told the result for some considerable period of time, and I think Dr Mayne suggested it would have been at the next routine appointment, but certainly there were no special arrangements made for communicating the diagnosis prior to the patient's next general attendance, at least as a matter of general practice. There may of course have been individual symptoms.

If we look at the bottom of this page, we can see a response from Dr Mayne to the observation by a witness that she did not offer any support or counselling after informing him of the HCV diagnosis. She says:

"Neither support nor counselling were available. At that time it was significantly problematic trying to establish a good clinic for hepatitis patients to attend. Additionally, as the witness' wife mentioned in her statement ... 'we, rather naively, thought that Hepatitis C was not so

dire'."

Top of the next page Dr Mayne says this:

"Many of the clinicians, myself included, could not in 1995 foresee how complex, disastrous symptoms and complications of the virus would develop, sadly."

Again, you will need to assess that by reference to what you, sir, conclude a clinician could or should have understood in or by 1995.

If we then go to WITN0736009 and we go to page 41, we pick it up at the bottom of the page, at 62.1 Dr Mayne asserts that:

"... patients infected with [non-A, non-B] hepatitis were informed of the existence of their abnormal liver function tests. At the time the condition was termed Non-A Non-B. At that time although patients had raised liver function tests they were otherwise well."

It doesn't say that they were told that they had non-A, non-B hepatitis. It doesn't say that they weren't, but what it says that they were informed of the existence of the abnormal liver function tests. Then next paragraph she says:

"It was not possible to inform patients of active hepatitis C infection until the specific blood test for this virus became available ..."

If we go over to the top of the next page she says:

"It had been suspected for many years that regularly treated patients were likely to have the virus previously known as Non-A Non-B hepatitis, subsequently known as hepatitis C. Patients had been attending the Centre regularly for many years and receiving advice before the confirmation of their diagnosis. They were informed that they had a chronic viral infection of the liver that was causing inflammation."

Again, there is evidence to contrary effect from some of the patients in their written statements to the Inquiry, and then she refers to advice about alcohol consumption and diet.

If we then go further down the page, she says, to the date given here in paragraph 63.1, that:

"The Centre began testing patients for Hepatitis C in 1993 when the test became available."

So we do have a range of different tests -- a range of different dates, of course, there were different tests being developed. She says in the next paragraph:

"All patients were routinely assessed for liver function and for unknown viruses, up until the

definitive test for active Hepatitis C became available in 1993."

Then towards the bottom of the page, picking it up -- well, perhaps halfway down that paragraph it says:

"Patients were surprised at the clinical examination but the abnormal test results were explained, they were told they did not have Hepatitis B, a condition of which patients were well aware."

Just pausing there, some statements relate patients not being aware that they had had hepatitis B:

"Likewise, they knew they did not have any symptoms of Hepatitis A, therefore they were not surprised when they were told that they probably had a condition called Non-A Non-B hepatitis."

Then if we go over the page she continues in that paragraph her views about the seriousness or otherwise of non-A, non-B hepatitis and then 63.3 says this:

"Some 3-4 years prior to 1993 tests for Hepatitis C antibody became available. That test, if positive, only indicated that the individual had met the virus at some time. In a similar way, adults, if

tested, would show the presence of anti-measles antibody although of course they had no clinical evidence of the condition. During discussion with patients they found it difficult to understand the explanation of having HCV antibody. Some were worried that I was keeping secrets from them."

Just pausing there, again a common theme from the witness statements is that they were not given this information about the results of early tests. Dr Mayne continues:

"When the specific tests became available in 1993, the results indicated in many cases active disease. Even in 1993 it was difficult, even impossible, to give any precise prognosis or details of how the diagnosis may play out in time. As developments progressed viral load testing became capable of the estimation of infection. Likewise, different subtypes of the virus were accurately diagnosable. At this time a special liver clinic was established."

And she gives a little more information about that.

If we go over the page, in response to the question how many patients were infected with hepatitis C her answer is in excess of 100. Then if

we look at the third paragraph, 65.3 -- sorry, the third paragraph under the question in 65 she says this:

"With regard to HCV, the tests were done in batches to facilitate the effective management of the laboratory. The patients were informed at their next routine clinic visit. That may have been some time later."

And the evidence certainly suggests also in many cases a very significant gap of time in that regard. She says in 65.4:

"It is important to state that a positive antibody test required no action at this time. Positivity merely showed that, at some time in the past, the patient had been exposed to the virus ..."

And she develops that theme.

Then the last paragraph on this page:

"The antibody tests were explained to patients at the next routine visit. The timing of routine reviews depended on the severity of the patient's condition. Those on Home Treatment or severely affected were seen on a monthly basis. The moderately severe were seen theoretically on a six-monthly basis -- I say theoretically because if they had no problems they would cancel for perhaps a further

3-6 months. The very mildly affected were seen annually."

So the Inquiry has evidence of patients who were not seen even annually. Now, that may have been a matter of patient choice, of course, but there doesn't appear to have been any arrangement for bringing those patients in for a period of testing, and we see some examples of testing a number of years later.

Top of the next page what Dr Mayne says is that:

"At a later date from late 1993 onwards, if their definitive test showed active disease the patient was contacted and seen as soon as possible. Then management would proceed, after discussion, to the Liver Clinic and possible treatment with alpha interferon."

It's not clear what's meant by "their definitive test [showing] active disease", because there are individual accounts and I think not disputed in Dr Mayne's responses to them of patients, for example, not being told their hepatitis C results until 1996 in some instances.

So that's the account, the main account in Dr Mayne's most recent and most detailed statement.

We've looked at the example referred to in one of her earlier statements of testing in 1991 patient being informed on 1996. We've given further examples in the written note and of course, sir, you have all the individual statements available to you to consider. Perhaps one or two further examples may be worth looking at for present general purposes.

If we go to WITN257001, this is an example, if we go to the third page -- WITN2570001, sorry.

If we go to the second page of that, first of all. So if we pick it up at paragraph 5, towards the bottom of the page, this is an example of a patient account, of them being invited to go in for screening because of a brother's diagnosis of hepatitis C. And then if we go to the next page we can see in paragraph 4.1 patient saying that they were given their diagnosis in 2003, after, I think it was, the brother's death in 2002. So that's one example.

There are then accounts that we have and, again, we've sought to summarise them in our written note, of some witnesses only becoming aware of relatives' hepatitis C infections after the patient had died or some only becoming aware in recent years of hepatitis C infections and we may hear some relevant evidence from Dr Benson in relation to that

tomorrow.

If we go to WITN1382001 and, again, these are just examples of some of the broader themes that emerge, and we go to the fourth page, I've referred already to a theme about patients not being given what they regard as sufficient or adequate information or being given overoptimistic reassurance. We see in paragraph 18 -- I should say this is an example of a patient asking to be tested and being tested and being told their diagnosis in 1992, so tests clearly were available earlier than the dates that Dr Mayne's other statements might suggest.

Then in paragraph 18:

"I was told by Dr Mayne that despite my Hepatitis C, I would probably have a long and normal life and that it was just a risk of having Factor VIII. Dr Mayne did not discuss any of the potential health issues; she just brushed over it very quickly. She did not discuss any treatment, although there wasn't any available then, or provide any advice on how to manage and understand the infection. She simply told me that I had it and it would do me no harm."

So that's one example. Then if we go to WITN2569001 and we go over the page. So this is

another account of -- and it may, I think, be a sibling potentially of one of the statements we have already looked at but I'm not sure of that, but we see again an invitation in paragraph 4, at the bottom half of the page to being screened following a brother's death from hepatitis C.

If we go to the next page, at paragraph 4.1 the witness says in the second line:

"There was a time when I didn't attend hospital for a number of years and that was because I wasn't sent for. I think this was between 1997 and 2003. Hepatitis C was only mentioned to me after my [brother's] death."

Then if we go over two pages, top of the next page:

"I wasn't offered any support or counselling at the time of being diagnosed. I think if I had been offered counselling in how to manage this infection, I doubt I would be suffering with depression now. The only information offered was not to share my razor. I was informed of my diagnosis in a clinical manner and felt there was little empathy for me."

Then if we just look at a couple of letters from Dr Mayne on the issue of hepatitis C, so first of all WITN2655002, this is a letter from Dr Mayne,

April 1992, about a particular patient, Richard Lowry -- and you will no doubt, sir, I'm sure remember the evidence of his widow in Belfast -- mildly affected haemophiliac.

If we look at the bottom of the page, we can see Dr Mayne saying in the last four lines:

"... he has had elevation of his liver enzymes for a number of years. This is related most likely to infections with Hepatitis C virus. His results vary between two and three times the normal range of values."

So, April '92, Dr Mayne feeling able in this case to articulate a diagnosis or likely diagnosis of hepatitis C.

Over the page she says in the second line:

"Hepatitis C is an unknown quantity to some degree, between 80 and 90 per cent of treated Haemophiliacs are known to be positive, all are clinically well. From liver biopsy specimens obtained in some centres it would appear that a small percentage of patients may ultimately develop cirrhosis or chronic active hepatitis."

Perhaps a particularly difficult letter to read now in light of what we know happened to this gentleman.

SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: But there's Dr Mayne setting out her apparent understanding of the condition in April 1992. If we then turn to WITN1382003, second page, this is a letter at the end of 1992, 21 December 1992. It's in relation to one of the witnesses whose statements we looked at who said she was led to believe that the hepatitis C wasn't a problem and this, I think, would appear to confirm the accuracy of her recollection because, if we look at the bottom paragraph, it says:

"I have explained to Anne that there are several viruses which cause positivity to Hepatitis C. Generally it is thought that it is very unlike Hepatitis B infection and it may not have any serious sequelae for liver function in the future. Presently Professor Eric Preston and other Colleagues in the Haemophilia Centre Directors Organisation are carrying out an assessment of the benefit received by a 6-month course of Alpha Interferon. The results to date are quite promising and if Anne's tests suggest that she should fit into this category I will discuss it further with the patient and with yourself."

So that is apparently Dr Mayne's understanding in December 1992 of the nature of hepatitis C.
SIR BRIAN LANGSTAFF: Well, it's what she wrote but it

doesn't quite fit with what she wrote on 15 April '92 --
MS RICHARDS: No.
SIR BRIAN LANGSTAFF: -- in that last letter about Richard Lowry.
MS RICHARDS: Yes, and it doesn't quite fit with what we have heard more generally about the position.
SIR BRIAN LANGSTAFF: No, it doesn't easily reconcile with that.
MS RICHARDS: Then just picking up on the point in relation to interferon, we can see from this that that was again, just as we've seen HIV infection being treated by Dr Mayne, we see in the early years at least in the 1990s Dr Mayne taking responsibility for the treatment of those of her patients who had by that time been diagnosed with hepatitis C.

We see the letter in relation to Richard Lowry that we looked at also refers to her offering interferon treatment as at April 1992. So she was taking it upon herself at that stage as, indeed, we've heard other haemophilia clinicians were doing, I should make that clear, to be the treating clinician in relation to this virus.

We saw the reference in one of Dr Mayne's earlier statements to seeking a degree of specialist

input and if we go to -- this is in relation to hepatitis C -- if we go to WITN0736001 and we go to paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2:

"... up until the Hepatitis C virus was identified in 1991 no-one really knew what to expect."

Et cetera.

"Always I had an ominous feeling about the virus ..."

She says, and then she refers to the weekend meeting in 1995 and exhibits a programme for that. Then she says in the last sentence:

"Thereafter, [so at some point after the weekend in 1995] a combined Haemophilia/Hepatitis clinic was established in the Centre under the egis of Dr ME Callender, Consultant Hepatologist in the Royal Victoria Hospital."

There's also reference if we go to WITN0921001. This is the statement of Dr McNulty. Go to page 5 -- no, sorry, page 7. We know Dr Mayne retired in 1999 and we've seen the reference to her setting up the joint venture clinic.

If we look at paragraph 3.16 in Dr McNulty's statement -- thank you -- we can see she's referring

in the last sentence:

"There were many discussions between me and Dr Jones" -- and he took over as acting director when Dr Mayne retired -- "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic and were in regular contact with the hepatologists to press our case."

So the position in relation to when such a clinic was established is not entirely clear. Dr Anderson in her statement describes when she arrived there being limited hepatology input only and that being a particular concern of hers and she's described that in some considerable detail in her witness statement and, again, no doubt Dr Benson will be able to assist us tomorrow with the position in terms of hepatology care, at least in general terms from 2008 onwards.

So that's the summary of the material relating to testing and providing information about diagnosis to patients in relation to hepatitis C, sir.

If I can then pick up on a slightly different theme, which is that of record-keeping, we've said in our presentation note that a number of patients report difficulty in obtaining their medical records or not having complete medical records, and that's absolutely

right. But we've suggested in our note that the general processes in relation to record-keeping are presently unknown. In fact, we do have some information about record-keeping which I should have referred to.

First of all, Dr Anderson in her statement, perhaps -- I think you have this, Soumik. It's WITN4027001. If we go to page 60 -- it's a very long statement. I should say Dr Anderson joined Belfast centre in November 2000 and we'll see -- sorry, it's page 16, not 60. My apologies.

We'll see her description of the state of medical records at 6.8.23 of her statement. She says:

"Medical records were handwritten and kept meticulously. There was excellent administrative and secretarial support and it followed that the filing was good with the medical records kept within dividers in the case notes and any written results filed in separate sections."

She says in the last sentence of that paragraph:

"These case records were of a superior quality to those I had seen at many other institutions I'd worked at previously."

Then she describes in the next paragraph the

medical records being kept within the day ward records department in a separate section to other records belonging to other haematology patients, and then describes the transfer because the centre relocated. So she describes the transfer of records, which she says she personally oversaw at the time of the centre's relocation, and then, bottom of the page, she described introducing a typed record of all patients attending for day case assessment. Of course, that would have only been from November 2000 or whatever date she introduced it onwards and wouldn't relate to the quality of the notes at an earlier stage. That's Dr Anderson describing the notes as she found them.

Then we do have the more general statement about record-keeping within the Trust. Soumik, this is the document you should have received today. It's WITN3449007. This is a statement of Caroline Leonard for the Belfast Health and Social Care Trust, and if we go to -- if we go perhaps just to the last page, there's a description of what archives the Trust hold and a history given of the Trust's archiving system.

Then we see an account -- I'm sorry, can we go to the page prior to that. Thank you. We see a description there of retention and destruction policies and processes from 1948 to date. I'm not

going to go through the detail of what are, I think, a number of exhibits but I just draw your attention to the fact that there's said to be or there is a retention and disposal schedule. It's said to be based upon the principles contained within a Department of Health guidance -- that's paragraph 5.2 -- and she refers to policy being adopted by the Trust. Then she says at 5.3:

"Prior to this, records were retained and/or disposed of in accordance with the Trust and legacy organisations' retention and destruction policy that was in place at the relevant time."

Then there are a range of Northern Irish circulars that are referred to relevant to the question of document retention and document destruction.

Then we look in paragraph 5.4, so if we just go further down the page, we see reference to a suspension of the destruction of any records in August 2015. That was in response to the Historical Institutional Abuse Inquiry and we are told that suspension of destruction or records continues to remain in place. Now, there's a lot more detail there that will need to be unpicked at an appropriate stage but, having said in the written note that the general

processes in relation to record-keeping are presently unknown, that wasn't a fair characterisation of the fact that we have also got this material.

How any of this then explains individual missing records is an exercise that we'll have to undertake to the extent that we are able to do so and it may be is that Dr Benson may be able to assist us again tomorrow with what at least the position's been since he has been director of the service.

Then in terms of the provision of information more generally to third parties -- oh, I note the time. I've still got a handful of matters I need to dealt with; so it would be more than a few minutes, so perhaps we could take a break at this point.

SIR BRIAN LANGSTAFF: Yes, certainly. Roughly how long do you think you have left?

MS RICHARDS: Half an hour.

SIR BRIAN LANGSTAFF: Yes. Well, we will take a break now until 3.45.

MS RICHARDS: Thank you, sir.

(3.18 pm)

(A short break)

(3.46 pm)

MS RICHARDS: Sir, I'm just then going to refer on the topic of data and records to examples of information

being provided to third parties, most commonly Oxford and the Oxford returns.

We've already looked at some examples of the annual returns in relation to Belfast which are not just the generic annual returns but also contain detailed patient data with named patients, information about dates of birth and so on, the nature of their bleeding disorder and the treatment they've received.

If we then look at BHCT0000850, this is a letter from the Oxford Haemophilia Centre from Ms Spooner dated 21 October 1992 to Dr Mayne, Professor Bridges and Dr Dempsey and it says:

"On reviewing the cases of AIDS or AIDS Related illness reported to us on FORM AIDS/3, CDSC's FORM AIDS 1 or the Paediatric Surveillance Forms, we find it is several months since we last had news of some of the patients. I should be most grateful if you could complete and return to me as soon as possible the enclosed form(s) for your patient(s) to give up-to-date information. The information will be treated in strictest confidence; the completed forms will not be passed to anyone outside Oxford Haemophilia Centre."

Then if we go over the page we can see an example of a completed form from Dr Mayne. So again

we have redacted the details of the individual patient but it's headed:

"Confidential

"UK Haemophilia Centre Directors' Survey of Patients with AIDS or AIDS-related illness"

And then we can see information, if we go further down the page, about the patient's clinical condition and about their treatment being provided.

And then further down the page we can see under the heading "Additional comments", a number of matters set out about the individual patient.

As I say, although we've redacted the patient's name, the name and date of birth are there in the material that's sent to Oxford. That's one example where information relating to HIV or AIDS diagnosis is being communicated.

If we go back a number of years and look at an example of another kind of data, HCDO0000054_005, we can see here in a letter from Ms Spooner to Dr Mayne dated April 1977 an expectation that Oxford will be sent a form giving names and details of patients. That was by reference to a particular cohort: five von Willebrand's disease patients treated in Belfast during the year 1978.

Then if we look at HCDO0000153_008 -- again

these are by way of example -- we can see here we've moved forward to May of 1984, and it's Dr Mayne sending Ms Spooner information about the treatment received by identified named patients.

Then if we go to BHCT0000861_003, we can see a request here coming from Dr Rizza to Dr Mayne, Dr Bridges and Dr Dempsey in December of 1986. It refers to a recent survey of anti-HIV in haemophiliacs and says:

"... the patient(s) listed below attending your Centre have reported as being anti-HIV positive in the 1986 survey, having been anti-HIV negative in the 1985 survey. In order to find out how this seroconversion relates to use of heated or unheated factor concentrate I should be grateful if you could let us have some more details ..."

We can see the reason is for the monitoring of safety of heated blood products. So the requests may be entirely understandable requests; the issue that they give rise to, as we've seen with a number of other centres and clinicians, is the extent to which patients were aware of or asked to consent to or did consent to the dissemination of information about them. And if we look down the bottom of the page, we see again this is a request relating to a specific

named patient.

If we then go to BHCT0000831_001, again we can see Dr Rizza asking for information, this is now January 1989, about a particular patient, trying to locate a death certificate, and information is requested. If we go to the bottom of the page, to the handwritten note it says:

"I am surveying all death certificates of anti-HIV positive haemophiliacs to see how many ..."

I'm not sure --

SIR BRIAN LANGSTAFF: "... might have died ..."

MS RICHARDS: "... might have died of HIV-related illness but not certified as AIDS."

So, again, an understandable reason, and this is in relation to a deceased patient, but raises the question of what patients or their families understood.

If we go to BHCT0000831_003, I think we've only got the first page of this letter but we can see it's a fairly detailed response from Dr Mayne to Dr Rizza giving information about the patient and their circumstances.

Then if we look at what Dr Mayne has to say about the provision of information --

SIR BRIAN LANGSTAFF: Just -- what's the date of that?

MS RICHARDS: The date of the letter? If you go to the top of the page, it's February 1989.
SIR BRIAN LANGSTAFF: Yes. And the cause of death there was liver failure related to a non-A, non-B hepatitis.
MS RICHARDS: Yes.
SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: And of course that may cast into an interesting light some of what we've seen Dr Mayne saying in her statement about her understanding -- and, indeed, in her correspondence in the 1990s -- about the nature of hepatitis C.

If we go to Dr Mayne's statement at WITN0736009, and we go to page 51, please, Soumik, Dr Mayne is asked a series of questions about involvement of patients in research studies. She says they weren't involved in research studies without their express consent. Then she's asked at paragraph 76 about patient data:

"Was [that] used for the purpose of research or ... any other purpose without ... express consent?"

She answers "no".

Then in relation to the sharing of patient data (anonymised or otherwise) with third parties such as UKHCDO or the Oxford Haemophilia Centre, she says this:

"All patients attending the Centre were aware of the existence of UKHCDO."

Top of the next page:

"They were aware that the secretariat collected and compiled stats on an annual basis relating to their treatment and they realised the procedures were necessary in order to estimate changes in treatment product availability year by year. In those circumstances it was a matter of implied, rather than express, consent."

Now, it may be right that patients had knowledge of UKHCDO. It may be right, I know not one way or another, that patients were aware of UKHCDO's secretariat collecting and compiling statistics.

It doesn't, I think, follow as a matter of logic or inference that patients must be taken to have been aware that named data, in particular sensitive data about matters such as HIV status or the progression of medical conditions, was also being provided to UKHCDO.

Again, we've seen this is not an issue unique to Belfast. It's an issue that's arisen in relation to many centres, probably all of them, and one which UKHCDO itself was attempting to wrestle with at some stage.

SIR BRIAN LANGSTAFF: What I think it appears to be saying is that no-one was actually asked to agree that this is how the information should be shared.
MS RICHARDS: Yes.
SIR BRIAN LANGSTAFF: Or shouldn't be shared.
MS RICHARDS: Then I just want to pick up next on the issue of what was or was not recorded on death certificates. If we go to WITN0736001 and we go to page 10, bottom of the page, Dr Mayne says this:

"... it is important to point out that the universal practice throughout the United Kingdom was to omit HIV on any death certificate; however, it was important and prudent on all doctors concerned to inform the undertakers in question so that appropriate precautions could be taken."

If we look at Dr McNulty's witness statement, so WITN0921001, and we go to page 8, what she says in paragraph 3.19, so bottom half of the page, is this.

"When dealing with the issue of death certificates it must be noted that Northern Ireland is a small place and it's difficult to go somewhere without meeting someone you know. This is particularly true in rural areas and the privacy and discretion which was paramount in the Centre did not always filter down to those places. It must also be

noted that 25 years ago there was a lot of ignorance and fear associated with HIV and hepatitis and it was felt to be an act of humanity not to use those terms on the death certificate in order to protect the deceased and their relatives. Very often ..."

She doesn't say "always", but:

"Very often this was at the specific request of the patient or their family and was not done in any underhand way."

So that's the evidence from those two clinicians about the approach taken to the completion of death certificates.

Can I then turn relatively briefly to evidence relating to Dr Mayne's involvement in research. She describes in her evidence having undertaken some full-time research in the course of the 1960s and early '70s but she says in her statement once she returned to Northern Ireland and took up her post in the Haemophilia Centre she had little, if any, time or opportunity to carry out meaningful research.

There are examples of Dr Mayne participating in some studies, trials or pieces of research. There are the two papers we've looked at in the Ulster Medical Journal in relation to hepatitis B and patients with HIV. There's some work and publications in relation

to porcine products. Dr Mayne and I think Dr McNulty had some involvement in a study in relation to the purity of NHS Scottish concentrates or at least some anticipated involvement in that issue.

If we have a look at MACK0001300_002, we can see Dr Mayne being sent a copy of a protocol for a PUP study in December 1988 and that appears to be from other documents in relation to a further Scottish product said to be purer than Z8. It's not clear what happened in relation to that study, I should say.

Some other handful of examples of Dr Mayne's involvement OXUH0000451, if we go to the second page we can see this is a reference to UKHCDO's Factor VIII inhibitor working party and there is a trial of Factor VIII versus Autoplex and it says a meeting of the participants in this trial was held in February 1982 in London and then a number of participants are listed including Dr Mayne.

If we look further down the page there's reference to a discussion about a draft clinical protocol and then the trial comprising a double-blind random allocation assessment of Factor VIII versus Autoplex. So that's again one example at least of anticipated involvement in a trial.

If we then look at BHCT0000951, there's some

whether it's -- I think it is made in life actually. If we look further up the page, first paragraph on that page, the last four lines, it says:

"... he had liver failure related to his carrier status for Hepatitis B and Hepatitis C ..."

So again, that may be an indication which casts some further light upon what Dr Mayne is elsewhere saying about the serious or otherwise nature of hepatitis C at this time.

There's a reference -- we can take that down, thank you -- there's a reference again in one of the documents to Dr Mayne receiving some modest funding, £500, for a piece of work on the immune response for patients with haemophilia. That's from The Haemophilia Society. It's not known what that work then entailed.

Then if we look at BPLL0005964, this is about provision of clinical data and not participation in any specific trial as far as I can tell, but it's an internal memo, BPL memo, 19 April 1991, and it says:

"I attach up-to-date lists of users of products formerly issued from PFL, mostly without charge on the understanding that clinical data would be provided."

Again, we've seen I think an example of this in relation to another clinician. There appears to have

evidence of involvement in a clinical trial, so this is the Concorde trial, and there's a request there by the Medical Research Council for information relating to the patient's death. That's a request in September 1992. Dr Mayne's response, we should perhaps go to this for what it may indicate more generally about her knowledge, is at BHCT0000948.

If we go to the second page, we can see in the first paragraph -- so it's a letter 30 November 1992. She refers to or she says -- apologises for the delay in responding to the letter regarding the patient involved in the Concorde trial. She then gives a detailed description of his admission to the haematology unit.

If we go over the page or rather back a page, these letters are in the wrong order, again she gives further details leading up to the patient's death. If we just look at the third paragraph it says this:

"In summary; severe haemophiliac who was a carrier for Hepatitis B and Hepatitis C who developed HIV illness ..."

And then gives details of that illness.

So again we can see in relation to this patient at least a diagnosis of hepatitis C having apparently formally been made by -- it's not clear I think

been some arrangement whereby some products were provided free of charge to clinicians in return for the provision of clinical data.

Then if we go two pages further on, there's a list of some 52 clinicians, but bottom of the page we see there listed Dr Mayne as one of them.

I want to move next to a separate topic which now postdates Dr Mayne's retirement which is in relation to the vCJD notification exercises. There is a very detailed account from Dr Anderson in her recent witness statement which I'll come to in a moment and it was just one contemporaneous document that I'm going to invite you to look at now, sir.

It's at DHNI0000049_036, so this is a letter dated 22 January 2001. It's from Dr Anderson to a Dr Carson, Medical Director, Royal Group of Hospitals, and this concerns the first notification exercise with which Dr Anderson had any involvement, so the 2001 notification. She provides a useful summary in this letter:

"I am writing to update you on the current situation at the Northern Ireland Comprehensive Care Centre. I have now identified six patients who have been affected with the implicated batch ... this includes two adults and four children."

Then in the next paragraph she deals with the issue of patient notification and says this:

"With regards to the action being taken to inform or not inform patients, as you know there was considerable controversy over whether or not patients should be informed, and if they were to be informed in what manner. As you are aware, a letter was sent from the Haemophilia Society to its members and was received in Northern Ireland on Friday, 19th January."

She encloses a copy of that, and then says:

"I have tried to gauge how different haemophilia centres have approached the problem around the [UK]. The Scottish Centres are minimally involved as they do not use BPL products. The Welsh Centre in Cardiff have informed all their patients (17 last week) by phoning them and asking them to come up to the haemophilia centre, and thereafter informing them with appropriate counselling. In Sheffield, a different approach was taken, following along the lines of Dr Frank Hill, the Chairman of [UKHCDO]. A letter was sent from the Sheffield Children's Hospital on Wednesday and it would appear that the majority of parents want to know if their children have received the implicated batch."

Over the page, again this is in relation to

Sheffield:

"On the other hand, in the adult population only a minority wanted to know."

And there's reference there to information that Dr Anderson had received from Dr Makris. She then says:

"I do know that two hospitals in London, the Oxford Haemophilia Centre and the Canterbury Haemophilia Centre are directly informing their patients.

"After several lengthy discussions with Dr Dempsey, who has the majority of affected Factor IX patients, it was felt appropriate to take the situation forward in Belfast by directly writing to affected patients, all of which now parents of children involved, outlining the situation and asking them to ring Dr Dempsey urgently. The mother will also be informed by Dr Dempsey. It is hoped that this counselling will take place later this week."

Then there's a reference to another adult patient described as being a prominent member of The Haemophilia Society, and then Dr Anderson says this:

"... it was felt both by myself and also by Dr Mayne, with whom I discussed the situation on Saturday morning, that it was essential he was

informed. The patient was counselled by myself and took the information relatively quietly, with the comment that this was probably inevitable for any patient receiving plasma derived blood products."

Then there is discussion about the problem about whether or not to inform patients with antithrombin III who had received the antithrombin III concentrate. And she describes how there are relatively few centres where that arises, the only other identified centre being the Royal Cornwall Hospital.

If we go to the next page she refers to anticipating Department of Health guidelines and says:

"Perhaps it would be appropriate to wait until these guidelines are available prior to informing the patients who have received the antithrombin III concentrate. There are also implications from informing other patients who have received immunoglobulin G, albumin and plasma derived products from this affected donor. This obviously involves UK-wide population.

"I am concerned that I may be accused of withholding information from one set of patients whilst informing another set of patients. This is of concern ..."

And she raises concern about whether that is professional misconduct, and then says:

"At the end of the day I think this is an extremely complex situation. Dr Dempsey and I have chosen to approach the situation by considering our centre on a particularly individual basis."

So that's an account of Dr Anderson's thinking in January 2001. There is, as I say, a very detailed account from Dr Anderson in her witness statement and it covers some 30 or so pages of her statement. I am obviously not going to go through it all now but I will just flag up, if I may, where the relevant passages are and then just look at a couple of them.

So it's WITN4027001. Her evidence in relation to vCJD starts on page 140 and she deals in paragraph 83 of her statement, which runs through to page 144, with the circumstances in which she became aware of possible risks of transmission of vCJD. I'm not going to read through that but that's where she sets out her background knowledge and understanding.

If we then go to page 144, the bottom of the page she's asked the question how and by whom were decisions taken either nationally or locally or both as to information that should be provided to patients about vCJD and as to any steps which should be taken

in relation to patients and their care and treatment. Then she deals with the position at both a national and a local level. Her statement also covers Edinburgh because she moved from Belfast elsewhere and then on to Edinburgh.

So if we go over the page there is then a useful summary on this page and the next of the notification exercise, so we can see at the top of the page, paragraph 84.1.1 she refers to the first notification involving BPL products in January 2001, refers to the proposed approach from UKHCDO, and then the next paragraph she talks about there being a consensus view that patients had the right to be informed of receipt of an implicated batch of product.

If we go further down the page she refers then in paragraph 84.1.3 to The Haemophilia Society letter, and we saw that referenced in Dr Anderson's own letter a few minutes ago.

We see reference in 84.1.4 to a draft letter being circulated by UKHCDO and then if we go -- so that's the 2001 notification in a nutshell in terms of what was considered on a national level.

If we go over the page, she then refers to the second notification involving SNBTS products in November 2002 and gives details of what advice was

received at a national level in relation to that.

Then in paragraph 84.1.7 she refers to a further notification process in September 2004 which, in fact, was completed after she'd left her position as the director of the centre and refers there to the national discussion in relation to that.

Then she goes on to talk about, if we go further down the page, discussions at a local level, and we've seen one example of that in the letter we looked at. So she gives an account in relation to the first notification exercise of local discussions in January 2001.

If we go over the page she gives information about an urgent meeting convened to discuss it. She then gives similar information in paragraph 84.2.2 about the second notification exercise and, again, I'm not going to read through it but we can see that's where it's located within her witness statement and if we continue down the page she refers to there being ongoing discussions in relation to Scottish and Northern Ireland haemophilia doctors group and so on.

If we go over the page, we can see in paragraph 84.2.5 she says:

"As the second notification involved SNBTS product and affected patients in Scotland and

Northern Ireland, it was felt appropriate to inform patients through a notification process in the same manner in both regions and at exactly the same time, with the same letter albeit with minor local modifications to reflect the prior notification exercise in Belfast."

Then she gives further information following that about the 2004 notification exercise and explains, if we go just a little further down, at paragraph 84.2.8, that she wasn't involved in final decisions about the exact nature of the notification exercise in 2004 as she left her post.

Then if we go on to page 150, there is then question 85:

"What was the process at ... Belfast" -- also at Edinburgh, but I needn't refer to that for present purposes -- "for informing patients about possible exposure to vCJD?"

And again she goes through the detail, if we follow over the page, of the procedure that was adopted to identify patients and ascertain what information to provide.

That is a detailed account which continues over the page, until page 153. If we just pick it up at paragraph 85.1.8.5, so the third paragraph down, she

refers to:

"... [recalling] very few telephone calls to the Centre, and I can recall that no patients requested counselling following the letter ... However, at clinic visits, patients did seek more information about the situation in general, and this enabled a general discussion to take place and any queries to be answered."

Then in the final paragraph she says:

"I found, in general, that the majority of my patients did not wish to be informed of an implicated batch in the future. We recorded the patient's wishes in the case notes."

Then there's the BPL antithrombin III discussion again we saw alluded to in the letter from Dr Anderson, and over the page we see details being set out of the procedure followed.

If we go to page 155, we can then pick up the picture in relation to the 2002 notification regarding SNBTS and again there's a detailed account from Dr Anderson about the procedure that was adopted and that continues for most of the following page, page 156. She gives such details as she is then able to on the following page about the notification regarding the third implicated batch.

If we go on to page 158, there's then also a detailed account of how and when patients were provided with information and, as I say, that continues again over a number of pages, and I'm not going to go through the detail of that.

If we pick matters up on page 163 she then, in response to question 88, sets out what information was providing to patients about risks of vCJD at the Belfast Centre and she summarises that on page 163 and over the page on to page 164.

Then if we turn to page 165 she's asked about counselling support and advice and says in paragraph 89.1.1 -- thank you, Soumik -- in relation to the 2001 and 2002 notification exercises she refers to help-lines, counselling being available through face-to-face sessions with herself and the associate specialist should patients wish it. Patients were also giving counselling and support and updates at review clinics and then she also refers to the availability in 2001 of face-to-face sessions of the paediatric centre if required.

Then finally, if we go to page 166, the question is asked at the bottom of the page about measures put in place regarding vCJD at the Belfast Centre from a public health perspective and she begins

to answer, the bottom of the page:

"In January 2001, to the best of my recollection, there was no advice available regarding the public health measures required in relation to the care and treatment of patients who had received factor concentrate ..."

She explains she raised this issue with the Director of Public Health and in the next paragraph she explains it was problematic. She recalls an instance when the dental school at the Royal Hospital site was required to shut for decontamination of surgical instruments.

She refers then to all surgical instruments and ventilators being quarantined for patients who had received implicated batches of product, many of whom had not wished to be informed of their exposure:

"Patients were not able to undergo endoscopy and colonoscopy as the public health risk had not been clearly defined, leading to waiting lists for procedures and delays to diagnosis. From discussion with other Centre Directors at the time, this was a common situation around the UK and not unique to the Belfast Centre."

Again, that accords with the evidence the Inquiry has heard.

She then refers to further revised guidance in 2003 regarding decontamination of surgical instruments and again refers to endoscopy being viewed as a high-risk procedure, so endoscopes were quarantined and reused for single patients. Then says in paragraph 91.1.6:

"With such practical difficulties for the multidisciplinary team in terms of knowing which patients had wished to be informed, and those who wished not to be informed, to the best of my recollection around 2003 I think we took a pragmatic approach at the Belfast Centre to apply the same infection control measures to all the patients. As this involved quarantine of only some surgical instruments this was relatively straightforward. Operating theatre staff would be informed of the need for disposable instruments, and it seemed that these were becoming more commonplace in use."

Then she refers to her recollection about the position in 2004 and then explains again that she wasn't involved in the execution of the 2004 vCJD notification exercise.

So there is then some further evidence in the pages that follow from Dr Anderson about some specific issues relating to the antithrombin III product

notification exercise and various communications that Dr Anderson had at the time but, as I say, it's a very detailed 30-plus page account from her perspective of what happened in Belfast in relation to vCJD.

Sir, in our written note we have sought to summarise Dr Mayne's involvement with UKHCDO as chair in 1990 to 1993. We've referred to her membership of The Haemophilia Society's Medical Advisory Panel, which she seems to have been on from 1982 to 1994, although there's little documentation revealing the substantive content of her involvement, and we've referred to her appointment as trustee of the Macfarlane Trust between 1991 and 1996 and then her appointment to the Eileen Trust from 1993 to 1996.

I'm not proposing to deal with any of those matters now because the focus yesterday and today is upon Belfast rather than some of Dr Mayne's later and more national activities.

We've also in the written note highlighted some documents describing interactions that Dr Mayne had with pharmaceutical companies. We've looked yesterday at some of her exchanges with Speywood.

There are bits and pieces of correspondence, for example, Dr Mayne providing an account of a named patient requiring Hemofil to a pharmaceutical company,

discussions about patients' adverse reaction to Hyate:C, again with Speywood.

There is some evidence of sponsorship by pharmaceutical companies of attendances at conferences. So, for example, there is documentation to suggest that Speywood sponsored Dr Mayne to attend a conference to present a paper on porcine factor, and there is also some evidence of Dr Mayne having a role, perhaps in her capacity as chair of UKHCDO, with an inspection of the Octapharma plant in Vienna in 1992 and attending with Dr Lee, Dr Jones, Professor Peake and Professor Preston to obtain detailed information about the fractionation procedures. That was at the time of an outbreak of hepatitis A.

Those are, in broad terms, the interactions that the documents reveal in relation to pharmaceutical companies.

If we go to Dr Mayne's own statement WITN0736009 and it's -- first of all, if we turn to page 13, paragraph 11.1, bottom half of the page she suggests that the relationship which existed between the centre and the pharmaceutical companies was business-like and professional.

Then if we turn -- if I can find the page reference -- to page 70 she says, bottom of the page,

she's "never provided advice or consultancy services to [a] pharmaceutical company".

Top of the next page:

"... never received ... pecuniary gain ..."

Then if we look at paragraph 117:

"... never received any financial incentives from pharmaceutical companies to use certain blood products."

And then she says at 118.1:

"I believe it became known throughout the pharmaceutical industry that I was unreceptive to gifts. If a company product was in use or if a pharmaceutical company so desired, educational gifts at the centre or extra accessories for the patients were acceptable, i.e. slides, pamphlets and books."

She refers then to getting sponsorship for the meeting on hepatitis C (that's the hotel conference she describes elsewhere in her statement) in 1995 and she says funding was accepted for travel to scientific meetings, either to present a paper or take part in discussion groups.

So that is again an outline of the position in relation to involvement with pharmaceutical companies. It's perhaps relevant to note that, following her stepping down as chair of UKHCDO but whilst sill an

active member, in September 1994 the minutes of the UKHCDO meeting record Dr Mayne introducing a paper setting out a process for Haemophilia Centre Directors to make declarations of interest, which was agreed and it doesn't appear that there had been any such requirement prior to that in relation to UKHCDO rather than local Trusts.

So that's the documentary evidence and the thrust of the witness statement evidence received in relation to policies and practices at the Belfast Haemophilia Centre.

SIR BRIAN LANGSTAFF: Yes. Well, thank you very much. So tomorrow we have Dr Benson.

MS RICHARDS: Tomorrow Dr Benson at 10 am.

SIR BRIAN LANGSTAFF: Ten o'clock. Ten o'clock it is.

MS RICHARDS: Thank you, sir.

(4.28 pm)

(Adjourned until 10.00 am the following day)

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