Friday, 16 December 2011

(9.30 am)

PROFESSOR GORDON LOWE (continued)

Questions by MR GARDINER

THE CHAIRMAN: Good morning.

MR GARDINER: Good morning, sir. We have Professor Lowe again.

Professor Lowe, you have previously given evidence to the Inquiry but today you are giving evidence about the C5 topic. That's right, isn't it?

A. Yes.

Q. Perhaps we could just have a look at that to remind ourselves what it is. We see that this is the topic which is about the information given to patients or their parents about the risks of non-A non-B Hepatitis and the severity of the condition before their treatment with blood or blood products; the tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products; and the information given to patients who might have been infected, or who were found to be infected, and their families.

So it's very much to topic to do with information between doctors and patients.

Could we have a look, please, at the collective

response, [PEN0180649]? Perhaps, Professor Lowe, you could explain to us what this document is exactly?

A. Yes, indeed. Well, we have had discussions amongst past and present haemophilia doctors in our regular meetings' at the Central Legal Office, and when we came to considering how to approach this topic, the discussion focused on the number of doctors and nurses, all around Scotland, over quite a long period of time, during which Hepatitis C or non-A non-B Hepatitis was transmitted to patients.

It obviously goes back to the 1960s and goes through to the current day. So it's a very broad range of time. And we reckoned there were probably at least 30 doctors and nurses involved across Scotland, it's very general, unlike HIV, which was largely confined to the central belt, Edinburgh and Glasgow.

And we recalled as doctors that round about 1999, during the previous Scottish Government Inquiry into Hepatitis C, we were all called to St Andrew's House and spent a day, and we were asked to collectively recall information given to patients about hepatitis.

I think a summary of what we said is given in that report, the 2000 report. So we have been through that before and we discussed that it might be helpful to the Inquiry and our legal advisers in the Central Legal

Office agreed, if we could try and collate our memories all across Scotland, all across a wide period of time.

So we put together this and -- we -- the document was drafted by myself, by Professor Ludlam, who, as you probably know, had already made a number of fairly detailed records of the approach in Edinburgh Royal Infirmary. And by Dr Gibson, who was the director at Yorkhill Hospital in Glasgow, for the period of time of Hepatitis C testing. So the three of us --

Q. Can I just stop you there?

A. Hm-mm.

Q. So who produced the first draft, if you like, or perhaps it was done in bits. Can you just tell us how that worked?

A. Very much in bits. Professor Ludlam had already written several relevant sections on a number of occasions. I think he was involved not only in the 2000 Inquiry but also in collating other information over the years for various bodies. So we started with that and then --

Q. Which bit was that?

A. Several bits.

Q. Right. How much of the response did that represent?

A. At least 50 per cent, I would say.

Q. So you started with --

A. We started with the Edinburgh perspective and then

Dr Gibson --

Q. Sorry, I just want to clarify, Professor Lowe, you started with a document produced by Professor Ludlam which represented about 50 per cent of the final document?

A. I would estimate that. There were several documents. Professor Ludlam had written down a whole number of things about different aspects of Hepatitis C. So basically we took those and Dr Gibson and I then went through what we thought would be happening in the West of Scotland during that period of time and what would be the equivalent and then, as we have said, it was disseminated to past and present haemophilia directors in Inverness, Dundee and Aberdeen for them to reflect upon what happened over that period of time.

Q. Okay. So just to be clear, Professor Ludlam produced a draft and you and Dr Gibson added to that draft? Is that correct?

A. Yes, the three of us put it together.

Q. So when you and Dr Gibson had finished, how much of the document was completed?

A. Well, I think it was about half and half, between Glasgow and Edinburgh. Then, of course, it was circulated to the peripheral centres in Inverness,

Dundee and Aberdeen and then people would write back and say, "Well, actually in our centre ..." this, that and the other.

Q. So after the document went to the other centres, did you say Dundee and Aberdeen?

A. And Inverness.

Q. And Inverness?

A. Yes.

Q. How much revision took place of the document?

A. Oh, how much? It's difficult to say in percentage terms. I would have thought a few per cent would change. And it's not only geographic, it's historical. For example, Dr MacDonald, who was haemophilia director in the 60s, 70s and early 80s, and is still alive, he contributed some memories of, in particular the early days of treatment. So it was not only the other centres but our predecessors in Glasgow at least.

Q. So I think you are saying that the substance didn't really change very much after yourself, Professor Ludlam and Dr Gibson had finished your input. Is that right?

A. Yes, there are relatively few changes made, yes.

Q. Okay. I see that there are a list of people who endorse, if you like, this collective response. That's right, isn't it?

A. Yes, at the end.

Q. Could we have a look at that page, please? It's the second.

Apart from the people that we have already mentioned and the other people that we are familiar with, Dr Forbes and so on, who are the other people in this list? Could you explain who they are?

A. Yes, do you want me to just go down the list? You know about myself, Professor Forbes, Professor Ludlam. Dr Watson is the current haemophilia director in Aberdeen Royal Infirmary. I think he started in the mid-1990s, and his two predecessors, who looked after patients in the 60s, 70s, and 80s, were Dr Bennet and Dr Dawson. Dr Gibson was the haemophilia director at Yorkhill and succeeded Dr Hann, and Dr Pettigrew was the clinical assistant, as you know.

Liz Chalmers is the current director at Yorkhill Hospital. Isobel Walker, consultant haematologist, was my co-director from 1990 until we both retired a couple of years ago. Dr McDonald was a co-director, really from the very beginning, I think, with Professor Stuart Douglas in the 1950s.

Then, when I came to the department of medicine in the mid 1970s, he was a co-director with Dr Prentice, who was succeeded by Dr Forbes. Dr Tait is the current haemophilia director at Glasgow Royal Infirmary, our

successor. He was a junior in the 90s and joined us as co-director with Dr Walker and myself about 1999. Dr Kerr is the current director in Dundee and he succeeded Dr Cachia, who was director from the early 90s for about ten years, I think.

Dr Taylor was originally the director at Raigmore Hospital in Inverness and he, I think, retired in the 90s and was replaced by Dr Murray, who retired a couple of years ago.

Sister MacDougall, a haemophilia sister currently, and from about 1985/86, I think, at Glasgow Infirmary. Sister Hook is her equivalent at Edinburgh Royal Infirmary. I can't remember how long she has been there, quite some time.

Chris Murphy was the haemophilia nurse at Yorkhill Hospital, Glasgow, in the 80s and 90s. Dr Morris was the hepatologist primarily involved, at Glasgow Royal Infirmary, in treating patients with Hepatitis C from the mid-90s until a year or two ago. And I think the Inquiry has heard recently from Professor Hayes, who is the hepatologist at Edinburgh Royal Infirmary.

Q. You have told us that you discussed your recollections of these events with Professor Ludlam and Dr Gibson. Did you discuss your recollections with anybody else,

any other doctors?

A. Well, yes. Over the years. Obviously, during the evolution of Hepatitis C, it was regularly discussed at meetings of Scottish haemophilia directors and UK haemophilia directors, and then, as I say, with the Inquiry in 1999, we had, you know, some meetings at St Andrew's House with the civil servants who took us through all this collectively.

Q. During those meetings was it Professor Ludlam and Dr Gibson that you were discussing your recollections with?

A. 1999, certainly Professor Ludlam. I think Dr Cachia and Dr Watson. I can't remember who was there from Inverness, Dr Gibson and/or Dr Chalmers. So it would be the haemophilia directors at that time.

Q. Thank you.

A. Sorry, just to say, and subsequently -- I mean, every few years from the Scottish Parliament questions arise about information given about hepatitis and we do it all again. So it has really been a continuing process over the years.

Q. And more recently, leading up to the production of this document, the Collective Response, did you discuss your recollections with anybody other than Professor Ludlam and Dr Gibson?

A. Oh, yes. We have regular meetings at the Central Legal Office which includes --

Q. I'm not talking about your discussions with your solicitors, I'm talking about your discussions with other witnesses, if you like.

A. Not -- well, mostly done by written communication rather than oral.

Q. But only with Professor Ludlam and Dr Gibson. Is that right?

A. For the current -- for the current round.

Q. Yes, okay. Professor Lowe, do you think it's possible that in discussing your recollection of these events, which you have described in the Collective Response, that you may have been influenced by other people's recollections of what happened?

A. Well, yes, it's possible. And the same would be true all through the last 10/20 years, when we have been asked to make collective responses.

Q. I mean, just focusing particularly on this document, do you feel that your recollection has been influenced by your discussions with Professor Ludlam and Dr Gibson.

A. Well, my own statement is obviously -- which is a separate document, reflects my own experience and I might have been reminded about things, but on the whole I think my own statement is my own statement, my

own recollections.

Q. Would you accept that your own statement is probably a better description of your recollection of these events?

A. Yes, indeed, but our legal colleagues suggested that a Collective Response would be a useful supplement to the individual statements, bearing in mind that it was unlikely that the Inquiry would be able to take statements for all the doctors and nurses who had ever given information about hepatitis over the years.

Q. Do you know how the endorsement of the people at the end of the document was actually obtained?

A. The draft was circulated by our colleagues at the Central Legal Office to the list of people that you see there and they were given, I think, a month or two to come back with comments on it.

From memory, the majority said, "Well, that accords with our own memories for the particular time that I was there in that particular haemophilia centre," or sometimes to say, "Well, we never actually did that or had that in Aberdeen," Dundee or Inverness or whatever.

Q. Hm-mm. So is everybody that the document was circulated to listed on that list or were there some people that the document was circulated to who were not on the list?

A. I can't remember any other people.

Q. All right. Sir, I propose to pass to Professor Lowe's statement.

THE CHAIRMAN: There are one or two questions I would like to ask. Whose language is this written in? Only medics or does it reflect modifications introduced by lawyers?

A. I don't think there is any modification introduced by lawyers, sir. It's in the words of ourselves as doctors.

THE CHAIRMAN: When an individual doctor wrote in or communicated with you and your colleagues a view that differed from the draft, how was that dealt with? Was the draft modified?

A. Oh, yes. I think it was handled by the lawyers in the Central Legal Office. So they would send us a table of all the comments received from everybody and then there would be discussion about how we should then modify the draft so that it was accurate with regard to their points. So that was a joint exercise.

THE CHAIRMAN: I have got great difficulty in understanding what the outcome of that particular exercise might be. If a view came in that differed from what, up to that point, had been the collective view of the draftsmen, any modification introduced must, one might think, be a deviation from the previous collective view of the draftsmen. Is that right or wrong?

A. I suppose it is. But would it help if I gave a couple of examples?

THE CHAIRMAN: No, I just want generalities at the moment. I would like to understand how something that was a collective view could cease to be a collective view when someone else made a contrary representation.

A. Like all collective reviews, some person or persons draft it, circulates it and then you incorporate the comments of other people. I would think that's a normal way in which the collective document evolves.

THE CHAIRMAN: I have to tell you that as a judge I have got no familiarity at all with collective views being treated as evidence, Professor Lowe. They are usually unreliable, simply because they cannot properly represent the individual views of all the people involved.

Of course, what they can represent is a lowest common denominator of opinion so that if someone says, "We all do one, two, three, four and five," and someone else comes in and says, "We don't do five," what you end up with is one, two, three and four. What's the nature of this? Is it a lowest common denominator type of statement?

A. I don't think it's a lowest common denominator. I think from my memory of discussions with colleagues over the

whole period in question, which would be, I guess, attending meetings of Scottish and UK haemophilia directors from the late 1980s, what to do about hepatitis and the evolution of Hepatitis C was very commonly discussed and that's really the point of having specialist meetings. You can say, "Well, what are you doing about this in your part of the woods?"

So I think the medical approach is to have regular meetings to exchange information and exchange ideas about how best to communicate information to patients. That's the -- that's what medical groups and medical societies are about.

That has been systematised in recent years by the formal evolution of clinical practice guidelines, in which doctors, nurses, other healthcare professionals and patients are involved. So I think we have the mentality in healthcare professions that if there is a difficult topic, the best way to spread knowledge and information and good practice is to talk to each other.

So in a sense, that's what we have been doing and when we talked about this, our legal colleagues from the Central Legal Office said, "If you do produce a collective statement, we think that that would be helpful to the Inquiry", and that's what we did.

THE CHAIRMAN: At the very least, none of the persons taking

part in this exercise as authors or agreeing to it could ever be heard to deny that the duties they had towards their patients were any less than set out in this document, could they?

A. I suppose not.

THE CHAIRMAN: Thank you. Certainly you would never deny giving evidence here to me, that these statements were, at very least, a measure of your obligations to individual patients?

A. Yes, I would think so.

Q. Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Could we have a look at your statement now, please? I think you have a hard copy in front of you, Professor Lowe. It's [PEN0180839]. Thank you.

If we have a look at the first page, we see in the first paragraph you make a reference to the Collective Response that we have just been discussing, and there are appendices that go with the Collective Response, are there not?

A. Yes.

Q. And throughout your statement you make reference back to these appendices. Is that right?

A. That's correct.

Q. If we could just go to the second paragraph where you

say:

"My ... recollection, as a trainee doctor, 1976-87, then co-director, 1988 to 2009, is that patients attending Glasgow Royal Infirmary were routinely informed of the risk of hepatitis (B and non-A non-B) before ... their treatment ..."

I just want to ask you about the phrase you used there, "trainee doctor". I think we discussed that a little bit the last time you were here but am I right in thinking that during this period, 1976 to 1987, you are training to be a Consultant, are you not?

A. In fact -- sorry, I see there is a typo. In fact I was a trainee between 1976 and the end of 1985. Apologies for that. Previous statements have clarified that. I became a Consultant at the end of 1985 and then I succeeded Professor Forbes as co-director at the end of 1987/start of 1988.

Q. Yes. During this period, 76 to 85, you are medically qualified to treat patients. You are a Registrar, then you are a Senior Registrar. That's right, isn't it?

A. Yes, I think we went into some detail when I previously appeared at the Inquiry.

Q. Yes. I mean, I just wonder if it's right to call you a "trainee doctor" during that period?

A. A non-Consultant.

Q. I think what the rest of this first page is taken up with is what you refer to as reinforcements of the information that has already been given to patients about the risk of non-A non-B. If we can just go through these fairly quickly, I think paragraph (a), one of these reinforcements, you say is:

"The nursing and medical staff taking precautions ..."

You talk about education and information leaflets. Paragraph (c), further information about NHS or commercial clotting factor concentrates would be given in information leaflets provided with the concentrates.

Then if we go over the page, (d) you talk about Hepatitis B vaccination, information given at that time. Then, paragraph (e), you talk about cryoprecipitate being preferred to concentrates for newly diagnosed people with haemophilia. (F) is clinical trials of heat-treated clotting factor, and then (g) is the recombinant clotting factors concentrates.

All of these you point to as things that reinforced the original message. Is that the right way of looking at it?

A. Yes, I think that's right and just to supplement that, I think I said at my first appearance here that in 1976, when I started helping out in the haemophilia unit, my

first impression on going in there was all the signs on the wall saying "Hepatitis", and it was to me very clear that this was continuously advertised, if you like, to patients and visitors to the unit. I forgot to put that in.

Q. Okay, thank you.

If we just look at the top of page 0841, we see that you are dealing here with information given to patients or their parents on the severity of non-A non-B Hepatitis. In that paragraph you refer, first of all, to the preliminary report summarising the asymptomatic stage and so on, and then half way down that paragraph, you say:

"From 1985 it was increasingly realised that the chronic asymptomatic stage of non-A non-B Hepatitis could progress in severity, initially through research studies ..."

And so on. Professor Lowe, did you advise your patients about this increasing realisation?

A. Oh, yes. I mean at clinic reviews, hepatitis was a standing item, if you like.

Let me take you through a clinic review. Firstly, as part of chatting to the patient, you would say, "Well, what has happened since we saw you last? Any health problems and in particular any jaundice that

might indicate an episode of hepatitis?"

During your clinical examination as well as examining the joints, the main problem in severe haemophilia, you would routinely examine the abdomen saying, "I would just like to examine your tummy and feel for your liver and spleen," as an index of liver disease. Then you would discuss the cumulative results of liver function tests that were done routinely, and if somebody had elevation of liver function tests, you would go through, then, the possible causes of that, ask about alcohol, consider other influences, like obesity, drugs, et cetera. And then if there was no explanation say, "Well, there is the possibility that you have non-A non-B Hepatitis," and people would say, "Well, what is that?" and then you would give them, to the best of your knowledge, the up-to-date on what it was, the difficulty of diagnosis and the prognosis, which was evolving.

And I think 1985 was about the time, as I think several people have said to the Inquiry, that the perception changed as a result of these publications in the mid 1980s, that it wasn't a benign disease, that some patients could develop serious liver disease, either as shown in biopsy or in the course of time, with the evolution of cirrhosis and cancer.

Q. Okay.

A. Although the cancer wasn't described, I think, until later.
Q. So you are talking there about your perception as a doctor?
A. Oh, yes.
Q. What I'm interested in is how you communicate that perception, that increasing realisation of the severity of the condition to the patient. How do you do that?
A. Well, I think what I have just told you. You say -- well, it would vary according to the patient's individual circumstances. Obviously, patients with abnormal liver function tests, there is more evidence that they are likely to have it than not. But we would take them through the hepatitis story.

What --

Q. Sorry to interrupt you. So a patient who hasn't got abnormal liver function tests, would you not discuss this increasing realisation with them?
A. No, no, no, everybody. Everybody at clinic review, because, particularly in 1985, we now have Hepatitis B vaccination. So in addition to the routine Hepatitis B tests that you would explain, you would say that, "If you have not been exposed to Hepatitis B before, if you don't have an antibody, we would strongly recommend that you be vaccinated against Hepatitis B because that

may still be transmitted by blood and blood products."

And then, having done the Hepatitis B bit -- because there was a practical issue of importance to all patients, you know, patients were all checked for immunity to Hepatitis B and if they weren't immune, they would be offered the vaccination, you would take them through that. As part of that, you would say that, "This vaccination will protect you from Hepatitis B, but we know that the majority of cases of post-transfusion hepatitis are not Hepatitis B. It's non-A non-B. This vaccine will not protect you from that." And then you would go through the steps being taken currently to virally inactivate concentrates in the hope that that would reduce the risk of all types of hepatitis, and at the same time say to patients, "It's important that we continue to regularly test you for hepatitis, both clinically and biochemically." And then you would give them a discussion as to what was the current state of knowledge about non-A non-B Hepatitis.

Q. Right. Okay. It's at that point that you would discuss the increasing realisation of the severity of the condition. Is that right?

A. Oh, yes.

Q. Can you tell me when you started to discuss that with your patients, to the best of your recollection?

A. Well, discussions about hepatitis were there from the time I started on the unit.
Q. But I'm not asking you about that, Professor Lowe. I'm asking you about your perception that this condition is more severe than it was thought. I'm asking: when did you start to pass on that information to patients?
A. Well, my best memory is about 1985, when the evidence was coming out.
Q. Right. So before 1985, when you got to the bit of the discussion at clinical review about what the implications of a diagnosis of non-A non-B would be, what would be the difference between what you told patients before 1985 and what you told patients after 1985?
A. Before 1985 you would talk about non-A non-B Hepatitis, and people would say, "Well, tell me more about it." And you would explain that a percentage of patients with haemophilia treated with blood or blood products would have intermittently or persistently elevated liver function tests. That suggested that something was going on in the liver. The term "non-A non-B Hepatitis" was used.

You would say that that was a chronic inflammation of the liver. It had been known about since the mid 1970s, and the general feeling was that over that period

of time very few patients with haemophilia had developed any clinical liver disease and that there were biopsy studies that showed that the changes in the liver tended to be relatively mild. So it was thought to be a chronic but mild condition. It should be kept an eye on. It reinforced --

Q. Sorry, "chronic but mild". Is that what you would say to the patients?

A. Yes, in the sense that, you know, while it's early days, it has only been known about for ten years; the general perception amongst experts and haemophilia doctors was that very few patients were developing chronic liver disease.

However, the important thing was that all patients should be regularly checked, clinically and biochemically, for liver disease and an eye kept on that, and that they would be given information, year by year, as to what the perceived significance was and what the implications were, and what the practical steps that could be done to minimise it, like heat treatment of blood products, trying to avoid blood products in the milder patients and, as I have said repeatedly, the importance of Hepatitis B vaccination.

Q. Yes. So what's the messages to the patient in terms of how concerned they should be about having this

condition?

A. Well, we would say that, "Non-A non-B Hepatitis is a concern. We need to monitor you for it. We will explain what we are doing collectively to minimise the risks through safer products and immunisation, and regular medical review is important and it gives us a chance to continue to update you on the significance."

As I have said in my statement, copies of the Haemophilia Society news letters and bulletins were readily available in the unit and distributed it patients to supplement that --

Q. We will deal with that -- Professor Lowe, I'm sorry to cut across you.

I'm trying to look at this from the patient's point of view and I would imagine that a patient will be asking you, "How worried should I be, doctor, about this condition you are telling me about?"

Before 1985, what would you say to a patient about how worried they should be?

A. Well, it would be -- I would say that it's something we collectively, as doctors and yourself, need to keep an eye on because we know that liver disease can be serious. We know that some patients with hepatitis, it can progress to cirrhosis, which is where the liver ceases to perform its functions and you will feel ill.

Q. So before 1985 would you explain to a patient who is asking you "how worried should I be?" the process of cirrhosis, leading to liver cancer and so on.

A. Oh, yes, that was unit policy. That's what all the doctors on the unit were doing.

You know, I was trained on the unit and when I started training, I would sit in with the consultant, Dr Forbes and Dr Prentice, and, you know, this is what they would be saying to patients, "You have abnormal liver function tests, there is a risk of hepatitis, this is what we collectively think about it." That was the way I was trained and we never said it was something not to worry about.

Q. I'm not suggesting that to you. I'm just trying to be clear about what you were telling patients. I mean, a chronic but mild condition, which might lead to liver cancer?

A. Liver cancer came along later. We were talking about cirrhosis.

Q. We are talking about before 1985 your discussion with patients. Would you talk about the possibility of liver cancer with patients?

A. Cirrhosis and -- I think liver cancer was starting to appear in 1980s. I would have to think a bit. Liver cancer was well recognised as a complication of

Hepatitis B, so that would come up under the discussions there. Concerning non-A non-B Hepatitis, that was all a bit vague and it wasn't until Hepatitis C, that was identified in late 80s/early 90s, that the story started emerging about liver cancer becoming a complication of Hepatitis C as well as Hepatitis B. So there is an evolution.

Q. So I think you are saying that before 1985 in your discussions with patients, you wouldn't be discussing that possibility?

A. I would say that if you have chronic hepatitis, there is a risk of serious liver disease and the most common form of that was cirrhosis, but certainly, with Hepatitis B, liver cancer was a possibility and then, in due course of time, with Hepatitis C that became a possibility. So what you would say to patients, clearly, is what was the state of the knowledge at the time.

Q. And I think what you are saying is that before 1985, you are telling them it's a chronic but mild condition which has a risk of leading to serious liver disease --

A. Over a period of time.

Q. Over a period of time, which would be cirrhosis?

A. Correct.

Q. And is that what you would tell every patient or is it only patients that have abnormal liver function tests?

A. Oh, every patient because every patient was being monitored for liver disease, both clinically and biochemically. Every patient was being tested for and offered vaccination, if required, for Hepatitis B. So it was a routine part of the review of all patients who had received blood products.

Q. Okay, thank you.

After 1985, what was the difference in your message to patients about that?

A. That we were collectively, in the medical and scientific community, concerned that, you know, an increasing percentage of patients were starting to develop serious liver disease, either in research studies of liver biopsies or in terms of clinical complications. Because I think the general experience in the United Kingdom was that every centre now was seeing one or two patients who clearly had clinical evidence of liver disease. And that was being monitored by the chronic hepatitis working group, chaired by Professor Preston, which regularly reported to not only doctors but to the Haemophilia Society representatives, who attended the annual meeting of the UKHCDO and disseminated through the Haemophilia Society literature.

Q. So your message after 1985 is more or less the same except that you are advising the patients that there is

an increasing percentage of patients who are progressing to serious liver disease?

A. Indeed, because some patients would say, "Well, how many patients attending this centre have had serious liver disease?" and, you know, without breaking any confidentiality you would say, "Like other centres we are starting to see a small number of patients who have clinical liver disease and that's why we need to keep a close eye on all our patients."

Q. Right. So would you be putting a percentage figure on that or --

A. Yes, I think it's always helpful in uncertain situations to make an estimate of risk. So I would say, "Okay, we have got, you know, over 100 patients regularly treated with blood products here," and then give them an idea about how many patients, not only in the West of Scotland but across the UK, were developing this condition, to give them some idea -- but to point out that the natural history seemed to be that this condition could progress over many years and that all you could give them was the best knowledge and estimate of the time. I think the other thing I would like to --

Q. Before you go on to that, can you remember what percentage figure you would have given a patient after 1985?

A. In 1985, from memory, we had had, I think, three or four patients who had developed cirrhosis. The majority of these had either Hepatitis B or heavy alcohol use or both. Hardly any in 1985 had developed clinical liver disease who did not have either Hepatitis B or alcohol. But I think the first patient we probably had would be about 1987, where we thought it is a patient who is not a heavy alcohol user, not got Hepatitis B; it looks like this is the first case that we have had of non-A non-B Hepatitis causing first evidence of early cirrhosis. So from memory it would be about 1987.

Q. Right.

A. Of course that gradually increased over the years. Could I just say from --

Q. Professor Lowe, can I bring you back to the question?

A. Please do.

Q. During this period between 1985 and 1987 that you have mentioned, can you tell us if you were giving patients a percentage of other patients that had progressed to serious liver disease or was it simply at the level of "there is an increasing percentage"? Did you put a figure on it? That's what I'm getting at.

A. Yes, I would usually try and put a figure on it but that figure would change from year to year.

Q. Well, 85 to 87.

A. 85 to 87? I think that I would be giving an estimate that about a quarter of patients who had been studied in liver biopsy studies had evidence of cirrhosis. So it could be that perhaps about 25 per cent of patients with non-A non-B Hepatitis would be showing the early stages of cirrhosis and would it be expected that a high number of those patients would then become clinically unwell.
Q. So your recollection is that between 1985 and 1987, at annual clinical review, you would routinely tell all patients, whether they had abnormal liver function tests or not, that there were 25 per cent of patients with this condition who would progress to cirrhosis?
A. Yes, during the discussions about hepatitis, which would start with Hepatitis B and go through the vaccination story, and then go on to non-A non-B and say that, "There is an evolving literature, we are concerned about it and we need to" -- you know, "the UK haemophilia centre directors has a working party that's studying it carefully and we will be keeping you informed of the best estimate of this risk."
Q. Yes. After 1987 did that estimate change?
A. Yes. I think so. There would be a -- I think an increasing estimate year by year. I'm sorry, I cannot recall what the -- and it's difficult because a lot of these -- a lot of this information was coming from

studies from liver biopsies. The hepatitis working party, set up to monitor hepatitis in the UK, would produce an annual report and that would, you know, summarise the literature and research studies --

Q. Professor Lowe, remember that we are interested today in what the patients were told.

A. Yes.

Q. Could you tell us what the patients were told year by year after 1987 about the percentage of patients that progressed to cirrhosis?

A. After 87?

Q. Yes.

A. I think it would go up from the quarter, presumably, to a third.

Q. Within what sort of timeframe would that be?

A. I would think in the 1980s.

Q. Well, we are talking about after --

A. The late 80s?

Q. The late 80s.

A. Hm-mm.

Q. So sort of 88/89.

A. Yes, I think it would have gone up from about a quarter to a third, yes.

Q. But in sort of 1988 and 1989?

A. Yes.

Q. Sorry, if I could just keep on that point. So that's what you are telling your patients: in 1988 and 1989 it has moved from a quarter to a third; is that right?
A. That's my recollection, as best as I can recall.
Q. That's very helpful. This is your recollection of what you were telling your patients.
A. The patients I reviewed at the clinic.
Q. Yes, the patients that you reviewed at the clinic. Can you tell us what other clinicians in the clinic were telling their patients at the same time?
A. Well, we would have regular discussions on the unit on information given to patients; all the junior staff were trained in this. Most patients were reviewed by the haemophilia junior doctor, who was in post for doing that, and there would be regular discussions on this coming back from any --
Q. I had better clarify: who in the unit is carrying out these annual reviews? Which clinicians are doing the annual reviews?
A. Myself, my haematology colleagues, who were largely haematologists in training, under Dr MacDonald's supervision, and we had a dedicated haemophilia senior house officer at the time.

So at the clinic review there would usually be about four of us: myself, I think it would be Dr Soo at the

time, who was the haemophilia Senior House Officer, and hematology colleagues.

Q. Right. Is this all in one room, those four of you?

A. No, we have separate rooms for seeing patients in but we would have collective discussions at the end of the clinic and that allowed the opportunity -- I mean, I have always been a strong believer at the end of every clinic, you sit down together -- and with the haemophilia nurses -- and you sit down and you collectively review what's happening with the patients. That allows an opportunity for, you know, continued training of the juniors, we can discuss, you know, what follow-up may be required of any points that are raised. So we would have a group discussion.

Q. Okay --

A. And obviously from these group discussions we kept in touch with each other about who was telling people what and what the collective information given to patients was.

Q. Right, okay, I had better just get from you very clearly, Professor Lowe. How many people at this time -- and we are talking 1985 to 1988 -- would have had the responsibility of doing an annual clinical review at which this topic would be discussed? We know yourself.

A. Yes.
Q. Who else?
A. Well, obviously Dr Forbes until he left at the end of 1987. He was the Consultant in charge of the clinic.
Q. Okay.
A. He was also at this time chairman of UKHCDO. So he knew all the information that there was.
Q. Just the names of the people, please.
A. Dr Forbes, myself, the senior house officers in haemophilia. 85? Probably Dr Greer, then Dr Spowart and then I think Dr Soo. They would change every year or two.
Q. Okay, and who else?
A. Then a number of patients -- a number of registrars training in haematology, because training in haemophilia is a routine part of their training there. So as I think we have made clear, the unit was run jointly by the university department of medicine and by the department of haematology. It was a shared endeavour at Consultant level and at junior level.
Q. Thank you. So how would the more junior doctors, if I can put it that way -- the senior house officers and the registrars -- how would they know what to tell patients about the severity of the condition? How would they know to make an estimate of about 25 per cent of

progression to cirrhosis and then later a third progression to cirrhosis? How would they know to do that with patients?

A. Yes, let's start in 1985, if you like. So Dr Forbes will come back from meetings of United Kingdom haemophilia centre directors. He was the chair of that organisation and he obviously was the main source of knowledge in terms of what was happening, not only with hepatitis but obviously the dominant worry at the time was HIV. That was what was in everybody's mind. Patients, doctors, nurses. HIV was the thing that everybody wanted to know about.

I think this is an important point because at this period of time, 85/86/87, that's the time when patients and haemophilia centre staff are coming to terms with the evolving disease of HIV. That's what dominated everybody's mind.

Q. Yes, thank you.

A. Anyway, what patients were told about hepatitis -- non-A non-B --

Q. The question was about how the junior doctors would know what to say to the patients about this increasing realisation of the severity of the condition.

A. Well, any doctor first starting on the unit, their first several clinics, they would sit in with the

Consultant -- that would be Dr Forbes initially in 85, or myself once I became a consultant -- and would be taken through the routine procedure for reviewing all patients. That would include discussions, clinical examination and talking about the blood tests and talking about hepatitis, HIV, et cetera.

Dr Forbes was the chair of UKHCDO and was intimately involved in, obviously, the evolution of the story about hepatitis, as well as HIV.

Q. So that means that junior doctors would see how it was done?

A. See how it was done but also get regular updates. So after every meeting that Dr Forbes attended, he would come back and we would have a session on the unit at which he would give an update, not only on changes in haemophilia management, changes in treatments, like virally inactivated products and what we should say to patients about those, but also the emerging risks of HIV and hepatitis, and what should be communicated to patients at clinical reviews about that.

And obviously, of course, the Haemophilia Society literature, which we used to order --

Q. We are going to come to that. So the meetings that Dr Forbes obtained. Is that the clinical review meetings?

A. Yes, often at the end of a clinic. So we would have a clinic and then we would sit down at the end and the routine, which we continue to this day, is to discuss all the patients, medical and nursing staff, compare notes and often, of course, the haemophilia nursing specialist would come and say, "Well, you know, you spoke to him about this and then they said this to me", and we would communicate amongst each other as appropriate. So we would try and but together a collective picture of what was happening with the whole patient.

Q. What would the junior doctors be told to do about this increasing realisation? What, if anything, would they be told to do?

A. Speak to the patients about it and then if the patient wished to speak to one of the consultants and get more information about it, offer that as well.

Q. Obviously speak to the patients but what would they say to the patients about the increasing realisation? Was there an instruction to them from yourself or Dr Forbes that they should communicate this increasing realisation?

A. Absolutely. For hepatitis, as well as for HIV, it was regularly discussed, you know, "What should patients be told about it?" Dr Forbes, as I think I have said

before to the Inquiry, was very keen that if any patient seen by a trainee doctor had any further questions, then it would be him as the director who would wish to see them and provide further information.

Q. So would the junior doctors be told about the percentage figures that you have mentioned?

A. Oh, yes.

Q. They would be told about that and so they would be instructed to tell patients about those percentage figures? Is that what you are telling us, Professor Lowe?

A. Yes, well, I mean, in 1985 I was a trainee doctor myself. So I would be one of the trainee doctors and Dr Forbes would come back from a meeting and say, "This is the latest. This is what the policy is going to be on the unit, this is what we are going to say to our patients and this is the supplementary material which is available, the Haemophilia Society".

Q. What was the policy then?

A. What was the policy?

Q. What was the policy about this increasing realisation?

A. To tell patients about it and to explain, as I have already said, that all patients should be asked about symptoms of liver disease, examined for liver disease, have blood tests taken for liver disease and to explain

to them -- often at the time that you were discussing blood tests, you would say, "I want to check you out for Hepatitis B and non-A non-B, and the current situation with these problems in haemophiliacs in the United Kingdom is this, and this is why it's important that we do this", and, "Keep coming to the clinics and we will keep monitoring you for the complications."

Q. Yes. Was that policy written down anywhere?

A. I don't recall that we had a written policy. We have not been able to find one. As I think I have said before to the Inquiries, every trainee was given a ten-page protocol all about haemophilia, all about the bleeding complications. The emphasis very much on treating bleeding, particularly out-of-hours --

Q. Professor Lowe, I'm really interested in the communication of information about the increasing realisation of the severity of the condition.

A. Sure.

Q. Was there no written policy about that during the period of 1985 to 1987?

A. I can't recall a written policy. We had --

Q. Thank you. That's all I wanted to know.

A. Right, but we had a verbal policy, I think is what I'm trying to say.

Q. Thank you. After 1987, right on beyond, has a written

policy ever been developed?
A. For the clinic?
Q. For communication with patients about the severity of the condition?
A. About the severity of hepatitis? I think the unit policy was always to use the Haemophilia Society literature.
Q. I'm asking you about the existence of a written policy at the moment, Professor Lowe.
A. Right, within the unit? I don't recall a written policy about -- it was made very clear to everybody reviewing the patients that hepatitis and its consequences would be discussed. In terms of what patients were told, we were told verbally to give an indication of the prognosis --
Q. You have told us about that. So in your time at Glasgow Royal Infirmary there was never a written policy about this?
A. I can't recall one.
Q. So you can't recall if there was one or you can't recall one being in existence?
A. I don't think there was one. I cannot recall any policy. Any written policy.
Q. Do you think that would have been a good idea in terms of making sure that the junior doctors knew what to tell

the patients?

A. Well, it could have been. I think, though, my -- I mean, my recollection as a junior is that we were -- it was -- the policy was to lead by example. You would go -- I mean, at any specialty clinic that I attended -- and I trained in general medicine, I did a whole variety of clinics during my training. And the usual policy at all these clinics is you go in, you sit with the consultant through several clinics, you see how they do it and you pick it up that way.

So I would go to diabetic clinics, renal clinics, endocrine clinics, general medical clinics, so a whole variety of these, and in my training in the 70s and 80s, that was the way in which information was transmitted to patients. You saw how the consultant did it and then that's what you did.

Very few of these specialist clinics had written instructions about what you say to patients about diabetes complications or renal disease or whatever. But you would learn by example.

Q. Thank you. I think you have told us about that.

A. But could I just say that all of these clinics tended to have information leaflets for patients, and in the haemophilia centre what we used for that purpose was the Haemophilia Society publications. Other clinics would

have similar publications from -- for diabetes or renal disease, for liver disease, et cetera. So I don't think we were exceptional in the haemophilia centre in not having a written policy of what you tell patients about the disease.

Q. Okay, thank you. Could we have a look at page 4, which is 0842? In the middle of the page the heading "General information given to patients about hepatitis before or after their treatment with blood or blood products".

And you say at (a):

"It is my recollection that patients referred to Glasgow Royal Infirmary from Yorkhill Hospital or other haemophilia centres had already been informed of the risk of hepatitis from blood or blood products."

I just wondered how you knew that?

A. If a patient is transferred to your haemophilia centre, you start -- at their first visit you have a fairly long review where you go through everything. You have got the referral letter, obviously, from Yorkhill, which was the usual route by which patients came to us in their teenage years. And you would go through -- you would introduce patients to the unit, you would introduce them to the staff, you would talk about reviews, you would talk about where they come for emergency treatment and you talk through a variety of matters.

You review the haemophilia, you review their knowledge about haemophilia, knowledge about the treatment and that would include the complications of the treatment, and that would lead on to, "Okay, tell me what you know about hepatitis". And I cannot recall a single patient that I saw for the first time at the centre who hadn't been told about hepatitis.

Q. Right. Okay.

A. Certainly Yorkhill Hospital, you will get statements no doubt from the doctors there, they had routine testing for hepatitis and education of patients and their parents about hepatitis. So nobody ever threw up their hands and said, "I didn't know about hepatitis".

Q. Thank you. You have answered my question.

If we keep on going on that page, we see that you make reference at (c) to the UK Haemophilia Society being conversant with the risk of hepatitis, and then over the page, 0843, second paragraph, you talk about meetings of the Haemophilia Society. Then, (d), you refer to notice boards on the Haemophilia Society and then, (e), books about haemophilia being available and then leaflets accompanying bottles of NHS and commercial concentrate. And these are all ways in which patients -- I think you are suggesting -- would know about hepatitis. That's right? Or the risk of

hepatitis specifically.

A. Yes.

Q. You have alluded to this a couple of times this morning, professor, but would you agree with me that really the best way for a clinician to give a patient information about treatment and prognosis is for the clinician to give that information directly to the patient?

A. Absolutely.

Q. Yes. So it wouldn't be acceptable for a clinician to simply rely on a patient getting information from another source, such as the Haemophilia Society?

A. Correct, but as I have said a few minutes ago, the Haemophilia Society produced a whole range of educational material, which was very valuable for the doctors and nurses at the centre to go through with the patients.

To give you an example, patients being trained for home treatment, there were these very useful books that Dr Peter Jones developed, and the patients and the parents, or anybody else assisting the patient, would be taken through this very systematically and given this information to read during the course of the training, and that would include the precautions to be taken when making up the treatment, administering the treatment, disposing of the equipment, et cetera.

Q. Yes, I think you have set that all out in your statement.
A. Okay.
Q. It was really the other point I was asking you about.
A. The point I'm trying to make is that, yes, the best way to give information is for the doctors and nurses to continually educate the patients and their family about it. Having said that, what I have tried to do here -- and we did the same in the collective enquiry -- is to list, to the best of my memory, all the ways in which you can reinforce that information, because I'm sure the Inquiry is well aware that there is a lot of research now about information taken in by patients, and studies have been done where a patient leaves an interview with a doctor or nurse, is asked about what was discussed and only retains certain things.
Q. We have had some evidence --
A. So education is a continuous process and we provide here a list of all the ways in which we tried to reinforce that.
Q. We have heard some evidence about that. Thank you, Professor Lowe.
You also referred to information being passed over by patients reading leaflets on concentrates but again, you would agree with me that it wouldn't be acceptable

for a clinician simply to rely on that as a way of passing information over to a patient. That's right, isn't it?

A. Correct, but our policy on the unit, anybody being trained for home treatment, for example, which many of our patients were, would be taken through these information leaflets as part of the training and then any change in product, the treatment, it was routine to take them through the information leaflet given with that product and explain why the change in product was occurring, for example it was more virally inactivated or whatever, and they would be taken through that.

Q. I think you have mentioned --

A. And that was always there as something that they could refer to.

Q. I think you mentioned that on top of page 6, if we could look at that. So it's (g):

"Patients' relatives and partners received education before and during home treatment with factor concentrates, usually from the haemophilia centre's nurse specialist. This included education on the risk of hepatitis transmission and the need to take care ..."

Were the nurse specialists instructed by the clinicians what to tell patients?

A. Absolutely. I mean, specialist nursing care in

haemophilia was evolving very much all through the 70s, 80s and 90s, and a major role of the haemophilia sister or nurse specialist was patient education about haemophilia and the complications, and particularly when it came to home treatment.

Clearly, in the 80s, with the emergence of HIV, there is great anxiety, obviously, amongst patients and anybody exposed to the equipment, the needles, the blood. So this was an absolute prerequisite of visits of patients to the unit, particularly the majority who were on home treatment, and the nurses would have a huge emphasis on safe disposal of needles, needle stick injuries. Everybody who was trained to assist patients in making up and administering their treatment, that could be parents or partners, were advised about the risks in great detail. They were advised to be vaccinated against Hepatitis B and in the event of any needle stick injury, to immediately contact the unit for consideration of prevention, if they had been exposed to Hepatitis B.

So --

Q. That's to do with the risk of transmission. It's not really to do with the severity of the condition. That's fair?

A. Well, we have already discussed that --

Q. We are talking about the nurses here, Professor Lowe. We are talking about the nurses at the moment.
A. Yes.
Q. Yes.
PROFESSOR JAMES: That's also to do with Hepatitis B. The needle stick injury and the precautions are Hepatitis B.
A. Yes.
MR GARDINER: I follow that.
A. Could I say, certainly our nurses were kept informed of the developments, not only with Hepatitis B but with non-A non-B Hepatitis, and that emerging problem, and HIV. All of these, you know -- an evolving part of nursing care was to counsel patients about safe sex, as well as care with blood for all these reasons.
Q. So the nurses were made aware of the increasing realisation that we were talking about earlier?
A. Absolutely, because the nurses, as well as the doctors at haemophilia centres, as I say, in the later part of the 80s, were starting to see patients with cirrhosis, not merely due to alcohol and Hepatitis B but the emergence of non-A non-B. So they were fully aware that some patients were developing --
Q. I'm not talking about them being aware, I'm talking about clinicians advising nurses about the increasing realisation with a view to that being communicated to

patients. Did that happen?

A. Yes, so as I have already said, Dr Forbes would come back from meetings of the UKHCDO and we would sit round in the unit and he would give us all an update, nurses as well as social workers, physiotherapists, dentists, medical staff, senior and junior, and we would have information sharing.

Q. But would the nurses be instructed to tell patients about this increasing realisation, as well as the junior doctors?

A. Yes, absolutely.

Q. All right. Can we just go to the bottom of page 6, please? We see paragraph (i), you are talking here about the risk of sexual transmission and at the bottom of the page, the last sentence:

"Sexual transmission was routinely discussed with carriers of Hepatitis B or C at Glasgow Royal Infirmary."

Could you just explain that a little bit more? We are particularly interested in Hepatitis C here.

A. Well, let's -- well, okay. Hepatitis B, it's standard practice that if somebody is discovered to be a carrier of Hepatitis B, there is a high risk of sexual transmission and they would be fully informed about that, not only at the --

THE CHAIRMAN: Professor Lowe, can I ask you, please, to answer Mr Gardiner's questions. It's very dangerous if you simply use this as a opportunity -- as you clearly are doing -- for making speeches on a whole variety of things. In the first place, that is not very persuasive evidence. It tends to suggest that you have come with an agenda other than that that we are interested in.

In the second place, it takes up a great deal of time, partly because it is very repetitive and I really would like you, please, to pay attention to the question and answer it.

A. Yes, so I'll leave Hepatitis B.

MR GARDINER: If you wouldn't mind.

A. So when Hepatitis C testing was introduced, we told all our patients who had positive Hepatitis C tests that there was a possibility of sexual transmission, and that was routinely discussed.

Q. Right. So what era are you talking about here?

A. We, I think, started Hepatitis C testing about the end of 1991.

Q. Thank you. Could we just move to the next page, page 7? We are looking at 5(b) and (i):

"Routine surveillance for hepatitis viruses and liver disease at Glasgow Royal Infirmary haemophilia centre, prior to Hepatitis C testing from

1991 onwards."

In this paragraph you talk about when Dr Walker and you took over from Dr Forbes and McDonald, you continued their policy of routine surveillance for hepatitis viruses and liver disease. What were patients told about the purpose of these tests?

A. The tests for hepatitis?

Q. Well, we are talking about the routine surveillance.

A. Routine surveillance. As I have said already, as part of the talking to the patient, you say, "Any jaundice since we saw you last?" Examination. We routinely examine the abdomen and say, "We would like now to look at your liver and spleen and see if you have any signs of chronic liver disease that might be chronic hepatitis", and then we would talk about the liver function tests as being non-specific measures of liver function damage that were done routinely, and then testing for hepatitis viruses.

Initially that was for Hepatitis B. It was not thought, until about 1992, that Hepatitis A could be transmitted by blood or blood products, but then in 1992 there were reports, as I say, later on about Hepatitis A being transmitted by some commercial blood products, at which point we routinely checked Hepatitis A, and if patients were not immune, offered them Hepatitis A

vaccination. Then when Hepatitis C tests came along at the end of 1991 --

Q. I'm going to come to that, if you wouldn't mind.

If we look down the page, we see that the tests that were done, full blood count, measure haemoglobin and then (b), liver function tests, and if we can go over the page, urea and electrolytes to assess kidney function, (y) assessment of clotting factor deficiency, sample for virology for Hepatitis B antibody and antigen, and then you are refer to Dr Colvin's evidence about the diagnosis of non-A non-B Hepatitis and you list the reasons for the difficulty, and at the bottom of that page you say:

"Hence interpretation of those blood liver function tests was difficult, as was information and advice given to patients."

So if interpretation of abnormal liver function tests was difficult, what, if anything, did you say to a patient who had abnormal liver function tests?

A. Well, I would explain what transaminases were. They are non-specific elevations, indicating disturbance to the liver but also some other organs. We would then go through the alcohol story, the drugs story, the obesity story, and in the absence of any other obvious cause, I would say to patients, "If you have abnormal liver

function tests and the Hepatitis B is negative, you have probably got non-A non-B Hepatitis, but it's difficult to be certain of that because we don't do liver biopsies in patients with haemophilia. They are dangerous because of risk of bleeding and some patients died of bleeding.

"So it's something of concern. It's something we need to monitor, we will check you out clinically for liver disease. If you are negative for Hepatitis B, that's good news but there are other hepatitis viruses," and explain what was known at the time as "non-A non-B Hepatitis", give some indication, as we have already discussed this morning, as to the prognosis, and then when Hepatitis C was discovered, we would say, "Now tests are becoming available for that and we will do those as well".

Q. Okay. Just looking at the next paragraph, you say:

"The few patients at Glasgow Royal Infirmary in the 70s and 80s, with clinically suspected acute hepatitis, jaundice and/or other symptoms ..."

Just to be clear, what "other symptoms" are you referring to there?

A. The main symptom of acute hepatitis is jaundice but at the same time people feel sick, so if, for example, someone came up to the unit and said, "I'm just vomiting

all the time, I can't keep my food down," we would examine them, we would look for jaundice, we would measure the liver function tests in case that was a non-icteric, a non-jaundiced case of acute hepatitis.

We had a few patients in the 70s and 80s before Hep C came along, I think probably half a dozen at most of patients, who actually had jaundice and these were all admitted and investigated and treated in the local infectious disease unit.

Q. Thank you. Could we just go on to the next page?

THE CHAIRMAN: It's just about 11 o'clock. We should stop now.

(11.01 pm)

(Short break)

(11.25 am)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Professor Lowe, could we have a look now at page 0848, which is the next page after the one we were looking at.

We see there, number 3, the heading is "When did you start testing your patients for HCV?"

You say:

"Following the identification of the Hepatitis C virus and the development of tests for exposure

(antibody tests) and carriage (PCR tests), UKHCDO recommended in 1990 and 1991 that testing for Hepatitis C be added to established routine surveillance ..."

Just reading that short, the next paragraph:

"Accordingly, Dr Walker and I added HCV testing to routine surveillance for hepatitis/liver disease in 1991, following discussion with the Regional Virus Laboratory at Ruchill and with our gastroenterology/hepatology colleagues."

Perhaps you could clarify for us the different tests that you were doing over the time?

A. Yes, thank you. There was an evolution of testing. As I remember, the antibody tests became available in 1990, the test --

Q. Sorry, to be clear, is that the Ortho test?

A. The name rings a bell. I think -- yes, at least one commercial -- they were initially commercial tests and then I think more than one manufacturer made them, as I recall. I think they appeared about 1990 but the initial antibody tests, there was some question as to reliability; they could be non-specific and insensitive. And I think others can talk in detail about that.

But I think it was about 1991 that the tests became more reliable and in particular one called the RIBA-2

test, which seemed to be more sensitive and specific.

So my recollection --

Q. Professor Lowe, sorry, our information is that the RIBA-2 test is a confirmatory test?

A. That's correct. So you would have the initial test but it was important to confirm it with the RIBA test. So that was the situation when we started testing about the end of 1991, and this followed recommendations from UKHCDO. There was a chronic hepatitis working party chaired by Professor Preston, and in his report in 1990 it was recommended that all patients should be tested for antibody to determine exposure to the Hepatitis C virus.

That was repeated the next year.

So we discussed this with the Regional Virus Laboratory at Ruchill Hospital, who were already doing routine Hepatitis B testing and indeed, from the following year, Hepatitis A.

Q. That is Dr Follett, is it?

A. It was Dr Follett, I think, in charge at that time, yes.

Q. Right. So how did it come about that you got the first antibody test? I mean, did Dr Follett phone you up and say, "Look, I have got this new test"?

A. Yes, we had fairly regular discussions with the regional virus laboratory, initially, of course, updating Hep B

testing, Hep B vaccination. I think we met usually about annually and would discuss, you know, any changes to the Hep B policy, which, as I have already said, was immunising all patients, checking the level of immunity and giving them booster doses of Hepatitis B, and that would involve a general discussion about Hepatitis B testing.

Q. Just focusing on when this first test became available, how did you find out about it? Do you remember?

A. Obviously everybody in haemophilia centres was following closely the evolution of Hepatitis C, and we would get regular reports from Professor Preston's working party and as I say, I think about the end of 1990, they recommended that centres should -- given that all centres were routinely screening patients for non-A non-B Hepatitis, here at last we had a test for the virus that might be responsible for most if not all cases of non-A non-B Hepatitis.

Q. So who is responsible for arranging for the test to be used in the centre?

A. Well, the haemophilia centre, Dr Walker and I had a meeting with Dr Follett and his colleagues and we were advised that the tests were now sufficiently reliable that they might be meaningful to use as part of routine screening for non-A non-B Hepatitis.

Q. Right.
A. And of course, the hope was that, you know, this would lead to identification of patients who in due course, following the PCR test, which was some years later, were found to then be carriers of the virus and those patients could be offered antiviral treatment, such as interferon, which was starting to be trialled. So that was the --
Q. So when was this meeting?
A. Oh, I would -- well, as I say, we had meetings approximately annually.
Q. But the one that you just mentioned, Professor Lowe.
A. The one where we started testing. That would be agreed in 1991, I would think.
Q. Right. So although there was a antibody test available at the end of 1990, you didn't use it?
A. My recollection is that Dr Follett was concerned about the unreliability of the tests and I remember some years earlier, he and Dr Forbes had a lot of discussion about reliability of the initial HIV test. So here we were again, a new virus has been discovered and Dr Follett was keen that we didn't start testing until there was a reliable test, and I think it was about the same time, late 1991, that these tests were introduced for routine screening of blood donors and became generally used

across the National Health Service.

Q. So what was the first test that you used? Do you know what it was?

A. I think it was the screening test for antibody confirmed by the RIBA-2 test. That's what Dr Follett and his colleagues would report on the forms. Precisely the origin of the screening tests, I can't honestly remember.

Q. Right.

PROFESSOR JAMES: Would you mind, sir, if I just asked one question?

A lot of the haemophilia centres actually used their stored samples to, you know, have some idea of the possible prevalence of HCV antibody as soon as the test became available to viral laboratories, probably at the turn of the year 1991. Did you do that at all or did you just wait until there was a "proper test" around, towards the end of 1991?

A. I think as far as I recall, Dr Follett and his colleagues in virology were concerned about stored samples and deterioration and suggested it would be far better to use fresh samples and, of course, we were keen to do that so we could explain to patients about Hepatitis C testing and that they would get a result --

PROFESSOR JAMES: So as a matter of fact, you didn't really

start testing your haemophilia patients for the HCV antibody until towards the end of 1991, around the same time as the blood transfusion screening started?

A. That's my memory, yes.

PROFESSOR JAMES: Thank you. Thank you very much.

MR GARDINER: It might be helpful to have a look at a description of the tests that were available at that time to see if we can clarify with you, Professor Lowe. Could we have a look at Dr Hay's report, which is [PEN0180961]? This has been produced quite recently. I don't know if you have had an opportunity to look at this, professor.

A. I have read it briefly.

Q. Could we just go to page 0971. In this section of his report, Dr Hay is talking about the first tests and he writes:

"The Hepatitis C virus was finally identified in 1988. A first generation test, an RIA based solely on the c-100-3 antigen of Hepatitis C was developed shortly thereafter. This first generation test missed 20-40 per cent of infected patients and was particularly insensitive in the early stages of the infection leading to a long window period. False positive tests were also a problem with the first generation ELISA test."

Do you think that that was the test which you were

referring to earlier, the antibody test at the end of 1990, which you didn't use?

A. Yes, I would guess so. Yes.

Q. Okay. If we could just go over the page to 0972 at paragraph 21, where Dr Hay says:

"These limitations were compounded by the absence of a true confirmatory test."

He explains what a confirmatory test is. Just reading that short, half way down that paragraph:

"The first confirmatory test was a recombinant immuno-blot assay (RIBA-1)."

Then in the next paragraph he talks about the second generation testing:

"In 1991 a second generation ELISA anti-HCV antibody test became available. This test used not only the c100-3 antigen, but also the c-22 antigen and the c-33 antigen. This test had much improved predictive value, sensitivity and specificity."

Do you think that is the test that was recommended to you by Dr Follett and used by you?

A. Yes, I think it was. I do remember that we started testing our patients at clinic reviews at the time that blood donor screening was introduced, and I think Dr Follett was involved in both the Scottish blood donor screening programme as well as with haemophilia

patients. So I think that was what we had: the second generation anti-HCV ELISA and the RIBA-2 confirmation test. That, I think, was what appeared on the report forms we got from Ruchill Hospital.

Q. Because Dr Hay in his next paragraph talks about the RIBA-2 test, but of course that's confirmatory. So that wouldn't be the first test that you used. That's right, isn't it?

A. That's right. What I clearly remember is we would get reports back saying "screening test result" and then confirmed by RIBA-2.

Q. Yes, thank you. Could we go back to your statement now at 0848? Question 4:

"In what circumstances were blood tests carried out during the periods 1990-1995 and from 1995 onwards? Were patients tested individually or as a group? Were fresh blood samples taken for the purpose of testing or were stored samples used? Who carried out the HCV tests?"

Could you just answer that in your own words, Professor Lowe; just that question, please?

A. Yes, fresh blood samples. So patients would come up to the clinic and we would say, when it got to blood tests, "Now, in addition to the routine blood tests, the liver function tests and the Hepatitis B, we now have a test

for Hepatitis C, and this is a recently discovered virus, which is thought to be the cause of most cases of non-A non-B Hepatitis and it's important we test for this because, like Hepatitis B before it, there is the potential that antiviral treatment may be available for those patients who are found to carry the virus, to try and clear it from the circulation," and that we and other haemophilia centres were now introducing Hepatitis C screening as part of monitoring for chronic hepatitis and liver disease, as recommended by UKHCDO.

Q. Yes. Just to read on, the next paragraph, question 5:

"Did they tell their patients that HCV tests were being carried out?"

You have just addressed that but if we look over the page at 0849, the top of the page:

"Patients were routinely informed that HCV tests were being carried out. They were told that Hepatitis C was a recently discovered virus which was thought to be the commonest cause of non-A non-B ..."

"Patients were routinely informed that HCV tests were being carried out"; that doesn't sound as though you are offering the test to the patients; it sounds like a fait accompli.

A. Well, what I would say to the patients when it came to blood tests, I would routinely go through what we wanted

to measure, the blood count Us and Es, liver function tests as usual, Hepatitis B as usual, but we would now say, "This new test is available. It's a recently discovered virus" -- as I have said -- "thought to be the commonest cause of non-A non-B Hepatitis and this is" -- you know, I would say to patients, "This is quite good news really because we now have a handle on this rather vague, non-A non-B Hepatitis."

And we would say to them that publications were coming out indicating that most patients who had received unheated blood products in the past would have a positive test. That indicated exposure to the virus. As I have said in my statement, it didn't necessarily mean that they were carrying the virus. That would have to come further down the road.

So I would make it clear to patients that HCV antibody testing was the first stage of a long journey that we were going to have to undertake over a period of some years. And the analogy I would use would be Hepatitis B and say, "Well, remember" -- we had been talking about Hepatitis B by this time for, you know, 15 years.

We knew about Hepatitis B, we knew about the importance of vaccination. And I took them back to the 70s, when most patients who had received blood products

had been found to have antibodies to Hepatitis B, that that meant exposure but only a minority of patients with Hepatitis B turned out to be carriers of the virus, and it was that minority of patients who were at risk of having serious liver disease.

What I said was, "This is the start of testing for HCV but it's going to be a long process. This will just tell us if you have been exposed to Hepatitis C and if you have had blood products before 1985, the chances are that it will be positive.

What --

Q. Sorry --

A. -- then happens is that we need to do further testing to see if you carry the virus or not."

Q. I'm interested, Professor Lowe, in whether patients are told, "We are going to test you for this newly identified virus," or, "You can have a test if you like."

A. The way I would put it to patients is, "We are now coming to the routine blood tests and we would like to" -- or we would want to -- "this is now our policy," at which points patients could say, "Well, I don't want that test". If they wanted. I can't remember anybody saying no because if you explain to them -- they already knew that they were being screened for non-A non-B

Hepatitis and I think most patients shared our view that any advance over the woolliness and vagueness about non-A non-B Hepatitis was in their interests to know about.

Q. It's just the way you have put it in your statement, that patients were routinely informed that HCV tests were being carried out as opposed to patients were routinely informed that there was now a test which they could have if they wanted?

A. Yes, well, as with any other of these tests, patients could say, "I would rather think about this virus before having a test." I can't recall any of the patients I saw ever doing that if you went through, as you say, at every review clinic, the hepatitis story.

And of course, many patients had already heard through the grapevine about Hepatitis C. It had been talked about in the general press, it was being talked about by the Haemophilia Society and it was being talked about in the haemophilia community.

Q. I understand that. At what stage is this conversation happening? Is it before the blood --

A. Before the blood is taken, yes. So the doctor would see the patient at the clinic and then at the end of that discuss what we now wanted to do in terms of blood tests or other measurements. Sometimes you would take the

blood yourself, sometimes they would be sent through to the haemophilia sister to do that as well.

Q. So this new test is only being discussed at an annual review. Is that right?

A. Reviews were at least annually. Sorry, we tried to make sure that every patient with haemophilia, no matter how mild, was seen at least annually. Many of our patients were reviewed more regularly than that.

Q. Sorry, I'm not being clear. You have now got this new test that you can use; do you simply wait until the patient comes in for their annual review before discussing it or did you ask patients to come in to be tested with this new test?

A. No, from late 91 we introduced it into reviews. So most patients would then be tested between late 91 and late 92.

Q. So if your annual review was six months away, then you wouldn't hear about this new test until six months later?

A. Yes, but that was not really a matter of concern because, you know, you weren't going to take any immediate action as a result. Patients expected that their reviews, which could be three-monthly, six monthly, 12 monthly, they would have their liver and hepatitis assessed and that was --

Q. Professor, I understand that. I'm just trying to get at the essentials of how the testing was carried out.
A. Sure. So it was from the time of introduction, in I think about October 1991, as patients came through the review clinic, we then spoke to them about it and tested them.
Q. It wouldn't be a question of blood being taken as usual and then, as the blood disappears, you saying, "Oh, by the way, we have a new test and we are going to test for that as well"?
A. No, I would speak to my patients all about testing before the blood sample was taken.
Q. Okay. Who else in the unit would be having this kind of conversation with patients?
A. Well, by the time -- by 1991, my co-director was Dr Walker. So we would both be at the clinic. The junior staff at the time -- there was a bit of transition. We had previously, all through the 70s, 80s and 90s, had a haemophilia SHO in the medical unit but that post was terminated, I think, around that time. So the junior staff were all training haematologists, training in haemostasis and thrombosis under Dr Walker.
Q. Right, so --
A. And they would be attached to the haemophilia unit for six months or a year.

Q. So which of these people would have this job as well?
A. All of us.
Q. Right.
A. Again, we would go through the same procedure, so we have our regular unit meetings. When we added Hepatitis C, Dr Walker and I would sit down with the nurses and juniors saying, "Right, we have now agreed with the regional virologist. This is what patients are to be told about the virus and about the test."
Q. Right. What was that message that you gave to the junior doctors? What were the patients to be told?
A. All junior doctors, as I have said, would sit with a consultant at the start and go through the whole story about what to ask the patient, how to examine them, what to tell them about the tests, and what to tell them about test results from previous testing.
Q. What were they told to do?
A. Exactly what I have just told you: the significance of the Hepatitis C antibody test and what interpretation could be made from a positive result or a negative result.
Q. Were they told to offer the test or were they told to tell the patients that the test was being done?
A. We taught by example. So a junior haematologist, a physician training thus, would sit in with us at the

clinic and would be party to the discussions we would have with the patients and told to follow that.

Q. Right.

A. Could I say that the haematologists, of course, in training, were also doing other clinics, at which Hepatitis C testing was now being performed. Obviously, many patients with other haematology conditions had had multiple transfusions. So the same process was going on at all the clinics that they were doing. Not just haemophilia.

Q. Okay. At this stage, when you are discussing the new test, did you discuss the implications of a positive result with the patient?

A. Yes, as I have said, we would say to them that a positive test result, firstly, was very likely in any patient who had had pooled blood products.

Publications were coming out in the UK and other countries that the majority of patients would have a positive test. So I would say to them, "Be prepared, if you have had blood products, for a positive test. It would be surprising if you didn't have a positive test," and then to say, "Now, that tells us about your exposure to the virus. You have met the virus at some time. You have made an antibody against it. That's what we are picking up. What we don't know is did you clear that

virus, as most patients with Hepatitis B did, or will the virus be in your body somewhere, in your liver, with the propensity over a period of time, to cause chronic liver disease?" So this test is the start of a journey.

Q. And that was before the blood was taken?

A. Yes.

Q. Okay. Thank you. Do I take it then that there weren't any written guidelines in the unit about what patients should be told before the test?

A. No, but we discussed it in detail. And there were presentations from the hepatologists about Hepatitis C. I mean, Hepatitis C was the hot topic at that time at the regular general hospital meetings. The hepatologist, Dr Mills from Western Infirmary, would come over and give a whole hour on Hepatitis C and of course, throughout the hospital surgeons were now, you know, saying, "Look, should we know, before operating on somebody, about Hepatitis C?" and there was a lot of discussion about that. At general medical clinics, which in Glasgow Royal Infirmary were, as you might imagine, full of people at risk of liver disease -- they were -- you know, Hepatitis C was being introduced as part of liver testing because, hitherto we had assumed that in the West of Scotland, anybody with a suggestion of liver disease, raised liver function tests or

whatever, alcohol was by far the most likely cause but, you know, a second major cause of liver disease was happening.

So I was doing general medical clinics at the time, haemophilia clinics and, you know, many patients were now getting, you know, the story about liver function tests are disturbed, here is a new hepatitis virus. So there was lots of discussion at clinics, a lot of discussion in the hospital and a lot of education given to all doctors and nurses, not just those in the haemophilia centre.

Q. But no written guidelines?

A. None that I can remember.

Q. Okay.

A. We did eventually, as hepatitis -- well, the UKHCDO produced its first guideline for haemophilia management at the start of --

Q. I'm talking about guidelines in the unit here?

A. -- and that's what we used in the unit.

Q. I'm looking at making sure that the junior doctors are, you know, giving the necessary information to the patients and so I would like to ask you, Professor Lowe, if you wouldn't mind, if in retrospect you think it would have been a good idea to have had guidelines like that or a written policy, so that it was absolutely

clear to the junior doctors what they should be telling patients about this new test?

A. Well, I hear what you say and I have been thinking about it over the coffee, because you raised this before. I go back to the same answer. I think the best way to train a junior doctor is to get them to sit in with you and to see what you do, to see how you put it.

In particular, giving information to patients. It's very much an individual process, so what I want to show the junior doctors, who were coming in and learning how to review a patient with haemophilia, is to see how we did it, which is to say, "How are you? What's life like? What's your main concerns at the moment?" And then go through the different aspects, chat to them and then, when it comes to hepatitis, see how we approach it and say, "Well, you will recall that in your individual case, you have had this treatment. You may or may not have had abnormal liver function tests. We have talked in the past about Hepatitis B," and to lead them through the process leading up to Hepatitis C.

Q. I think you have answered that now.

A. It would have to be a pretty long-winded protocol and it would be so general as to probably be counter-productive. I think the best way is to lead by example.

Q. Right. Surely it would have been possible to produce quite a short document. It wouldn't have to be long-winded, would it?

A. Yes, but what I'm trying to say to you is that you are trying to cover a lot of things in a haemophilia review appointment and, you know, the best way to show that is the subjects that might be covered and how you interact with the patient in doing that. Yes, you could do but I think it's better to show, with real patients, how you do it than to produce some piece of paper, to be honest. I still think that.

Q. Yes, okay. If we look at page 0849 now, please, at the top of the page. Just reading on, the patients are told about Hepatitis C and then you say:

"As with other routine blood tests, including liver function tests and Hepatitis B tests, verbal informed consent was obtained."

You have discussed that:

"UKHCDO and haemophilia centre directors were advised by their medical defence societies in 1990 that Hepatitis C testing could be undertaken on the same basis as other liver function tests (ie HIV type counselling was not necessary)."

You make a reference to one of the annexes to the collective response.

We had better just have a quick look at that. That's [PEN0180793]. What is this document?

A. This is a minutes of a meeting in February 1990. It's one of the regular meetings that occurred two or three times a year, of haemophilia directors for Scotland and Northern Ireland.

Q. Okay. We see that you are chairing the meeting.

A. Hm-mm.

Q. And that Dr Ludlam is there?

A. Dr Hepplestone is from Dundee, Dr Taylor is from Inverness.

Q. If we go to page 0794 and at the bottom, paragraph 6:

"Hepatitis C tests."

It says there:

"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 LFTs (ie HIV type counselling was not necessary)."

So this is a reference in this meeting to another meeting, at which an unnamed Medical Defence Organisation -- is it a lawyer?

A. My memory is that it was a Dr Iain Simpson, who at the time was, I think, the chief executive -- or whatever

the title is -- of the Medical and Dental Defence Union of Scotland.

There are three Medical Defence Organisations in the UK, as you know. There is two based in England, there is the MDDUS, and Dr Simpson came to a meeting of the UK regional haemophilia centre directors just before this meeting, I think, at which both Dr Ludlam and I were. The UKHCDO was only for -- what we now call the "comprehensive care centres", in other words the major centres. The title was slightly different at the time, they were reference centres.

So Dr Ludlam from Edinburgh and I, representing colleagues in Glasgow, would go to the UK meetings. So it was at that recent meeting that Dr Simpson came along and obviously was talking mostly about HIV and AIDS and medico-legal issues. But at that meeting he was asked by UK haemophilia directors, "What about Hepatitis C because we have now got Hepatitis C coming in? And do we have to go through the great counselling about HIV" that had increasingly been advocated, and we talked through the position, and at the end -- which was that every patient attending for haemophilia review across the UK was being regularly screened for hepatitis, Hepatitis B, non-A non-B, Hepatitis A, if they became jaundiced, and what about Hepatitis C. And his opinion,

on behalf of medical defence organisations, was that if patients are well used to being regularly monitored for post-transfusion hepatitis, and Hepatitis C is being added to all these other tests, they could see -- he could see no special case.

He said, more or less, "It's a no-brainer. You are saying to patients they are regularly being checked out for non-A non-B Hepatitis and this will be a positive step in that direction." He didn't see any particular need for information other than what I have just been telling you, telling them about the test, explaining that this is now being added to the other hepatitis screening measures that have been used for years. And we are then relaying this conversation, Dr Ludlam and I, having been at that recent meeting, to our colleagues across Scotland for their information.

Q. Yes. Was that the basis on which you decided that pre-test counselling was not required?

A. Well, we gave pre-test information about the test. You know, all our patients, as we have been saying, throughout the 1980s, had been told about non-A non-B Hepatitis and the possible severity of it. And we now amplified that by saying, "Let's now come to hepatitis testing. We are doing the liver function tests, we are doing Hepatitis B and," as many patients had already

heard, "there is now Hepatitis C," and then we would explain the nature of the Hepatitis C antibody test, what it meant, what it didn't mean, and that this had now been recommended by haemophilia doctors to be added to the screening tests. And as I say, my recollection is that, having explained to patients about that, they said, "Fine". I mean, some patients wanted to know more about it, so you would talk in more detail about Hepatitis C, and some would say, "That's just fine. I have had enough information."

Q. Yes, but was it the opinion of Dr Simpson that was the basis for you deciding not to have, as you put it, HIV-type counselling at the time of testing?

A. Dr Simpson and all the other haemophilia directors who were at that meeting across the UK. I mean, Professor Preston gave a very strong case for Hepatitis C testing. He said, it is becoming increasingly clear that this is the cause of non-A non-B Hepatitis. It's important to have this information. It's important to have it so we can see the extent of it in the haemophilia population but most of all, it's important for the individual patient.

Patients and the Haemophilia Society said, "Well, look, we have to know about this because there is now the prospect of antiviral treatment and we need to start

evaluating patients so we can identify who has been exposed to Hep C, in due course which patients then carry the virus" --

Q. I understand all of that.

A. So we had a long discussion at this meeting.

Q. Which meeting are you talking about? Are you talking about --

A. The meeting preceding that.

Q. -- the meeting in February 1990 or the other one?

A. Yes, I think it would be earlier that month.

Q. Is it the Dr Simpson meeting you are talking about?

A. The Dr Simpson meeting.

Q. Let's just be clear: the basis on which you decided that HIV-type counselling was not necessary was because of what Dr Simpson said at that earlier meeting, and also because of what haemophilia clinicians said at that meeting. Is that right?

A. Yes, the consensus emerged at this meeting of UK reference centres, that Hepatitis C should be added routinely to the routine monitoring for non-A non-B Hepatitis that was going on across the country. And with regard to that, you know, patients should be told about the tests but it was not thought that you needed to go into all the detailed HIV-type counselling, given that patients were already being monitored for non-A

non-B Hepatitis.

Q. Thank you.

A. In a sense it was a refinement.

Q. Thank you. Can we just be clear what the difference would be? If you had decided that HIV-type counselling was necessary, what would you have done differently when you spoke to the patients at the time of testing?

A. To say that -- well, to explain again about the Hepatitis C test, to go through it and say, you know, "The likelihood is, from what we know, that the majority of patients treated before 1985 with unheated blood products will have a positive test. The reason we are keen to do this is to identify which of our patients have been exposed to Hepatitis C virus and that will then lead to further testing. And the point of doing this is obviously to give you more refined information about your own risk of getting liver disease and also to have the potential for what to do about it, in terms of antiviral treatment, and also the question of sexual transmission."

I mean, all our patients who had received --

Q. Professor Lowe, sorry to interrupt you there but is that different from what you said you did --

A. I think the same thing. We then might have said, "Now, it has been recommended that you should, you know, have

more thinking about that. Do you want the test or do you not want it?" But my recollection --

Q. So that's the difference, is it?

A. Yes, I suppose not doing the test immediately but saying, "Would you like to come back at your next annual review, and we can test you then?"

Q. Right. Okay. So the difference is that you would give the patient more time to think about the implications of a positive diagnosis and to decide whether they want to go ahead with having the test?

A. Yes.

Q. That's the difference?

A. And indeed, knowing that the likelihood was that it was going to be positive anyway, in patients who had received blood and blood products.

Q. So from what you are telling us, the information that you are giving to the patient is not very different in the two scenarios.

A. Correct. Yes.

Q. It's giving the patient more time to make the decision. Is that what you are saying?

A. Yes, that's right. That's right.

Q. Okay. Thank you. Has your view about the necessity of that kind of counselling changed or did it change throughout the 1990s?

A. Well, we tested all our patients, really, within that fairly narrow window at the time. We started in 1991 --

Q. Professor Lowe, I'm asking you about whether your view about whether you needed to do HIV-style counselling has changed? Did it change in the 1990s? Did there come a point when you thought, "Actually we should be giving the patient thinking time here"?

A. I don't think so. I think the general reaction from our patients was that if they -- if a new hepatitis virus had emerged, they wanted to know about it, particularly as effective treatment would soon be available.

Q. Okay. Thank you. Can we have a look at [PEN0180419], please? This is a supplementary statement from Dr Vivienne Nathanson, who has already given evidence to the Inquiry. Have you had an opportunity to read this?

A. Yes, I have.

Q. If we could go to 0421, the question which Dr Nathanson has been asked is:

"What was the correct approach to testing for HCV between 1991 and 2000? In particular, what information should a clinician have provided to his/her patients about the disease and the implications of a positive diagnosis? What was the current GMC/BMA guidances on this point and how did it evolve? Were there any circumstances in which testing could be done without a

patient's consent?"

And what Dr Nathanson says, just reading on:

"The correct approach to testing for HCV, or any other condition, between 1991 and 2000 can most easily be summarised by the introduction to the chapter on consent in the BMA publication 'Philosophy and Practice of Medical Ethics'. This was first published in 1988, and states:

"'The basis for any discussion about consent is that a patient gives consent before any investigation and treatment proposed by the doctor. Doctors offer advice, but the patient decides whether to accept it.'

"That chapter goes on [to] argue against the concept which remained fairly common at that time, that patients do not want to be bothered with the information, or that they would prefer to let the doctor make the decision."

Just pausing there, I imagine that you would agree with all of that?

A. Yes, that sounds entirely reasonable.

Q. Just reading on:

"While at this time the GMC advice was far less detailed, the relevant section is contained within the 1988 advice 'HIV infection and AIDS: the ethical considerations'. Paragraph 12 starts:

"'It has long been accepted, and is well understood

within the profession, that a doctor should treat a patient only on the basis of the patient's informed consent.'"

And her commentary:

"Again, the emphasis is upon the requirement for consent from the patient."

Then she refers to the GMC advice on serious communicable diseases, dated October 1997. Have you had an opportunity to look at that?

A. 1997? Not recently.

Q. Okay. We can show it to you in a second. Just reading on:

"That falls within the period in question ..."

That's 1991 to 2000:

"... and again states the primacy of consent from the patient before testing other than in exception circumstances. Those exceptions are detailed."

She mentions children not being competent and so on.

She then refers to paragraph 4 of this GMC advice, which says:

"Some conditions, such as HIV, have serious social and financial, as well as medical, implications. In such cases you must make sure that the patient is given appropriate information about the implications of the test and appropriate time to consider and discuss them."

If we could just go over to the next page, reading from the top:

"It is clear and explicit that in 1999, the GMC required doctors seeking consent to have regard to the implications of the test result. This is more explicit than the earlier advice on testing for HIV, but is in accord with it. While the advice relates to HIV, it is important to note that it identifies 'some conditions such as HIV' and is not, therefore, limited only to testing for HIV."

The next paragraph:

"Given that in the nine years from the production of advice on testing for HIV to this advice on serious communicable diseases more and more doctors have had to test for HIV, and therefore had to consider how to advise on testing for conditions with serious non-medical consequences, the GMC was almost certainly reflecting best practice and a recognition that not all practitioners were as yet practising at this level."

So just having looked at that section of Dr Nathanson's report, Professor Lowe, would you agree that Professor Nathanson is suggesting that from 1997, the best practice for HCV testing was to discuss the implications of the test result with the patient and give the patient appropriate time to consider whether

they want to go ahead with the test before actually having the test. Would you agree with that?

A. Yes, that's what she is saying in 1997. By that time we, and probably every other haemophilia centre, had already tested extensively our patients for Hepatitis C, on the background that we had been doing that for 20 years beforehand, looking for hepatitis testing. So I think the timing and the context is not necessarily applicable to what we and other haemophilia centres were doing in 1991.

Q. Right.

A. I mean, the patients were well educated about hepatitis, non-A non-B, and as I keep saying, my recollection is that when you explained to patients that a Hepatitis C test was now available, and they were likely to have been exposed to it, and that it was our recommendation that they should go ahead and start the process which would take a number of years of evaluation, they were quite happy to have that.

Q. I'm asking you about what Dr Nathanson is saying and I think you told us earlier that your view about the necessity of HIV-type counselling remained the same throughout the 1990s. So that would include 1997, would it not?

A. Yes, I mean -- okay, from 1997, you know, Dr Nathanson's

opinion is there. To what extent that is practised in -- I mean, I hadn't been involved in --

Q. Can we take it --

A. -- Hepatitis C testing since 1997 because we did all our patients long before that. I take her point of view. I think that the reality was that in 1991, patients, doctors and nurses in haemophilia centres all across the UK were concerned about Hepatitis C and there was a general agreement that we should get on and know about it.

Q. Let's be clear. Are you saying that in 1991 you would disagree with what Dr Nathanson is saying here, the necessity for HIV-type counselling, but by 1997 you would agree that best practice was HIV-type counselling for HCV testing?

A. Well, one has to respect Dr Nathanson's opinion. She chairs an ethics committee and she is charting the evolution of thought.

Q. So what is your answer to my question?

A. Sorry, repeat the question.

Q. Are you saying that in 1991 you would disagree with what Dr Nathanson is saying here, the necessity for HIV-type counselling, but by 1997 you would agree that best practice was HIV-type counselling for HCV testing?

A. Yes, I think it would be. From that time.

Q. Thank you. What's the difference between 1991 and 1997?
A. What's the difference?
Q. Why has best practice changed from 1991 to 1997? Is it knowledge? Severity of the condition, for example? Why has there been a change? Why did you not need to do HIV-type counselling in 1991, but in 1997 best practice would be HIV-type counselling?
A. I think one factor has been increasing knowledge of the severity of Hepatitis C. In 1991 we were keen to find out which patients had been exposed to it so that that could clarify advice given to patients and for management. It was hoped, I think, initially, that rather like Hepatitis B before it, the majority of patients would have cleared the virus and only a minority would then progress to liver disease. And I think the part of the change in opinion, which Dr Nathanson has considered, is that during the 1990s, we now know that only about a third at most of patients clear the Hepatitis C virus and two thirds are carrying it, and we also know that the proportion of patients developing serious liver disease is increasing. So I think there is a change in the perception of the severity in Hepatitis C.
Q. Okay, thank you. Can we have a look at Dr Hay's report at page 30 of [PEN0180961]. Dr Hay has been asked to consider

these questions, communication to patients at the time of testing, and at this stage in his report he is discussing it but the specific paragraph that's relevant to what we have been discussing is over the page on 0991. At paragraph 64 he talks about his practice:

"... my practice in Liverpool and Manchester to inform patients that I was testing them for Hepatitis C and go over (again) an outline of Hepatitis C. Consent and counselling was and is not the norm prior to HCV testing and hepatologists would and do routinely test for HCV as part of an investigation for abnormal liver function test without discussing the test specifically with the patient. They may tell them they are testing for hepatitis viruses."

Then the next paragraph:

"Some patients have complained, many years after the event, that they were tested 'without their permission'. In some cases they may, indeed, have been tested without being specifically informed and in other cases it is documented that they were informed both that they were being tested and of the result. The idea that an HCV test should engender prolonged pre-test counselling derives from the practice adopted after 1985 by most centres, of counselling prior to HCV testing. The implications of a positive HCV test could be perceived

as a death sentence, led to loss of insurance, marriage breakdown and even, in some cases, suicide. There is no comparison between this and HCV testing. For that reason, there has never been a specific consent process attached to HCV testing, even though it would be normal practice to inform the patient that they were being tested and to inform them of the result."

Then reading on to the next paragraph:

"In our centre, we informed them we were testing them for HCV, discussed the result with them when available, and wrote to the GP and documented the discussion."

Have you had an opportunity to absorb that, Professor Lowe?

A. Yes, I have.

Q. Do you have any comment on what Dr Hay has written there?

A. Clearly he has got different views from Dr Nathanson, in the specific instance of HCV testing. I have to say, talking to hepatologists over the years in Glasgow, it's my impression that, like Dr Hay's colleagues in Liverpool and Manchester, it is not routine to give detailed counselling when investigating patients for liver disease. So it seems to me there is a discrepancy between Dr Nathanson's opinion, which is basically

saying HCV is like HIV, and the opinion of Dr Hay and most hepatologists. They are doing their job. The commonest cause of liver disease increasingly is Hepatitis C in the UK, and it's part of what liver doctors do, to say, "Well, as part of routine testing there it is." So there is a spectrum of opinion, I think is my response to these two statements.

Q. Yes. Is there not a difference between the context of being tested at your haemophilia centre and being tested when you have been sent to a liver specialist? Is there not a difference there?

A. Yes, and of course it will vary from patient to patient. If somebody is referred to a liver clinic or general medical clinic because the GP has randomly done liver function tests because somebody is not well, the amount of pre-counselling, if you like, from the GP will vary, the patient intake and response will vary, and then what they are told by the doctor at the general medical or the liver clinic will vary.

I mean, my response -- I think Dr Hay has a realistic approach and I think his experience and his thoughts probably echo those of most haemophilia centre directors over the past 20 years, with regard to consent for HCV.

I mean, our practice seems to be very similar to

what Dr Hay has said that he did. We informed them that they were testing them for HCV, discussed the result and wrote to the GP and documented it. I think that's pretty standard for haemophilia centre practice.

I really don't think I can talk much about liver clinics and general medical clinics since I have not done those for years, but I think Dr Hay represents what was thought and what probably is thought by current and recent haemophilia centre directors.

Could I just make one comment --

Q. Just before you do, is that including yourself?

A. Including myself.

Could I just make one comment about Dr Nathanson? I know Dr Nathanson. I respect her opinions, she has done a huge amount of work in ethics. But my response is: where do you stop? I mean, take a haemophilia clinic, do you say before the full blood count, "This may show that you have leukaemia or cancer"? Do you say before the urea and electrolytes, "This may show that you have renal disease, which could kill you and lead to renal dialysis"? At what point, when you are doing 20 plus routine blood tests, you have to be cognisant that you have 30 minutes to cover a whole variety of things, and talking about testing is a percentage of that? Where do you stop? If you carry Dr Nathanson's

argument to the extreme, patients are going to get ten pages of possible things that could happen when you do routine blood testing. And essentially, Hepatitis C, like measuring people's weight and asking them about their alcohol, is becoming a routine test for picking up the serious and treatable problem of liver disease.

I have to say, I'm more sympathetic with Dr Hay's opinion than Dr Nathanson's.

Q. I think, to be fair to Dr Nathanson, I think what she would say is because a diagnosis of Hepatitis C has serious implications for the patient, they should have the opportunity to consider whether they want to go ahead with the test. I think that's her rationale.

A. Yes. Okay. That's a reasonable point of view. In practice I'm more sympathetic to Dr Hay.

Q. Thank you. Can we turn to what you did do with the results that you received. If we go back to your statement at 0849, at the bottom of the page, the question is:

"What was your practice in relation to telling ... patients of an ... HCV-positive test? Did you inform ... patients immediately upon receiving their results? If not, why not?"

Your answer is:

"Patients with positive (or negative)

anti-HCV-positive tests were informed of their test results at the next clinic review. It was not appropriate to inform patients immediately, as no immediate action was required ..."

Can you just explain that briefly?

A. I was a bit puzzled first of all by what "immediately" meant. It sounded to me as if you should ring up the patient, and we didn't see any point in doing that. What we did do routinely, if we got somebody with a positive HCV test, is that we would send them an appointment, an early appointment for a clinic review, so that they could know within the next few weeks or months at the most about the result and the implications.

And we didn't think that there is any point in dragging them up immediately. Haemophilia units are busy places. Day in and day out we are dealing with people coming in with bleeds, having teeth taken out, running around having surgery, trying to stop the bleeding after surgery, and we had a weekly clinic where we had the dedicated time that we could arrange for a number of rooms. And particularly in the 1990s, we had a pretty cramped unit at the end of a ward and the clinic -- we were able to corral rooms so there were rooms for all the four doctors and the nurse specialist

to sit and see patients privately, and it would all be planned. As I have said in my statement, people want to know the context of what does a positive HCV test --

Q. Sorry to interrupt you there, Professor Lowe, because we are up against the time pressure.

A. Sure.

Q. So there could be a gap of maybe as much as nine or ten months before a result would be passed over?

A. We would send out an appointment that week.

Q. So it's not the annual review?

A. It's not the annual review. I have said at the next review at the clinic. We wanted a dedicated time, we wanted half an hour at least in a room at the clinic, so we could sit down with the patient and have a full discussion about the implications of the positive Hep C test. What did it mean, what did it not mean, what were we going to do now. And that also allowed us to collect from storage areas the patient's old treatment records over the past 20/30 years. Their old medical records. So we could sit down with the patient and say, "Now" -- one of the questions clearly is, "When did I get this?" and the best guess that we can make is the first time you received a pooled blood product --

Q. How much time would elapse from result of test to seeing the patient, approximately?

A. It would be a number of weeks between getting the test -- I can't say how long. The other thing I should say --

Q. That's very helpful. If we could just move on to the next question, to make sure we finish in time. Could we go on to the next page, 0850?

THE CHAIRMAN: I think before you do that, we might have a short break. The stenographer is finding it very difficult.

Professor Lowe, you speak very quickly and that puts added strain on the stenographer. So we should just have five minutes at this stage, to let her settle.

(12.29 pm)

(Short break)

(12.37 pm)

THE CHAIRMAN: Yes?

MR GARDINER: Thank you, sir.

Professor Lowe, before the break I was asking you about how much time would elapse between the result of the test and the patient coming into the centre, and I apologise but I cut you off -- sorry about that.

Can you remember what it was you were going to say?

A. Yes, so we get in a positive test result for that patient and then the same week, my recollection is we would send them out an appointment for the clinic,

specifically for the purpose of coming back to discuss the result. We would allow ample time for that and we would collect -- in the meantime, which could often take some time to get them out of storage -- we would try and trace all their previous treatment with blood products in their previous notes, so we could answer questions about "When might I have got that and what's the overall pattern of my liver been?" and that could help us discuss what the prognosis might be for that particular patient.

Q. Thank you. If we just go back in time slightly. At this stage would you have done a confirmatory test?

A. Dr Follett advised us that we should only start Hepatitis C testing once we had -- once he had the facility to do not only the screening test but also to confirm it.

I mean, I do say in my statement that we were quite cautious with these first tests, given that there was an evolution of specificity and sensitivity.

Sorry, could I have the statement up again?

Q. Yes.

A. I think I used the word "probably". So the first time we talked to patients about a positive antibody test, this probably means exposure but we have to be a bit careful about the sensitivity and specificity of the

tests, or put that in layman's terms.

Q. It's the first line of the paragraph, which starts with the heading "What did they tell their patients about the implications of HCV?" Does that mean that when you got the result back from Dr Follett, you got the first result and the confirmatory result at the same time?

A. My memory is that they came together. I do remember seeing, you know, positive for antibody to Hepatitis C, confirmed by RIBA-2. I can't actually remember getting results saying "not confirmed by RIBA-2". There may have been a few patients, and I think what would be advised by Dr Follett in that situation -- although I'm struggling to remember an individual case -- is "Repeat the test and we will do it again".

Q. So you wouldn't have a situation where you would be speaking to a patient until you had confirmation one way or the other?

A. That was suggested by Dr Follett as the expert, and I think it was the same for blood donor screening. You didn't want something that had lots of false positives.

Q. Okay. Could we just look at 0850 again? The question is:

"What did you tell your patients about the implications of HCV?"

So this is at the point when the test result was

positive. So instead of just reading this out, perhaps, Professor Lowe, you could just tell us in your own words what your practice was about what you told the patients. You have touched on it a little bit but if you could just answer that.

A. I would say, "Right, you have got a positive Hepatitis C test. What does that mean? The only tests we have at the moment are those that tell us that you have been exposed at some time -- and we can't necessarily tell you when -- to the Hepatitis C virus. So what this test has picked up is an antibody. That's something your body makes in response to the Hepatitis C virus. Some of these antibodies to other viruses are protective, like Hepatitis B, so you are immune and that's good news because, you know, you can't get it again. But we don't know that at the moment for Hepatitis C.

"The important question is -- and which we can't answer at the moment -- are you actually a carrier of the Hepatitis C virus. Do you still have the virus in your body and what are the chances of that virus sitting in your liver causing future trouble down the line, which could take many years. We don't know at the moment."

And we would explain that tests were under development for the PCR test that would tell us whether

the patients were carrying the viruses, but it might be next years or the year after before those were sufficiently robust to guide clinical practice.

And said, "All we can do in the meantime is inform you that at some time you have met the Hepatitis C virus. You are not alone. Just about every patient in this clinic, in the haemophilia centres in Britain, and all around the world, everyone has been exposed to this virus because it's very common. So it's bad news in the sense that you are at increased risk of future liver disease compared to people without this positive test, but only time will tell and this is, as I keep saying, going to be the start of a journey. So what we want you to do is keep coming to the clinic. We will keep monitoring your liver tests. As the new Hepatitis C tests become available, we will get these done -- if you agree -- so that we can get a better handle on this. In the meantime, as we have been telling you for years, keep the alcohol consumption low, and in the meantime, keep the precautions with sexual intercourse and blood which we had been recommending since 1985, when HIV appeared, and in common with many other haemophilia centres we said to all patients who had received blood products, "Safe sex regardless of your HIV test because there are other viruses out there".

I have to say, we gave the same advice to people with negative Hepatitis C tests and said, "Well, good news. It doesn't look as if you have been exposed to Hepatitis C but we will keep an eye on it. We will do that test annually, bearing in mind that the tests are not quite 100 per cent accurate at the moment, and keep the same precautions with blood and sex, because we don't know what the next virus might be down the line. There may be other hepatitis viruses or whatever."

So that would be the tenor of the chat and that, together with going through the patient's notes and records and also talking with them about when they might have acquired it, would require a bit of dialogue, and we would have to say, "Let's go back. Was your first treatment as a child. You might have to ask your mum about where were you first treated," because patients wanted to know when were they exposed to that, and I say, "Look, it's quite difficult. Our colleagues at the virology laboratory at Ruchill are a bit -- even if they have stored samples, they are a bit uncertain about the robustness of the test. If you want, we can try and do samples further back but there is a bit of concern about the accuracy of those.

"It's most likely that you first acquired Hepatitis C the first time you either had concentrate or

the first time you had several treatments with cryoprecipitate."

Then we would help the patient, we would say, "We are happy to write to your GP, or to previous hospitals that you attended as a child, to say that you want this information and can they try and answer the question with details of your treatment."

So we did our best. We tried our best to indicate what the test meant, what it didn't mean, what action we were going to take. We would touch on the sexual transmission and we would say routinely, "Please discuss that with your regular partners and we are very happy if you want to bring them back" -- and some brought back their partner within a week -- "and we can chat to them about that and the implications, go through safe sex and to counsel -- and our nurses and social workers were also involved in that counselling of partners -- to counsel the partners that they could themselves be tested for Hepatitis C if they wished.

And that was definitely a situation where you would tell them about it and then tell them to go off and think about it. Because, unlike the patients with haemophilia who had been coming for years and years and been hearing all about hepatitis, this was coming to them fresh, and we could point out that if they wished

to go ahead, after thinking about it, with the Hep C test, they could go to their own GP, they could be referred by their GP or directly go to a department of communicable disease, which was now setting up Hep C services off the street, "Or if you want, we can do it here on the unit, it's up to you".

Q. To what extent were the implications of the diagnosis discussed in terms of prognosis?

A. Well, as I have said earlier, we are now talking about 1991/1992 when patients are getting positive tests. So we give them an update on the information available about rates of progression, and I think the Haemophilia Society bulletins were now becoming more specific.

So the Haemophilia Society was turning from regular three-monthly updates on HIV, to, "Now, let's talk about Hepatitis C." And the Haemophilia Society organised meetings throughout the country for patients, including Scotland, and we would routinely use the latest Haemophilia Society bulletin for a discussion about that and I would give that to my patients saying that this is the latest --

Q. For advice about prognosis?

A. To reinforce what we talked about at the clinic.

Q. What was that about, as far as prognosis was concerned in 1991/1992?

A. The one I remember using most frequently was the one that came out about 1993, and I think we submitted that as an annex to the Collective Response because it was about 1993 that obviously most of our patients had had their Hepatitis C result. It had been confirmed. And were then starting to educate them about the imminent tests for carriage of the virus, interferon et cetera. And that was, I think, a very good booklet produced in 1993, which I used very often with patients.

Q. Yes, but aside from that, Professor Lowe, at the meeting, the appointment when you are discussing the positive result --

A. Yes.

Q. I was asking you did you discuss with the patients the implications of the diagnosis as far as --

A. Absolutely.

Q. Right. What did you tell them?

A. That there was a -- if subsequent tests show that they were a carrier of the virus -- and we weren't sure in 1991/1992 what percentage that would be -- they would, you know -- that group in particular would have to be carefully monitored for liver disease and referred for consideration of antiviral treatment.

Q. Did you discuss the percentages of patients at that stage that were progressing to cirrhosis and the risk of

progressing to liver cancer, and so on?

A. Yes, I think it would be about that time that liver cancer was being reported, associated with Hepatitis C, in the early 1990s.

So we would talk about cirrhosis, what was cirrhosis and what would the symptoms be, and what would the prognosis be for somebody who developed cirrhosis and what treatment would be given, and then to say that particularly patients who have developed cirrhosis -- the liver as part of a cirrhotic process, it's prone to forming tumours. So that, in due course -- "so what you can expect is regular reviews. We will carry on examining you, doing the blood tests, and we may start doing liver scans but" -- we also said that, "Once we get the tests to see if you carry the virus or not, if you do carry the virus, we will then be referring you to Dr MacKenzie's liver clinic for more detailed information from the liver doctors, the experts. We are going to essentially hand over your hepatitis care to the professionals." As we had already done for HIV a few years previously.

We said, "We will continue to follow you up and give you whatever advice and support we can as haemophilia doctors and nurses, but it's time for the specialists to start taking over your liver disease and they will give

you full information about the up-to-date prognosis, estimates and further tests, like genotype and scanning. And the good news is that we have antiviral treatment starting to be developed. It has worked in some people with Hepatitis B. The hope is that it will work in some people with Hepatitis C."

So again, this is part of a journey, where we are all learning about the virus, we are all learning about the tests, the prognosis and the treatment, and we will keep you informed as much as we can."

Q. So this is in 1991/1992?

A. Yes, from giving patients the --

Q. Presumably you were testing beyond 1992. Is that right?

A. Absolutely. We were now doing this at every clinic. So what we arranged with our virology and hepatology colleagues -- and we had regular meetings with them -- is, "What do we do now?" And they said, "Repeat the tests" -- because of a concern about reliability of the initial tests -- "We will tell you from the virology lab when we have a reliable test for carriage," which is the PCR test. Which, as I think I said in my statement, came in about 1994, and the hepatologists said, "Right, who to refer? We can't cope with, you know, hundreds of patients all coming at once but carry on sending us anybody with any clinical suspicion of liver disease,

like possible early cirrhosis, symptoms, signs, of liver disease. We want to see them. And once you have got the PCR test to show which people carry the virus, send them and, you know, obviously if somebody has got highly abnormal liver function tests, you know, and you are concerned about them, we will see them." So we agreed a kind of prioritisation about who the hepatologists want to see.

Q. Thank you. So in 1991/1992, when you are meeting the patients and giving them this information, did you give them a percentage estimate of how many patients were progressing to cirrhosis?

A. Okay. I think we are still in the kind of -- about a third of patients from the biopsy studies seem to have cirrhosis.

Q. Is that what you told the patients?

A. That's my recollection about that time.

Q. Right.

A. But I would be careful to say, "This is an evolving disease, we can only give you an estimate. A lot of the estimates are based on these small studies of selected liver biopsies." And, you know, that, "The more important thing is the epidemiology, how many people are actually becoming sick with the disease. That's being monitored internationally and by the UKHCDO and we will

keep you fully updated on that."

Q. Did that advice change over time, as time went on?

A. Of course it would but, essentially, that role about updating patients was then taken over by the liver clinic. The first UKHCDO guideline came out, I recall, at the start of 1995, after a lot of discussion across the UK, and it emphasised that patients should now be referred to a hepatologist to take over the further diagnostic tests, scanning, liver biopsies, genotypes and all the rest, and they would be giving, you know, from the latest liver meetings, the best prognosis.

In fact at the Royal Infirmary, with Dr Morris appointed as a hepatologist, his first remit, in 1995, was to see all our patients; there was a clinical nurse specialist, Sister Neilson; and they came to the haemophilia clinic and took over in great detail the management and the information of the patients.

Q. Thank you. Who else in the department, other than yourself, would be giving this information to patients about positive diagnosis?

A. The staff at the clinic would be myself and Dr Walker. We were the two consultants. And one or other of us, or both, were at the weekly clinic. The juniors over the period 1991 to 1995 would be trainee haematologists, most of them experienced, who, as I say, were already

doing other haematology clinics, where Hepatitis C was an issue, including Dr Tait, who ultimately joined us as a consultant and co-director at the end of the time.

Q. So they had that job as well, did they?

A. Oh, yes.

Q. Right. How did they know what to tell the patients at these meetings?

A. Same thing. We had discussions. When they came to the unit, they sat in with myself or Dr Walker and went through the -- you know, "This is what we say to patients about haemophilia treatment, hepatitis, et cetera."

There was always a consultant at every clinic so that if a trainee doctor was talking to the patient and felt that, you know, the consultant should see them immediately with regard to further questions, we were available to do that.

Q. And I think, if we go over the page, 0851, down at the bottom we see the question:

"Were there any written guidelines or policies on communicating positive results to patients produced by [your] unit ..."

And the answer to that is no.

A. Again we taught by example. So we would have the juniors in with us when we went through this story and

then they would do it themselves, but we would be available next door, if required, if the patients wanted to see a consultant as well.

Q. Thank you. So, just to move away and have a look at some of chapter 4 of the Preliminary Report, you maybe remember, Professor Lowe, that chapter 4 of the preliminary report is the experiences of patients and their families. Could we go to page 65, which is paragraph 4.35? If we just go up the page a little bit, we will see that the heading on this bit of the preliminary report is:

"Knowledge of the risks associated with treatment by blood/blood products."

Back down to 4.35 again, it says:

"The great majority of witnesses told the Inquiry that they were not warned about risks associated with the treatment that they were receiving."

So this is about the question of knowledge of risks. Could we now go to page 68, paragraph 4.51. The heading here is:

"Consent to testing for Hepatitis C and HIV."

Paragraph 4.51:

"A theme that emerged from speaking with witnesses was their recollection that they did not know that they were being tested for Hepatitis C and/or HIV."

Could we go to page 70? If we have a look at paragraph 4.62, this section of the preliminary report is anonymised descriptions by witnesses of their experience of being told diagnoses and so on. 4.62 says:

"This witness went on to tell the Inquiry, 'The day I was told of my diagnosis was a very odd day. It seems as if everyone who attended the clinic that day was being told that they had acquired the virus too. People were coming out of their appointments saying, "Hepatitis C, what's that?"'"

Then, could we have a look on the same page at 4.66, under the heading, "Delays in being informed of their infection" -- this is the previous paragraph, sorry:

"The Inquiry asked witnesses about how the person telling them of their infection had come to know and how long that person had known."

The next paragraph:

"In response, a number of patients spoke of their concern that there may have been a delay in telling them of their infection."

Could we now go to page 72, under the heading, "What patients were told about Hepatitis C/HIV."

4.76:

"The Inquiry was keen to hear about patients'

experiences in the very early days of their diagnosis."

And over the next few pages there are descriptions of what patients were told, which I'm not going to ask you to read, Professor Lowe, but, just summarising what patients have told the Inquiry, they weren't told very much about the implications of the disease, the severity of the disease and so on.

So, just putting all of these experiences together at a very general level -- I'm not pointing to specific patients -- the Inquiry has been told by many patients and relatives that patients weren't told about being tested and weren't told about their results quickly and weren't told about the implications of the diagnosis.

So, given your evidence to us today about all the steps that were taken in your hospital, how do you account for this evidence that has been given to the Inquiry?

A. Yes, well, it's difficult, isn't it? For a start, we are talking about people, both doctors and patients, thinking back over a considerable period of time. We are talking about 20 years now since Hepatitis C testing came in. I guess it's always easier if inquiries like this are held nearer to the time so we can perhaps have more accurate memories.

But clearly there is a gap between what doctors and

nurses like me are saying. We give our statements. It is our genuine recollection that we discussed hepatitis fully with patients. Particularly in the 1990s, I seemed to spend a very large percentage of my professional time talking with patients and relatives about Hepatitis C.

So I think we really did make an effort to keep patients informed about it.

I think one of the problems with patients' recollections is that, as I keep saying, Hepatitis C testing was a journey. You start off with an antibody test and you say to patients things like, "We are not sure if it's accurate or not at the start." And then we have to give the explanation about, "This means exposure but not necessarily carriage," and patients may well have said at that stage, "Well, that's okay then." And then a year or two down the line you say you do or you don't have a positive test for being a carrier.

So patients and doctors and nurses have been having a long conversation over the whole of the 1990s about the significance of the tests and what they meant, and I think that some patients may have been reassured about the initial story about it's relatively benign, and then, as time goes by, the news gets worse and worse because many more patients turn out to be carrying the

Hepatitis C viruses -- 70 per cent -- compared to Hepatitis B, which was the only example we had to go for at the time.

So, basically, I think patients and staff were all going through this learning curve about the virus. One thing that we cannot do is predict, with a new virus, what the eventual outcome is going to be. All you can do is say to patients your best information at the time. But I was always careful to point out to patients that this was a learning curve for all of us. It was like HIV five years before. We all had to just go along and we did our best to communicate with patients our state of knowledge. We did that as doctors.

There are many studies showing that somebody comes out of an interview with the doctor and can't remember a word of what was said. I think Dr Hay's statement says that that is his experience as well.

But they then have a chance to talk to the nurses as they are taking the blood and giving the treatments, and the social workers, and we all tried to provide an environment in which patients had a number of people at the unit that they could chat to about it and we always had a very open policy saying, "Look, it's a lot to take in."

This was like HIV five years before, as I have

already said to the Inquiry. You go through a period of what is this all about. The quotation in the preliminary report saying, "Hep C, what's that?" Yes, a good question. The response to that is, "We have an open door, come back and we can keep you updated and answer the questions that you have."

Our policy in Glasgow Royal Infirmary was always to have a very open discussion with our patients and to make ourselves available.

To me, obviously, it's disappointing, as I am sure to everybody that I worked with at the time, that patients 20 years later are angry about not being told this or not being told that. There are many reasons for it, some of which I have tried to expand on. We are sorry if patients didn't think that they were communicated enough with but I think we did our best.

Q. Dr Nathanson suggested, when she was last here, that the best way for a clinician to deal with the problem that you have referred to, the fact that patients might not be able to absorb bad news, is to reinforce the message on subsequent meetings and make sure that the patient has enough time to take it in and understand the implications of the diagnosis that way.

Do you think that that would be an explanation for why the Inquiry has this evidence from the patients,

that there might have been a failure in clinicians reinforcing the message about the bad news?

A. Well, when patients were given the diagnosis, they were told, as I have just said, "It's a lot to take in." They can come back at any time. We were a unit that was operating 24/7. I used to go in on a Saturday morning and see patients who didn't take time off work but wanted to come up and chat then, and the haemophilia sister and I would spend hours, at their time, out of clinics pursuing these issues.

They could pick up the phone. All you can do is offer. As I say, I spent a huge amount of time, as did my colleagues, in the 1990s: Hep C, Hep C. Every day, every week, we spoke a lot about it and we did our best to communicate.

Q. But that could be an explanation, could it, a failure to reinforce the message?

A. Well, all of these conversations were trying to explain to people the current state of knowledge about Hepatitis C, the implications of it and what they could do about it and what we could do about it, and that was an evolving process. What more can you do?

Q. Could you just bear with me a second, Professor Lowe?

(Pause)

Thank you very much, Professor Lowe.

THE CHAIRMAN: Yes.
MR GARDINER: We seem to have run out of time, sir.
THE CHAIRMAN: We seem to have run out of time.
Do you have a substantial body of material that you want to put to --
MR DI ROLLO: Sir, this is obviously an inquisitorial process and there is material that's contained in the evidence and in the other material that was referred to, which I would wish to explore in the course of this topic. My learned friend has made reference to material already that -- there is obviously a disagreement from the patient point of view and the doctor point of view which the Inquiry needs to explore and obviously we will want to explore that with other witnesses in due course.
THE CHAIRMAN: Well, that is far too general for me. I need to know what that means. I don't expect you to tell me now. But my question was really related to how much time you will need with Professor Lowe. Have you any idea?
MR DI ROLLO: I would certainly want the opportunity, if it's available, to ask him questions and I would think that -- I would seek --
THE CHAIRMAN: Are we talking about an hour, a morning, a day, two days?
MR DI ROLLO: I think I would like to reserve my position on

that actually and wait and see how the evidence on the topic develops and see where we are. There are other witnesses giving evidence on this.

THE CHAIRMAN: I appreciate that.

Mr Anderson, are you intent on raising more?

MR ANDERSON: I don't think so, sir.

THE CHAIRMAN: Mr Johnston?

MR JOHNSTON: I don't think so.

THE CHAIRMAN: I think that we have to adjourn now and come back to matters.

You are off to Australia?

A. Yes, sir.

THE CHAIRMAN: Are you coming back?

A. I intend to come back.

THE CHAIRMAN: Perhaps we can make arrangements one way and another to accommodate you when you come back.

A bit of information: it appears reasonably clear that the meeting of the UK haemophilia directors at which a great deal of advice was given by the Medical Defence Union was on 9 October 1989. We do have a reference for that in paragraph 9.153 of the preliminary report.

The meeting that then followed is not one that we have been able to trace, so far as I understand it, despite your best efforts, Keith. We are still looking

at that but -- if you have got it, of course, it would be helpful to us to have it.

A. We have tried, sir.

THE CHAIRMAN: Anyway, we will adjourn now.

(1.12 pm)

(The Inquiry adjourned until Tuesday, 9 January 2012 at 9.30 am)