Friday, 11 December 2020

(2.00 pm)

PROFESSOR GORDON LOWE, continued

SIR BRIAN LANGSTAFF: Once again, in case there is anyone who is watching who has not been watching for the last few days, we (that's counsel, Ms Richards and myself) are in Fleetbank House, a large room, largely empty, with three members of the legal team, three members of the Inquiry staff, including Mary who does the swearing in, and Soumik, whose job is to make sure we all see the right document at the right time.

You, professor, I imagine are still at home?

A. I am, sir.

SIR BRIAN LANGSTAFF: And your solicitor and counsel are elsewhere, as are other counsel for other recognised legal representatives. Thank you very much.

We have I think about 100-odd people watching again, professor, so that's who you are talking to as well as directly to us.

Further questioned by MS RICHARDS

MS RICHARDS: Professor Lowe, I want to ask you next about testing for hepatitis C and the arrangements that were made at the Glasgow Royal Infirmary in that respect. I want to look first with you at two minutes of meetings and then ask you to tell us about the

that took place very soon after that and then ask you about it, professor. So that was 12 February.

Then if we go to PRSE0000999 please, Soumik.

We can see this is a meeting on 26 February 1990 of "Haemophilia Directors for Scotland and Northern Ireland" which was chaired by you and, if we go to the second page, please, and we look at the bottom paragraph, paragraph 6:

"Hepatitis C Tests.

"At a recent meeting of the Regional Haemophilia Centre Directors AIDS Committee a representative of the Medical Defence Organisation was quoted as considering that hepatitis C testing could be undertaken on the same basis as other LFT's (i.e. HIV-type counselling was not necessary)."

Against the background of those two meetings in February, Professor Lowe, can you tell us what you meant, if it's an accurate record of what you said at the first meeting, by saying you wondered if consent should be sought?

A. Yes. I wanted to raise the issue because I don't think the UKHCDO had considered it before and, as you can see from the minutes, I think, you know, some people thought, well, it's just another liver function test". And I thought, well, not really, it's probably

process.

The first minute, Soumik, is HCDO0000271_014.

If we go to the second page, we will see these are minutes of a meeting of the AIDS Group of Haemophilia Centre Directors on 12 February 1990, at which you were present.

We'll come back to this document later for other reasons but if we could go to the fifth page, please, Soumik, and if we could zoom in on the top paragraph -- so the first half of the page.

If we pick it up for present purposes where it says "Dr Lowe thought", so six lines down:

"Dr Lowe thought there was a difference between testing LFTs and testing for Hepatitis C and he wondered whether the patient's consent to testing should be sought. Dr Mortimer said he thought that reliable hepatitis C tests would be available in about a year. At the moment the tests were quite reliable, but it would soon be possible to do confirmatory tests. [Professor] Bloom didn't see why permission needed to be asked for Hepatitis C tests as this was just another LFT. Dr Savidge said that patients were now becoming more and more conscious of what tests were, so he would advise caution at present."

I am just going to look at one other meeting

the same as hepatitis B, where, once you do get a test, you want to think what you say, for example, to patients when you are testing them for hepatitis B.

Now, at that meeting was I think a Dr Ian Simpson and he was from the Medical and Dental Defence Union of Scotland, to which most Scottish trained haemophilia directors in Scotland belonged, including myself. So he, I think, was advising on various matters, but I did ask him at that meeting, I think following that discussion, I said, "Right, I'm the only Scottish Haemophilia Centre Director here and we're having a meeting shortly of the Scottish Haemophilia Centre Directors and it would be useful if you could clarify what you think should be the consent process for hepatitis C."

And I think, to summarise our discussion, he said, "Well, what do you do routinely already?"

So I said, "Well, we do liver function tests as routine and we routinely test for hepatitis B, we've been doing that since the 1970s, and that's monitoring the patients."

And he said, "Well, what do you say to them?"

And I said, "Well, routinely, at annual reviews we say we're testing for hepatitis, we're doing liver function tests, we're doing hepatitis B, so what

should we say when there's a hepatitis C test available on the NHS?"

And he said, "Well, I would consider that on the same basis. You would say: we're testing you for hepatitis B for years and now there's a new virus discovered, hepatitis C, and we now want to test for this because it's extending the monitoring that we're doing of you for hepatitis."

I think the concern at the time generally was, as you know, in the late 1980s that you needed detailed counselling before doing AIDS testing, HIV testing, and I said, "So we don't need to do HIV-type counselling?"

And he said, "No, this is routine hepatitis testing."

And that, I think, was the information I conveyed to my colleagues at this meeting of which you have the minutes, of the Scottish Haemophilia Centre Directors.

Q. Why was it a decision for Dr Simpson of the MDDUS? Wasn't the question of the most appropriate clinical course to take in the interests of patients a matter for your judgment and the judgment of your colleagues?

A. Oh, yes, indeed, and that's why I was raising it for discussion at the UKHCDO and then, of course, at our

Scottish meeting. I think I did say, "This is the MDDUS representative", but I think he attended UKHCDO meetings on behalf of all three of the UK medical defence societies, and in Scotland certainly, his organisation would be the one that we should contact about questions of information given to patients.

I think I did say, "I recognise that some of my colleagues may belong to other defence organisations and you should maybe check with them". So I think we were all of the same mind in Scotland, that that's fine. When we're talking to patients about hepatitis C testing, we would undertake it on the same basis, that you didn't need HIV-type counselling, you just considered it as you would when you were talking about testing for hepatitis B.

Q. Did it occur to you and your colleagues or was there any discussion about, irrespective of what the legal requirements might be, that it might be the right thing, desirable thing, to do some form of equivalent to HIV testing in relation to hepatitis C, not least because of what had gone wrong for so many patients in terms of the way in which they were tested and told of their HIV diagnosis?

A. No, I think all my colleagues -- I mean, I wasn't making this as a recommendation, I was raising it for

a discussion, and I said: what do we think in general as haemophilia directors, not only in Scotland but in England, what should be the process? Because this is something that might arise.

And I think the general feeling was: well, we've been testing for LFTs and hepatitis B since 1970. We tell the patients. They will realise it's in their interest. It is, you know, just trying to clarify what type of hepatitis we're testing for, and what the appropriate treatments for that virus might be once it's identified.

Q. Is it right to understand that the kind of discussions that we've seen in the minutes, particularly the UKHCDO AIDS Group minute, as identifying possibly three approaches to this question. One would be -- which may or may not have been Professor Bloom's view, from the minutes -- just add it to the range of tests, do the tests, and you don't need to say anything to the patient in advance. The second would be treat it like an LFT or hepatitis B test but tell the patient, "We're going to test you for hepatitis C as well now that there's a test". And then the third would be to discuss with them the implications of testing and invite them to agree to testing for hepatitis C, which would be more akin to the HIV counselling process. Is

that broadly accurate?

A. Yes, I think, just looking at what patients -- what haemophilia centres said they did across the 1990s, I think that was summarised very well when Dr Charles Hay was asked, as Chairman of UKHCDO, to outline the generally accepted procedure in 2011. And there was some discussion at that Inquiry between Dr Vivienne Nathanson, who was wondering if there should have been a more AIDS-type approach, and Dr Hay who said robustly no, we were pursuing the same treatment for hepatitis and telling patients about it, it didn't need that type of counselling. And he, I think representing UK or English Haemophilia Centre Directors, said there wasn't a comparison between them, on the basis that AIDS was thought in the late 1980s to be a very fatal and immediate disease, a big social stigma, and that was what influenced the need for pre-counselling and saying before testing, "We realise that this is a very sensitive issue and requires a lot of counselling".

Whereas hepatitis C, like hepatitis B, was on the basis that, well, finally we've got another hepatitis virus, it's important to test for this because we then know what the appropriate treatment would be. If you turn out to be a carrier, you will

need, you know, information about emerging knowledge about what the prognosis is of hepatitis C disease and appropriate investigations, and as and when we think there's a treatment for hepatitis C you will be referred to hepatologists for assessment or for treatment.

We thought that it was -- so I think what I'm saying is my understanding that not only in Scotland but across the UK this was the general approach taken.

And I think, just talking about Dr Hay, because as you know he and Dr Preston were very involved in the early studies of liver biopsies -- and it was Dr Hay's study in 1985 which we recognised was an important contribution because it showed progression of disease in some patients who had repeated liver biopsies.

Dr Hay and Dr Preston, I think, were very involved in production of UKHCDO guidelines on testing for hepatitis C that came out I think from about this time period we're talking about in circulations to Haemophilia Centre Directors in the UK, and then I think a published guideline in 1995 about the management of hepatitis C. Reading these guidelines recently, I see no mention of having to do HIV-type counselling before them. You just did the test and

got on with it.

Q. Yes. You'll appreciate, Professor Lowe that just because something's not in a UKHCDO guideline doesn't mean that it's not the appropriate or proper course.

What was the actual course undertaken at Glasgow Royal Infirmary by you in terms of hepatitis C testing?

A. Well, I and my colleagues thought this was entirely reasonable, so at routine clinic reviews we would go through the lists of tests, as all of -- we're going to do, the routine blood tests, the biochemistry, and then say, "Liver function tests, hepatitis B, and we want to inform you that there's now a test for hepatitis C and we think it's very important that we test for this as well, because, as I've said, there will be specific treatment available and we want to know about it and keep you updated on what the progression of hepatitis C liver disease would be over the years, share that with you and share appropriate decisions". I don't recall any patient saying, "No, I don't want to know about hepatitis C". If they did say -- I mean, fair enough, "I don't want a hepatitis C test", we would say, "Okay, talk to you next time, but we do recommend it."

Q. Which generation tests were used at Glasgow Royal

Infirmary, and when was testing first introduced?

A. Oh, dear. I have to go to my written statement here. Sorry. I think it started with an antibody test, and that became generally available in -- I think 1991 it was approved across the UK, and then that -- let me think.

Yes, so we started with the first antibody test, and we informed patients that if this were positive, it would mean they would be exposed to the virus. But we needed to follow that up with future tests that would be developed, as with hepatitis B, and these would be the antigen tests, and that would show the patient whether or not they were a carrier of the virus. Because as with hepatitis B, a percentage of patients would have been exposed to it, they had an antibody, but the carriers had obviously the risk of progressive liver disease over the years, as with hepatitis B.

So, when the antigen tests arrived, that would be, I think, about 1992/'93. So we were generally using them. And, at that time, if somebody had a positive antigen test, as per the UKHCDO guidelines, it was then recommended that patients with positive antigen tests should be referred to hepatologists for management. As I've said in my written statement, we

then referred all these patients who turned out to be carriers of hepatitis C to the liver clinic, which was run by Dr John Mackenzie initially and then by Dr Morris who set up a very comprehensive hepatitis C service from 1996.

In the meantime, we always gave patients the current information leaflets, either by the British Liver Trust or The Haemophilia Society which explained all the different types of hepatitis, what the tests were, what they meant, and these were regularly updated. So after the -- at the end of the clinic, we would say, "This is the current information for you to read. If you have any questions, do come back and we'll try and answer them."

Q. So is it your recollection that the patients who were tested both with the first generation and the next generation tests, for both tests you spoke to them in advance about hepatitis C testing?

A. Yes, that's my recollection.

Q. Would those discussions or the fact of it having been mentioned to the patient and the patient having agreed, would that be recorded in the patient's records?

A. Yes. So you would put in the case records: "Hepatitis C discussed with patient and test

performed," and then in your letter to the general practitioner, it would be normal practice to include that and say the patient has been tested for hepatitis C and, depending when the dictation was done, inform the general practitioner of the result.

Q. Was the testing, both generation testing undertaken by Dr Follett again at Ruchill?

A. Yes, that's right. So as with the HIV testing, it was the Regional Virus Laboratory. I think Dr Follett initially and then I think he was succeeded around about the mid-1990s, but it was always the regional laboratory that did all the hepatitis testing way back from 1970s with Hep B, then HIV, and then with the Hep C.

Q. Glasgow Royal Infirmary had a large number of patients. In relation to the first generation testing, were all patients tested or only some, and if so, how did you identify which to test?

A. We tested all patients. I mean, there were -- there would always be a small number of patients who had not previously been exposed to blood products, but even they -- we would say to them, "We want to test you for hepatitis C," because from, I think, about 1991, we were starting our previously untreated patient study, which I think you know about. We published the

results. It was very important that we do baseline testing with the patients' consent because the whole point of the studies were to monitor them after first exposure to an SNBTS blood product, and then to establish after some period of treatment that the product was safe; in other words, there was no evidence of seroconversion to any of the pathogenic viruses, and that would include hepatitis C. So all of that would be explained to the patients before their first exposure to a product.

Q. The testing that you described, as I understand your written and earlier evidence, that was undertaken at the routine clinic appointment. There wasn't any kind of special arrangement whereby patients were called in earlier; is that correct?

A. Sorry, called in earlier?

Q. In terms of the arrangements you made for testing your patients, as I understand the evidence you gave in writing and to the Penrose Inquiry, that was done at routine clinic appointments. So you didn't, as it were, the moment the test became available write to all your patients and invite them to come in. As and when a patient came to the centre, the testing would then be undertaken; is that correct?

A. Yes. Once we had the test available from Dr Follett,

we would routinely do it at the clinic. But I think what you're saying is supposing somebody has not been at the clinic then comes in for treatment, one would obviously want to do their routine blood tests, including hepatitis C at that time. So whenever you first saw the patient when the test was available.

Q. Then, as I also understand your evidence, the results were given to the patient -- and I'm talking about the patients coming in regularly -- at their next attendance which might not be for many months; is that right?

A. Yes. The initial tests were antibody tests, and that might be -- I mean -- sorry, we would routinely write to the general practitioner and give the result along with all the rest of the tests. We told patients that it might take some time for the test, and if they wanted -- so we said, first of all, we're not sure -- at the start of it, we said we don't know how long the tests are going to take, but we will inform you at your next visit, and if we think there is anything significant about it, we will let you know or you're very welcome to ring and get your test result.

Q. You referred to telling the GP the test result. Does that mean there may have been cases in which the GP found out that the patient was hepatitis C positive

before the patient had been told?

A. I think -- I'm thinking particularly of patients at a distance, the patients who lived 100 miles from the centre. And I think if it was a remote patient, we would say to the GP, "We may not see this patient for some time, and can you ask the patient if they could contact us to arrange another appointment?"

Q. I don't think that quite answers the question.

Were there cases or might there have been cases when the GP was told the hepatitis C result of the patient before the patient had been told?

A. No, I think when the result came, we would inform the patient. Sometimes a GP would have had the letter before the test was available, let me put it that way, and then if we got the positive result we would write that extra information to the general practitioner, but I think we would also contact the patient at that time, particularly if they didn't have an appointment to come back with near future. So we didn't leave it a long time.

Q. Were patients asked to agree to give their consent to their hepatitis C status being notified to their general practitioner?

A. Well, I think all tests that we conducted we said, "Right, we will include the results of these tests in

the letter that we send to your general practitioner". The only exception to that was, as I think we were talking about yesterday, when we had the HIV tests, and some patients initially, discussing with Dr Forbes, when he and Dr Wilkie were counselling, he said there were several patients who really didn't want the results to be put in a letter to the general practitioner, at least not at that time.

So, apart from that, all results were shared with the general practitioner as would be normal medical practice.

Q. How long do you think the process of testing your existing cohort of patients in the early 90s took? Was it something that effectively took place over two or three years or something that was concluded swiftly?

A. Sorry, the testing process?

Q. Yes.

A. Well, we added it to the routine test, so it was done on every patient who either came up to the out-patient clinic or who was admitted. And then we had a system that if patients were not attending to -- for review, if there had been a period of time, we had a standard letter that was written to the patient, copied to the general practitioner, saying: you have not attended

and it's now been X months and we think that it's important that you come because we want keep you and your blood tests under review. So that was standard practice.

Could I say that at about this time, 1991, when the test became available, we were very keen to see the patients, because we were starting a series of clinical efficacy and safety trials of the new SNBTS products. This was the high purity products -- I think we've sent you documentation about the evolution of these studies -- and were very keen to get all patients seen at the unit, given information sheets about the studies we were going to do, and ask them to read them and give a signed -- written, signed consent to participation in these studies, so that they could -- this would be sorted out before we had to give them their first treatment with the new high purity SNBTS products which were replacing, from 1991 to 1992, the Z8 products which, although virally inactivated, were intermediate purity. So we were very keen to have patients signed up to this.

These information sheets would say: to ensure the safety of these products, we want to make sure that you are tested for -- all tests for hepatitis have been performed before we start these studies.

Q. Typically with a patient who has tested positive for hepatitis C in '91/'92, what kind of information did you tell the patient on informing them of their diagnosis?

A. So we would say that: this is the virus which we think is probably the cause of what we previously called non-A, non-B hepatitis; in other words, it's sometimes been symptomatic in the past, it may have given you jaundice or other symptoms. And then a percentage of our patients, as in all the centres, quite a high percentage of patients have intermittent or persistent slightly elevated liver function tests, and that's what we call non-A, non-B hepatitis.

We said to patients that: this will, I think, clarify the cause of these abnormal liver function tests that we've been seeing. And if you're hepatitis C positive, particularly when it came to the antigen test, that means you are a carrier, and that is by far the most likely explanation of any raised liver function tests you have had in the past.

If patients are repeatedly hepatitis C negative, you would then have to consider some other cause of the liver function tests' elevation, but the hepatitis C testing would very much clarify that you were a carrier of the virus, if you had a positive

antigen test, and that would mean that you needed follow-up by a hepatologist, and careful monitoring of your liver disease.

Q. What did you tell patients, again typically in the early 1990s, about prognosis and the possibility of developing, in what was known by then at least to be a progressive condition, serious liver disease?

A. Okay. So when I became a consultant at the end of 1985, and I think I've mentioned that in my written statement, I sat down with Dr Forbes and we reviewed all the policies and, as the two consultants at the clinic now, what should we be saying to patients about non-A, non-B hepatitis.

So, first of all, because -- the study I briefly mentioned at the start of yesterday's session, Dr Steven, the consultant rheumatologist on the unit, had been reviewing all the patients at the haemophilia clinic, both for their arthritis but also he had been assembling all the information over the years about abnormal liver function tests, et cetera. And he'd also been examining all the patients clinically for any clinical evidence of liver disease, not only jaundice but enlargement of liver and spleen, and he wrote up two papers in 1986, which I think I mentioned yesterday, one is the detailed survey of

arthritis in all our patients and the other was a summary of the liver abnormalities in terms of liver function tests, previous tests for hepatitis B, et cetera.

So we had quite good information generally, so what we would say to the patients is: we've now completed the study and a high percentage of our patients have intermittent or chronic abnormalities of liver function tests. The significance of these in 1985 was that we had quite a good estimate of what the percentage risk was over the next number of years of a patient with non-A, non-B hepatitis progressing to clinical liver disease; that is, cirrhosis.

As I think my evidence to the Penrose Inquiry said, and I repeat for this Inquiry, I would give our -- and Dr Forbes, would give our best estimate from the current aggregate data. And this was based on the Hay et al 1985 liver biopsy paper and the Aledort paper of the same year in America. And putting all that evidence together, we could give a fairly definite estimate that 13 to 15 per cent of patients who had biopsies showed evidence of cirrhosis or, in general, serious liver disease.

So we give them some idea about what the risk of that would be over the years. And we would refine

that over the years. So we would give them an honest estimate of what we thought the risk of liver disease was.

The other thing I think we said from 1985 was that: the study we've done -- by Dr Steven -- all our patients that have attended the clinic have had an examination over the last five years and in none of them is there any clinical evidence of liver disease, but against that we have to predict the future, and we have to, you know, monitor you carefully with clinical examination for liver disease at every routine visit, keep testing the ...

And then, from the early 90s, add on to that that hepatitis C -- and this is what we will now be judging -- or the decision to refer to a hepatologist and giving them the information about the connection between hepatitis C and how that built upon the previous information that we and other centres had on non-A, non-B hepatitis.

I think the phrase I used, and it's in the transcript of the Penrose Inquiry, was something like: This is going to be a long journey. We can't answer all your questions now. But you and I and you and my colleagues are going to be sitting here year by year just giving you the information about how this is

progressing. The more we know about hepatitis C, the more information we'll be able to give you, including what you should do in terms of alcohol use, lifestyle changes and, in due course, if we think -- if we have evidence that you have become a carrier of this, we will get you straight to a hepatologist and they will have specialist follow-up and they will keep you fully informed about not only the development of any disease but what investigation should be done and what treatment should be given. That, as you know, would start with Interferon.

Q. Do you think it's possible that you may have, with some, at least, of your patients in the early 90s, telling them about hepatitis C, underplayed the seriousness of it or told them that it wasn't really anything that they needed to worry about?

A. No, I don't think so. I think what we're talking about yesterday was the evolution of knowledge over, say, 1975 to 1985 before I became a consultant where we were really quite uncertain, and we've had that discussion. But I think definitely from 1985, I don't think Dr Forbes or I or Dr Walker or any of the doctors doing the clinic would underestimate it to say these are the figures and we know they might be frightening, but we can't predict will you be one of

the 15 per cent who in five or ten years' time is starting to get symptoms of serious liver disease, no, but we can assure you we will keep you up-to-date, do all the monitoring that we can and, as soon as we think you need hepatological treatment, we will make sure you get that.

Q. Can I ask you to look at one paragraph in your witness statement. It's WITN3496013, Soumik, and it's page 69. In paragraph 30.12, you refer to having had three or four patients who developed cirrhosis, the majority of whom had either hepatitis B or heavy alcohol use or both, and then refer to it being about 1987 when you saw the first patient who had non-A, non-B hepatitis without heavy alcohol use.

To what extent were you inclined in your treatment of patients with liver disease to assume that problems were due to alcohol consumption as opposed to the consequences of a transfusion-transmitted infection?

A. I don't think we ever made any such assumption. So what I've said there is that -- I'm trying to think about the timescale here. So before 1987, my recollection was that out of our 100 or more patients, we only had three or four patients who developed cirrhosis and there was a ready explanation. These

patients were the small number of patients who had been hepatitis B carriers for many years or heavy alcohol use or both.

So, you know, that -- it wasn't until then 1987 that Dr Forbes and I saw the first patient with clinical -- the first clinical evidence of early cirrhosis and there was no history of alcohol use, no evidence of hepatitis B. So that was the first time we saw a patient getting clinical evidence of serious liver disease from non-A, non-B hepatitis and, as I've said, that number of patients gradually increased over the next decade or two.

Q. But why would you assume in a patient who you knew had been treated with blood products for many years that their signs of early cirrhosis, or whatever it might have been, was attributable to alcohol use or abuse rather than non-A, non-B hepatitis?

A. I -- well, I don't think we excluded non-A, non-B hepatitis because we knew about non-A hepatitis. But if you had a patient who had cirrhosis, then in Glasgow by far the commonest cause was heavy alcohol use. But if you had had a blood transfusion, that was certainly going to be another factor and then, as I say, the few patients we saw had hepatitis B and that was known by that time to be a definite and very

important cause of cirrhosis.

Q. As treatments became available in the 1990s, in particular interferon and then obviously ribavirin, pegylated interferon, and so on, what role, if any, did you have in arranging for your patients to receive those treatments?

A. Well, before interferon and subsequent drugs were even licensed for that treatment, Dr Forbes and I had discussions, oh, right through the 1980s. We had two very good gastroenterology colleagues, Dr Russell and Dr Mackenzie, and we regularly spoke to them about non-A, non-B hepatitis particularly around the time I became a consultant when we had Dr Steven's study. And we reviewed it with them and said, "Well, what should we be doing? Do you want every patient with abnormal liver function tests referred to you?" And we said, "Well, we're probably going to not be of much help." You can do liver scans, but they are insensitive and they don't tell you much and don't indicate any particular treatment. There's no effective treatment.

Dr Sherlock in London and colleagues had shown that steroids were ineffective. There was nothing apart from advice to minimise alcohol, which was a cofactor in any type of viral hepatitis for its

progression. And Dr Forbes and Dr Russell and Dr Mackenzie said there's no point doing these biopsies. We know that there's a high risk of bleeding if you do a liver biopsy on a haemophiliac, even though they have treatment. They were quite sceptical about these liver biopsy results.

They said, "People have done studies on livers at post-mortem, and cirrhosis is a knobbly liver." And he said it depends which bit you hit with the needle. And it's a bit hit and miss, as regards estimating what the disease is. And they never recommended it, so they said, you know, if a patient develops clinical liver disease, or if a treatment becomes available, or if we get more sophisticated means of investigation of the liver, by all means, but we don't think there's anything else you can do.

But by the time we had hepatitis C, they were getting very interested in it and particularly agreed that when the hepatitis C antigen test came in, they should start referring it, regardless of any clinical evidence of liver disease or what the liver function tests were like. Because, as Dr Preston says in his studies and his UKHCDO guidelines, in the biopsy studies, there's no relationship between the patients' pattern of liver function tests and the degree of what

you see at biopsy.

So they were very keen to see the patients, but as I think I said in my statement, that was quite a number to see, so we started referring every patient with hepatitis C antigen to Dr Mackenzie. And he eventually came to see me: "That's lovely, Gordon. I would like to see them all immediately." But the problem is that in Glasgow, like many other cities, there's a huge intravenous drug use problem. So I'm now getting flooded not only with your hundred or so patients with haemophilia but a lot of patients referred by the general practitioners who are drug users who have got hepatitis C.

So that was when Dr Mackenzie and I campaigned very vigorously with the managers to get a new specific post in hepatology, with its number one priority being the patients with haemophilia because my argument to the managers were: these are not the drug users or the alcoholics; these are the people who have got their disease through NHS treatment. They must come first. And they agreed, and they appointed John Mackenzie, and he went and trained for three months in a specialist centre, and then came back and set up a service.

And the joint clinic we established was in the

haemophilia centre. It wasn't the routine clinic day. We had a specific clinic day, and all the patients with positive hepatitis C antigen tests were booked in. And Dr Morris, Dr John Morris -- and he had a hepatitis C sister, Sister Neilson. They were a very good team. So they would see the patients together and also with either our haemophilia sister or the haemophilia staff nurse. So they would all have a very long meeting with the patients, partner, whoever else they wanted to come, and start the very intensive education about hepatitis C, including the treatment options. And, at that time, interferon I think was being licensed and becoming available.

That could only be prescribed by designated consultants in Glasgow, as in most places. It couldn't be prescribed by a haemophilia doctor or a GP. It had to be either infectious diseases consultants or hepatologist consultants. So they arranged as rapidly as possible the antiviral treatment, starting with the interferon, and then over the years as that progressed to double or triple therapy. They provided a very good service, and they gave written statements on their combined haemophilia liver clinic to the Penrose Inquiry, and I'm sure these are available to yourselves as well.

Q. Yes. The question, Professor Lowe, I think you may have answered it but just to check was -- we have access to those statements -- is: what, if any, involvement you had in either prescribing interferon or monitoring the side effects of interferon? Was that effectively dealt with by Dr Mackenzie, Dr Morris and the hepatitis C sister, rather than by you and your colleagues in the haemophilia centres, is the question.

A. No, it was always joint management. So our patients with haemophilia who are hepatitis C carriers, we had to have joint care between the two departments, as we had set up ten years previously for the patients who were HIV positive.

So our haemophilia sister and staff nurse and ourselves, we rapidly learned all the details about the treatment, and we tried to make it as easy for the patients as we could so that when they attended the clinic, they would have all the investigations done, both for haemophilia and for the hepatitis. And then after a few years, because of the increasing load of patients with hepatitis C, Dr Morris and Sister Neilson moved to the out-patient department at the other side of the hospital, and all the patients were seen there. But, again, one of our haemophilia

nurses would go over there, so we always had joint management.

Then a lot of the monitoring, particularly of the double and triple therapy, required regular laboratory tests. So our sister and staff nurse in the haemophilia unit rapidly got together with the pharmacist who was controlling all these anti-hepatitis treatments, what tests were needed when, and we tried to make it as simple as possible for the patients that we would try and do as many of these tests at the appropriate time and send them off for monitoring of interferon at the same time as we were treating them for haemophilia. So it was a highly organised liaison service.

Q. Did your patients at the time of undergoing their interferon treatment have access to psychological support?

A. Yes. Either we or Dr Morris and colleagues could refer a patient for -- patients for psychological support. And the route of contact had actually started with the HIV patients. So quite a good psychological support was set up at the Brownlee Centre, which was where the infectious diseases department had moved to from Ruchill about 1996, and that was not only for HIV but for hepatitis C. And

they had psychologists there, and I think the lead was a Dr Roger Wong whom we got to know quite well because he had been involved with our patients with HIV infection. So there's an established route of referral.

Q. I want to ask you now about a separate topic, Professor Lowe, and that's the question of post-mortems and post-mortem tissue and samples.

Do you have any knowledge yourself, direct knowledge yourself, of circumstances in which post-mortems were undertaken on bleeding disorder patients?

A. I think there are very few. So when I came to the Royal Infirmary in the 1970s, like in most hospitals, post-mortem autopsies were very routine, but then they rapidly, after the introduction of lots of testing, including scans et cetera, those diminished being done routinely. So I cannot remember from -- oh, certainly by the time I became a consultant, any of our patient -- attending any post-mortem of any patient with haemophilia.

Q. Do you know anything about what tissue or other samples from deceased patients might have been held within the Royal Infirmary or any of the other Glasgow hospitals?

A. What post-mortems were done, and I can't remember any patients with haemophilia having one, I think the procedure was that the pathologist would do the autopsy and then select what tissue samples should be stored. I think Professor Ludlam covered this last week. It would be the same procedure as in Edinburgh Royal Infirmary, but you would have to ask the pathologist for details about what studies were done and how long they kept the samples.

Q. I'm going to ask you next a little about research. We have touched on it already, to some extent.

Could we start by having NHBT0000094_043, please, Soumik. This is a 1986 publication in the Scottish Medical Journal. "Liver dysfunction in haemophilia". You are one of the named co-authors, along with Dr Steven and Dr Sturrock, who you've already mentioned, Dr Follett and Dr Forbes.

I am not going to ask you to look at it in any great detail, but we can see from the summary:

"Liver function studied in 139 of 291 haemophiliacs."

And then if we go, I think, to the bottom half of that page, please, Soumik, right-hand column, last few lines, we can see it says:

"We have examined the current prevalence of

liver abnormalities in the haemophiliac population of the west of Scotland and reviewed the liver function of 57 patients prospectively for five years."

Then it says:

"In addition, we have ..."

If we go over the page, to the top of the next page -- if we could zoom in a bit closer -- thank you.

"... carried out immunological tests and related the results to those of liver function to examine the possible relevance of immune factors in haemophilic liver dysfunction."

Then we can see under the heading "Patients and methods":

"139 out of 291 patients known to the Regional Haemophilia Centre at Glasgow Royal Infirmary and the Royal Hospital for Sick Children were seen and examined by a single clinician as part of a study on the prevalence, severity and pathogenesis of haemophiliac arthritis."

And then it goes on to talk about, if we look halfway down that column:

"Information obtained about details of previous hepatitis or jaundice. Blood samples were tested for evidence of past or present hepatitis B infection."

And then various liver function tests are then

described. And then it refers to 57 patients being the subject of a more detailed analysis of liver function.

Then if we look at the very bottom of the left-hand column:

"Liver biopsies were not carried out, but post-mortem histology was available on patients who died of unrelated causes after the clinical study."

And so on.

What was the purpose of the research that's being described in this paper, professor?

A. So, as I think I mentioned yesterday, following the symposium that Dr Forbes held at the end of 1980, and I did mention it to you at the start of yesterday's session, because -- you ended that by saying, but what were patients told about chronic liver disease at this time. So I recalled that in the early part of 1981, at the monthly research meeting of the department, Dr Forbes and Dr Sturrock, the consultant rheumatologist, they wanted to study two of these unsolved problems in the population of patients attending our review clinic: liver disease and arthritis.

So Dr Steven's main topic for his MD thesis was a five-year study of arthritis. So all the -- that's

a separate paper as was published at the same time as this one on liver disease. That was monitoring the patients' joints clinically and radiologically and looking at relationship to treatment because, as you know, the aim at this time was to see which patients in particular might benefit from home treatment to prevent progression of arthritis, and they followed up particularly the patients who were on home treatments at that time.

So Dr Steven would be the clinician mentioned in this "method" section.

So he would go to all the haemophilia clinics the patients were seen not only by a haemophilia registrar but by Dr Steven, and he'd say, "Right, I'm the senior registrar in rheumatology, I'm doing the study, I want to examine all your joints carefully, and we're also interested in looking at, in all our patients, the liver function tests that have been done over the years", and he would give them the update on what was known at that time, which is the question you asked me the other day, you know: what is liver disease? And he would say, "Well, we've been to this symposium and we know it's an increasing problem. That's one of the reasons that we want to monitor not only your joints but we want to keep an eye on your

liver."

So he would be not just looking at the joints he would be looking at -- for enlargement of liver and spleen, which, in fact, never occurred. And then when it comes --

Q. Sorry, professor, can I just stop you there and just ask you, so it was Dr Steven, as a rheumatologist, you are saying, would be advising the patients about the risks of liver disease?

A. Well, the people who would be at the clinic would be Dr Prentice and Dr Forbes, as the consultants, who knew the patients, and then one of their registrars, who at that time I think would be Dr Small and then Dr Greer, and then they would be seen by Dr Steven, and he would say that, "As well as for joints, I'm collecting information about your liver disease" --

Q. Professor Lowe, you say he would say that. Were you actually present? Are you able to tell us from your own firsthand knowledge that he did say that? Or is this your hypothesis?

A. No, because I'm not doing any of these clinics. I'm off doing general medicine and thrombosis clinics during this period of time. But we got regular updates on the progress of the studies at the unit research meetings. Everybody in the department

including me.

Q. Do you know from your own knowledge, rather than what you might assume would be the case as a matter, for example, of good practice, whether the patients who were here being studied were informed and asked to consent to their involvement in these studies in all their aspects, not just the arthritic aspect but in relation to the immune function studies and the 57 patients who were the subject of a more detailed analysis?

A. Well, I never attended these clinics that Dr Steven was doing because I wasn't doing -- from 1980 to 1985 I wasn't at these clinics. But we got regular descriptions of the progress of the study at the research meetings.

Q. And did those --

A. It would be routine for patients to be informed about what treatment they were having. There were changes, as you know, at that time, between some patients being put back on to cryoprecipitate, et cetera. Patients were kept fully up-to-date, as far as I understand, about their treatments, and about their liver disease. They were being examined for liver disease.

Q. Professor, the question is -- and it may be that you are not able to answer it, which is fine. The

question is: do you know, from your own knowledge, what the arrangements were in terms of seeking patients' consent to being part of a research programme? Rather than generally being kept up-to-date about their treatment and their progress but actually being told they were going to be the subject of a study and asking their agreement. Do you have any direct knowledge of that whatsoever?

A. I think the only -- well, this is writing up -- it's really an epidemiological study. It's following all the tests that are routinely done at the clinic, so it is examination for arthritis, the tests are routine tests. The only difference, which I think Dr Steven would tell them, that they wanted to take an extra teaspoon of blood at the blood sample for these immunological tests, and that was tests like rheumatoid factor, anti-nuclear factor, complement, things that rheumatologists do. And this was because one question they are asking is: is it all virus or are there disturbances of the immune system which are relevant to liver disease and its progression?

So that was the only kind of difference in the information collected from the routine assessment of the patient.

Q. So are you saying, in terms of the ethos of the

Royal Infirmary in the early 1980s, first half of the 1980s, when this work was being undertaken, that there was no need to tell the patients that they were being studied?

A. Well, I think there would be. I mean, the default in the Royal Infirmary, which was a very research-orientated hospital -- I mean, many patients from the clinics and patients admitted to the wards were asked to be involved in research studies. So it would be standard practice to submit to the research ethics committee the study, and if they advised that written informed consent as distinct from verbal express consent should be obtained, they would do it.

I mean, I never saw the information sheet but it would say we do want to take one extra blood sample which is not routine, and that would be the immunological test study.

Q. So what was your role in this study?

A. Only reviewing the paper, because I had no involvement in it but, at the end of 1985, when Dr Steven wrote this paper, I'd become a consultant and, as with many of the other studies, I was invited to give it a critical review and add any extra information to the paper. So I'm an author of the paper because I critically reviewed the paper but I was not involved

at the coalface.

Q. Could we just have the paper up again, Soumik, NHBT0000094_043, and go to page 5.

Look at the bottom half of the page. So the acknowledgement, Professor Lowe, reads this:

"We would like to thank Dr MLN Willoughby, formerly of the Royal Hospital for Sick Children, Glasgow, for permission to study his patients ..."

What was the basis for asking the clinician rather than the parent for permission to study children?

A. Well, I didn't know until I read the paper that this study also involved Dr Willoughby's patients at the Yorkhill Hospital, but I see that Dr Pettigrew is one of the authors. So it would be Dr Pettigrew and Dr Willoughby who would be explaining to the children and their parents that the study is being performed and obtaining their consent, I presume. Is that what you are asking about Yorkhill?

Q. Bearing in mind that your involvement at least extended to looking at and critically analysing the paper, it was the particular text written there that had caught my attention, professor, that I was inviting your observations on.

We will move to a second piece of research,

which is the research about immune function initiated by Dr Forbes. We will do it perhaps by reference to the published article.

PRSE0001121, please, Soumik.

We can see this is published in the British Medical Journal in October of 1983:

"Immunological abnormalities in haemophilia: are they caused by American factor VIII concentrate?"

And if we just look at the text:

"Abstract.

"Scottish patients with haemophilia, most of whom had received no American Factor VIII concentrates for over two years, were found to have immunological abnormalities similar to those in their American counterparts ..."

And then various details given.

If we go back to the text, Soumik.

We can see under the heading "Methods", it talks about patients with severe haemophilia A being selected, and then there is detail of the testing that was undertaken.

If we just go over to page 2, please, Soumik, bottom of page 2, last paragraph on the right-hand side, it says:

"Our results, however, argue against a disease vector that is specific to American blood products. In terms of lymphocyte abnormalities, Scottish patients with haemophilia yield results that are consistent with those seen in [AIDS] and in acute viral infection. Whether these abnormalities in the T cell ratios and in the response to concanavalin A are sufficient to render the patients immunodeficient and therefore, possibly, in a prodromal stage of [AIDS], will become apparent as the patients are followed up clinically."

Then we can see on the next page, just the date, if we can zoom in on the top half of the page, Soumik, beneath the various references we can see "(Accepted 25 August 1983)".

So this is a paper submitted to the BMJ or accepted by the BMJ in August 1983. What was your involvement in it, first of all, professor, because we see you again as one of the authors.

A. It's the same thing. It's critical review.

So I remember Dr Froebel presenting this paper at the monthly unit research meetings and, as I think I've said in my written statement, by that time, as part of preparation for writing up my own MD thesis, I'd done a course in medical statistics, and became

quite proficient in that. So, as I said in my statement, I was quite often sought out as a kind of statistician on the unit, as it were, at least the clinical one, to critically review the statistical tests performed and the -- what it told you about the results, not in terms of the discussion about the clinical implications but just: did the data as presented -- could you make a conclusion about this being carefully analysed?

So I think, in return for this statistical comment, they put my name, very kindly, on the paper.

Q. Do you know --

A. Sorry.

Q. Do you know when in 1983 this study commenced?

A. I think it would be sometime in 1982, but I wasn't directly involved.

Q. Was it your understanding or is it your understanding now that the trigger for this study was the reports from the States of AIDS in haemophiliac patients?

A. Oh, I think very much so. That was definitely the background. I think I read some of the -- I told you I subscribed to The Lancet, so that was very much the British journal which was commenting on it. And I remember Dr Forbes again presenting at the research meeting, saying, "This is Dr Froebel and she and

Dr Madhok are going to be doing these studies because we really want to know, you know, if these lymphocyte abnormalities are present in our population of patients with haemophilia. What does it mean? You know, it may be a virus" -- but the other theory -- and I think last week Professor Ludlam gave you a pretty detailed -- information about the thoughts at the time and why they were doing very similar studies in Edinburgh. So I won't go into any detail of that.

Q. Were the 19 Glasgow Royal Infirmary patients who were involved in this study told that their immune functions were being studied because of the risks of or possible risks of AIDS?

A. Well, I think Dr Forbes and Dr Madhok, who were seeing these patients at the clinic, I would expect them to explain. I think that it was fairly well known in general amongst patients with haemophilia and The Haemophilia Society was issuing information. I think there was concern. But, again, I wasn't present. This would be the routine haemophilia clinic and when Dr Steven was doing all the immunological aspects of liver disease tests, Dr Madhok would be saying, well -- in a subset of these patients, he would say to them, "We want to do these tests of your lymphocytes to see if there is any similarity to what has been

reported in patients with haemophilia in America, which might be of importance to your treatment."

Q. So you don't know as a matter of fact what was said to patients but you would agree, as a matter of principle, that the patients involved should have been told of their prospective involvement?

A. Oh, absolutely. So just as I expect that Dr Steven would explain why he wanted to do additional tests that might explain the emerging problem with chronic liver disease, Dr Madhok and Dr Forbes would do the same thing.

Q. If we just have the document back on screen, please, PRSE0001121, and go to page 2, Soumik, bottom of the page.

Now if you just look again at the last paragraph this is saying, isn't it, that the Scottish patients studied is showing results consistent with results seen in those with AIDS, and it's recognising in the last sentence the possibility that these patients may be in a prodromal stage of AIDS.

Do you know where the patients themselves were told that that was what their results showed?

A. Well, I wasn't at the clinic but I do remember Dr Forbes and I having a discussion with the chairman of the local Haemophilia Society and he was regularly

reporting back to Dr Forbes, you know, feedback from the patients, et cetera, and he said, "Oh, we're very interested in these studies", and I think in that they may have been supporting these studies financially with a grant from the Scottish Haemophilia Society, and saying, "Well, we know it's all trying to work out if there will be an increased risk of AIDS whatever its cause, and we're very keen to support this work being done". But that's the only direct memory I have of patients talking about it and saying they knew what it was about and they were very supportive.

Q. Do you agree -- as a matter of principle, as you weren't involved in the actual arrangements, but as a matter of principle -- those of the 19 patients whose results were consistent with those seen in AIDS, and who could possibly be in a prodromal state of AIDS, should have been told that at the time? As a matter of principle.

A. I would have thought so. I think Dr Forbes was asked about this at the Penrose Inquiry and he said the problem was we didn't really know what these meant. We knew there was a change but, as it says in the discussion there, whether that will be a virus or just an effect of having lots of Factor VIII was very uncertain.

Q. Do you know again, as a matter of fact, professor, whether the outcome of this study, which would be known to Dr Forbes by August of 1983, led to any change of approach to the treatment that was provided and the treatment policies applied at the Royal Infirmary haemophilia centre?

A. I think, again, I would quote what Dr Forbes said at the Penrose Inquiry, and I think he said that, yes, we looked at the treatment we were giving the patient. And he said that there was very little use by this time of the American commercial concentrates. Scotland was self-sufficient now in the Factor VIII concentrates. Because of the concern about age, some of these patients -- of AIDS, sorry -- some of the patients had been offered to revert to treatment with cryoprecipitate rather than concentrate just to reduce the number of donors.

So I think all of that was in his mind, generally. Whether he spoke to specific patients about their treatments in addition to the general policy, I do not know.

Q. Is the answer to my question, which is not about what Dr Forbes said to the Penrose Inquiry but is about your own knowledge, that you don't know, from your own knowledge, whether this led to any change of approach

within the Royal Infirmary?
A. No, I didn't.
Q. Then one final study. PRSE0003671, please, Soumik. So if we look at the article on the bottom half of the page, please, Soumik. "Impaired cell mediated immunity in haemophilia in the absence of infection with HIV". Again, you're there as a coauthor, along with Dr Madhok, Dr Froebel, Dr Follett and Dr Forbes and others. And it refers to skin tests amongst other matters. And we can see from patients and methods, bottom of the page, it's a study of 29 patients with clinically severe haemophilia attending the Glasgow haemophilia centre.

If we go over the page:

"Including 12 of 15 patients known to be seropositive for antibody to HIV, et cetera. All patients were examined for features of disease related to HIV."

And then if we just look at the conclusion, third page, please, Soumik, we can see the conclusion:

"... suggests that cell mediated immunity is decreased in patients with severe haemophilia treated with Factor VIII concentrate. This is related to the amount of Factor VIII used. Whether this abnormality is related to risk of infection with HIV or its

sequelae is not yet known."

Now, again, what was your involvement with this study, professor?
A. So no direct involvement. I became a consultant and was doing the clinic from about the end of December. I was aware that the study was going on. My understanding was that Dr Madhok, who performed the study, was obtaining permission from the patients to do the study and explaining that we wanted to know whether these changes in the lymphocyte counts were confined to patients who they now knew had HIV infection, or were they to be seen in the HIV negative patients, in which case one needed to look for another explanation. And the best way to do that was this DMCB test which was a skin test, and patients would have to give consent to this because it wasn't a routine test at that time. And the finding of it, as you can see, is that cell mediated immunity is decreased in patients with severe haemophilia treated with Factor VIII concentrate. This is related to the amount of Factor VIII used in the absence of HIV infection. So they needed to do further studies to find out what the significance was. And as you know from Professor Ludlam last week, they were very involved in Edinburgh in doing similar studies to find

out what was the cause, and Professor Ludlam discussed that extensively with you.

Again, I was only asked to comment on the methodology, the statistical significance, et cetera. And Dr Madhok continued this work for a few years, looking at different aspects that might lead to further explanation.
Q. Were you involved at all with the process of either obtaining patients' consent to participation or in what might have been told to patients about the results of the testing?
A. No, I don't think so. Dr Forbes, as I say, at the time, and he and Dr Madhok knew much more about the immunological aspects and the interpretation than I did.
Q. Final question on the topic of research: you may, as I think is clear from your answers, you listened to Professor Ludlam's evidence last week. I asked him about research on the sexual contacts and household members of HIV positive patients, and you may recall -- I'm not going to put any of the documents up -- that Professor Forbes, in his capacity as Chair of the UKHCDO AIDS Group, had suggested or invited Directors to participate in a survey of sexual contacts and household members. And you will recall

Dr Jones expressed concern about ethical implications.

Do you know whether at the Glasgow Royal Infirmary any such study was undertaken?
A. I think that Dr Madhok and Dr Forbes wrote a letter in The Lancet. Is that available to you?
Q. I don't have the reference to hand. We may be able to obtain it, but we can read what's in The Lancet, professor. So it is really: do you have any knowledge -- particularly bearing in mind that you took up your post as consultant in late '85, and this was a study that was being mooted by Dr Forbes within UKHCDO in the second half of 1985, do you have any knowledge or recollection of whether such a survey or study was undertaken in the Royal Infirmary?
A. So this is a study of HIV positivity in sexual partners of the patients at the Royal Infirmary?
Q. Yes. Sexual partners and household contacts.
A. Well, it was part of the management of these patients that they were advised to discuss with their sexual partners, and then they would be counselled, particularly by Dr Wilkie or by consultants at the sexually transmitted diseases who were much involved in the Glasgow AIDS programme, given information and asked if they wanted to be tested. And I think our report in a letter on the frequency of -- oh, yes, and

at the same time, there was concern about household contacts, nonsexual household contacts. So I think these were done as part of the clinical management.

And I think that Dr Madhok wrote a letter on the numbers of such patients which basically was: of the numbers tested to the time, there had been no evidence of transmission of HIV to sexual partners or to household contacts. I think it was an answer to that. I may have been wrong.

Q. I am going to ask you to deal very briefly with the issue of vCJD, professor, because we have a significant amount of documentation about it. But there are two documents I wanted to ask you to look at. The first is at GGCL0000152_001, please, Soumik.

This is a letter dated 25 October 2002. It's from you to Dr Armstrong, Chief Medical Officer, and you -- the heading is "SNBTS Factor VIII and Factor IX vCJD notification strategy":

"Further to our letter of 25 September 2002, to date, we've had no reply from yourself or from the Banner Committee. It is now eight months since Haemophilia Directors in Scotland and Northern Ireland, having been informed of the relevant batches of SNBTS coagulation factor concentrates, to which a donor who subsequently died of vCJD contributed,

prepared information sheets for haemophiliacs in Scotland who are potential recipients. In the absence of any comment from the Banner Committee, Haemophilia Directors in Scotland and Northern Ireland met at the UKHCDO annual meeting in Liverpool on 10 October 2002 and agreed to proceed to circulate their patients with information sheets we prepared in February."

And then you go on to say there's a proposal to discuss that at the next -- at an annual meeting of the Haemophilia Society in November and then send it to patients.

Now, just pausing there, it would appear from this that there was some kind of delay in the notification process or the information sheets being sent out, and you were writing to express concern to the Chief Medical Officer at the absence of any response to the proposals of Haemophilia Directors in Scotland and Northern Ireland to undertake this exercise; is that correct?

A. That's correct.

Q. Do you know what had caused the delay?

A. I think, on your behalf, I spent some time trying to access the relevant documents back in September and I've outlined for you the best information of the progression of this matter in my written statements.

So very briefly, this was an instance of possible exposure of UK patients to vCJD, and this was notified by SNBTS when they discovered that a blood donor from previous years had been found to have evidence of vCJD at -- sorry, just found to have vCJD, and this applied to several of the SNBTS concentrates used for treatment between '87 and '89.

So we had several discussions, which I've outlined at meetings of Haemophilia Directors, the coagulation working factor working party in February, at which we involved SNBTS as well. And then in January, Professor Ludlam reported that he had written to the Banner Committee. Now, this was Sir Michael Banner's national UK committee which the Government had asked to investigate any reports of this and what should happen to transfusion patients who had received these batches.

Back in February, Haemophilia Directors and SNBTS thought, well, as with the previous outbreak from BPL a year ago involving patients in England, we should prepare press releases and information sheets for patients so we could inform them.

The response we had from the Banner Committee clearly stated that patients should not be contacted until the panel had advised on their individual risks.

And they asked all the haemophilia centres in Scotland for anonymous data on the numbers of vials of the relevant blood products being forwarded to the panel for consideration. And then also in June, we had the annual meeting of Scottish Haemophilia Directors, SNBTS directors and Dr Armstrong who at that time was the Chief Medical Officer for Scotland. And we expressed our concerns to him about the delay, and we said there had been a very timely release by BPL and Haemophilia Directors in the English episode a year ago. We had assumed that fairly rapid information should be provided and what was happening.

Now, my recollection was that Dr Armstrong was very understanding of the desires of SNBTS and Haemophilia Centre Directors to get some action and, you know, when could we release the information publicly and to our patients? He agreed to raise the matter at the next meeting of the UK Chief Medical Officers.

I think what had happened in-between 2001 and 2002 was that following the BPL outbreak, all the UK Chief Medical Officers in the four nations had got together and said, "We don't think patients should be told because there's nothing you can do about -- we don't know what the risk is, and we think that

patients who had received these things should, in general -- shouldn't be told."

Now, we thought poorly of that, but clearly this was Dr Armstrong's position. He said, "Well, I want to discuss with the other UK Chief Medical Officers." So we gave him a list of questions at that time saying, "Look, these are our concerns. Please share them."

Then we kept getting no information until this -- at this meeting in Liverpool that you discussed. We thought, well, look, it's now been several months. We've heard nothing from the Banner Committee. We think we should be open with our patients, both SNBTS as the providers and the Haemophilia Directors who are looking after their patients. And that was when I firstly consulted my Glasgow Royal Infirmary medical director, and he said "Yes, the trust supports you in this action." And I sent this letter to Dr Armstrong, and at the same time I think Professor Ludlam had direct conversations with the Deputy Chief Medical Officer for Scotland, Dr Keel, because Dr Armstrong was on holiday. And we said, "Look, this is the kind of statement we think should be issued to the public and to patients."

Then the response to both Professor Ludlam and

myself from Dr Aileen Keel was that -- her advice was that, yes, Haemophilia Directors should proceed to inform their patients and offer appropriate counselling and thought that instead of statements from the Trust, which we had suggested, it would be better to have a national Scottish information release from the Scottish health department and SNBTS.

So that was finally agreed, what these documents would be, and the letter was sent to patients on 26 November. And I've sent a copy of that letter as well as the press briefing to -- we all send it to all our patients, and the statement was issued on 27 November.

Q. Is this right, Professor Lowe: your understanding of the reason for the eight or nine months' delay that elapsed between you and your colleagues indicating that you wanted to provide this notification to your patients and the notification going out towards the end of 2002 was because of a Central Government and/or Scottish concern or view that patients shouldn't be told, but once you wrote this letter that we've just been looking at, you got a response saying, well, go ahead anyway.

A. Well, we were frustrated about the Banner Committee's delay. Now, we understood that they wanted to make a

risk -- they were considering a risk assessment which might be varied, depending on how many vials the patients had received, but we never received any information about that. And when it got to a stage we thought, you know, this has been almost a year, we should really be sharing this information, and this was our level of frustration.

I think you could ask the relevant departments of health or the Banner Committee -- I don't know if it's still going -- about what was the reason for delay, but we thought that we should get on and tell the patients.

MS RICHARDS: Thank you.

Sir, I note the time, and I am going to move on to another topic, but we could take a break there.

SIR BRIAN LANGSTAFF: We will take a break now until 4.15.

MS RICHARDS: Is Professor Lowe able to come back a little earlier than that?

SIR BRIAN LANGSTAFF: Seeing as it is a Friday, we may want to finish earlier if we possibly can, so what about four o'clock? Would that give you long enough?

A. Four o'clock would give me long enough, Sir Brian.

SIR BRIAN LANGSTAFF: Four o'clock.

MS RICHARDS: Thank you, sir.

(3.31 pm)

(A short break)

NEW SPEAKER:

(4.00 pm)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Professor Lowe, we're going to dot around from topic to topic now because a number of the questions that I am going to ask are just questions on discrete issues that have been raised by Core Participants through their legal representatives.

Could we start, please, with a document on screen HCDO0000278_109, please, Soumik. This was a letter written by you in October 1996 to Dr Ludlam. If we just look at the first main paragraph you say -- it's entitled "Exclusion of employees of manufacturers of treatments for haemophilia from delivery of haemophilia care":

"As you know, I raised this question at the last UKHCDO Regional Representatives Meeting on 16 September 1996. The reason was the recent decision by our Trust to involve employees of the [SNBTS], (which currently manufactures several products for treatment of haemophilia) in Blood Transfusion within the Trust; which might potentially involve them in delivery of haemophilia care. I suggested that this possibility must be expressly forbidden by UK Health

Departments, because it is a clear conflict of interest. An employee of one manufacturer of products for haemophilia treatment is clearly liable to choose their employer's products over those of another manufacturer. It is therefore as much a conflict of interest for such employees to be involved in haemophilia care, as it would be for employees of pharmaceutical companies to have any involvement in a healthcare provider's Pharmacy Services."

Can you assist, Professor Lowe, with what your concern was and what the outcome was of the issue that you had raised?

A. Yes, I can, and I think it's in my written statement at 114. The situation was that Dr Ian Franklin, who has given evidence to you, who had worked in Birmingham, he was appointed the bone marrow transplant director in the Glasgow Royal Infirmary, and then in 1996, the time of this issue, he was appointed as regional director of the West of Scotland Blood Transfusion Service, and at the same time he was given a university appointment as professor of transfusion medicine in the department of medicine in which I worked, and he had a senior lecturer.

So they became my research and teaching colleagues, so obviously I got to know Dr Franklin

very well, and he recognised that in 1996, Dr Walker and I had been including Dr John Davidson, who ran the blood bank -- the three of us had done a kind of one in three cover at the haemophilia service. Dr Davidson in particular covering for us when Dr Walker and I were attending meetings, et cetera.

Now, Dr Davidson became ill at that time and was often off on sick leave for the next couple of years and at this time Professor Franklin kindly offered to participate in cover of the haemophilia unit because he'd had previous experience in Birmingham.

So Dr Walker and I were -- very much appreciated his kind offer but we were aware that in some English centres as well it was being mooted that providers of blood products were also keen to get involved in haemophilia care and, therefore, my concern, and also some colleagues in England, was as you see in the letter. It's potentially a conflict of interest to people who have involvement in haemophilia treatments and their production, which he was, to be ever in a position that he would be choosing what products to use.

So Dr Walker and I, and indeed Dr Davidson, discussed with Professor McKillop, my boss -- and

Dr Davidson was the head of haematology, and we agreed that to avoid any potential conflict of interest we politely declined Dr Franklin's kind offer, and he and his colleague, in fact, continued very impressive clinical research activities in the quite separate field of bone marrow transplantation.

Could I just add that, in addition to what I said in my statement of 30 September, I was listening, of course, to Professor Franklin talking to you a few weeks ago, and I noted in his statement that he had -- sorry, from his written statement to the Inquiry, he had stated:

"In Glasgow I had only one job, running the BMT Unit with some general haematology work. Because I had haemophilia experience I occasionally -- meaning rarely -- provided consultant oversight at weekends or out of hours to enable both of my consultant colleagues with an interest in haemophilia to attend meetings. I had no control or say over what products were used."

Having read that, I sent you a brief supplementary statement saying: I agree with Professor Franklin, it was a very kind offer, explained the situation, and confirmed that Professor Franklin occasionally -- meaning rarely --

provided cover at the haemophilia centre in Dr Davidson's absence. And I agreed that he had no control or say over what products were used. So there was no problem from our point of view.

Q. So leaving aside the position of Dr Franklin or any particular individual, the concern, as a matter of principle, was that an SNBTS employee should, just as with a pharmaceutical company employee, not have involvement in decisions relating to haemophilia care because of the possibility of conflict of interest?

A. That is correct.

Q. Then another document now on a different topic. ARCH0003312_020, please.

This is a document we looked at with Professor Ludlam last week, Professor Lowe, and I just want to ask your input, please.

We can see it is a note of a meeting, 10 February 2000, "to discuss the information required to assist in the examination of circumstances surrounding the safety of SNBTS blood products from hepatitis C". We can see that you were in attendance. We can see also from paragraph 1 there was an outline of the minister's meeting with The Haemophilia Society:

"... the Minister's undertaking to examine the

circumstances surrounding the safety of SNBTS products from Hepatitis C with particular reference to the Society's claim that Scottish patients were exposed to [Hepatitis C] longer than patients in England were."

So that was the context of the meeting.

If we then go on to the fourth page of the document please, Soumik, paragraph 9, we can see here that you are raising the question of whether it's necessary to contact patients to make them aware. There's a response, which is:

"... it should be borne in mind that the information might be used in future Court actions. Professor Ludlam also sought advice on whether ... [there should be attempts by haemophilia directors] to try to identify ... patients whose whereabouts and status were unknown."

And then Mrs Towers says you should follow Central Legal Office advice.

Do you have any reflection, Professor Lowe, on what it was that led you to raise this question, and can you recall what you thought of the response, which appears to be seeking to deter you and Professor Ludlam from undertaking the exercise there contemplated?

A. Okay, so the point I raised first -- because at this

A. Yes. I think the process that we used, which was co-ordinated by Dr Khair, who was the secretary to the Scottish Haemophilia Directors, was that we would collectively do all we could to identify which patients had been treated with this product at that period of time. I think we recommended that we should contact UKHCDO database in addition to our own notes, and I think we spent a lot of time trying to identify what patients were treated with what product at that time and to help with identification of episodes of hepatitis.

Q. Do you know -- if you don't, please say so -- how many patients of the Glasgow Royal Infirmary were identified as a result of this exercise and how many may have subsequently been identified later?

A. I think we discussed this briefly yesterday, Ms Richards. I think from my memory, we had two patients treated in this time period; I think one with cryoprecipitate, and one with the SNBTS concentrate at the time.

I think my impression was the minister and the Scottish Executive were very keen to get a quick answer, so I think we did what we could in the time permitted, and then you'll have seen the report of the Inquiry.

period of time, the directors of the haemophilia centre were Professor Forbes and Dr McDonald, and I thought at least -- you know, while as current directors, I and my colleagues were very happy to help, but I wondered if they should be involved in helping to assess information about it. That was a simple enquiry.

As regards Mrs Towers' thoughts, I didn't think it was relevant that this could result in future court actions. I just thought it would be courtesy to inform our predecessors. And I don't quite understand Mrs Towers' point that haemophilia directors should follow CLO advice on whether further investigation was necessary. I think it's irrelevant. I think that we were -- all accepted that the patients requesting this enquiry had a very valid case and we should be investigating the patients and the batches as a matter of course, regardless of any -- I don't think we ever took CLO advice. I think we just got on with the investigation to establish the facts.

Q. So as far as you're concerned, at the Glasgow Royal Infirmary, did you do what Professor Ludlam is here asking about? Did you undertake a look-back at the Royal Infirmary to try to identify patients who had not hitherto been contacted and tested?

Regarding subsequent investigations, it may have been our successor, Dr Tait, possibly on behalf of the Penrose Inquiry may have got further information, but I don't know.

Q. Next document: HCDO0000271_014, please, Soumik. Go to the second page.

This is the minutes of the same meeting we looked at earlier, Professor Lowe. We looked previously at the discussion about testing for hepatitis C and patient consent. I want to look at this now for a further purpose.

So we can see it's meeting of the AIDS group of Haemophilia Centre Directors. Can you just assist us, first of all, with this: what was the purpose and function of the AIDS group?

A. So I recall the AIDS group was set up by my predecessor, Dr Forbes, in January of 1985 specifically to hold regular meetings to address the issues merging about AIDS in haemophilia. And then I succeeded Dr Forbes as a member of this. And by this time, as you can see, it's pretty well every major haemophilia centre is represented at that time, and I represented Glasgow Royal Infirmary.

Q. Would it be fair to say that the purpose of the AIDS group, or at least a main purpose of it, would have

been to try and ensure the best possible care and decisions taken in relation to patients who had been infected with HIV in consequence of their treatment?

A. Yes.

Q. Now, if we look further down this letter, we can see in paragraph 1 (b) the Chairman welcomed Dr Simpson, joint secretary of the three defence unions. And then we can see there's a prolonged discussion which starts at the bottom of this page under the heading "Litigation":

"Dr Savidge raised the point that one member of the AIDS group was acting as an expert on behalf of the Plaintiffs and wondered whether it was acceptable for him to take part in the Group's discussions on Litigation and the Defence of the main statement of Claim. Dr Simpson said this was an awkward position. It would be less awkward if the expert was advising on the 'generic' action. Dr Aronstam said he was the person referred to. He had not been asked to be a medical expert witness for the plaintiffs. If the group felt it was awkward for him to be present he would leave the meeting. He pointed out some other directors were in a similar position and more might be in the future. In reply to a question Dr Simpson said he could no reason for Dr Aronstam to leave the

prove very awkward if an expert witness for the plaintiffs was present."

Go over the page:

"It was pointed out that Dr Jones was acting for 5 Plaintiffs in Scotland. After further discussion it was agreed the Chairman would write for advice to the Consortium of Defence Lawyers and to the Central Legal Office in Scotland."

Then there's a discussion about, in the next paragraph, the health authority's defence to the Statement of Claim:

"Discussion followed as to how the lawyers would put together a generic defence in the light of the varied practices at Centres. It was agreed that Barbara Simpson's letter was helpful and that the Chairman would ask her to [find] further reports ..."

And then if we go to the bottom paragraph:

"Dr Lowe suggested that Dr Simpson's advice should be sought regarding the Haemophilia Society's request for information on hepatitis. Was hepatitis likely to be another item for which haemophiliacs would seek litigation and was it advisable for the Haemophilia Centre Directors to continue to collect data? Dr Simpson said it would not be advisable for the Directors to stop collecting data as they had

meeting."

Dr Rejman, so he is a representative of the Department of Health, I think, professor; is that right? Dr Rejman?

A. That's correct, yes.

Q. He talks about cases of plaintiffs in the Wessex region being held back and would follow on after lead cases:

"Dr Aronstam said he knew of at least two cases involving his patients which were going ahead as lead cases; it was news to him that Wessex cases were being put back. In view of the feelings already expressed he thought he should leave the meeting for the time being while the matter was discussed. After Dr Aronstam had left the room the situation was discussed further. Several Directors said they would feel nervous discussing details of their clinical practice with a representative of the plaintiffs in the room and some suggested that the Health Authorities' defence lawyers might be put in an embarrassing position. Professor Bloom thought that Health Service Solicitor's advice should be sought. Professor Preston thought the problem went beyond HIV and that discussion of liver disease in view of the Haemophilia Society's request for information might

already started to do so. Dr Hill pointed out that hepatitis was not a new thing; only the test was new. After further discussion, Dr Simpson agreed that the Haemophilia Society should not be given hepatitis data."

Then there's an expression of concern about Haemophilia Society representatives hearing Hepatitis Working Party reports. Then the discussion we looked at earlier, which I don't need to go over again. Last paragraph on this page:

"Dr Aronstam returned to the meeting and intimated in view of the obvious concerns of his colleagues that he would resign from the Group. The Chairman expressed his regret and asked Dr Aronstam to consider the matter further before making a final decision. The Chairman would write to the Defence Lawyers to get their response to the situation and would let Dr Aronstam know the reply. Dr Lowe asked the Chairman to take advice from the Central Legal Office in Scotland regarding Dr Peter Jones' involvement in the cases in Scotland. This was agreed."

Then I don't think I need to read the rest of the discussion which goes on to talk about other matters.

Professor Lowe, first of all, why was a representative of defence unions being invited to the AIDS group in the first place?

A. So, clearly, this is -- a major focus of the meeting is the impending litigation which was, I think, particularly going on in England. And I assume that, as part of that discussion, they would want one of the defence union representatives, and I think at that time it happened to be Dr Simpson, to reply to any questions that the directors had.

Q. To what extent had the AIDS group, established by Professor Forbes to discuss matters relating to the interests of patients, become a meeting to co-ordinate a defence to the HIV litigation?

A. Well, I had replaced Dr Forbes going to back to about 1988, so only really had direct involvement from that time. My memory is that this was unusual because the usual discussions at the AIDS group meeting, I think, were very much what you said at the start: what information should we be collecting, and what would be the general advice on UKHCDO about management of AIDS ?

So this seemed -- I was, I think, surprised that this was all about litigation. But, anyway, I turned up and listened to the situation. So I don't know why the Chairman would ask the lawyers to get

involved.

But with regard to what's up on the screen at the moment, it seemed to me, as a Scottish representative, that this seemed to be mostly about events and difficulties going on in England. And I thought that it would be appropriate that if there was discussion with legal representatives, as regards Scotland, there should be some communication with the Central Legal Office in Scotland, recognising that Scottish law, as you know, is different from English law. So I was really there as a slightly puzzled observer and thought that, as a Scottish representative, I should just make sure that the communications were joined up between England and Scotland.

Q. If Dr Aronstam and Dr Jones had a different perspective to offer because they were, for example, providing advice to expert reports for the purposes of litigation, would it not have been important for all Haemophilia Centre Directors to understand that different perspective, rather than simply co-ordinate a unified defendant response?

A. Yes. So I think a recurrent theme of the UKHCDO was that they should be very active in involving all the haemophilia centres because all haemophilia centres

would be involved in litigation, whether it be for HIV or hepatitis. And I think that was part of the point I'm making here was: could we make sure that all the haemophilia centres, including the Scottish ones, whose representatives didn't go to this meeting, and I think it was Dr Ludlam from Edinburgh and myself or Dr Walker from Glasgow, and I thought that it would be appropriate for this committee to co-ordinate with all the haemophilia centres across the UK.

Q. Why were you asking the chair, Dr Rizza, to seek advice from the CLO regarding Dr Jones' involvement in Scottish cases? What had that got to do with the CLO or, indeed, with the AIDS group?

A. Just for information, really, that these were the -- this was the -- these were the legal actions going on. I didn't know of any cases in Scotland being adjudged by Dr Jones at that time. This was news to me. I hadn't heard about this. All I wanted to do was to make sure that the Scottish Haemophilia Centre Directors and the appropriate legal office which represents NHS in Scotland should be kept involved in these discussions.

Q. Can we go to the previous page, Soumik -- bottom of the previous page. If you look at the last paragraph, why were you seeking the advice of Dr Simpson, the

secretary of the Medical Defence Unions, on whether or not to provide information on hepatitis to The Haemophilia Society?

A. I thought that as he was there, as he'd been invited to the meetings, I thought that the AIDS group should be discussing with their collective Medical Defence Unions, of which I think Dr Simpson was the representative at the time, his views on behalf of the medical defence societies. I wasn't proposing any particular course of action. I just wanted it discussed.

Q. Someone, and it may or may not have been you -- the minutes read as though it's you, but the minutes may not be particularly clear in that respect -- is posing the question about whether Haemophilia Centre Directors should continue to collect data. It appears as though what is being said is: collecting data might lead to us being sued; therefore, we shouldn't collect data. Is that the view that's there being expressed?

A. That would certainly not be my view. I think it was very important that we should continue to collect data on every aspect. That was what we did routinely. And, you know, it was certainly not our centre's practice to stop collecting data. Why should we? The main problem emerging at this time, as we have

discussed, was non-A, non-B hepatitis and the emergence of hepatitis C as a test, and it was clearly very important that we should collect all the data that we could and give that data and information to our patients.

I don't think this was anything I was advocating. I think you're quite right, minutes are difficult. There are general discussions, and I don't recall saying -- ever suggesting that we should stop collecting data.

Q. If we go to the top of the next page, the third and fourth line, there is, however, it would appear, a decision or an agreement by Dr Simpson that data on hepatitis won't be given to The Haemophilia Society. Why was it decided that hepatitis data should not be sent to The Haemophilia Society?

A. Well, it puzzles me because we were always very clear that all information on hepatitis in general and on their own results should be given to the patients. I don't see -- I'm not quite sure about the extent of involvement by the Haemophilia Society at that time. I don't know if this was English phenomenon.

I mean, in Glasgow, we had very regular meetings with the local branch of The Haemophilia Society, and while obviously we couldn't give their

representatives individual patient data, we were very happy to say what our process was and that such data was being collected. And, indeed, all this hepatitis data was openly published at regular intervals by UKHCDO in their regular reports.

Q. You see, Professor Lowe, it could be said and certainly patients reading this might think that this comes across as doctors, the Haemophilia Centre Directors, clubbing together to exclude those who might have a different view, Dr Aronstam, query Dr Jones, with the Department of Health, Dr Rejman, to try and defeat patients' attempts to obtain compensation.

Do you have any observation to make about that, professor?

A. Our policy was always to be very open. We told our patients what data we were collecting. We told them that it was being collated and discussed by UKHCDO in the patients' interests. I can -- I'm puzzled about this story about hepatitis data. I'm sorry, I've no further thoughts about that.

SIR BRIAN LANGSTAFF: It reads, Ms Richards, as though this was a group of people who regarded themselves as being under attack in litigation. Can you just remind me who was the defendant in the action which was then

ongoing in respect of HIV?

MS RICHARDS: Primarily Central Government.

SIR BRIAN LANGSTAFF: That's what I thought. Indeed, one can see, if one goes back to please 3, please, Soumik, there was a specific question which makes it absolutely clear, I would have thought. Dr Ian Simpson, who was the Scottish Medical Defence Union representative, made it clear that medical staff would not be sued. That was quite clear. That's plainly referenced to the current litigation. And Professor Bloom asked if they could be sued at a later date and, of course, that is everyone's right to sue if they wish. And Dr Simpson gives the appropriate reply.

Can you help, professor? Did Dr Simpson say, well, if you're asked to give your expert opinion, you must give it. You should co-operate. And if it's your honest opinion, you should do so, and you shouldn't be excluded from a group of others who appear, if they are excluding someone, possibly to be clubbing together in defence of not themselves but the Government?

A. Well, I have to say, Sir Brian, I was quite mystified at this discussion. I wasn't really aware at this time of the actions that were going on in England, and

all of this was kind of news to me at the meeting, and I think I was really trying to seek clarification as to what was going on and what were the issues.

I would certainly not approve of any over-defensive reactions. I think in our Scottish haemophilia directors meetings, of which I'm sure you have the notes, we were always very clear that we should do what we can in Scottish centres to collate all the data across Scotland and discuss it and to communicate regularly to our patients in Scotland what was going on at the Scottish Haemophilia Society meeting. So I think -- I was puzzled at the time and I'm no clearer 30 years on as to what the issues were.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: I should say, of course, also health authorities were defendants -- some health authorities -- defendants to the action.

SIR BRIAN LANGSTAFF: Yes, that I thought was the case. But it certainly wasn't -- it wasn't the UKHCDO, was it, or individual doctors?

MS RICHARDS: No.

A. Could I just come back on that?

So I think the situation's quite different in Scotland, as it often is. So we don't have health authorities, we had health boards in Scotland.

SIR BRIAN LANGSTAFF: Yes.
A. And those were collectively represented by the Central Legal Office and the name's on the tin. They co-ordinated all the legal and defence issues across Scotland, and that was the reason why, at UK meetings, I would just religiously point out that Scottish law was different and the organisation of the NHS and its legal aspects was different in Scotland.
MS RICHARDS: Moving to a separate topic, Professor Lowe, you referred in your evidence on Wednesday to a paper from Professor Markova of the psychosocial benefits to child and adult patients of home treatment. Can I just check with you the paper to which you are referring.

Could we have RLIT0000305, please, Soumik.

If we just look at the top half of the page, we can see it's a 1983 paper, "The haemophilic patient's self-perception of changes in health and life-style arising from self-treatment", Professor Markova Dr Forbes and others. Was that the paper to which you were referring, professor?
A. Yes, it is.
Q. We can see from the date it is 1983. Would you agree, therefore, professor, that this isn't going to tell one anything about how patients might have viewed

home treatment if they had known at the time, for example, of the risk of infection with AIDS?
A. I agree.
Q. Thank you. Can we then, please -- I don't think we need to put it back on screen, but you will recall we spent some time yesterday, professor, considering the letter of 8 January 1985 to which you and Dr Forbes had appended your names and signatures.

Did you consider at the time, or do you consider now, that putting your name to a letter when you couldn't verify its content or accuracy because you weren't at the time working at the haemophilia centre, does that or did that, in your view, give rise to any ethical considerations?
A. Well, as I think I made clear, this was Dr Forbes' letter, and I was given very little time on a busy day to look at it. I think Sister Campbell and I said: okay, if you want to send this out, we're happy to look at it. But we had only I think about half-an-hour to look at it.

I think Dr Forbes was asking me as a friend and a colleague -- he had been supervising my studies in thrombosis over many years -- he just wanted some help. Not really with a detailed critical analysis, because, as you say, I had not been involved in the

studies and the information. I think he just wanted me to look at it and say could I be added as a cosignatory, as a contact in the case that patients rang up and wanted to talk about it.

I knew from our recent experience with that unfortunate AIDS patient, I knew something about AIDS, and I knew the impending availability of routine tests and I just offered to help.

In retrospect, it may have been a mistake to sign that but, as I said, I think it was a draft that was going to down for discussion at the AIDS Committee and I'm really not sure if that letter was sent out in that format.

In contrast, the April letter, when I was told that I was going to join a consultant and be involved in due course with AIDS counselling and testing, I was happy to sign it as a kind of introduction that I would be becoming Dr Forbes' co-consultant.
Q. You have told us about the model of how treatment was arranged in Glasgow, in the sense of bleeding disorder patients being looked after -- with certain exceptions -- by physicians in the Department of Medicine, such as you and Dr Forbes. We've heard elsewhere of more typically a model of haematologists, some, not all, of whom are from an essentially

pathological background. Why had Glasgow developed a different model from the model elsewhere? Is it just an accident of history or were there particular reasons for it?
A. I think, as I tried to say in my outline of the history, it very much started with Professor Douglas at a time when haematologists were physicians, who were usually general physicians, with an interest in haematology, supported by a haematology laboratory. And then, with the appearance of Dr MacDonald in 1962, building up a department of haematology at a time when clinicians were now training both as physicians and as laboratory haematologists were developing.

But the arrangements in Glasgow Royal Infirmary was that these people all trained together. Dr Forbes and Prentice stayed as physicians, Drs Davidson and Walker joined the Department of Haematology. But they all knew each other and they all collaborated well, and that was the situation that continued.

The particular advantage of our department of medicine was the involvement of rheumatologists, because that's the main problem in haemophilia. And we always provided a very co-ordinated service with our rheumatology colleagues, as I've described repeatedly.

So basically when -- so Dr Prentice moved off, Dr Forbes was then co-director with Dr McDonald, and when he moved to Dundee, I met with my haematology colleagues to say, "Well, you know, do you still want me as haemophilia consultants", and they said, "Yes, indeed we do, because you've been very involved over the past year or two with seeing the patients, counselling them about AIDS and you and your rheumatology co-consultants have been extremely important in running the centre". The centre is based on the unit and the department of medicine, and they were entirely happy that I should continue and, indeed, to replace Dr Forbes as a co-director, because we then had a team that was three haematologists, Drs McDonald, Davidson and Dr Walker, and myself, and Dr Sturrock in rheumatology, and within a short period of time Dr Madhok was appointed a consultant. So we had a service which provided comprehensive haemophilia care.

I've taken care to point out to you that at no time would I or my predecessor physicians directly order blood products. That was all, by law, done by the haematologists. But we collaborated closely together and that seemed to work well.

Q. You told the Inquiry over the last couple of days,

when talking about information provided to patients, that as a result of the sign in the centre about hepatitis and the conversations that were had by or between patients, that hepatitis was, as you put it, the talk of the steamie.

Was information of the nature spoken of by Drs Triger, Underwood and Thomas at the 1980 symposium shared with patients?

A. Yes. So as I said just an hour or two ago, following -- well, Dr Sturrock was actually at the meeting, and he and Dr Forbes immediately afterwards, as I understood it, said: right, this is emerging information on the severity and the future problem of non-A, non-B hepatitis, and how can we collectively do something about it? So, as I've just been saying earlier, that was when Dr Steven started coming to the clinic, carefully examining the instance and development of arthritis, and at the same time collating all the information on liver function tests, et cetera, over the years.

Now, as I said earlier, I was not present at these meetings, at the clinical reviews, but these were regularly reported at the unit research meetings, and all I can say is that I thought a lot of information was given to the patients. But I wasn't

there.

Q. Would you accept, as a matter of principle, that information of that nature was material to the patients' decision-making as to whether to accept treatment or not?

A. Yes, and at these review clinics I recall it was standard practice for Dr Forbes and Dr Prentice to regularly discuss what treatment the patient was having and any implications for change, such as, for example, in 1983, some patients going back onto cryoprecipitate.

Q. Now you have referred in the course of your evidence, and you refer in your written statement a number of times, to the "collective response" that was provided to the Penrose Inquiry in relation to the provision of information or availability of information about hepatitis.

Now, I'm not asking you about the contents of that document, professor, but about, really, its existence.

Did it not occur to you that a collective response could lead to one person's recollection being influenced or distorted by others?

A. Well, I think that as haemophilia directors in Scotland, we had very close relationships and we had

regular meetings. I think that at the Scottish Executive Inquiry -- and we've been discussing these letters from 2000 -- we were asked collectively could we gather together information as to over what period of time and at which haemophilia centres information about risk of hepatitis would be given. So we were directly asked by the Scottish office to assemble that information. So that was what we did then.

Then for the Penrose Inquiry, we discussed at the Central Legal Office if it would be useful to follow that exercise and try to collate, particularly from retired colleagues, what information they would have provided in previous years. Because, in particular, what the Penrose Inquiry was asking was: before patients were first treated, you know, at that time, what would be said to patients or parents about hepatitis risk? And for those of us who had only been working in haemophilia centres in recent years, we thought it was only fair to see if we could circulate previous directors, saying: have you any -- I mean, we couldn't all be called to the Penrose Inquiry -- have you any recollection of what would be given for the information of the Inquiry?

Q. Professor, isn't the fallacy of a collective response that it assumes that there was a universal practice,

that every centre did the same thing, and thus obscures differences and variations between different centres and different clinicians?

A. Well, I think Lord Penrose himself commented on this at the Inquiry, and it will be in the transcripts of the Penrose Inquiry. He said he was a bit uncertain about this process for the very reason that you give. So he preferred to concentrate on the individual statements that were given by myself and other witnesses. And I can understand that.

I think -- but I think it was a useful exercise just to -- I mean, just to collate the information. If the Inquiry wanted to accept that, fine, and that if it didn't, fine. But we thought it's something that we've been asked to do in repeated inquiries, in 2000, in 2010, for Penrose, and now. But I accept that the Inquiry may not want to accept it for the very reason that you give.

Q. Was the objective --

SIR BRIAN LANGSTAFF: I don't think we have asked --

MS RICHARDS: We haven't asked for it --

SIR BRIAN LANGSTAFF: -- for that, have we?

MS RICHARDS: No, we haven't.

I'm not sure Lord Penrose did, because he said it was inappropriate in his report to rely upon it for

his understanding of what happened at the Glasgow Royal Infirmary. But that's a different inquiry. We haven't asked for any collective response, no.

SIR BRIAN LANGSTAFF: There's a world of difference between a collection of responses, each of which is individual, and a collective response, which by definition is not.

MS RICHARDS: Yes.

A. Yes, I'm sorry. You didn't ask for it and I'm sorry you got it, but that's --

SIR BRIAN LANGSTAFF: That's -- you don't need to take it any further. I have said what I have had to say.

MS RICHARDS: Just picking up then on, again, some evidence you gave I think yesterday or the day before about treatment and choice of products.

First of all, you told us, I think, that Dr Davidson, when a new batch of factor concentrate arrived in the blood bank, would check it to see if the Factor VIII which it contained was what it advertised. How did he do that?

A. He would make up a vial, as I understand it, and check out that the number of units in the vial was what it said on the label. And that, I think, from experience, was that there was variation, whether it be SNBTS products or commercial products. And he felt

that it was part of his responsibility, as director for blood products laboratory, to run quality control.

I was trying to find if he ever wrote this up as a paper, but I remember him giving it as a presentation to the effect of the importance of quality control in a local blood products laboratory.

Q. You talked again yesterday or the day before about, in the case of inhibitor patients, who might need specific products, a joint decision being taken between you or Dr Forbes or whoever the physician might have been and Dr Davidson, or another in the blood bank, as to what product to use.

In relation to non-inhibitor patients, who presumably would have been the majority of patients requiring treatment, was the system that, effectively, the patient got what was on the shelf, and what was on the shelf had been decided by Dr Davidson?

A. No, I think there were always frequent discussions on what should the policy be of the haemophilia centre. As I said at the start, the haemophilia centre wasn't just the ward 3 Department of Medicine centre that the severe patients came from. The haematologists by tradition continued to look after and regularly review many of the milder patients, those who didn't have joint disease, and were quite happy to continue coming

to the blood clinic run by Dr MacDonald, Dr Davidson and Dr Walker, and remaining under their care.

That really only changed when Dr Walker joined me as co-director and we decided that we should try to unify the service, particularly because at that time we had the emerging problems of how to manage AIDS, which the mild patients didn't have, but increasingly it was discovered that some of these milder or moderate patients had hepatitis, so it seemed entirely appropriate to bring them into the system and have the contact with the haematologists.

So there were always discussions about what treatment should be had, and my point is that it's only the haematologists who can prescribe and order products. It is not the physicians. Clearly, it's important that the physicians, like Dr Forbes and Prentice initially, and then myself, should be involved, so that we could have input as well, but the decision, by law, had to be made by the haematologist.

Sorry, if you just look at the minutes of the UKHCDO meetings, and indeed the Scottish haemophilia directors' meetings, which were started in the early 1980s and initially were chaired by Dr McDonald, there was always discussion amongst all the haemophilia doctors in Scotland, whether they be haematologists or

physicians, about the general policies of Scotland, which was important, because SNBTS was the default supplier of products, and then to collectively share our experience. And when it came to the use of commercial products, that again very much involved discussion at a Scottish level, hence the importance of these meetings, because if -- take the case of inhibitors. You have a very expensive commercial concentrate -- I mean, the cost of the porcine and the activated prothrombin complex concentrates, that was an enormous cost. And it was important that general policies be agreed at a Scottish level because a small health board, like from Aberdeen, Dundee or Inverness, they couldn't afford to have one expensive haemophilia inhibitor patient because they would, you know, have an enormous cost to a small health board with limited capacity. So it was very important to have a Scottish policy.

And then I think from about 1988, through the coagulation factor working party, for which you've had documentation from Professor Ludlam, who was the chairman of it, that we had an arrangement whereby there was a co-ordinated policy across Scotland on the purchase of commercial products. And that allowed us to spread the cost of these products across the whole

of Scotland.

Q. In your evidence yesterday you referred to Dr Forbes having been working on AIDS solidly for two years by late 1984. What work were you referring to?

A. His interest in the subject. Sorry, the work. He was widely involved in discussions with UKHCDO colleagues. His interest was evident, that he was the chairman of the AIDS group which we've just been talking about, of UKHCDO, and he initiated the greater Glasgow AIDS information and policy group. So it really became his main interest from 1983, in terms of getting information, setting up collaborations, and he was also, I think, in quite close touch with American colleagues. He had been trained by Dr Ratnoff, in Cleveland, who kept in touch with him, and he kept in touch with his colleagues about the emergence of information in the States. So it was, I think, his main interest.

Q. Given all that and given the research we looked at earlier which first resulted in that October 1983 publication which recognised the possibility that the immune function results could be an indicator of an early stage of AIDS, why did it come, as you reported in your evidence yesterday, as a surprise or shock to Dr Forbes that the test results he got back from Gallo

in 1984 were positive?

A. I think, as I said yesterday, my impression of his thoughts at the time was: well, we had had to use some commercial product at the Glasgow Royal Infirmary centre, firstly for these inhibitor patients where there was no alternative, there's nothing made in Scotland or the UK that could treat these patients and, secondly, because the efforts of SNBTS mean that we were pretty well self-sufficient in Scotland by 1983.

I think that was the time when he thought, well, at least we're only using the Scottish concentrate now, rarely have to use the commercial. And I think he was hopeful that that might have solved the problem because AIDS had not yet entered the Scottish donor pool. Well, I'm sure you know what Professor Ludlam's response was when he got his results that all his patients who had been treated with SNBTS concentrates, a large number had become positive. I think it came as a great shock.

Q. I want to ask you next about reporting hepatitis reactions. If you had a patient who had an acute hepatitis reaction to a factor concentrate, what was the process in terms of reporting that to the manufacturer, whether that be SNBTS or

a pharmaceutical company; was it reported and what information would be provided?

A. So, firstly, it would -- well, if there was a clinical event, like a patient becomes jaundiced, it was standard practice to investigate that case of jaundice in somebody who had had a blood transfusion.

I can remember from the mid-1970s when I started, Dr McDonald marching across and saying, "Right, let's have all the information about the patient, let's have the tests, we're going to check the products, and we must get that very rapidly to SNBTS, as the manufacturer". And it was important to contact the public health/infectious diseases people for investigation. So that would be investigated.

Q. Over what -- my question was about reporting to the manufacturer. Over what period of time, as far as you can recall, was it the practice of the Royal Infirmary to report an acute hepatitis reaction to the manufacturer? Was that always the position from 1975 onwards?

A. Oh, I think before that. I think.

Q. I put it at 1975 because that's when you arrived, professor, rather than asking you to look back before your arrival.

A. It was my understanding, as a medical student, that if

somebody got jaundice and had had a recent blood transfusion or blood product transfusion, it was very important for that to be reported by whoever, general practitioner, hospital doctor, to the public health department. I mean, hepatitis B at least was a notifiable disease. It was a legal obligation to report to the -- well, within a hospital it would be reported to the haematologist, the blood bank locally, and they would ring up the -- well, if it was -- say, it was plasma, cryoprecipitate, they would report it to the Regional Blood Transfusion Service in whichever part of Scotland it was, and then, if it was a concentrate centrally prepared by the PFC, the Protein Fractionation Centre in Edinburgh. So it was very important to rapidly report it, for the very good reason that if -- they could trace the donor if it was single unit plasma cryoprecipitate, or, if it was a batch of concentrate, they would trace all the donors and try to work out what the source of the problem was.

Q. Do you know, again whether at the Glasgow Royal Infirmary in the time that you were there, if there was a batch which was identified as having caused such a reaction in a patient, was there follow-up by the Royal Infirmary of other patients who'd received

a batch implicated in possible hepatitis transmission?

A. Yes, that would routinely be done by the -- our haematology colleagues in the blood and blood products laboratory and by SNBTS or the alternative manufacturer. There was a very rigid system about what had to be done.

Q. Did that system encompass telling the patient who had received the batch, or patients who'd received the batch or been given it for home treatment?

A. Oh, absolutely. You would have to say to the patient, "You've probably got this through blood transfusion, and we're telling you." And, well, if you have jaundice, you obviously have to treat any symptoms of the jaundice. Most of these patients, from memory, would be immediately transferred to Ruchill Hospital or the appropriate infectious diseases ward, and there they would be informed about the risk of infecting other people. And during the acute jaundice, there would be strict management of blood and body fluids, and then any sexual contacts would be followed up and tested as well. It was a standard procedure.

Q. Forgive me, my question was not sufficiently clear. I wasn't talking about the patient who had the acute reaction but other patients who had received the batch but not, or at least not yet, reported any reaction,

would they be proactively contacted to ask them to bring the batch back in or to be told to look out for signs of jaundice or the like?

A. Yes, that would be my understanding. That would be arranged by Dr Davidson and colleagues.

Q. Do you know whether it was routine for the Royal Infirmary to send details of clinical reactions to blood products and patients' ALT levels to UKHCDO, to Oxford?

A. So, as I understand it, UKHCDO from the start of its database in, what, 1970 or whatever, routinely collected information on jaundice, and that was produced in the regular reports. If it was asymptomatic transaminase-itis, as we used to call it there, I think that took a bit longer before being systematically, collected. And I think it would be some time during the 1970s, but, you know, that was before my time. I think the dates, you'd want to ask UKHCDO.

Q. Do you know -- again, if you don't, please say so -- what reports were made of viral hepatitis as a notifiable disease to the chief administrative medical officer, in respect of Glasgow Royal Infirmary bleeding disorder patients in the period from when you began there, 1975 to the early '90s?

A. The Chief Medical Officer, you would report it to the -- you would report it -- well, through the process, as I've described, of Blood Transfusion Services. And the notification of hepatitis would be to local the public health department.

Q. So the chief administrative --

A. *(Overspeaking)*

Q. To the chief administrative medical officer of the local area health board I think was the requirement, but that doesn't matter, I think.

The question is: do you know how many reports were made of viral hepatitis from 1975 onwards, in respect of Royal Infirmary bleeding disorder patients?

A. I couldn't tell you the number because, as you know, I wasn't regularly involved in clinic reviews or anything until I became a consultant.

Q. I asked you yesterday or the day before about record-keeping systems. Do you know whether records were held separately from the type of records you've described under the name of research? So research records relating to patients.

A. No. I think they were all -- every patient had a folder within the filing cabinets, and in that we tried, as I said, to always keep the patient's entire case records if possible but as a fail-safe because

those would go off to surgeons or other things from time to time, and we always ask for those to be returned. We had a kind of file of the basic details of the patient so we knew exactly who they were, what they had, and what to treat them with as they attended as emergencies.

The position with research was that any relevant consent forms or information sheets would be put that into that file, as far as I know. There would also be files for keeping track of studies. The ones I recall are when all the haemophilia centres in Scotland were doing trials of clinical efficacy and safety of the high purity SNBTS products in the 1990s. Each centre would keep a file of the patients enrolled into these studies as a study file, if you see what I mean, so that could be reviewed. SNBTS wanted to collate the numbers and things from these trials, and those would be kept in a study file as well as in the individual patient files. That was my memory.

Q. So if you had, for example, by reference to some of the research that we looked at earlier this afternoon, professor, the studies by Dr Froebel, or the rheumatology study, or the immune function study, the data that was collected in relation to individual patients that was being analysed for the purposes of

those studies, might there be separate files -- call them research call them study files, whatever you will, but separate -- patient data, patient-identifying data held separately from the core patient records in the haemophilia centre?

A. So, for example, the laboratory studies. Are you talking about the T cell subsets, that kind of --

Q. Well, any of the studies that we've looked at.

A. There would be a file of the collated results for analysis -- patient number 1, patient number 2, et cetera. The study investigator would obviously keep a file of the results for analysis for the period of the study.

Q. So does that mean there might exist in the Royal Infirmary, or indeed in Ruchill, or wherever the study was being conducted, specific test results, for example, relating to individual patients that exists outside of the haemophilia centre records?

A. Well, after the study, I think the rule was that the investigator would keep the file of the study results for a period of time, certainly up until publication, and then I think it was good laboratory practice to hang on to those files for a period of time. But eventually, the results of these studies would be destroyed, as with any other documentation.

Q. Did you in December 1975 see the World in Action documentary? I'm sure you know which documentary I'm referring to.

A. No, I didn't because didn't have a television at the time, but it was in the newspapers, obviously; there was some publicity about it. And I think it was referred to -- sorry, what was the date of that?

Q. December 1975, I think. I hope I've got that right.

SIR BRIAN LANGSTAFF: Yes, I think 8 December.

MS RICHARDS: 8 December 1975. Thank you, sir.

A. '75. So I think, as I said, you got the programme about symposium I attended at the Glasgow college, but that was maybe --

Q. That was September.

A. That was September, right, yes. So it wouldn't be mentioned then. No, I think I read about it in the newspapers, and obviously it was discussed, you know, just, "Oh, what about these commercial blood products?" And I remember Dr Forbes and Dr Prentice saying, oh, yes --in fact, Dr Forbes, I think, was asked this at the Penrose Inquiry and he said, "Yes, I thought it was shocking." And I seem to recall him saying that, "Oh, well, better make sure that any commercial products that are ordered by the haematologist are not that kind of product," or words

to that effect. So there was talk about it.

Q. And then can I ask you -- nearly there, professor. Can I ask you about something in your statement? If we go, please, WITN3469013 and go to page 48. If we look at the top paragraph, paragraph 16.2, you talk there about the combination of DDAVP and the response to injury:

"... (which raises levels of Factor VIII/von Willebrand factor) often allowed us to not have to give blood products."

I just wanted to ask you about what you say there about the response to injury.

How does the response to injury work, and does it work in a similar way to the desmopressin itself?

A. It's independent of the desmopressin. So response to injury phenomenon was described in Glasgow Royal Infirmary in the 1930s. It's a metabolic response, but one of the components of the metabolic response is that the endothelial cells, which line blood vessels, respond by raising levels of von Willebrand factor, which is an endothelial product, and that's the carrier protein for Factor VIII. And that whole complex of both of these things goes in -- rises in the blood by somewhere between 50 per cent and up to 300 per cent; it's highly variable according to the

individual and according to the level of injury.

So the point is that if you have somebody with mild haemophilia, then if they say have a 10 per cent level of Factor VIII or a von Willebrand factor, their response to injury could put that up to between 15 and 30, but highly variable. So it was important if you had somebody with mild haemophilia and, say, an injury to get a baseline level and then give the injection of desmopressin and then assay the pre and post desmopressin levels, you could find, not always, that the combination of injury and desmopressin actually allowed the patient to have a reasonably haemostatic level and allow us not to have to give blood products.

So the point I'm making is that if you have a patient without injury, desmopressin doesn't give you that double benefit. But if you have response to injury, that might help, and that might allow you to carry on with desmopressin, rather than to have to use a blood product.

Q. Does that response to injury, as you've described it in your statement, rely upon the patient being conscious or aware of the injury, or is it the body's own response, as it were?

A. No, it's the body's own response.

Q. Then if we go on to -- no, we'll go back to I think

it's page 14 of your statement, paragraph 8.4.9, you describe here the use of tranexamic acid. And we look at the top of the next page, you go on to talk about how:

"Tranexamic acid was shown to be effective in minimising blood loss and hence minimising blood and blood product use after dental extraction and other types of minor surgery in patients with mild or moderate haemophilia."

So this is a series of questions I have been asked to ask of you, professor, by interested Core Participants.

Would the infusion of tranexamic acid with a clotting factor product, whether that's fresh frozen plasma, cryoprecipitate, or concentrate, reduce the amount of clotting factor product required?

A. The more important thing is that tranexamic acid, which was usually given orally, so you could give it before the dental extraction; it didn't have to be infused, that was shown in these randomised trials by Dr Forbes and colleagues in Glasgow but also in other studies in Oxford and London -- those were the two big trials that were done at this time -- that -- I mean, tooth extraction was great because you could see exactly if it was working or not. So the patient

would be kept in hospital, monitored, and the -- if you read these papers, it says that the procedure was to give tranexamic acid, watch the patient, and often it worked. So the standard practice would be to give a five- to seven-day course, and then just watch the patient initially, and then discharge them and say come back if you get any bleeding and, in fact, the study by Dr Forbes had very careful documentation of the quantitation of bleeding.

So it had a very dramatic effect on these minor patients, that in many patients you didn't have to give any blood or blood products and, by implication, you reduced hepatitis risk.

Q. For a patient in respect of whom you've judged that you can't justify on tranexamic acid, would the combination of tranexamic acid and a clotting factor product potentially either enhance the effect of the clotting factor product or allow you to use less of it?

A. Well, what we used to do in patients with mild haemophilia and von Willebrand's disease was to give both tranexamic acid and desmopressin. So you are giving two synthetic drugs, and you crossed your fingers and hoped that that would allow you not to have to use a blood product.

Q. But was it ever used in combination with blood products, I think is the question I've been asked to explore with you.

A. I'm sorry. Yes, it would make sense because you are quite right, you would hope that the blood product required, the dose of it, would be less than if you didn't give tranexamic acid.

Q. The last question I have, professor, is this: what lessons do you think have been learned by you and your colleagues at the Glasgow Royal Infirmary as a result of the infections and, indeed, in many cases deaths of patients treated there in the '70s and '80s?

A. Well, looking back, as I think many of us does, it was a tragic emergence of transfusion-transmitted infections. It must have been heart-breaking for my colleagues, my predecessors Dr Forbes, Dr Prentice, et cetera, to see it emerging. I and Dr Walker from the late '80s/'90s were in the position that we ourselves never prescribed these products. But, nonetheless, anybody in our situation watching first the HIV epidemic, but then the double whammy was hepatitis, and that was very tragic because these are patients who have suffered with the risk of AIDS, and then they think, well, at least I haven't got that. And then you've got hepatitis and this slow burn virus

which has been there for years but, you know, it's now becoming clinically evident. That was heart-breaking. That was heart-breaking to watch.

We tried our best by building up a team of the hepatologists, the ID colleagues, our nurses, social workers, psychologists. We made every effort to provide safer treatment, and I think in Scotland we succeeded in providing virus-safe treatment quite quickly. But it was very sad to watch, and we recognise that across the whole United Kingdom many patients and their families have questions about their treatments, and I think I and my colleagues hope your Inquiry will answer them, and we wish the Inquiry well.

MS RICHARDS: Professor, thank you. Those are my questions, sir. Do you have questions for Professor Lowe?

Questioned by SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: Just a couple of short questions arising out of some of this afternoon's exchanges.

First, you can educate me a bit. Talking about the injury response and desmopressin, my understanding is that desmopressin works, in effect, by multiplying the effect of whatever Factor VIII there may be in the bloodstream by two to four times the amount.

The injury response, that presumably also liberates the Factor VIII protein which is already there, does it, in some respects? How does that -- the question is this: do the two, that's desmopressin and the injury response, are they multiplicative in effect, or are they additive?

A. It's a very good question, and as a clinical scientist I often think, you know, how I would have tried to do that. I think probably I would have addressed that question, had we had it earlier, by measuring a very sensitive measure phase reaction called C reactive protein. And our laboratory became very interested in that and its evaluation as a risk predictor for thrombosis and that kind of thing.

The experiment that -- well, no, the study, should I say, that should have been done is: every patient who came in with mild haemophilia and an injury, it would have been very instructive to measure serial C reactive protein levels and correlate that with the extent of the Factor VIII response, and then on top of that to try and measure the effect of the desmopressin response, and that would give some quantitative answer to your question. I don't know. There's no doubt they had an additive effect.

SIR BRIAN LANGSTAFF: The second question isn't

a question, really; of just borrowing from your expert knowledge for a moment. It's about the question of the testing which was done.

You mentioned that Dr Forbes may have been surprised when he got the results back in October/September of 1984. Two questions arise out of that. Would you have expected the study which was reported by -- which you told us about this morning -- reported in the BMJ in, I think, it was August 1983 dealing with T cell levels and ratios, that might have alerted someone, I suppose, to the possibility that patients treated with Scottish concentrate or commercial concentrate, in either case, might be on their way to getting AIDS.

A. I think that's right, Sir Brian. Yes, and it's been a recurring theme. You know, what was AIDS due to? The discussion of both the Froebel paper in Glasgow and Professor Ludlam's parallel experience in Edinburgh was: what are the possibilities?

I was very interested, actually, in Professor Ludlam's comment last week, because I hadn't thought about this before, and he said: I think I've only just realised that the -- probably the main cause of these low -- these abnormalities in T lymphocytes -- and you mentioned earlier this paper

that Dr Madhok did, saying the HIV negative patients also had this phenomenon, so it wasn't HIV, what was it due to?

I think Dr Ludlam probably told you the answer last week. He said: I've only just realised that the Factor IX patients have got a completely different preparation of concentrate, which did not have immunoglobulin levels. They never had these abnormalities. It was only the Factor VIII patients. And it's probably the immunoglobulin content of the concentrate, which was quite high, which was responsible. So it may take 30 years to work out the answers to these questions, but I think that was probably it.

I would ask the question: suppose it had been the other way round, suppose it was the Factor IX concentrates and the minority of patients, who had haemophilia B, who had all the abnormalities, and the Factor VIII preparations for whatever reason had no immunoglobulins. We would have never seen these abnormalities. It's one of these questions with the retrospectoscope to say: well, we didn't know the answer then, and it may have taken us 30 years to realise the answer now.

I think the point I'm making is that, suppose

we had very pure concentrates in those times, which we didn't, we wouldn't have seen these changes in lymphocyte count, and maybe we would have realised that it was definitely a virus even before HTLV-III was discovered.

SIR BRIAN LANGSTAFF: I'll come back to that in a moment, but the thing which has been puzzling me a bit is this: if a test is done and a sample is sent off for a test, you might expect a result back. You might know what result you would like to see but the whole point of the test is finding out what the result is, isn't it? I mean, that must be logical, otherwise why would you test, if you already know the answer?

A. Well, you're testing to see what, in UK patients with haemophilia, what changes you might see --

SIR BRIAN LANGSTAFF: I'm sorry, we're at cross -- I'm sorry for stopping you, I don't mean to be rude and cut across you, please, but it's just I'm thinking now of the -- what's puzzled me a little bit about the reaction of Dr Forbes -- because you have described how, when he got the test back, he spent quite some time really thinking about how on earth to manage the consequences of the results which had come through, and you have told me how he had to formulate the involvement of counselling and draft a letter and so

on.

If he sent off samples for a test, what has been puzzling me is why he didn't expect that they might come back with a result which showed that some were positive and he'd have to deal with that, and prepare for it in advance.

The point about asking about the 1983 study was that that might have given him all the more cause for thinking, well, there might just be something going on here. Because at that stage he wouldn't have given the explanation which Professor Ludlam gave me last week or so: because he wouldn't have known it. He would just have seen an amber light, if not a red one, warning him that there might be something up.

So I've been wondering, did he not contemplate beforehand what he might do if the results came back as they did or something like it? You can help me with that. Did he ever mention to you or were you aware that he might have been thinking before the results came back as to what to do if they did show a problem?

A. So can I be clear, Sir Brian, you're talking about 1983 and the results of --

SIR BRIAN LANGSTAFF: I'm talking about '84, the tests coming back showing there are positive HIV infections,

sero-positivity in a number of patients.

The question is, really, the samples are sent off from stored sera to the laboratory, Gallo's laboratory, they come back, there is shock and horror because they are positive. The question really is why didn't you -- not you, personally, but why wasn't it anticipated that that might happen? Because that's the whole point of testing. And all the more so -- this is where 1983 comes in -- all the more so because there might have been a red flag flying or a warning, amber light, however one describes it, from the year before, given the results of the T cell study in August.

So the question for you, with that introduction, is: did Dr Forbes give you any indication that he had, in advance of the results coming back, thought about what he might do if they were positive?

A. I don't know, Sir Brian, because, you know --

SIR BRIAN LANGSTAFF: Can you remember anything that he said which might indicate that he had thought about it?

A. No, I didn't. So, as you know, I was working on another unit, I was on summer holidays, so I knew a bit about AIDS in general but the first I heard

about Dr Forbes getting the results was him saying, "Right, we've got some results back and can you come and meet with Dr Melbye and discuss the paper that we're going to put together."

So during that time, when he said, "Right, I think we should send the samples off", I had no interaction with Dr Forbes, I didn't know what was being done. So I can't tell you what he was thinking at that time. All I know was he said, "It's bad news, we've got these results, and I'm trying to struggle what to do with them". And we discussed at length yesterday the ethical problems that he faced, particularly -- I mean, I was there when Dr Froebel said, "You do know that this not a test that you can provide reliable clinical information", and I think I saw a moment when he thought: oh my God, you know, I've got the information, but Dr Follett tells me -- there's no way, as a local clinical virologist, he could defend a clinician giving an unreliable result, a false positive or a false negative.

And he said, "What we all have to do is to get a reliable test but, meantime, go ahead and, you know, say that we've done the study, there is this public health aspect, as we have to, you know, change the non-heat-treated concentrate ASAP to prevent any

further things" -- and that was the important thing -- "and you have to communicate that there's a risk now for patients in Scotland and advise them about precautions with blood, sexual partners" -- you know, that's the public health imperative, as I said yesterday. That was very clear.

The difficulty then, which I think Dr Forbes addressed very quickly, was to encourage Dr Follett to get a reliable test as soon as possible. As everybody does. It wasn't just Glasgow. As I said, Dr Tedder, at this AIDS meeting in February, you're -- read the minutes, he says, "Oh, my test's not very good either". I mean, he was concerned -- Dr Craske was concerned. He said these are not tests that are reliable. And that was a bit of a problem.

So when people say, as the newspapers do in this Inquiry, patients should have been told immediately, well, that's difficult when you have a situation where a reliable test is still coming along. You can give a general message, but it would be devastating to be told, "It's okay, you're HIV negative", and then a few weeks or months later to be told, "I'm sorry, it's positive", or vice versa. I mean, there are consequences to that.

So I think that in diagnostics the clinician

has to be very aware of the limitations of a test.

And I think that also gave Dr Forbes the window of getting an experienced counsellor in our centre to intensively focus upon speaking to the patients about AIDS tests, and particularly focusing on those patients that Dr Forbes knew to be positive. Because he wanted to start addressing the subject of them -- preparing them to think about the test and then getting the fresh samples done for the validated response.

So I think -- I can hear what you're saying, Sir Brian, but I think the correct ethical decision that Dr Forbes made was not to instantly ring up the patient and say, "A research test is positive but it might not be positive"; I don't think that would have been appropriate medical practice.

SIR BRIAN LANGSTAFF: Thank you very much. That's all I ask, Ms Richards.

MS RICHARDS: Sir, I should have said Mr Bowie, who represents Professor Lowe, has indicated to me he doesn't have any questions for him.

Professor Lowe is there anything that you wanted to add?

A. No, nothing to what I have said already, thank you.

MS RICHARDS: So, sir, that concludes for today.

In terms of the timetable for when we resume, I can indicate what the first week is going to be.

SIR BRIAN LANGSTAFF: First, let me just say something to Professor Lowe, because you deserve our thanks.

We've invaded your home. You have given us -- in your, if I may describe it, your chatty way, you have illustrated or enlivened perhaps, with anecdotes from your personal history and those around you -- an insight into what happened during your time in Glasgow and your best efforts to tell us what you may have picked up at times when you weren't really concerned with haemophilia care. And you've given us a huge amount of detail. And you're an enthusiast, I think, for detail, such when you can remember it.

So thank you for that and for allowing us to come into your home and take your evidence from there. It's been three days, three half days, perhaps a bit more than half days possibly, but thank you.

A. Thank you, Sir Brian.

MS RICHARDS: Sir, so in terms of when we resume in January, because today concludes the hearings for 2020, we resume on 12 January, when we will hear evidence from Dr David Bevan. That's the Tuesday of that week.

On the Wednesday, 13 January, there will be

a presentation by me in relation to the Manchester Haemophilia Centre and on the 14th, the Thursday, we will hear from Dr Janet Shirley.

We had previously scheduled for that week a presentation and possibly evidence about haemophilia treatment and care in Northern Ireland. That will now be in the week of 29 March 2021, when there was a presentation on the Belfast Haemophilia Centre. There will be evidence called from Dr Gary Benson. It's possible that there may be further evidence. We're still making some enquiries in that regard.

In relation to the timetable in between, there are still some --

SIR BRIAN LANGSTAFF: I will say something about that in a moment.

MS RICHARDS: They will be published on the website in due course.

SIR BRIAN LANGSTAFF: Thank you very much.

This has been the last day of hearings for this year, and like so much in the New Year period, it's a chance both to look back and to look forward.

It's now two and a half years since the Inquiry began. It would have been great if I had been in a position to present its report before 2021 begins. Not a week goes past without my remembering that speed

is important, but I promised also to be reasonably thorough and I would hope that, whatever your perspective on the Inquiry, you can see for yourselves that the Inquiry has been and is being just that.

Without the time taken in preparation and the evidence given in writing and orally, often deeply moving, often troubling, always valuable, the Inquiry would not have been able to ask the questions Ms Richards and her team so searchingly have done over the past three months. The evidence of one clinician is not always easy to reconcile with that of another, or the documents, or the evidence of those infected and affected. Like all of us, they are people. They have different ways of looking at what happened and different abilities to address it when recalling the past. But overall a broad picture of what happened and why is slowly beginning to emerge for me and a foundation for concluding what might have been done is gradually being laid.

Thank you for your patience so far through the current pandemic. Many of you will have wanted to see witnesses give their evidence in person rather than on a big screen, and I've little doubt that many of you would have welcomed the collective comfort of meeting in Fleetbank to hear that evidence. Witnesses too

have said they would rather be here in person. You know I would have preferred it. But we've done what we could so far as the restrictions have allowed it.

So much for looking back. What about the future? Well, I hope that from January it will be possible to hear more evidence in person. Indeed, you will see that the timetable, some of which Ms Richards has outlined, envisages this. Obviously, we may have to adapt for the whim of the virus.

That evidence will continue to come from haemophilia doctors, and then towards the end of January we will hear from the expert group of medical ethics. They may have had something to reflect on.

In February and in March, we shall take evidence on The Haemophilia Society and trusts and schemes. In late March, on Treloars school and, as you just heard, in the Belfast Haemophilia Centre. Counsel team will also give a presentation on the smaller haemophilia centres.

After Easter, we plan to take evidence from campaigners and then Government witnesses, including ministers and civil servants, those who had responsibility for decisions taken at the time within Government who can best shed a light on the events

this Inquiry is charged with investigating.

Looking further ahead still to the autumn, then we will be scrutinising the evidence about the blood services and pharmaceutical suppliers. Infections transmitted by blood transfusions will come to the fore in many of those hearings.

But, as always, the hearings are just the visible tip of the Inquiry's work. The great bulk of the work continues until the hearings begin again in January, even while this Inquiry room stands empty, though you will, I am sure, understand that there are one or two days or so during the Christmas period when no-one is likely to be at work.

Just to emphasise the sheer scale of the investigation. More than 14 million pages have been reviewed for potential relevance. This material has come from over 600 document providers, including international, archives, trusts, haemophilia centres and Government bodies, as well as from individuals. The documents stretch back to the 1920s. There is more yet to come but throughout be assured I am conscious of the passing of time.

Finally, let me turn from past and future to present. Christmas is an enjoyable time of the year for many but it can be a very difficult time for those

who have lost loved ones or are struggling with the difficulties of infection, especially this particularly challenging year which has, more than most, brought the realities of infections home to people. I hope that whoever you are, you are able to make the best of this holiday season. I'm sure you will join me in wishing all involved in this Inquiry, in whatever way, a better 2021.

Thank you.

(5.41 pm)

(Adjourned until Tuesday, 12 January 2021)

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