Tuesday, 17 January 2012

(9.30 am)

PROFESSOR JOHN CASH (continued)

Questions by MR GARDINER

THE CHAIRMAN: Good morning.

MR GARDINER: Thank you, sir. Good morning Professor Cash.

A. Good morning.

Q. I'm sure you will be pleased to know that this is your last appearance before the Penrose Inquiry.

A. I'm very pleased.

Q. This morning the topic is C5, which is information to patients, and we are considering in particular look-back and the tracing and testing of patients. Very broadly, the Inquiry is interested in why look-back was started in 1995, when screening for Hepatitis C began in September 1991.

So just to be clear, you will agree that look-back occurs when a donor tests positive for HCV and then in this case the SNBTS look back to see who has received blood products, which have been made from previous donations, and recipients of the blood products are traced and counselled and offered testing. That's a fair definition?

A. I would only make one very important comment, in that, if you take Scotland and if you take the UK, it's not

the SNBTS that traces back to the patient; it's another completely different organisation.

Q. Yes.

A. That certainly applied, as you know, in the West of Scotland. That's very important.

Q. Okay. We will have a look at the detail of that. What I would like to do is have a look at the letter that started off look-back in Scotland. So could we have a look at [SNB0084848]? Is this a letter that you are familiar with?

A. I am with the Inquiry but not previously.

Q. You didn't see it at the time?

A. I don't recall, unless you are going to show me I got a copy, but I doubt, in 1994.

Q. Yes. But you have read this recently, have you?

A. Not recently, recently, no.

Q. Would you like to just take a moment and read it?

A. Yes. (Pause)

Yes. I would only comment that -- you may smile -- that when the Southeast of Scotland in this particular context says it's feasible, that will raise a lot of doubt in many areas because they had a huge resource, and it was a very special, interesting area and they could deliver this, really relatively easily. Yes, I recall.

Q. I'm just showing you the letter so that I can ask you some questions about it. I'm not asking for a general comment.

A. Sorry.

Q. Have you read the first page then?

A. Yes.

Q. Could we go over to the second page, please? Would you just take a moment to read that, Professor Cash?

A. Yes (Pause). Yes. Good stuff.

Q. Okay, thank you. If we go back to the first page, please, would you agree that there are three important points about this letter? The first one is Lord Fraser says that:

"The Southeast blood transfusion study has shown that look-back is feasible and practicable."

That's the first thing he says. The second important thing is that treatment is now available, and the third thing is that a factor for him is not initiating look-back could result in liability for losses?

A. Yes, I strongly support all those.

Q. So you would agree with these reasons for starting look-back at this time?

A. Yes, and that was the basis of our debate in our committee, as you know, in May 1994.

Q. Yes. So this was the right decision?
A. Yes.
Q. We also see at the bottom of the page there Lord Fraser says:

"I am conscious that the matter of a look-back policy for HCV was considered by the Microbiological Safety of Blood and Tissue for Transplantation Committee (MSBT) at their recent meeting and that they have advised that procedures should be put in place to identify those at risk but 'whatever is done should be done equally and uniformly throughout the UK'."

Then he talks about other recommendations but he says:

"The advice which I have received from my medical and legal staff is such that I consider that it is no longer a matter of policy but of legal liability, and that look-back should take place as soon as possible in Scotland."

So we see there that Lord Fraser is conscious that this advisory committee is not advocating immediate implementation of look-back but not withstanding that, he is going ahead in Scotland?
A. Good for him.
Q. Yes. So just using that letter to help us understand the position back in 1991, who do you consider had

responsibility for deciding whether look-back should be implemented in Scotland?

A. I think I must have -- I mean, I think you are aware that in 1990 -- I think I have got it right but before we introduced testing, I was raising the whole issue and I think I raised it in the first instance with Jeremy Metters.

Q. We are going to look at all of that correspondence.

A. Well, you have asked who and ultimately the straight answer to your question is the Scottish Office, because this is -- a huge resource was going to be required and little of it has actually the resource to do -- the difficulties with blood transfusion service, they are about matters relating to the health board, which in my view at the time would have required a CMO letter to get things going. So, yes, it would be the department that --

Q. In Scotland?

A. In Scotland.

Q. The position was the same in 1991 as it was at the time of this letter?

A. Yes.

Q. Yes.

A. Yes, absolutely.

Q. So just to try to understand how the procedure would

work, in 1991 there was the SNBTS who had a board of directors and a committee, Medical and Science Committee, and that committee would make recommendations to the board of directors and then the board would implement them. Is that the way it should work?

A. Well, it should work. It would implement them or not implement them. The board had that authority. But in this context one would envisage that if the directors, which they had in 1990, had said, "Look, we think we ought to be beginning to consider this," they would have anticipated that whoever was in charge at any particular time would have taken that issue up because it was an issue that was felt the ultimate responsibility lay in St Andrew's House. So they would take it up with the medical colleagues there.

Q. Yes.

A. In 1991, as I said on the previous occasion, the responsibility for that was recognised to be the general manager of the SNBTS.

Q. But in terms of decision-making, in a way the advice of the two advisory committees wasn't relevant to the decision. Is that not right?

A. Sorry, I'm not with you.

THE CHAIRMAN: Mr Gardiner I am slightly concerned that "the committee" is now being used with reference to two

bodies and it may be necessary to distinguish more clearly between them. The committee in the letter, of course, is the MSBT, which had a much wider remit than blood transfusion.

A. It had a much wider and wasn't, in a word, the property of the Scottish Office either; it was the property actually of DHSS.

MR GARDINER: Yes.

THE CHAIRMAN: And in particular they had responsibility for tissue transplantation.

A. Indeed, sir.

THE CHAIRMAN: And one may have to read the reference to "its work" in the letter --

A. It was the old advisory committee that was greatly expanded now in terms of its responsibility.

THE CHAIRMAN: Sorry, Mr Gardiner, it's just in the hope that we don't run the two together.

A. I'm getting mixed up because there was the SNBTS committees, the medical/scientific committee. That was very much SNBTS and it reported to the SNBTS board that was chaired by David McIntosh.

THE CHAIRMAN: I think we understand that, Professor Cash. All I'm concerned with is that the record shouldn't confuse the two since later on it might not be as easily understood by others.

A. Thank you, sir.
MR GARDINER: Let's have a look at the documents. So could we have a look at [SNB0053102]?
THE CHAIRMAN: It's suggested that perhaps we have a five-minute break -- ten minutes? We will have as short a break as possible. Thank you.
(9.50 am)
(Short break)
(10.08 am)
THE CHAIRMAN: Yes?
MR GARDINER: Thank you, sir. Sorry to everyone for the delay.

Just before we broke, Professor Cash, we were talking about some committees and I think it would be worth just clarifying the different committees we are talking about.

There is the Medical and Scientific Committee of SNBTS, who advised the SNBTS board?
A. Correct, sir.
Q. There was the Advisory Committee for Virological Safety of Blood, ACVSB, which became, or changed into, the microbiological safety of blood or Advisory Committee on Microbiological Safety of Blood and Tissue, MSBT, and that committee advised ministers?
A. Indeed.

Q. And then there was the Advisory Committee On Transfusion-transmitted Infections, ACTTD, sometimes called the ACTTI, which ended up advising the MSBT committee on transfusion-transmitted infections. Is that right?

A. Yes.

Q. Thank you. So if we could have a look at [SNB0053102], we are going all the way back to 1990 now and that's a letter to Dr Gunson; do you remember this letter?

A. No.

Q. No. Okay. But we can see there that you are talking about the "twilight period prior to the commencement of full anti-HCV screening", and raising a question about whether to do anti-HCV tests on donation aliquots. You are not talking about look-back here, are you?

A. Well, it's entitled "look-back" sir, is the letter.

Q. Are you talking about targeted look-back, if you like, going back and seeing where donations --

A. Not particularly. I think what I imagine I was trying to get Harold on a roll for was, well, we had done look-back with HIV, we are in this twilight period. I must say that's an interesting word. It was a very long twilight. But before we start, can we begin to think then about, as HIV, then beginning to do something similar with Hepatitis C. I think that's all, sir.

I can't claim anything.

Q. Yes. Do you remember what discussions, if any, you had with Dr Gunson about that at this point?

A. No, I don't. I do know that Harold was pretty -- and I had a lot of sympathy for him. He was pretty unenthusiastic for a very long period of time, at the whole notion of look-back because, I think I have already said, even this morning, that for England and Wales, the nature of their structure of their transfusion services made it a really, as you looked at it, a giant of a task.

Q. Yes.

A. They were kind of busy doing many other things.

Q. Let's have a look at the next letter, which is [SNB0045010]. This is 21 May and this is from Dr Gunson to you. Do you think that's --

A. That's not look-back now, although its title "look-back" is a response to my letter. I think Harold is saying, look, we would like to stay where we are, ie wait until we have a report from a clinician saying we think we have a patient here that's jaundiced and may be related to transfusion. Then we would do something about it.

Q. Can you remember, if you did have discussions on 27 June with him?

A. I don't remember but I'm sure we did. I'm sure we did

but I can't remember them, sir.

Q. Let's go to [SNB0045009]. This is a letter to you from Dr Mitchell.

A. Yes, from Ruthven, from Dr Mitchell.

Q. It's headed "HCV look-back". Could we just have a look at the last paragraph there? He says:

"I have advised Bob Crawford at the present time that we have no look-back policy, although you will understand that in doing so, the service could be considered to be negligent in not advising about potential future use of donor blood."

So what did you think was the SNBTS look-back policy at this point?

A. I need to just -- could I just check the date, sir, please?

Q. It's 14 May --

A. Yes, yes. I think we were fishing around to explore are we going to really push this or not and so on. It became, as I remember, much more crystallised in our minds that we really needed to think about this when, in later, as I recall, Jack Gillon's team, that I had set up, with the main task of producing new donor selection process -- that was a colossal task and was hugely important, but we also said, "Look, while you are at it, guys" -- which would have included Bob Crawford.

I think he was in Jack's team -- "would you think about look back?" I think late in 1990 they came back to us with a report which included, "Look, we think ..." you know, "From our point of view ..."

This went to the directors and as I recall, that triggered then the pushing this up to Dr Metters. I don't know whether I have got the right time.

Q. We are going to show you all of these documents.

A. To answer your question -- I'm repeating myself -- I don't think in May 1990 we were at all sure. We were just -- you know, we were saying to ourselves, "Well, we did this for HIV, shouldn't we be thinking about it?" and so on. And I think Ruthven here is signalling, if we do think about it for the West, it's going to be a big, difficult problem. And I know, Bob Crawford -- bless him -- he is now departed -- worked amazingly hard.

Q. Can I just ask you a little bit more about that letter? Dr Mitchell seems also to be referring to the service perhaps being considered negligent in not doing look-back. Is that not right?

A. Yes, yes, sure.

Q. Yes. So would it not be fair to read that as him sounding a sort of distant alarm bell --

A. I don't think he was the originator necessarily of that

alarm bell. We were all beginning to say, "Hang on a minute". That takes me back, which may be wholly irrelevant, to a meeting I had in the Scottish Office in September 1988, with a group of people, including Scottish Office lawyers, in which our friends in the Scottish Office were concerned about the potential litigation that would arise from HIV. And this was, for me, a landmark meeting in which we eventually began to talk about who had the duty of care and legal responsibility and so on and so on and so forth.

So the notion that we may be taken to task about look-back at a later date was not -- was -- didn't originate -- I'm saying nothing against my old friend Ruthven -- with Ruthven. We had been all fretting about this.

Q. So in 1988 there was a concern expressed about potential litigation?

A. No. Not about HCV, sir. It was a meeting specifically called by colleagues in SHHD to discuss the potential litigation problems that might arise from HIV.

Q. In itself or look-back?

A. No, just in terms --

Q. In itself.

A. The generic was: is there anything we did wrong as, you know, we march forward with HIV?

Q. But I think you just told us that at this time SNBTS weren't really sure about look-back. Does that mean that you didn't have a policy --

A. Yes, of course, I beg your pardon. Yes.

Q. Okay. Let's go on to the next letter, which is [SNB0053586]. If we go to the second page, please. Thank you. So this is a letter from you.

A. Yes.

Q. Copied to --

A. David McIntosh and Harold Gunson.

Q. Harold Gunson, okay. If we can go back to page 1 again, it's to Dr Whitrow, Urbaniak, Brookes, McClelland, Mitchell and Perry. So SNBTS directors?

A. Absolutely.

Q. "As promised, I have discussed this topic with Harold Gunson."

Just pausing there. At this stage in July 1990, can you remember what your discussions were with Dr Gunson about look-back?

A. No, I don't. But you have shown me an old letter, which you said, "Did you have these discussions?" And I suspect -- and I said, "I'm sure we did," but I can't remember them. I suspect that's the link.

Q. The same discussions?

A. That we did have the discussions.

Q. And broadly he is unenthusiastic?
A. Very unenthusiastic, yes, for the reasons I have given.
Q. Okay. What's your attitude?
A. My attitude is, "Okay, we will buy it so far, Harold," but, as you will see later, I took this matter further, and ultimately very much further, but that was later again.
Q. Yes:

"We both agreed the following, it would not, after we start anti-HCV donation screening, be appropriate to introduce a systematic look-back programme on previous recipients -- as was done for HIV-1."

Just thinking back to Lord Fraser's letter, why did you think that an important factor in making this decision, look-back or not, that you had to discuss the topic with Dr Gunson and then report to the SNBTS? Would it not have been the other way round; you would have discussed it with SNBTS directors?
A. I think we have evidence from what we have just seen earlier, sir, that we did discuss it and I said, "Look, I'll start liaising," and so on and so forth. So it had been discussed, as I understand it, before July 1990. Indeed -- I mean, I need to check the dates, I can't remember -- but Jack Gillon's very important report, as I'm now recalling, in fact emerged in November 1990, and

we had included him in that remit for him, "have a look and think about look-back for us", and I'm pretty sure that that request for Jack and his team to do this went many months -- it will have taken them many months. So --

Q. I'll show you the letter.

A. You may have something that doesn't fit.

Q. I appreciate that this was a long time ago and I'm not trying to trip you up.

A. No, I appreciate that.

Q. I'm just trying to get your reaction.

A. I completely appreciate that.

Q. Let's have a look at [SNB0055023]. This is a letter to Dr Gillon. So this is back --

A. This is June, this is before the one we have just seen, that's right.

Q. Yes. You see, first sentence:

"The SNBTS directors believe it is now very important that UKBTS prepares itself for the commencement of full anti-HCV donation screening. As part of this exercise, they believe a high priority should be given to producing operational guidelines for BTS doctors ... in the context of counselling ..."

So what discussions have gone before with the SNBTS directors about what you are asking Dr Gillon to do?

Can you remember?

A. No, not specifically, but I mean, if you take what I have written there, sir, I can assure you that we -- and I think there is records of this -- were really quite concerned that the operational guidelines for our donor selection teams needed major updating and quickly, and so that was -- you know, it was discussed at some considerable length among the directors. And I'm absolutely certain in my mind that they, the directors, would have asked me, "Look, could you get Jack Gillon or anybody you think might be interested in doing this work," it was a big job.

Q. Just to go back slightly, Professor Cash, do you think that it's correct that during May and earlier in 1990, when you were talking about look-back, you might just have been talking about identifying donations, which were potentially transmitting the virus, as opposed to going another stage back and actually chasing the components that had been made from it?

A. I can't recall, sir, because the huge step after you have identified -- it's not the donations -- it is the donor. A huge step after that was into the area of patient records and so on and so on and so forth. That may be correct, I cannot recall.

Q. Yes.

A. But that would have been the easy start, simply stacking up donors. That would be happening anyway. But the key thing in look-back was what you did with that information.

Q. I mean, just looking at the letter to Dr Gillon -- it's asking him for operational guidelines in the context of counselling anti-HCV confirmed positive donors -- when you were asking Dr Gillon to carry out this exercise, did you consider that he would look at the question of a more systematic, extended look-back, or was it just the counselling you were asking him to look at?

A. I think this is a very important question and I will address it because I'm not absolutely sure. First of all it wasn't donor counselling, it was maybe about donor selection, hugely important in terms of safety of the blood. And Jack, I know, is coming to see you soon, and he would be the better recorder, but looking at that letter, there is no mention of "look-back".

Whether -- and you may say, "When they produced their report, they delivered to you, the directors, their donor selection new programme, but they also delivered a view about look-back", and I can't honestly remember whether, when I said, "Please give me a ring if you wish to discuss the matter further," and he did that and we discussed it, and the more we discussed, Jack

would have said, "What about look-back?" and I said "Yeah, why not?" -- because these are the guys, like Bob Crawford and him, who would be masterminding it. I honestly don't remember, but Jack might.

Q. So at that point SNBTS didn't have a policy about that?

A. No, no, not yet.

Q. Okay. Who decided to ask Dr Gillon to do this work?

A. As you probably know, the SNBTS -- I'm absolutely sure, as we discussed it as directors, going round and round and round, I might claim I -- I doubt -- we just -- it emerged that we were running -- as we ran into the Hepatitis C testing, we didn't have proper donor exclusion, and one of the problems we had was at that time -- and I think there is a record of this -- again, Harold Gunson's team -- I think Brian McClelland has made this statement at some point -- he is absolutely right -- that our friends south of the border really weren't very enthusiastic at developing a whole new set of donor selection, and in the end, I think you will find, Jack's -- and his team's -- document, in the end, was taken on board 100 per cent by our friends south of the border.

Q. We are coming to that. Let's have a look at the next letter, which is [SNB0045074]. This is dated 20 September 1990, and this is Dr Gillon's response to

your request, is it not?

A. Yes, it looks like it.

Q. We see:

"As requested, I enclose our deliberations on the subject of donor counselling in the event of positive tests for HCV antibodies. We see this as a basis for developing our policies towards donors, and also as the background information necessary in the training of counselling doctors."

In the last paragraph he says that he sent an earlier draft to Harold Gunson but he has not received his comment.

A. I think we had instructed -- I don't like to use the word. We had asked Jack if he would keep closely in touch with Harold Gunson as they developed this. So that would fit very well.

Q. Yes. So enclosed with that letter was what was the draft, and if we could have a look at that, it's [SNB0053647].

A. Yes, this is the one I remember. I thought it was November but it's October. Yes.

Q. Yes. If we could go to 3656, at the bottom of the page we will see "JG. 20th September 1990". That's the date of this draft. Do you remember receiving these?

A. Not specifically but I have a very clear memory of being

bowled over by the quality of the work, and it's the amount of work involved and how it was going to be of huge value, not only to us but to the whole of the UK.

Q. Yes. Let's just go back to the first page, 3647. We will see there that the working party was Dr Gillon, Dr Crawford, Dr Galea and Dr Davidson. If we go over the page, the first paragraph:

"Dr J Gillon was requested by the NMD ..."

So national medical director, so that's yourself?

A. Hm-mm.

Q. So he is taking it as an instruction from you, as opposed to from the committee?

A. Yes, I don't like to use the word "instruction" because it was a request.

Q. A request?

A. "Could you help us, Jack?" And a lot of people instinctively always said "yes".

Q. Yes, okay. And 1, 2, 3, sets out what he has been asked to do, or his working party have been asked to do: to produce the guidelines.

If we go to 3651, the working party has set out the "Background information for SNBTS medical officers counselling anti-HCV-positive donors." That's on the next few pages. If we go to 3654 under the heading "Informing the Donor," this section deals with

communicating information to the donor who has been found to be positive.

A. Who has been found positive, yes.

Q. And it contains various recommendations about how it should be done, breaking the news and we see down there, the heading "Breaking the News", and it's done in a question and answer format:

"What does a positive test mean?

"Does it mean I have got hepatitis?"

If we go over the page:

"Will I die of this?

"How did I get it?

"Am I likely to infect other people?"

Next page:

"Can I ever give blood again?"

Then we come to the important section for our purposes today:

"What about my previous donations?"

Which says:

"The recipients of previous donations will be traced and their consultants or GPs informed. We hope to obtain results of any tests carried out. However, it may cause distress to the donor to discuss this matter in any detail. A general comment suggesting that we are going to check to see that the recipients are all right,

that they get any treatment they may require, should be sufficient."

So what's set out there, Professor Cash, is an expression of policy, if you like. Is that right?

A. No, it's a proposal. This is a document going back to the directors -- I don't want to sort of -- but in a sense, this is the small group of Jack's delivering, in a sense, their thoughts, that we need to do a look-back, and that is absolutely what it was and totally correct in terms of -- but I don't think it was -- I don't think we can say, "This is now policy".

Q. No, I'm not saying that.

A. This is Jack's group advising the directors that in the context of counselling donors -- this and this was an item, and I think a little later I write to him and say, "Could you take that bit out?"

Q. We are going to come to that.

A. Because, "Just at the moment, Jack ..."

Q. In the context he has been asked to provide suggested information to give to a donor in this situation?

A. Absolutely.

Q. And one of the bits of information that he is suggesting should be communicated is that the recipients of previous donations will be traced but in order to be able to say that, the SNBTS have to have a policy that

that's what they are going to do.

A. Absolutely. This is a proposal for a policy.

Q. Yes, okay. Thank you. So may I take it that when you read that, you realised that Dr Gillon was advocating a look-back policy?

A. Yes. If you go down to the question of, "could I be sued if anyone was infected?" that became a major court case in Edinburgh, that concept. No, I completely accept -- and as you already signalled, that was an issue that we needed to think about carefully.

Q. Yes. Could we look at [SNB0053646]? This is a letter of 4 October 1990 from your personal assistant to the directors, circulating the report that we have just looked at. And in that letter you are saying that this will appear on the agenda of the MSC discussion on 6 November?

A. That's right, sir.

Q. Yes. And Dr Gillon will be there?

A. Yes.

Q. If we could have a look at [SNB0044388].

A. They never got round to spelling "Metters" correctly.

Q. Yes. So this is a letter to Dr Metters, and who was Dr Metters, just to remind us?

A. He was the chairman of either the ACVSB or its successor, but that ...

Q. Yes. What has happened? Are you able to say what has happened between the letter that we just looked at, 4 October, and this letter, in terms of discussions about look-back and so on? Are you able to remember?

A. I can't -- I imagine what happened was we had had the recommendations from Jack's group with a vast amount of very important practical stuff, and embedded in this vast amount was the very question that you pulled out, which in effect was look-back.

We had -- whether it was because of discussions with Harold Gunson, I honestly can't know, but I must have come to the conclusion, either myself or my colleagues, that this might be a matter that we ought to touch base with, with the advisory committee. So there was me touching base really.

Yes, I mean, I'm sure that's right. The Scottish directors asked me to write to Jeremy Metters to just -- yes, to feel as to how the notion of look-back was developing at a UK level.

Q. Yes.

A. It's important to me -- or it was -- that Dr Archibald McIntyre, in the Scottish Office, was copied into this because he sat on Metters' committee, as did Ruthven and Bob Perry, and they are copied in there too, but they were briefed -- that they knew that

the Scottish directors were very keen that this was discussed.

Q. Yes. I mean, by this stage you had had Dr Gillon's --

A. Yes, absolutely.

Q. -- recommendations. What was your attitude to look-back at this point?

A. I can't remember. It's easy now in retrospect to answer that but my recollections, as best they are, I was enthusiastic about look-back but I stuck with the issue -- and we will come to this later. This is a very interesting philosophical issue that I have fought with with my two children, who are doctors as well, that if you haven't got some good news for the patient, ie, "We have got some treatment here that can be of serious benefit to you," that loading a lot of innocent people with bad news, unnecessarily, is not a good thing to do.

I certainly discovered when my two children graduated that that was not necessarily the view that they took -- that they took. Particularly one of them, who is a GP, that we should unload all the news for patients, so that it's up to them to decide -- and I had been brought up in a different era, in which doctors should do their best, as part of their caring, to filter in some way stuff that really they didn't feel the patient needed to know. My son used to describe, "You

are the God almighty syndrome doctors", and I'm pleased to say that 20 years later he is drifting in my direction, but that's a philosophical issue. So I was a strong supporter of look-back.

Q. At this point?

A. Yes, but when people are saying -- yes, but the idea of look-back I was very warmly in favour, but I wasn't prepared to push it until I had some good evidence that there was at the time -- and I remember this very clearly -- that there was a treatment option, and that raised a whole succession of things which no doubt we will see later.

Q. Yes, we will come to that. So you were enthusiastic, in favour, but you still had that concern at that time that you would be giving the donor bad news?

A. Not the donor, the patient.

Q. The patient?

A. Who had received that blood, yes.

Q. Yes, the patient bad news?

A. Yes, yes.

Q. Did that not make you unenthusiastic?

A. No -- well, yes, I was not enthusiastic unless we could say to that patient, and indeed the donor, but the patient -- because this is where we were going from look-back, "We can offer you some treatment, so let's

get you to a specialist hepatologist", and so on and so forth.

Q. So this was why you were slightly hesitant at that time because there was no treatment and you would be giving --

A. There were other causes but -- that people said, but for me, the big one throughout was the question of treatment.

Q. Yes. So --

A. Rightly or wrongly.

Q. I'm just trying to understand your position. So you are broadly enthusiastic but you have got this reservation about giving bad news without treatment?

A. Yes. If in fact we had known in 1990 -- and I am now aware of Hoofnagle's paper -- but if we had known in 1990 that there was a superb treatment regime for Hepatitis C, I would have been extremely anxious that as soon as we possibly can, however difficult it was going to be, we introduced a look-back programme.

Q. Yes, but at that point -- if you just let me finish the question -- because there wasn't any treatment option, as far as you knew, you had a reservation about implementing look-back?

A. It is correct.

Q. A reservation but you were still enthusiastic?

A. Oh, yes; and -- we will come to later how enthusiastic I was in the sense that I wouldn't go away on this and kept -- in 1993. It was very important.

Q. Yes. Why were you asking Dr Metters' committee, the ACVSB, to look at this question?

A. Because I believed, setting aside the treatment thing, that if all that was on, ie there was treatment -- and I was not to know that this was emerging at the time -- but if we wanted to go, I was of the view -- and this, I think, proved to be right -- that this would require to launch this, a CMO message to the regional health authorities and in Scotland to the health boards, because it would have required -- and we saw this very clearly in the West of Scotland, that ran into serious difficulties. It required active collaboration of clinicians, of peripheral laboratories doing blood and so on and so forth, all in the control, in Scotland, of health boards.

Q. Yes. So you thought, to make it happen, it would have to be UK --

A. No, not even UK -- at some point -- I mean, Archie McIntyre, from the Scottish Office, was batting for us on the Metters committee. So he would be in at the front edge of the discussions going on, but I had taken the view -- and I know it's easy now -- I had

always taken the view that ultimately this would be a CMO and therefore that required ministerial support and approval, and the only route we had at that time, that I was aware of, to get into ministerial approval was the Metters committee.

A great criticism is made, including from me, about the Metters committee, but it seemed to me that Scottish ministers, and certainly civil servants, were very conscious throughout the whole -- this whole period of Hepatitis C, that they wished at least to be briefed as to what this committee thought about whatever.

Q. Yes. Just thinking back to the Lord Fraser letter, did you not think that this was ultimately a question for the MSC?

A. MSC?

Q. The SNBTS committee?

A. The SNBTS --

Q. The committee that advised the SNBTS?

A. No, I would vehemently -- we could -- on 18 May 1993, was it, we had had enough, that committee, and declared, with Scottish Office colleagues that were with us -- that was Dr Aileen Keel -- that we felt we really had to do it now. It was absolutely imperative, and in a sense, reading Lord Fraser's letter, which came after that, is very interesting.

Q. Okay. Could we have a look at the next document, which is [SNB0018934]? These are the minutes of Dr Metters' committee, the Advisory Committee on the Virological Safety of Blood, ACVSB. And we see observers, as you told us, Dr McIntyre from Scotland, and we see names that we are familiar with: Dr Mitchell, Dr Mortimer, Dr Perry, Professor Tedder, Professor Zuckerman. The date is 25 February 1991. Could we go to 8939, paragraph 14. It says:

"The committee discussed the problems of look-back and recommended that it should not be undertaken as a service, leaving the option for those carrying out research. However, all cases of post-transfusion hepatitis should continue to be investigated."

A. That's almost a pick-up, you remember, of the letter I had from Harold Gunson.

Q. Yes. What do you understand by that, "not undertaken as a service"?

A. Oh. It would not be routine as part of the -- of our service delivery, which is what we wanted. That's when it gets really serious, yes.

Q. So all blood transfusion services throughout the UK?

A. We are into this -- my impression was that this committee advised ministers and maybe you need to ask the question: who are the ministers it advises?

My understanding had always been that the ministers in that reference included Scottish ministers as well. That doesn't prevent the Scots doing their own thing, and we see this developing here, which is marvellous, but my understanding was that there had been agreement that this committee, when it was established, the lead would be DHSS. There would be Scottish observers and Scottish members, but its deliberations would be included in the advice to Scottish ministers.

That has always been -- that was always my understanding.

Q. Yes. Okay. Well, let's have a look at the next document, which is [SNB0095668]. This is going backwards a few days but this is the medical and scientific committee of SNBTS, and we see present yourself, Dr Brookes, Dr McClelland, Dr Perry, Dr Mitchell. If we could go to 5671, under the heading "Donor Counselling: HCV donation testing":

"The committee examined Dr Gillon's final draft document, which had been previously circulated, and agreed it was excellent. The committee proposed and agreed that the latter pages be used as guidelines in leaflet form for use by the RTCs."

Then:

"In the light of national events, it was agreed no

look-back should be introduced at present."

So I just wanted to ask you, what are the "national events" that are being referred to there, do you think?

A. I can't recall, to be honest. I think you have already indicated to me this meeting was before the advisory committee. Whether -- I honestly don't know. Whether signals had been made through Harold Gunson to me, that I reported to my colleagues, I honestly don't know and regret the minute isn't more helpful.

Q. Yes. Well, we know that it's a long time ago, Professor Cash, but is that your best estimate of what that refers to, that you have had discussions with Dr Gunson and Dr Gunson has said to you, "We are against the idea of" --

A. No --

Q. If you just let me finish the question, "We are against a systematic look-back", and you had taken that on board and at this meeting you had reported that to the directors?

A. That's possible. It's also possible Harold said something different, that "It's coming up the advisory committee, John, I can tell you that", because I knew nothing about the agendas, and he said, "It's not going to run", and we were very anxious to get these guidelines up and running as soon as possible.

Q. Yes.
A. I mean, I can't remember but I would imagine that it had something to do with the dialogue that was going on, but I suspect Harold and I have just already said, the minute of that committee meeting is almost a pullout from Harold Gunson's letter of much earlier.
Q. Yes. But the dialogue has been between yourself and Dr Gunson?
A. Yes, yes, which was, I like to think, perfectly normal, and I would be drawing attention to my colleagues, when we met, you know, what I felt -- the way it was all going at the present time.
Q. Yes. Can you recall whether there was much discussion about the advisability of proceeding with look-back or not at this meeting?
A. I can't recall, to be honest, it would be a -- it would be speculation. I honestly can't recall.
Q. Would we be wrong to get the impression that you had come to the meeting and said to your directors, "I have had a conversation with Dr Gunson and it looks like look-back is not going to be proceeded with down south and therefore I don't think we can do it either."
A. No, no. We are on to an old theme of this Inquiry. Much more likely is it's not going to be a runner at that advisory committee, which advises our ministers as

well. So at the moment we need to wait and get more ammunition and that eventually emerged. Much more likely that. But I really -- I need to be careful. I'm sure that's speculation. You are asking me details of conversations.

Q. I understand.

A. But I would like to reiterate -- because I am aware that David McIntosh is going to appear again -- that the notion that England can't do it and therefore we can't do it, it had never -- I was never ever prepared to accept that at its face value. By all means I saw great advantages in us all doing all sorts of things together, but that alone -- it was up to Scottish ministers in my view to make decision.

Q. Yes. But based on the advice that they were getting from you?

A. The advice that -- Scottish ministers weren't getting directly any advice from me.

Q. Well, from the SNBTS?

A. From the SNBTS. I can't be sure that that was transmitted to them. I have no idea. That was somebody else's job. All I do know is that people sitting on the -- the advisory committee down in London -- there were two Scots, there was a third Scot, who was a senior, very respected civil servant, Archie McIntyre.

So there was a sense in which we as individuals -- we were engaged in a process that ultimately would advise Scottish ministers. And there is no doubt that Ruthven Mitchell, Archie McIntyre, Bob Perry, as they went, knew, because I copied them in, of my letter to Metters, in which I had said to him, "The directors of Scotland wish this to be given serious consideration". I think we tried to cover all -- as best we can.

Q. Just to return to the minutes, the next few lines record a comment by Dr Galea. If we go back to 5668, please, the first page, he is not listed as being present on the first pages. Do you think he would have just joined the meeting later?

A. I have no idea. George became director of the centre in Dundee, I think it was. He was a very active worker in this area. He wasn't a director at that time. Whether he was sitting in for Jack for this discussion, I don't know. But from what is recorded, that he was either there or he had communicated to us that if we made that decision, "At the moment hang off," then if we were going to say, "Carry on, get these guidelines for donor counselling out," we would have to adjust. Presumably the item 9 is the very one, which I can't remember.

Q. That's right, let's go back to --

A. This obviously, it's recorded, was agreed.

Q. So he says --
A. It sounds as though he was there.
Q. Yes:
"The wording of the last question on page 9 would need to be altered accordingly and this was agreed."
So we should see that as Dr Gillon has recommended look-back. You have discussed it and you have agreed not to go ahead with it at this point.
A. Hold fire, yes.
Q. And as a result, that alteration has to be made?
A. So that we can get the rest out. Absolutely right.
Q. So SNBTS policy at that point was not to have look-back?
A. Yes, I think that would be a moment, yes.
MR GARDINER: Okay.
Sir, I'm about to move on to another document, perhaps it would be a good time for a break.
(11.02 am)
(Short break)
(11.25 am)
MR GARDINER: Thank you, sir. Before the break, Professor Cash, and earlier, I asked you about what had gone on before your letter to Dr Metters on 22 November 1990, and I should have shown you the minutes of the MSC meeting from 6 November, which are now on the screen in front of you.

So this is obviously before you write to Dr Metters?
A. Yes.
Q. So you see you are present, Dr Brookes, McClelland, Mitchell, Perry and so on. And if we could go to --
THE CHAIRMAN: Could we record a number before you --
MR GARDINER: [SNB0095513].
THE CHAIRMAN: Thank you.
MR GARDINER: If we can go to 5516, at the bottom of the page, 5(ii). "Donor counselling: HCV":
"Dr Gillon's report, which had been previously circulated, was discussed.
"Dr Mitchell pointed out that Dr Gunson was anxious to take this Gillon document to the national advisory committee in the near future."
If we could go over the page, we see at the top:
"... Dr Gillon joined the meeting ... welcomed by the chairman. He grave a brief resume of the content of the paper and a lengthy discussion took place thereafter when details were clarified.
"Dr Gillon pointed out that there were additional data which were not available when the report was written."
And the third paragraph:
"The committee concluded that a draft standard operating procedure based on this report should be

prepared by Dr Gillon by 30 November 1990 and submitted to the members of the MSC for their consideration. This he agreed to do."

I just wonder if you can remember whether there was any discussion about that question 9 and the implications of a look-back policy?

A. I regret, sir --

Q. You can't?

A. -- you are exceeding my memory capacity.

Q. Yes. What about putting the Metters letter together with that document? I mean, does the Metters letter not suggest that it was discussed?

A. Oh, yes, you are asking for details. I honestly can't remember but, yes, I'm absolutely certain that, you know, the committee concluded -- they would have discussed this beforehand -- discussed around the topic in detail. And my understanding is -- because it certainly was my practice -- that I was asked by the committee to write to Dr Metters, and I convey that to him when I wrote to him.

Q. Right. If we go --

THE CHAIRMAN: There seems to be a strengthening of the documents role at this stage. It has gone from being guidelines up to an SOP.

A. That's correct, sir.

THE CHAIRMAN: Was that a significant change?
A. Wow. I think the quality specialists may -- I mean, the guidelines -- in my book -- and I did something on quality -- when you move from guideline to SOP, yes, you are into procedural -- it's like protocols, yes.
MR GARDINER: If we look at 5519 in fact, this is under the heading "HCV, 10(i), look-back". So there we have it.
A. Thank you, that's helpful.
Q. So that confirms your recollection that there was discussion, and that's the genesis of the Metters letter in fact.

Would you agree?

A. Yes, sorry, I was looking at the other box, I beg your pardon.
Q. Okay. So that's a missing bit of the jigsaw. So we can put that away now. Can we now have a look at [SNB0051689]? This is a letter dated 12 March 1991 from yourself to Dr Gillon and you are informing him that the committee agreed to the proposal that the latter pages be used nationally as guidelines in leaflet form but the section at page 9 -- "What about my previous donations" -- is not to be included, and this is again in light of national events.

What do you think Dr Gillon would have understood by that reference to "national events"?

A. I can't speak for him to be honest. Whether I called him and chatted with him -- he is coming to see you very soon, so Jack may be able to brief you. I can't -- I honestly don't think I should speak on his behalf in that context.

Q. Right. What were you intending to convey by those words "national events"?

A. That's a very good question too. I think by then I had received information -- I don't know who from, whether it was Ruthven, Bob Perry or even Archie McIntyre -- because I didn't get minutes of the advisory committee -- that we knew, I assume, when we talk about "national events" it was about the national committee, and I suspect that Harold had been in touch and talked and so on, and clearly I felt -- and I think my colleagues would have agreed -- at that moment of time we weren't -- look-back was not a runner at the moment. We needed to wait for fresh developments and therefore that small component in an otherwise critically important document, we were suggesting, look, in the meantime take that out. Jack may be able to give you much more useful information.

Q. Yes, but that was because of the attitude of the Metters committee?

A. I would think so, yes. If I have got my dates right.

Q. Okay.
A. I mean, I wrote to Metters in late 1990. But the Metters committee, as I recall, for my money, met very infrequently and I can't remember -- you have just shown us a minute of that meeting -- when it was. But here is me getting back to Jack on 12 March. It seems a long time, but presumably I was wanting to first touch base with the medical/scientific committee, the Scottish group, before I communicated to Jack and I think that's what happened.
Q. Yes. Okay. Let's go to [SNB0045590]. These are the minutes of the UK Advisory Committee On Transfusion-transmitted Diseases?
A. Yes.
Q. We see Dr Gunson in the chair, yourself, Dr Mitchell.
A. Mr Archie Barr, I should mention, sir, a distinguished laboratory scientific officer from the West of Scotland.
Q. Yes.
A. Blood transfusion centre.
Q. Can you just remind us, how was this committee operating in relation to the Metters committee at this point?
A. I think we have touched on this in C4. The relationship at times was a little strained. The people controlling the Metters committee membership didn't control this committee's membership and there were occasions when the

advice they received from this committee was not welcome, and Harold Gunson knew it wouldn't be welcome. So -- I think Jeremy Metters, if he is with us these days, would say that this was an advisory committee to them but it actually wasn't a committee that they control, if you understand.

Q. Yes.

A. Indeed, a terrible thing developed when the chairman of the committee, a Fereydoun Ala from Birmingham at one stage, requested that he as chairman of this committee sat on, even as an observer, the Metters committee, and this was hotly rejected and there was an awful crisis that developed as a result of that.

It's a rather long-winded response to your simple question, I apologise.

Q. But this committee, which you were on and Dr Gunson was on, did consider the question of look-back. If we go to 5594, at paragraph 4.4.1, we see:

"The appropriate sections of Dr Gillon's paper on counselling were agreed with amendments."

Then there is a reference to appendix 3. If we go to appendix 3, which is at SGF0012014 --

A. While the search is being made, sir, 4.4.2 does touch on the notion of guidance from which you prepare standard operating procedures.

Q. Yes, I'll give you another reference. SNB0051673. Just bear with me. (Pause)

I am afraid we have another IT glitch here but, Professor Cash, if you just take it from me -- and I'll show you this later -- appendix 3, which is referred to in the minutes, is Dr Gillon's recommendations and they include, question 9:

"What about my previous donations?"

So, on the face of it, that committee appears to be supporting a policy of look-back on that basis. But that wasn't the position, was it?

A. No, no. I'm very interested.

Q. Okay. We will arrange for that to be put into court book.

Sir, that should be [SNB0051763].

Right. My apologies. There we go.

THE CHAIRMAN: We see this is the July 1991 version. It has actually got its date on it.

A. Thank you, chairman. I suspect it's the copy that Harold Gunson was sent by Jack, as he had been asked to do, and was way out of date.

MR GARDINER: If we could go to page 4 of that, we see there:

"What about my previous donations?"

So it's still in there --

A. Can I just -- this is clearly a very early draft and I suspect that what we are looking at is a document that wasn't looked at carefully enough on the day, particularly by the Scots, which includes myself, to see whether 9 had gone. You know, I regret that. It's very interesting.

THE CHAIRMAN: Perhaps one would be unlikely to be able to tell from the minutes whether it was discussed at all, given their rather brief form.

A. It's true, sir, but nonetheless, as the Scottish directors had in fact themselves come to the conclusion that 9 should go out for a while, in retrospect you could have said that on the day that Ruthven and myself -- I don't think Archie Barr could be incriminated; he was a wizard technologist. But we should have picked up that.

Q. Thank you. We can put that away for now and I would like to show you a Scottish Office memo from around about this time. That's at [SGF0012163]. We see this is July 1991 and is a memo from Dr McIntyre to Mr Panton, and we see the heading is:

"Recommendations for counselling of HCV seropositive donors. Informing the donor".

He makes reference to a copy of the recommendations, concerned about, paragraph 3.4:

"In the case of regular donors, the fate of previous donations is determined and 'look-back' initiated in accordance with SNBTS policy."

Just jumping down to the paragraph where he has put "1A" next to it:

"In the present state of knowledge, donors who are only HCV seropositive donors without evidence of antigen may not be infectious. What purpose is to be served by going back? Will it cause the recipient of the blood (the 50 per cent who are still alive after two years) unnecessary worry and possibly distress? In certain circumstances it could also give rise to litigation and it may be that you would wish to discuss this particular point with our solicitors before this policy is put into effect."

Now, were you conscious, Professor Cash of that concern around about this time?

A. Within the Scottish Office?

Q. Yes.

A. I have no memory of that, sir. I'm fairly certain that I wouldn't have been.

Q. So that's not a consideration as far as you are concerned, about implementing look-back?

A. Sorry, when you say "consideration" ...?

Q. A factor that was taken into account.

A. What, the potential for litigation?
Q. Yes.
A. I think we have just touched on this before, sir. In the course of discussions, yes, you showed me a Ruthven Mitchell letter, way back a hour or so ago, in which he is saying -- so, yes in the course of our deliberations, that must have been touched on.
Q. Yes. If we could have a look at --
A. You notice that Archie is dialoguing with Metters about all this, which is good.
Q. If we could have a look at [SNB0018845].
THE CHAIRMAN: There is nothing of any interest in the manuscript footnote to the last letter, is there? It looks as if SNBTS was asked specifically about litigation risk.
MR GARDINER: Yes. Do you have any recollection of that, Professor Cash?
A. No, I don't, sir, to be honest.
Q. [SNB0018845]. Are you familiar with this document, Professor Cash?
A. I am but only since the Inquiry.
Q. Yes.
A. I don't remember it in detail. I think I know what it was, if I can get over the first page.
Q. Yes. So if we go to the next page, please, we see

"Introduction":

"There has been a considerable debate about the introduction of anti-HCV testing of blood donations, which has occupied many months.

"The UK Advisory Committee On Transfusion-transmitted Diseases has discussed, in detail, all aspects of this additional test to be applied to blood donations and the subsequent handling of donors thought to carry HCV infection."

It talks about the status of the recommendations. This is by Dr Gunson and it's dated August 1991. He was the chairman, was he not?

A. He was indeed, yes.

Q. If we could go to 8857, we see at the bottom of the page again the old question 9:

"What about my previous donations?"

So again, in the recommendations document we have still apparently got this policy about look-back?

A. The error has been perpetuated, yes. It's very interesting, absolutely fascinating. I was not aware of that, sir.

Q. Is it an error?

A. Well, it's an error in the context of the Scots decided they would take it out. Is it an error? We decided to take it out but clearly that has not been communicated

well to Dr Gunson, which I'm very surprised, because we would have been very pleased. I can't -- I have difficulty in commenting, sir, on that. Very interesting.

Q. If we could have a look at [SNB0019148]. These are the minutes of the Advisory Committee on the Virological Safety of Blood, ACVSB. So this is the Metters committee. I'm calling it the "Metters committee".

These are the minutes from 29 October 1991 and the members are Dr Gunson. At this point had Dr Gunson just become a member of this committee? We have not seen his name featuring before?

A. No, oh, no, no. This is the Metters committee and Harold was there from the very beginning.

Q. Okay. If we could go to 9149, we see there is a discussion of Hepatitis C:

"The chairman thanked Dr Gunson for the hard work put into compiling the compendium of recommendations made by the UK Advisory Committee on Transfusion-transmitted Diseases which had been circulated."

Then there is discussion of the first HCV test trials.

A. You see Dr Gunson said no decision had been taken for look-back.

Q. Sorry, I didn't catch that?
A. I was just saying that 4.2 at the bottom, it says there in the minute that Dr Gunson said:
"No decision had been taken as regards look-back."
And I see the word "study", which is quite interesting.
Q. Yes. So he is reporting that the other committee has not taken a decision about look-back?
A. I presume so, or he may be saying he understood that there was -- I don't know. But that's a possibility.
Q. Okay. So at this point, which of the two committees is looking at that question of whether to implement look-back or not? Do you know?
A. I don't but, I mean, I think the key thing is the committee that really counted -- because it advised ministers, and I think we all agreed that that was required -- was the ACVSB.
Q. Yes.
A. What the other committee might have done, if moved so to do, was to have established a study in England, much in the way that we liked to think that Jack Gillon was doing in Scotland.
Q. We are going to come to that?
A. That would have been an option for --
Q. Yes. What was your reaction to what was going on in

these two committees about the question of look-back? Were you waiting for a decision to be made or ... what was your attitude?

A. I need to -- it's very easy to now say things that may -- but my recollection is that I had no idea what was going on in this advisory committee. That was one of the fundamental problems that I and David McIntosh had. In terms of the Advisory Committee on Transfusion-transmitted Diseases -- and we made available minutes widely to all my colleagues -- I had the impression that our friends south of the border, who were on that committee, were not at all enthusiastic about the development of a look-back programme or even doing studies. But that's my best recollection.

In fact I get confused. I did get the impression once that -- reading some of these papers recently -- that there was a moment when they might have been moved and then the next meeting, we were back to, "Oh, this is all too complicated and too difficult," which actually may have been true.

Q. Yes. But at this point the SNBTS policy was not to recommend that look-back be pursued in Scotland?

A. That's correct. Our recommendations -- our policy was the introduction of those guidelines for the treatment -- for the looking after of donors. But the

little bit about look-back we had put on ice.

Q. Yes.

A. That's the way I saw it. I was sure -- I had enough clinical experience to know that antivirals were actively being developed in that period and sooner or later they would go for Hepatitis C.

Q. Okay. I would like to show you a section from Dr Gillon's witness statement. So could we have a look at [PEN0180410]. The Inquiry is going to hear from Dr Gillon tomorrow but this is his witness statement on this topic. Could we go down to the bottom of the page where we see he says:

"In June 1990 when SNBTS was planning the introduction of testing for anti-HCV, I was asked by Dr Cash and the SNBTS directors to chair a working party to provide recommendations for the counselling and management of blood donors found positive once testing was underway. One of the key recommendations of this group was that look-back should be part of this process. The report produced by the working party was shared with the other UK transfusion services, who accepted the recommendations on donor counselling, but rejected the proposal that look-back should be initiated from the commencement of testing. This decision was communicated to me by Dr Cash in a letter dated 12 March 1991."

That's what we have just looked at.

A. Yes.

Q. In the next paragraph Dr Gillon says:

"I strongly disagreed with this stance, and, with the agreement of the director of SEBTS, Dr Brian McClelland, I undertook look-back on all anti-HCV-positive donors with previous donations in SE Scotland as a routine from the onset of testing in 19 September 1991. The national medical and scientific director, Dr Cash, was aware of this and it was later agreed that this should be seen as a 'pilot study'. In 1994 SNBTS senior management was made aware that I and my colleagues had submitted a paper on our experience of look-back for publication (Ayob et al ...). Our conclusion, stated in the paper, was that look-back was feasible with little in the way of extra resource, and justified in terms of outcome."

Then he refers to the preliminary report.

Professor Cash, is it correct that SEBTS started look-back without reference to you or the MSC?

A. I honestly don't recall, to be precise. What I do know is that the inference that the Inquiry has had, that this was being done throughout in some clandestine way, in which nobody was -- knew about it, is absolute nonsense.

Indeed, there came a point when the directors were aware of this. They had been persuaded, rightly or wrongly, that this was a feasibility study. It was not part of routine but it was a feasibility study but much like the HCV donation testing that Glasgow were caught up into, funded by London.

So they took the view that that was a feasibility study and there came a moment in time -- and I think it's minuted somewhere -- where the doctors asked, "Could we have some information then?" -- I think they asked for a pre-publication copy of this article of Ayob et al.

So it wasn't secret, it was known and a vehicle -- a method of making this okay so it didn't ruffle any feathers was my suggestion that we called it a "pilot/feasibility study". And this was agreed, Jack says -- I don't know who agreed it but I remember vividly suggesting that this was -- this would be a good idea in the circumstances we were in.

Q. Yes. HCV testing started in September 1991?

A. Yes.

Q. And Dr Gillon started the look-back programme in SEBTS from September 1991. That's right, isn't it?

A. I don't know. I think you would need to ask him because you could easily, in December 1991, bring out donations

that had been given since then and check them.

Q. Let's proceed on the basis that he did?

A. Fine, they did.

Q. When did you first find out that he was pursuing look-back?

A. I have no idea. Are there any records for this? I don't recall. He tells us that I was aware of this.

Q. I'm asking you, Professor Cash, and you can't remember when you first became aware --

A. No, I don't.

Q. Okay. Let's have a look at the paper, which is [LIT0013802]. Do you recognise that?

A. Yes, I have seen it recently -- yes, yes.

Q. So this is the report on the look-back that was done in S --

A. It's the publication of a limited amount of work that they had done at that stage.

Q. Yes; okay, thank you. If we look at the summary, second paragraph:

"In the first six months of routine testing, 42,697 donors were tested."

Then:

"Of 20 confirmed to be HCV-positive, 15 were regular donors."

Could we go to the next page? We see the first

column, and at the bottom of the first column under the heading "Results":

"Between 1 September 1991 and 29 February 1992, 42,697 donors were screened routinely."

Do you think that you would have been aware by the end of that first period of screening that Dr Gillon was pursuing a look-back? So by the end of February 1992.

A. I'm repeating myself: I don't recall but I trust Jack. If his memory is that he came to see me -- or Brian -- I wouldn't hesitate to deny. I have honestly no recollection.

Q. I understand. It's a long time ago. On the first page of that report, we see that it was -- we can see it was accepted for publication on 21 July 1994. Surely you would have known before the date of publication at least?

A. Oh, yes, I'm quite certain. And I think I have already said that the directors asked in their deliberations, they were that there was a publication coming up, and the directors -- it's minuted -- actually asked, "Could we actually have sight of that?" And all this was leading up to the May, I think. This was received, I think, on 23 November 1993. It must have been well in preparation because I think you will discover that one of the MSC meetings in 1993, the directors were aware of

this and asked could they see pre-publication copies.
Q. Yes.
A. So, yes.
Q. Yes. So at the very latest it would be 1993 that you would become aware of this?
A. Yes, absolutely. I'm fairly sure that I would have known -- if Jack claims that I proposed that it was a pilot/feasibility study, I'm sure I wouldn't have delayed that suggestion until 1993. I'm sure of that.
Q. So your best estimate is some time between 1992 and mid 1993?
A. Yes, I mean, I may have known even before that. I'm sorry, you are trying very hard and I honestly can't remember.
Q. I understand. What was your reaction when you did hear about this look-back scheme?
A. You mean the publication?
Q. No, about the fact that Dr Gillon was doing it?
A. Well, again, this is entire memory but I'm sure I must have been aware that the notion of developing look-back had been rejected by the Metters committee at their first run in at it. I knew that Harold was very uncomfortable with it and I must say, the more I saw of what was going on in Edinburgh, it gave me reasons to have some sympathy for Harold because of the nature of

the way they ran their transfusion service.

I cannot recall, to be absolutely honest, that I was aware there was any hostility to look-back from our colleagues in the Scottish Office. I can't recall that. But I was aware of Harold. He wasn't hostile, he was just very nervous about it, and we knew that the Metters committee had done (inaudible), I've just said. And as a result, we had suggested that the 9 question came out of the -- so we had done all that, probably latterly, some of it not very well, and so I would presume that was the reason why I suggested feasibility/pilot study.

Q. Can you remember what your reaction was when you heard that Dr Gillon was pursuing this?

A. No, but I have just said, I can only assume that I was a little nervous because what was taking place -- I was absolutely certain in my mind and I am to this day, that this could not have been translated into the West of Scotland, for instance.

Q. We are going to come on to that. So your reaction, when you first heard about this, was that you were a little nervous?

A. A little nervous because I knew that there were elements in central government that were a little nervous about this and so why don't we actually use this as a pilot study to gather data that might be valuable when the

debate started again.

Q. Yes. What was the sequence? Can you remember? Your reaction was that you were a little nervous about it because you knew what the attitude was down south and what happened next? Who did you suggest the pilot scheme idea to?

A. That's where -- I mean, Jack may say it was to him or to Brian. I can't remember. But clearly, from the document you have showed us, he claims that I suggested it. To whom, I'm not entirely certain.

Q. Does that accord with your recollection, that you suggested --

A. I have no recollection but I'm perfectly prepared to accept responsibility. It was highly probable that it was me and I wouldn't wish in any way to deny that.

Q. Right. What was the reason for that? What was the reason for calling it a "pilot scheme"?

A. I thought I had made that clear, if there was vast amounts of sensitivity lurking around in government circles about this and if in fact we wanted to translate what was going on in Edinburgh, if we could, to other parts of Scotland, and notably the West of Scotland, we needed the support of ministers/CMOs or whatever, and it seemed therefore that the best approach to what was going on in Edinburgh was to label it "pilot," for those

very reasons. I should add, David McIntosh was very much involved in all this because he was general manager at the time.

Q. So you didn't regret this independent approach?

A. No, to be honest, I didn't, no. That may sound very strange but, as I think I have said earlier today, I actually believed in some form or other we had a duty of care to get to the patients that had been infected, and it was just the timing of this, the method by which it was done, that were the issues for me.

Q. Did you see any parallels with what happened in Newcastle with screening?

A. No, no. I'm not aware of, no. But I am aware that David McIntosh in his statement has implied some extraordinary things, in the context that this was done very secretly for fear of criticism and so on. None of that rings a bell with me.

Q. Okay. What did you tell Mr McIntosh about this programme when you found out about it, Dr Gillon's programme.

A. I can't remember but I think I have already said in this Inquiry, David McIntosh and I had very regular briefing meetings, usually every week, and these were all part of things -- whatever was happening, precisely -- one of the great problems with those briefing meetings -- and

I raised this, as I think I told you in C4 -- there were never any notes taken or minutes, so they remain very much left to memory and so on. But what I'm absolutely certain is, because there is a record of this, we had very regular briefing meetings. By this time in 1994, not 1991, we had other members of the headquarters unit that joined us in these weekly briefing meetings.

Q. Yes.

A. And anything that was on the go, we chatted about.

Q. Just to be absolutely clear, Professor Cash, when it started, this wasn't a pilot scheme, was it?

A. No, looking back, I think the real question, you could argue, was this all discussed in advance of 1 September, and my best memory is, no, it wasn't, but I mean, Jack would -- I would rely on Jack and Brian in terms of -- particularly Jack.

Q. But you would agree, when it started, it wasn't a pilot scheme?

A. That's right.

Q. That's right?

A. I agree.

Q. And did you ever tell Mr McIntosh that?

A. I must have done. I mean -- I must have -- I mean, you have spoken to him and so on but this would be part of the briefing session. I'll just have to say, I must

have done, yes.

Q. It's just that when he came and gave evidence recently, he seemed to have only discovered that this wasn't a pilot scheme fairly recently. Is that surprising to you?

A. Yes.

Q. Okay. Chronologically we have now got to about the end of 1991, so could you maybe just look back and tell us what your attitude was to implementing look-back at the end of 1991, just summarise it for us?

A. Very briefly, when I became aware -- and I don't know when this was -- that the advisory committee, the Metters committee, had rejected the notion at that point -- they had proposed something positive, that there would be some form of research, although they didn't delineate. I think I said this in my statement -- one of the things that concerned me was it became evident when I spoke to very close friends who -- personal friends, who were hepatologists, that the notion that we really had to move because treatments were coming in was not something that I sensed the advisory committee had, you know, asked a particular member of the committee to keep a watching brief on publications in that line. It's not my field.

Slowly but surely -- and so I was on the lookout for

any evidence that there was a developing programme of clinical trials in relation to virus inhibiting drugs in the context of Hepatitis C. That in fact led me, as you know, to the symposium in 1993.

Q. Yes. So what was your attitude to implementing look-back at that point? What were your reasons for not doing it?

A. I think I have told you that. It was primarily at that point that I was worried about the concept of treatment.

Q. Right.

A. That may have been a misguided conclusion and that was the area that I pursued pretty relentlessly.

Q. Yes. So I don't want to put words in your mouth but you didn't think it was a good idea to trace patients back, test them and counsel them when there was no treatment to offer them?

A. That was the main basis and I think it was apparent and is apparent that Jack Gillon -- and I'm not sure about Brian -- I don't have any -- but Jack Gillon didn't agree with that approach and I respected that.

Q. Okay. Can I just show you a paper that Dr Hay referred us to recently, which is [PEN0181384]? That's on the screen there. The heading is:

"A randomised controlled trial of recombinant interferon A in chronic Hepatitis C in haemophiliacs."

Makris, Preston, Triger. We see that at the end of the entry, it's copyright 1991 by the American Society of Haematology. You won't have seen this before?

A. No.

Q. No. If we just look at the summary there:

"Chronic liver disease associated with Hepatitis C virus ... is an important cause of morbidity and mortality in haemophilia. We have used recombinant interferon A in a randomised controlled liver biopsy trial to treat haemophiliacs with chronic hepatitis. 18 patients entered the study, 16 of whom were subsequently shown to have antibodies to HCV. All underwent liver biopsy at entry and were randomised to either treatment or self-administered interferon."

Just reading that short, if we just go to the last paragraph of the summary, the conclusion:

"We conclude that low dose recombinant interferon is effective in normalising transaminase and improving the histologic appearances in at least 50 per cent of haemophiliacs with chronic Hepatitis C."

So Dr Hay referred us to this as a paper, which showed at this time that some success was being had with HCV sufferers by treating patients with interferon. I take it that you weren't aware of this paper at the end of 1991 or in 1992; is that right?

A. Yes, that's correct. Is this Professor Hay from Edinburgh?
Q. Dr Hay from Manchester now.
A. Sorry. Yes. I see, I recognise some of the authors in this paper. So, I was not aware of it and was, to be honest, relying on my two very distinguished hepatologist friends to keep me posted if they thought anything interesting -- and you are aware of the symposium in 1993. I was to discover that at that time, even in 1993, the value of interferon was controversial.
Q. Yes.
A. And indeed, Jack Gillon in a paper he prepared for the SNBTS, position paper -- this is not his statement -- declared not many months ago that at that time interferon was regarded very -- as something very experimental and had got a long way to go before its toxicity and efficacy were understood sufficiently that one could say, "We really have something of great value".
Q. We had some evidence from Professor Nathanson recently and we asked her about this question: tracing donors and the merits of counselling and offering testing in a situation where no treatment was available.
One of the things that she said was that an indication that it was a good idea was that if you

didn't do that when you could, fairly early on, there was the risk that you would lose those patients. Even if there wasn't treatment at that time or not very well developed treatment, then the risk was that you would lose -- you wouldn't be able to trace the patients. Do you have any comment on that approach?

A. It depends -- I would need to ask her a little bit more about losing. You could argue -- you could go right up to the point in -- but I'm pre-supposing that we all think that the model that Jack had for doing the job was the best model, which I think is a fundamental issue actually. But if you take Jack's model and you go looking back and looking back but you stop short -- you have identified the patient, you know the patient is alive still, you could have stopped short at that point and said, "Well, if and when treatment comes, we could quickly get in there". I think that's a fair point.

I think what I was unhappy with -- and this may be entirely inappropriate -- was moving into that patient and the family and said, "You have been infected." unless we could say, "Don't worry, we have got some treatment". But I take Professor Nathanson's point. It might have shortened the -- dare I say it, the most effective way, and I made this point years ago, is why don't you go on the telly and say to people, "If you

have had a transfusion ever before, give us a shout". And that might have actually been hugely more successful than this long, complex, rolling programme. But I mean, I take Professor Nathanson's point.

Q. Yes. We have very little documentation about look-back during 1992.

A. Yes.

Q. But can we take it that your attitude to the advisability of look-back remained as it was at the end of 1991, throughout 1992, that you had these concerns about giving bad news to patients when there was no treatment?

A. Yes, I must have. I mean, getting a -- Professor James would say getting a symposium accepted in the Royal College of Physicians anywhere is quite a big undertaking, actually getting the council to agree to this, and I must have been, throughout 1992, tracking the notion that maybe treatment was coming along, and from that came the symposium. And after the symposium, rightly or wrongly, I was a source of great trouble to people who I believed were responsible.

Q. Yes.

A. So in 1992 I imagine -- I imagine I was collecting information as best I can, largely through my colleagues.

Q. Yes.
A. Could we break this treatment and then we go?
Q. Collecting information about possible treatment?
A. Yes.
Q. Did you receive any information from Dr Gillon about how his look-back was going?
A. I don't recall. I can't imagine I didn't, knowing Jack and Brian, but I don't recall that.
Q. Yes, okay. Let's have a look at the symposium. [PEN0180553]. We have got on the screen -- I take it that's the first page of a flyer for the symposium. Is that right?
A. I think so, yes.
Q. Could you tell us what this was, please? The symposium?
A. Yes, it was bringing together as many people who might be interested, some we actually targeted, saying, "We think you should be there, this could be very important". And it was a workshop, symposium. The workshop tended to be much smaller. In fact it required the full lecture theatre in the Royal College of Physicians here. So it turned out to be very well attended.

As I recall, as far as I was concerned -- I contributed to the organising of it -- the main central attraction was the clinical bit, which -- and

the rest was my local friends giving background on various things.

Q. This is the Royal College of Physicians of Edinburgh?

A. Yes.

Q. And at that point what was your relationship --

A. I must have been vice-president. So I had a leverage.

Q. Right. Was this organised by you, Professor Cash?

A. I'm almost certain it was. I can't be -- but I'm sure I would have consulted with a lot of people.

Q. Okay. Could we just go to the next page, please?

A. Looking at the speakers, it looks as though I organised it.

Q. Yes. So just looking down the page there at the speakers, we see Dr Follett. The Inquiry has heard of him, he was a virologist in Glasgow.

A. Indeed.

Q. Dr Peter Simmonds, Dr Gillon. Do you remember what Dr Gillon talked about?

A. No, I don't but I'm sure Jack will.

Q. Do you remember if he talked about the look-back that he was pursuing?

A. I can't remember. But I'm sure Jack would know that.

Q. Okay. Then if we go to the afternoon session, "Treatment of HCV infection".

A. Yes, that was the big ...

Q. That's Dr GM Dusheiko?
A. Yes. I shall add that my hepatologist friend was the now Reverend Professor Peter Brunt from Glasgow, a close friend, and the other one was a wonderful guy called Niall Finlayson here in Edinburgh. And I'm pretty sure that either both or one of them, as I was thinking about this, they alerted me to the fact that this guy has been heavily involved and would have the very latest information. And he was British, so the department people would have been able to cross-check.
Q. Latest information about what?
A. About the treatment.
Q. Treatment for HCV?
A. Yes.
Q. Okay. Do you remember what he said in that address broadly?
A. No, I don't but I have this memory, which may be purely spurious and something that is thought up for my convenience: I think he harangued us. He said, "Listen" -- I since learned that this may have been an exaggeration. He said, "Listen, there are now some good treatments for this condition". And I am almost certain in my mind -- I don't have any records of this -- he actually said, "You should be look-backing".
Q. So he was an advocate for look-back?

A. He was an advocate of being a good hepatologist. I don't think he was -- I don't think he -- he was just simply saying -- I'm pretty sure I must have briefed him and said, "Look, the reason you are here is, if there is any good treatment, plug the whole look-back."

I have no idea whether he was involved -- the Royal Free -- in any look-back programmes later on, I honestly don't know.

PROFESSOR JAMES: Could I just comment. Dr Dusheiko actually came from South Africa. He was a tremendous early proponent, as you have implied, Professor Cash, of treatment, as was Janice Main, who worked from St Mary's, who worked for Howard Thomas at that time. And I think Professor Thomas told us, when he was here, that to some extent the Hepatitis C-interested liver doctors throughout the world -- of whom certainly Dusheiko, Thomas and Main were among their members -- were sort of proselytising at that time for treatment with interferon, and to be honest were probably claiming cure rates that I think Professor Thomas himself has said turned out subsequently perhaps to be a little on the optimistic side.

MR GARDINER: Thank you.

A. Certainly that last statement is something I picked up later.

MR GARDINER: And so is it your recollection that Dr Dusheiko was recommending look-back?
A. It is my recollection, yes, thank you.
Q. Thank you. Professor Cash, was this the point at which you changed your mind about look-back?
A. Yes. I now took the view that we had a reason to run it. You know, I was enthusiastic from the start but I now felt -- and Professor Nathanson may get a little upset -- I felt ethically we could now really pursue this very hard.
Q. Yes. This is October 1993?
A. It is indeed, sir.
Q. Okay. Could we look at the next page, please? Just in another context, Professor Cash, we are just noticing that this symposium is supported by Abbott Laboratories Limited and the Wellcome Foundation Limited. Do you know anything about that?
A. No, I suspect you would need to ask a charming lady called Mrs Margaret Farquhar in the college. She would have said to me or to whoever, "Are there any companies that we can get a bob or two that are in this game?" And it's very interesting -- I hadn't noticed this. Old Wellcome are in and we haven't heard a word from them in the context of HCV, but I can assure you they were very much there.

Yes, I can put my hand up and say I didn't get a fiver from either of them and I wasn't involved in -- vice-presidents don't do that sort of thing.

Q. Okay. Next document is [SNB0052107]. The symposium was on 8 October and this is a letter by you on 15 October to SNBTS directors. Do you remember this letter?

A. Yes, I'm seeing it in detail again but I'm sure I saw it as part of the papers, yes.

Q. And you are referring to the symposium in the first paragraph and you are expressing the view that you do believe:

"This places an obligation on the BTS to use its best endeavours to advise clinical colleagues accordingly, when we have evidence that a recipient may have acquired HCV."

So are you there advocating a review of look-back?

A. Yes. And I think in those debates the whole question, as I said, of a television thing versus the long -- was brought up. But, yes, yes.

Q. Okay. And that's consistent with your --

A. And this culminated in May 1994.

Q. Yes. But that's consistent with you changing your mind at the symposium effectively about look-back?

A. I'm not changing my mind; I'm being told that if your concern and your inhibitions about treatment, about the

existence of treatment, the message was from Dusheiko: "Treatment is here now; it's worth running it". I simply said "wonderful".

Q. Yes.

A. It was not for me to decide that treatment was not available. That information was brought to us by an expert.

Q. Yes. Okay. Let's have a look at [SNB0099176]. This is a meeting of the MSC on 9 and 10 November.

A. Yes.

Q. You are present. Dr Mitchell, Dr McClelland, Dr Perry. Could we just go to 918 --

A. Can I just say, very importantly Dr Keel is present.

Q. And Dr Keel is present, thank you.

A. Scottish Office.

Q. Why is that so important?

A. Because if you want -- I'm repeating myself again: if you want to take this look-back really forward effectively, it was very important that we engaged our mates in the Scottish Office, who would be advising ministers. And as you know from Lord Fraser's letter that was to come in due course, they did.

Q. Yes. So had you specifically asked Dr Keel to attend this meeting?

A. I must have done. Because she is not a member of the --

the days of dear old Bert Bell from the Scottish Office regularly attending -- and she attended this and I think the next one where she played a very -- the May 18th one -- very critical.

Q. So why did you arrange for Dr Keel to be present at this meeting?

A. I don't recall. I mean, if we look down -- I noticed items 4 -- look at the items in her brackets, it must have been that I was keen that she knew what was going on in those areas.

Q. And what areas were those?

A. 4.4.4 -- it's there.

Q. It's look-back, isn't it?

A. Yes, yes, sure.

Q. So do you think --

A. So this was part of me upping the ante.

Q. Yes.

A. And my colleagues -- you know, I can take ...

Q. Yes. I'm just wondering about that, Professor Cash. How much of your new attitude to look-back, if I can put it that way, had been affected by discussions with your colleagues? I mean, your colleagues on the SNBTS.

A. Well, I wrote to them. The answer must have been -- must have had also some effect. It must have added on. But I wrote to them -- you have just shown me -- saying,

"Listen, that conference, that workshop that we were at" -- and we were all there. So was David McIntosh and so was Aileen Keel at that meeting. And a lot of friends and colleagues from England were there and I wrote to them, which you have just shown us, saying, "Listen, we are going to have to really start winding this thing up because treatment now appears to be a reality."

And I think -- you have just shown me. I said to them in that letter, "I'm going to bring it up at the MSC", and presumably this is it, this is the MSC meeting. Is that right? I haven't checked the dates.

Q. These are the minutes of the MSC meeting, yes, that's right.

A. Yes, so we are delivering on promises.

Q. Yes. Okay. So just to summarise: you arranged for Dr Keel to attend this meeting because you knew that look-back would be discussed and you thought it was important for her to be present in order to make progress with it?

A. That is my best recollection, sir, yes.

Q. We see Dr Keel present for items 4.1, 4.2, 4.3, 4.6 only, and if we could go to 9185, we will see, under the heading of 4.6, "New items", which she was present for, we have "Look-back":

"After a full discussion in which the principles of look-back of HCV PCR-positive donor archive samples and appropriate communication with recipients' GPs were agreed, it was felt that the position concerning PFC products required further consideration. The committee felt it would be inappropriate to make a policy decision at this time and that further discussion was required."

Then Dr McClelland to circulate look-back information.

A. Yes, I think that -- I refer to that. They asked Dr McClelland if he would do that.

Q. Can you remember how the discussion went at this meeting?

A. No, I can't, honestly. With hand on heart, I can't.

Q. Do you remember what you were advocating?

A. Oh, I was advocating, as is the letter before the meeting, that the position had changed and that we really needed to begin to think about this very much more seriously. I say that, it's not minuted, but I can't imagine it was any other than that.

Q. Right. So you were advocating the position that SNBTS should think about implementing HCV look-back?

A. Yes, really right across the board, rather than just the Edinburgh feasibility study.

Q. Think about but not actually making a policy decision

that they should do it.

A. These are nuances. If we had thought about it and discussed it, and decided at that point, now is the time to come up with a firm policy proposal, I have no doubt we would have done it, but it looks as though, after great discussion it was decided it wasn't quite appropriate. If you ask me what was not appropriate, I cannot honestly recall.

Q. I am curious. Why? Why was it not thought appropriate to make a policy decision at that point?

A. I can't recall. I can give you a guess but I would hesitate to do that.

Q. I don't know if you would like, Professor Cash, to speculate about that, sir.

THE CHAIRMAN: Does it involve the West of Scotland?

A. Yes. You knew that.

THE CHAIRMAN: I don't think there is much damage in asking for speculation that we could all fill in for ourselves.

A. Yes.

MR GARDINER: Could you, please, speculate?

A. The fact that Brian was asked, "Look, can we then actually see the nuts and bolts of what has been going on now in the southeast" and so on, I suspect that the difficulties facing the West of Scotland, which I have no doubt we will come to, the difficulties which faced

the whole of England and Wales, that in the context of the Scottish family, the call was from the West -- I should also say from Aberdeen and Dundee as well in particular -- "Could we actually see the details, then, of the pre-publication thing that was going to come out?" And I think that's my guess as to the way that the discussions went.

Q. So this would be directed at getting further material as to the feasibility and probability of look-back?

A. Yes, yes. What have you done? Where should we be targeting our resources? I haven't said this but I'm sure you are aware, Edinburgh was hugely well resourced. They had a post-doc, a Malayan, cost them not a penny because he had come there -- I was the director of that centre for about six years and we built a reputation such that people were very keen to come. So he had --

Jack had somebody, not a young lad, this was an experienced doctor, Dr Ayob. They got that for free. They had got a superb IT programme in the blood bank area, not just the other areas, which some of our colleagues in the eastern seaboard didn't have. Ruthven didn't have a thing such as a blood bank. That was the West of Scotland. And he was going to have to rely on all the information, the first trigger information, to be generated from the -- widely, from Oban to

Fort William to Ayrshire, central Glasgow, he had absolutely no control of.

McClelland and Gillon had control of a little over, I would think, 70 per cent of all the clinical crossmatching in the Southeast of Scotland. It was huge. And I ran this show, it was fantastic.

So at the press of a button, they also had a superb IT man, so did Glasgow, but they had no blood banking IT at all because they didn't do it. And all these things I'm sure, even the eastern seaboard, that did much the same as Brian, they were very concerned that they managed to get their clinical colleagues to collaborate. The one that we knew would, would be the Professor in Aberdeen, Peter Brunt. That was for sure.

So there was great anxiety about, you know, rushing to a policy. Until now we were all saying, "We have got to think about this; are we going to go?" I don't know whether that's any help.

Q. I'm surprised at the word "rushing" I must say, given that screening had started in September 1991.

A. I would say, to a lawyer, I can well understand that but I tell you for those on the ground, having to face up to these problems, I can only say I don't think they would have regarded this as rushing. This was the first time, because I had run the thing after the Edinburgh college,

"Look, we are going to have to get serious, boys". Before, they had clearly not looked at this really very carefully at all, with the exception of Bob Crawford. And Bob had determined in his own head, they couldn't do it. Now they were going to have to face it.

With respect, I can understand one saying, "Hey, you started this in November 1990 and here you are in 1991" -- I can understand that. But in operational terms, this was suddenly, "We are going to have to do this".

Q. Yes. Professor Cash, just for clarification, I think in an answer you just gave you said that Ruthven didn't have such a thing as a blood bank. What did you mean by that exactly?

A. Oh, that's very, very important. If you asked Ruthven when did he last crossmatch, we were talking about blood banks where you actually crossmatch donations or platelet or whatever for patients in the wards. Has nobody sort of sat you down and just taken you through that? Because that is a whole technology. It's what we call, if you like, the clinical interface with blood transfusion. If you went to Glasgow for instance, to the Royal Infirmary, to the Western, to Stobhill, you would find a department of haematology with a blood bank there that was supplied by just supplies of blood from

Ruthven but weren't attached to patients at that point at all.

So the requests for blood in Stobhill, Royal Infirmary, Ayrshire, Fort William, were coming in from clinical units to the local blood bank and in the Southeast of Scotland, in Dundee, in Aberdeen, and Inverness, the regional transfusion centres themselves dominated that what we called "clinical interface". The West didn't do it at all. So their blood bank -- this is practice really, forgive me -- was in fact a warehouse, a chilled warehouse in the West of Scotland. In Edinburgh or the others, it was a very busy, very busy area, where they were getting a request in to get the right group for the right patient and so on and so forth. So they had all the patient records there.

Q. Yes.

A. I don't know whether that helps.

Q. What you have just been telling us about the discussions, the concerns, about implementing look-back, particularly in the west and so on, do you think that those concerns were fully ventilated at this meeting by the respective people, people like Dr Mitchell and so on?

A. I can't, hand on my heart, say "yes" because it's not

minuted, and I've spent most of this Inquiry regretting the quality of minutes. But I can't escape knowing my colleagues, yes, that would have been ventilated very effectively.

Q. Okay. I just see that there is a note there:

"Dr McClelland to circulate look-back information."

No doubt that will be information about the look-back programme that is being followed in SNBTS [sic - SEBTS] Does that suggest that you yourself wouldn't have seen that information before this meeting?

A. It may have, yes. I mean, Jack will be a better judge than me but I think what they were actually referring to, I think, was Brian had -- in a sense they were quite heated debates going on, on this general area, and Brian had signalled that in fact the experiences, however limited they were, of the Edinburgh feasibility study were about to be sent off for publication or whatever, and that he would be delighted to let his colleagues have a copy of this, to let them get a feel as to what was involved, yes.

Q. Am I right in thinking, Professor Cash, that that aspect of it, the feasibility aspect of it, wasn't something that overly concerned you?

A. No, sorry, I'm a little lost. No, I mean, we have talked about the feasibility -- I mean, any information

in my view that helped my colleagues face up to making this decision, if they said, "Look, we wish to see what's been going on in Edinburgh then" -- and some of the real data and -- I should add that I'm fairly sure that Jack Gillon in his publication produced a logarithm or chart of the way you actually did it ... they would have wanted to see that sort of thing.

Q. I mean, by the end of this meeting what was your attitude to look-back? You didn't have the treatment concern any more but did you still have a concern about feasibility?

A. Yes, keep going, keep going, keep going. The lads had said -- I imagine I said, "Can we have more information?" Can we begin to think of it, take the Edinburgh document back home to the West of Scotland, read it and talk to the team there, the real folk in the West of Scotland and Aberdeen, and so on and begin to put together a picture? I'm sure this triggered off what was later to emerge, that they began to look at that. And my view was, I'm sure -- and it's not minuted -- that we are going to do this. It's just a matter of keeping going, keeping going, keeping going.

Q. So you thought that the feasibility problem would be resolved in such a way that you would ultimately go ahead with look-back?

A. Yes, I mean, I thought as night follows day, I'm sure at that point, when there was treatment, I wouldn't wish to ascribe Lord Fraser's comment -- I think we were reaching a point where we had a total moral obligation. We had to do this. The question was: how were we going to do it and what was the best way? At the back of my mind all along here was the Edinburgh way might not be the best for the likes of the West of Scotland.

Q. Yes. And how did that attitude that you had at that time affect your thinking vis a vis Dr Gunson? I mean, you knew that Dr Gunson wasn't enthusiastic. So did you think that that was going to create a problem?

A. It might have created a problem but I can tell you, because he stayed with us, Harold was at the workshop. He stayed overnight with us and we had talked and he was extremely anxious by the position taken up by Dr Dusheiko. And we talked about it and I either said to Harold, or certainly in my mind, "We are just going to press on ourselves and see where it takes us and I'll keep Harold informed but you are on your own, Harold".

Q. Right. When did you tell Dr Gunson that he was on his own?

A. I suspect the evening of the symposium that he stayed overnight with us. We were pretty social, he and I, and chatted.

Q. So the symposium was a real watershed for you, Professor Cash?
A. Absolutely. Absolutely. I can still see myself standing at the bottom of the lecture theatre by the lectern with Dusheiko. I can still see myself shouting to Harold, "Come over here", and getting some people -- and getting a bit passionate about it.
Q. Did you know what Dr Gunson's attitude was, having been at the symposium?
A. I can't -- I wouldn't wish to go -- I can vaguely remember the body language wasn't happy. As things turned out -- I hope we get to that at some point -- as things turned out, I'm not surprised he wasn't happy. I don't think -- I think he knew in his heart they couldn't deliver.
PROFESSOR JAMES: Could I ask one question? By this time, actually in the West of Scotland, like everywhere else, they had been screening blood for two years for HCV?
A. That's correct, sir.
PROFESSOR JAMES: Do you remember if you or Dr Mitchell or anybody else had an idea of the sort of size of the problem that might confront them in terms of actually the number of patients, you know, whom they were turning up positive? Because I think it would be fair to say that probably Dr Gillon's famous 0.088 per cent, that we

will no doubt discuss with him subsequently, had been in a way a "pleasant surprise" in the sense there weren't as many people as perhaps people had anticipated. Do you have any feeling for what Dr Mitchell thought he might be facing in Scotland, not in the logistics of going out to Oban and all that, just the numbers?

A. I don't have a recollection, but I do know -- and Jack knows this -- that Bob Crawford, who represented the West of Scotland in Jack Gillon's wonderful working party, was extremely anxious at the size and the nature, which is what -- the nature of the problem.

PROFESSOR JAMES: Thank you. Thank you.

MR GARDINER: So after the MSC meeting, which Dr Keel attended, the main issue to be resolved was feasibility of having a look-back programme in Scotland.

A. Yes, I think that's correct, sir.

Q. Right. Okay. Let's have a look at [SNB0055560], please. So does this look familiar?

A. Yes, but it's interesting. It implies -- my memory is obviously wrong -- that Harold wasn't there, at the symposium.

Q. Well --

A. That's interesting.

Q. Is that because you would have put "as you know", or something? Why do you say it implies that?

A. It's the way:

"At a recent symposium ... a distinguished speaker ..."

I would have thought I would have written, "Do you remember Harold ..." and so on and so forth. So it's that that makes me -- but I think the message is still there.

Q. It is a letter that you are copying to Dr Keel and to --

A. Oh, yes.

Q. Who are the other people that you were copying --

A. I can't see, sir. Ruthven Mitchell and Bob Perry, the two people on the advisory committee, the Metters committee. And silent copies. "MB", that would be Martin Bruce.

Q. The point I'm making is that you are copying it to other people who have an interest in this letter.

A. Maybe. Mitchell and Bob Perry were on the Metters committee. So if we came again, they would hopefully beat the drum. And Aileen Keel because she was part of a team advising Scottish ministers.

Q. Yes. In any event, we see that in the letter you are referring to the symposium, you are referring to the view discussed at the MSC meeting and that:

"... colleagues stepped back from introducing a look-back policy until such time as further (UK)

deliberations had taken place."

Is that right? UK deliberations? Because I thought we had agreed that the issue was feasibility in Scotland, as opposed to --

A. Yes, we had, but feasibility in Scotland -- and we may have proved to be wrong -- would require the Scottish ministers to say yes and the CMO to write to the -- particularly the West of Scotland -- but not just the West of Scotland but to the Lothian, Grampian and so on health boards to say, "This is what we are going to do". This is what eventually emerged. So the feasibility was all part of getting the Scottish Office -- us getting them on side, yes.

Q. Is that because you didn't think it could be done in Scotland without --

A. No, I have not made myself clear at all, I am afraid. Actually delivering this or getting near to delivering it -- and to the best of my knowledge, they never delivered it in England properly -- required the CMO or the department or ministers to say, "We are announcing to you, the health board chaps, to work very closely -- if we are going to take Jack Gillon's model -- very closely with your local transfusion service to actually undertake this look-back." And it required, in my view -- and I think it's a view that was widely

shared -- that level of authority so that -- as in fact happened -- and I don't know whether anybody has told you this yet -- there were clinicians that were not very collaborative.

There were in blood banking, the hospital blood banks, people who claimed they were far too busy. There were people who weren't prepared to go down to the bowels of the hospital and try and find records of transfusion practice because it was a lot of extra work and so on.

It required a CMO or whoever, ministers, to say, "I'm instructing, in the name of the minister, that you go and do it." Even then, south of the border, it didn't work.

Q. Yes. And that's why you thought further UK deliberations were necessary?

A. Yes, I felt that if -- the easy way for us would be MSBT saying, "We think the time has come, let's go". That would have been immediately flashed to the Scottish Office and something could have happened.

Q. And that's what we see in the next paragraph --

A. That would have brought great comfort to Ruthven Mitchell's team, I can assure you.

Q. Yes. The next paragraph:

"It occurred to me that it might be appropriate for

the item to be researched for, and discussed by, the MSBT. I would value your comments and support."

So that seems to be suggesting that before Scotland can take forward this possibility of look-back --

A. No --

Q. Let me ask the question, please.

A. Yes.

Q. That it needs to be looked at by the MSBT, which is the Metters committee. Is that not right?

A. No, I'm simply saying that one way we could speed things up would be -- I have just said it -- would be if the MSBT in fact advised ministers accordingly. I'm not saying that nothing can happen in Scotland without the MSBT. It's not my position or privilege to be in that position. To checking that, I made sure that Aileen Keel in the Scottish Office was in fact in the loop, so that if she felt the Scots should move without the advice of the advisory committee, then fine.

Q. Yes.

A. But it's not for me to take it upon myself -- and this is a recurring theme, I have felt. I wasn't in a position -- and quite rightly in a position -- to insist that without the MSBT, we can't do X, Y and Z. It was ministers that made that decision. If we could get MSBT on board, that might expedite decisions in our

favour.

MR GARDINER: Sir, I think that might be a good point.

THE CHAIRMAN: Yes. Thank you.

We will break at that stage.

(1.03 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Yes, Mr Gardiner.

MR GARDINER: Thank you, sir.

Professor Cash, in the interests of getting through the next bit of the story a bit quicker, I'm going to take the next two committee meetings as read but if I could just refer you to a schedule, which is at page 4 of [PEN0172511].

THE CHAIRMAN: Could you give us a reference at some stage to the documents you are taking as read?

MR GARDINER: We will see that from the schedule, sir.

THE CHAIRMAN: We will.

MR GARDINER: So this is a schedule that was attached to a letter to one of our other witnesses, Dr Keel. Just before lunch, I had taken you up to about the end of 1993. Could we go to 1993 on the schedule. You see paragraph 8; I'm just going to read this through:

"On 18 November 1993, Dr Cash wrote to Dr Gunson informing him of the discussions at the recent meeting

of the SNBTS MSC. He suggested that the issue of HCV look-back should be discussed by the ACMSBT. Dr Gunson suggested that the topic be put on the agenda of the next ACTTI".

At the meeting. Next paragraph:

"The ACTTI ... met on 18 January 1994. The minutes note support for the concept of look-back."

Could we just go over the page:

"Various members of the committee were to look into the issue further and report back at the next meeting. The next meeting of the ACTTI was held on 19 April 1994."

So, Professor Cash, could I just ask you to take that as read?

A. Yes, I think that was the moment where I thought we were off, so far as the ACT. I think the next meeting -- it goes back a bit, I sense. Okay, yes, certainly.

Q. The next meeting on the schedule is the one on 16 May 1994 and I would like you to have a look at these minutes. It's [SGH0040847]. So this is headed up "Minutes of SNBTS issues meeting ..."

What's an issues meeting?

A. Do you know, I'm struggling a bit. I couldn't recall this meeting because in this format, it was extremely rare. But I am aware that if you go back to

Duncan Macniven's time, rather than George Tucker, there were occasions, I remember vividly, in terms of the Medicines Act, where we had an issues meeting. But they were very infrequent as far as I was concerned, sir. I presume that David McIntosh on the other hand was in regular contact with colleagues in the department.

Q. Yes. we see that --

A. It's interesting, Dr McClelland is there... yes, it's interesting.

Q. So the SNBTS personnel: Mr McIntosh, yourself, Dr Perry, Dr McClelland and we see Dr Keel, Dr Young, Mr Tucker. If we could go to 0849, paragraphs 11, we see that Hepatitis C look-back is discussed:

"Mr McIntosh indicated that when Hep C testing of donations was introduced in 1991 it was not thought appropriate to look back over previous donations. Mr Panton confirmed that any claims for compensation following infection with Hepatitis C should be refuted."

Just to ask there, Professor Cash: again, is that a link that you saw being made between the look-back programme and compensation?

A. Oh, it was chronically there, as I think I said earlier this morning. That's pretty bold stuff. Rab Panton was a very mild, kind bloke. I can't imagine him being -- but there you go. But, yes, the whole concept of

liability and compensation lurked around in my memory all the time.

Q. Yes. Reading on there, we see:

"After discussion it was agreed that Mr McIntosh would send a draft policy statement about look-back to the department for clearance."

What would the policy statement have been saying at that stage?

A. I don't know but I think you have a copy of it. At least I have, somewhere. On the 19th -- there is a series of strange occurrences here. On 19 May -- I think that meeting was, when, on the 16th? On the 19th I have a document, which looks like a statement from David McIntosh.

Q. There is another document before then.

A. I'm sure I got the papers from yourselves.

Q. Yes. That's [SNB0099331].

A. This is it. Yes. 18 May.

Q. So this is the minutes of the MSC meeting on 18 May 1994.

A. Yes.

Q. We see you are present and Dr Gillon is present and Dr Keel is there as well.

A. Very important.

Q. So is this another example of Dr Keel being invited to

come along specifically?

A. Specifically for the look-back, and in the end she played a very critical role in the discussions as minuted.

Q. If we go to 9335, at the bottom of the page, we see under "Any other competent business", "HCV look-back":

"This very complex and extremely important issue was discussed at length. The committee unanimously agreed that on finding a known (or regular) donor who was now anti-HCV-positive, the SNBTS should ..."

If we go over the page. Then we have (i), (ii), (iii) and (iv), a list of all the things that have to be done, and that is effectively -- if you just take a chance to look at that.

A. Yes, it's the Jack Gillon protocol.

Q. So that's look-back?

A. Absolutely, game, set and match, we thought.

Q. Yes. So this is an important meeting?

A. Hugely important. Because Aileen Keel, as you will see in item (v), expressed a view that SHHD may not have a locus in this matter. I think at that point most of us fell off our seats, and that the SNBTS should make a decision on look-back based on their professional judgment. I mean, we had never heard those sort of words before.

"However," she said, "before you do anything, we ought to touch base with the Scottish Office."

Q. Yes.

A. And we agreed, okay -- we had to no option. All right.

So this was a very, very important meeting. One, the directors in a sense were saying, "We have had enough of procrastination, it's go for it time". The Scottish department representative who was there saying, "That's okay but, please, before you do anything, let the department have just some consultation in any way they wish".

Q. Why were you so surprised about the statement that SHHD may not have a locus in this matter?

A. Because we had gone through pretty painful, as I'm sure you know, the process of Hepatitis C donation testing, in which it was made absolutely clear to us that this was not a matter in which the professionals could decide themselves whether they would start testing and when they would start testing. We had -- I had assumed that the same was going to apply to HCV look-back, that ultimately -- and indeed this is what happened -- ultimately it would be ministers that would say to the Scottish Transfusion Service, "You can go ahead and do it now".

Now, I don't know whether we are going to look --

and David McIntosh jumped the gun and did something and we were hauled over the coals for doing that, and in a sense were told, "You will wait until a appropriate decision is made". So, yes, we were surprised.

Q. Surprised to learn that it was effectively your decision?

A. That it may be left to us, to be fair to Dr Keel.

Q. Yes. I understand. If we just read on on that page, paragraph 6:

"Once AK had communicated the SHHD position to JDC and provided SHHD were in agreement that the SNBTS should implement this policy, JDC would write to David McIntosh to provide details of the SNBTS policy, thereby allowing a decision to be taken on a starting date for the process. JDC would also formally advise NBA, NIBTS, SACTTI and MSBT of the SNBTS policy."

A. They are all laughing. I'm delighted to join in with the laughter. That's the number of committees that one way and another we were ball and chained to.

Q. Yes. I suppose what's surprising about what's written there is the way that it's put, that you will simply advise these committees, whereas for quite a while now SNBTS have been waiting for indications from them about what to do about look-back?

A. That's a very good point and it's easily responded to

because in (vi) we are making an assumption that in due course Dr Keel, Archie McIntyre, or the CMO or the minister, Lord Fraser, would come back and say, "You, SNBTS, get on with it". When we were in that mode we would advise anybody that that's what we were doing because our masters had spoken.

Q. Your masters in Scotland?

A. Absolutely.

Q. Yes.

A. I did not have any masters elsewhere, sir.

Q. Paragraph (vii):

"If SHHD agreed that SNBTS should develop and implement a look-back policy for HCV, AK subsequently would communicate this to DOH."

I'm going to leave those minutes now, sir, unless you ...

If we could have a look at [SNB0084777], that's dated 19 May from Mairi Thornton. Who was she?

A. Mairi Thornton was the national director for the donor management services.

Q. Yes. This is a memo to the board. And she is noting there was media interest and she is referring to a paper that sets out an agreed position. If we could have a look at that, [SNB0084776].

A. That's the policy position, sir, that you referred to.

Q. Yes.
A. Produced by David McIntosh.
Q. Yes. So on 18 May 1994; that represents the policy of the SNBTS?
A. I think it's dated the 19th, actually, sir. I beg your pardon.
Q. Thank you. If we could go to [SNB0084779].
A. Could we just scroll this one, sir, just for a second, please? Okay, thanks very much. I have got something that's slightly different.
Q. [SNB0084779]. This is a fax from David McIntosh to Mr Panton at SHHD, dated 19 May 1994, paragraph 1:

"The MSC ... has now formally recommended to me that the service should implement a look-back policy without delay."

Paragraph 3:

"I would therefore intend to give colleagues in England, Wales and Northern Ireland, prior warning of our intentions and to activate look-back with effect from 1 June 1994."

That's from, as we see, David McIntosh. I think you said that that was, in your view, premature?
A. Yes, it is actually fascinating. It was dictated and faxed from the donor management centre in Glasgow the day after the MSC had met. It was never clear to me

(a), the communication that David has said there, that the MSC had now formally recommended, but this was all caged and conditioned by we needed to wait and be sure the department would go along with this, the Scottish department.

This, I think, was very strange to some of us, that David had not only picked up half the message but astonishingly had given a date for June 1st, and I haven't the remotest idea how that date was arrived at. David in his statement has said it was always in the back of his mind to start on June 1st and, I mean, that predicates heavily on what might or might not have happened on the MSC committee meeting. So we got into a little confusion here in which eventually -- I think you are going to remind me -- the Scottish Office said, "Look here, we want to talk to you", and that took place.

Q. And that was on 24 May?

A. That is correct, 24th and 25th, yes.

Q. Okay, we can see that from [SNB0084783]. This is a fax from Mairi Thornton to SNBTS management board:

"David has asked me to let you know that he, John Cash, Brian McClelland, Jack Gillon and I attended a meeting at SOHHD yesterday where the SNBTS proposal for Hepatitis C look-back got a sympathetic hearing.

"SOHHD are to consult with the Department of Health in London before a final decision is reached ..."

Is that an accurate description of what was discussed at the meeting, so far as you can remember?

A. So far as I can remember, sir, yes.

Q. So there has still got to be a final consultation with the Department of Health before --

A. So it would appear.

Q. Okay. Then, if we could go to [SNB0084784], this is a fax from David McIntosh dated 30 May 1994 to SNBTS regional directors, copied to other management board members. He is saying:

"Following our meeting in the Scottish Office on 24 May, this is to confirm that official moves are now afoot to follow up the recent MSC discussions with active consideration of the steps necessary to put an appropriate look-back programme into effect.

"No final decision has yet been taken."

So just to be clear, Professor Cash, this seems to be a step backwards from what Mr McIntosh was saying before. Why was that?

A. Oh, I'm not sure whether there was a minute taken of that 24 May meeting but my best recollection of it is that the Department of Health officials that we saw made it very clear to us that the MSC meeting deliberations

that David refers to in his letter saying, "As a consequence, June 4 we are off," they made it very clear to us that the MSC committee members had agreed that Dr Keel would come back to them after she had done whatever consultations. And this did not seem to have been taken on board in David McIntosh's letter to Rab Panton.

And in a sense they were saying, you know, "You will not go ahead until we give you the instructions so to do". And my view is that -- in fact I'm quite certain, that David as a consequence -- that that letter of 30 May, he was advising his colleagues that the June date -- there was 24 hours to go -- was not on and that we were going to await further instructions.

Q. Okay. Could we look at [SNB0099571]? This is a letter dated 21 June 1994 from yourself to the directors.

A. Yes.

Q. "I thought it might be helpful to clarify the position -- at 20 June 1994 -- after the unusual events following our last MSC meeting."

What were you referring to, when you referred to the "unusual events"?

A. Of David issuing a promulgation that didn't in fact fit with the understanding of the directors who had been party to the discussions of the MSC.

Q. Yes. You say:

"There are three evolving approaches designed to provide the now necessary SOHHD approval for the SNBTS to commence a formal 'nationwide' HCV look-back programme."

"nationwide", is that Scotland?

A. Yes, I can only presume, "Look, chaps, we are in a bind here. We have had a meeting at the department and this is the best understanding."

Yes.

Q. Yes. And the approaches are, number 1:

"Advisory Committee on Transfusion-transmitted Diseases."

Then over the page:

"... donor consultants ..."

And 3:

"Consultation with ... hepatologists."

Are you saying here, Professor Cash, that the next step will have to involve consultation with these bodies?

A. I think 2 and 3 are -- begin to prepare, get in there, talk to your local hepatologist and so on. And for people like Ruthven Mitchell, this was a big, big task. Edinburgh easy. Jack Gillon had come out of a hepatology department. Easy. For others it was

a little more difficult. It was really tough for Ruthven.

And similarly, the donor consultants group would begin to in fact look very critically at across the board, begin to prepare, to introduce Jack Gillon's guidelines. The first one was, I'm sure, an interpretation of a message we had got in the department when we had attended on the 25th, or whatever, that the Department of Health in London wanted to get the advice of the ACTTI, and so in a sense we were just slightly scuppered there just for a short period of time.

Q. Yes, okay. Then if we look at page 2 of [SNB0099512], these are the recommendations. If we could just quickly go to 9515, we see at the bottom:

"The SACTTI feels that there is a serious case for considering a look-back policy for HCV."

So that doesn't seem to be taking it forward particularly quickly. Would you agree?

A. Yes. It's about a reluctant horse being dragged to the water. As I said before, I had a great deal of sympathy with our colleagues south of the border.

Q. And [SGH0040803], please. This is a conference and we see in attendance members of the Common Services Agency and from SOHHD various people, including Dr Keel. If we could go to 0805, paragraph 11, it's the last sentence:

"Dr Keel and Dr Perry awaited the decision but pointed out that MSBT had no real locus in this since it was not a matter of blood safety."

Again, this is under the Hepatitis C look-back. Are you surprised to see that?

A. I am in a way, yes, but I'm not sure I would be inclined to make a major issue of it. My impression was that the MSBT, with its broadened terms of reference, there was no major conflict here but it's a nice point actually. It would have been nice to have known that the advisory committee were a total irrelevance, and that was something that the Department of Health in Scotland were content with. But I wouldn't wish to pursue that, sir, unless you wish.

Q. I'm just asking for your comment. Just moving quickly on, if we could go to [SNB0084820], we see that these are the minutes of the advisory committee on the Microbiological Safety of Blood and Tissues for Transplantation, MSBT. So that is the Metters committee.

A. I think it's interesting that Archie McIntyre has gone, probably retired, I think.

Q. This is 15 December 1994. We see observers: Dr Keel. If we could go to 4824. I'm not going to go through it all but we see paragraph 7.1, 7.2, there are discussions

about look-back. If we go over the page, these are more discussions about look-back and down at the bottom, we see a comment from Professor Zuckerman:

"Professor Zuckerman shared the view expressed by Dr Mortimer that the question of look-back was driven by lawyers. It was important to distinguish between those infected with HCV through NHS treatment and by other means."

So again, this hint of concern about liability. Would you agree?

A. I'm not sure, and it wouldn't have been the first occasion that I would agree with Harry Zuckerman.

Q. Over the page, we can see that there is continuing discussion about look-back and at paragraph 7.10:

"Dr Keel said that the view in Scotland was that the Secretary of State was vulnerable as look-back was feasible, since donors could be identified and traced, and advice from Scottish Office lawyers was that look-back should start immediately. The Chairman stressed the need for maintaining uniformity in the UK but said that it was for the Secretaries of State and not for the committee to decide on whether Scotland should go ahead early."

Then down at the bottom, 7.12:

"Following the discussion the committee agreed its

advice to ministers as:

"i. In the committee's view there is a duty of care towards those infected with HCV as a result of NHS treatment. It follows that procedures should be put in place to identify those patients at risks;

"ii. Whatever is done should be done equally and uniformly throughout the UK;

"iii. Guidance should be drawn up as soon as possible."

And 7.13:

"The committee agreed that these conclusions would be passed on to the Secretaries of State of all four health departments."

What's your interpretation of what has gone on there at that meeting, Professor Cash?

A. Well, I look really to right at the end, and it seems to me they have decided they have no option, that the ministers should be advised to press the button and commence some form of look-back.

Q. Yes.

A. The reasons for this -- I was about to say "change in attitude". I wouldn't wish to put that too far. But the reasons for this were clearly multifactorial. One of them was the question of legal liability. There was no mention of treatment, but I think that may be

incorporated into the whole concept of legal liability anyway. So I don't think we need to discuss that.

Q. Yes. But we know that in the event, although all the ships seem to be sailing in the same line, Lord Fraser's letter comes out saying that Scotland has got to go whatever happens.

A. Yes, I would suggest you got Sir Graham Hart to come and sit in this seat and ask him a few questions on this. They could well say that, "Typical Scots, they are pushing it a bit before the others," and so on and so forth, to make a point. I don't know. But, yes, you could argue very simply that Lord Fraser of Carmyllie was briefed on this by either Aileen Keel or her superior, a senior adviser, and he picked it up with the lawyers and just ran and kept running. But I don't know. There is no detail of the briefing he got, just his letter, which is an excellent letter. But that's what he came to and it could have emanated from this meeting.

Q. Just bear with me. (Pause)

Thank you very much, Professor Cash.

A. Thank you.

THE CHAIRMAN: Professor Cash, over this long period, were the numbers of individuals who might have been identified diminishing?

A. Yes.
THE CHAIRMAN: A number of reasons for that would include what?
A. I think the data that Jack Gillon presented was mirrored -- other smaller studies, similar smaller studies -- that the big attrition in terms of success, of actually getting live patients to treat, was natural death. When I say "natural death", the original pathology, no doubt, that had taken them to surgery, poor things. And that number -- and I don't have it with me but Jack produces a good table of the number of donors and so on and so forth, and the number of patients that they finally said, "It's Mr Bloggs", and then finally, "He is dead". And there is no doubt, as the time went by, that must have increased.
THE CHAIRMAN: So that's one factor.
Would another factor be that as screening became more effective in excluding potentially infective donations, the scope for look-back that had its trigger in identifying an infected donation would fall?
A. I would have thought that the improved technology would have meant, as they were screening populations -- I think Brian McClelland and/or Jack has made the point, as you rescreen the same populations, even with improved technology, your hit rate in fact, in terms of old

donors, regular donors, diminishes. So in that context, sir, you are right. Whether and to what extent that would have been offset a little by your improved -- by your third and fourth generation tests, I really do not know, but, yes, that would be relevant. What happens to new donors? You have still got the fundamental point.

THE CHAIRMAN: What I was thinking of is that if you have excluded a significant proportion of people with your HIV testing and incidentally taken out potentially infected HCV people --

A. That too.

THE CHAIRMAN: -- they don't come back, so that the increasing number of steps that reduce your potentially infected population must mean that at the end of the day, fewer and fewer people are going to be traced through that.

A. Yes, that's right, and if you look at the brilliant paper that McClelland and Marcela Contreras wrote on NAT testing for Hepatitis C, that they had reached a point -- I can't remember, 2000 and something or other -- where -- I'm exaggerating -- only five or six positives appeared in a year from the whole of the UK, so effective had been the serological screening. So all that, I think, adds weight to what you are saying, sir.

THE CHAIRMAN: So that natural cynicism that develops over

nearly 50 years as a lawyer, one might think that the longer you could postpone it, the less likely it is to throw up people with problems.

A. Yes, I would have thought the lawyers win 2-nil again, sir.

THE CHAIRMAN: That's a very low score.

Do you want to follow that in any way?

MR GARDINER: There is just one point, sir.

I am conscious, Professor Cash, that you prepared a witness statement for us for this topic, and I have not gone to it yet but it's [PEN0180353]. That's a statement that you kindly provided for us, and actually I have covered things that are in it but in a bit more detail, so I'm not going to go through it, but that's your statement, is it not?

A. It is, sir, yes, thank you.

Q. Sir, I'm not sure how much questioning --

THE CHAIRMAN: I'm just about to ask, if you have finished?

Mr Di Rollo?

MR DI ROLLO: Sir, I don't wish to ask any questions.

MR ANDERSON: Nor I, sir.

MR JOHNSTON: I have no questions, either, sir.

THE CHAIRMAN: Thank you very much. I wasn't assuming that was the end. I merely want to see if --

MR GARDINER: It's just we are a bit short of time for

Dr Alexander.

THE CHAIRMAN: We can pick up the references, I think, in the minutes that we did just skim over, to the probability of finding people.

Dr Cash, thank you very much.

What do you want to do about a break? Is it easier to break now and have a short break or is it easier to get started?

MR GARDINER: It might be worth just having a very quick break, just a ten-minute break, if possible.

THE CHAIRMAN: Please keep it to ten minutes, just to try and keep things under control.

(2.49 pm)

(Short break)

(3.00 pm)

DR GRAEME ALEXANDER (continued)

THE CHAIRMAN: Mr Gardiner, I think that I must emphasise the need to allow Dr Alexander to get away, having had a bad experience on Friday indirectly, since it was my wife rather than I, getting out to the airport is not the easiest thing in the world these days and he mustn't be held up.

MR GARDINER: I understand that, sir.

THE CHAIRMAN: Sorry, I have just been holding everybody up, but let's see how we get on.

Questions by MR GARDINER

MR GARDINER: Good afternoon, Dr Alexander. You have previously given evidence before the Inquiry and we had a look at your CV at that point. But just to remind us, you are a consultant hepatologist in Addenbrookes in Cambridge?

A. Indeed, yes.

Q. And the Inquiry wrote to you and asked you certain questions about this topic, which is really about tracing and testing patients and information to patients, and if we could just have a look at that. It's [PEN0181241]. And that's the letter that we sent you, is it not?

A. Indeed.

Q. And if we look at 1243, this is a schedule that we sent you to set out the context of the questions. And if we look at "Snapshots and Landmarks", it says:

"The Inquiry has identified the following years as landmark dates in the story of non-A non-B ... 1974, 1985, 1991 and 1995."

The schedule talks about what was happening in the early 1970s. It refers to the 1974 Prince et al paper, the 1985 Hay et al paper, the Sheffield study. If we could go over the page, we referred to September 1991, the screening test and then, April 1995, the HCV

look-back exercise.

The first question that we asked you is set out under "Matters to be included in the statement":

"Anti-HCV testing.

"We know that an anti-HCV screening test for blood donors was introduced UK wide in September 1991 and that anti-HCV tests had been available for some time prior to this.

"When was the first anti-HCV test used in the UK? What type of test was used initially? Who carried out the early tests? Who would have had access those early tests? What was the correct approach to using the first generation tests?"

Could we have a look at your statement, which is [PEN0181360], and I think the first page is an answer to that first question. Is that right?

A. Yes.

Q. And perhaps I could just ask you to answer the question in your own way?

A. Okay. I think the antibody testing was available late in 1990, and I think most of us who were interested in this new disease, as it appeared to us, were performing tests using kits that we knew weren't very satisfactory, but they gave us a feel for what was going on. And then the testing was introduced on a more formal basis in the

autumn of 1991, when we started to use the test on a more logical basis in diagnosis and managing patients already under our care.

The testing at that stage was, in retrospect, very poor, both in terms of its sensitivity and its specificity. So it missed people who were positive and it told us people were positive who we found out later weren't. And it left a large number of people in between, not knowing whether they carried the virus or not.

Q. Yes. How did you resolve those poor results?

A. Well, I think the important point to make was that you had to look at a test -- it's true of all medicine -- in context. So if a patient was likely to be at risk of catching Hepatitis C, then the test was probably more valuable than in a patient who was picked randomly from the street who wasn't at risk, the test was less valuable. I think you always had to interpret the test with caution, and we were all expectation that there would be better tests coming along shortly, which happened, of course.

Q. You say that the false positive rate was between 50 and 70 per cent?

A. That would depend upon which population of patients you were testing. So if you take a group of people who are

at high risk of Hepatitis C, your false positive rate would be low. If you took a large population of healthy people, unlikely to have it, your false positive rate would be high. So it depends on which population you start with.

Q. Could you explain why that happens?

A. Well, if you take 100 people, 90 of whom have got Hepatitis C, even if the test is wrong, you are likely to get the right result. If you take 100 people who have not got Hepatitis C and you test them all, you will get some that are wrong; it's very simple.

Q. Okay. In your answer here, you mention the second RIBA test. You say:

"It was generally agreed that the second test was needed."

Was that a confirmatory test, that one?

A. It was called a "confirmatory test" but actually it isn't. It's exactly the same test, using the same proteins, but performed using a different approach. So one was done with an ELISA, where you stick proteins on a plastic plate, and the other one is done in a gel, where you stick proteins in a gel and get them to move. You are testing exactly the same phenomenon but by two different methods. So it gave us a group of patients who were positive by both tests, which made us more

confident. It was called "confirmatory" but actually it really wasn't; it was just another way of doing the test by a second method.

Q. What difference did the introduction of that test make to your management of patients?

A. That second group of tests were based on using different proteins. They were based on the core protein of the Hepatitis C virus, so these two tests made it much easier to be confident that the diagnosis was right. We were still left with a large group of patients who had equivocal results by both tests.

Q. Yes.

A. Or sometimes positive on one and negative on the other.

Q. Yes. Who would have had access to these tests?

A. Well, I suspect everyone who needed access would have got it but by and large, tests were performed by people who had a specialist interest in Hepatitis C. So that would be hepatologists, transport physicians, those working in transfusion medicine, and gastroenterologists who had an interest in hepatology.

Q. Yes. What would you tell your patients about these tests? The early tests.

A. At the time we met the patient and they were found to be positive, we would explain that we weren't confident these tests were as accurate as we would like them to

be, and a lot of the patients that we saw in those early years, the 1990s, came back to the clinic, in retrospect, needlessly, because they turned out to be negative in reality. And I suspect we missed a few patients that were positive and were called "negative".

Q. So you had a lot of false positives?

A. Yes.

Q. When did you find that out?

A. Four or five years later.

Q. Oh, right, I see. Is that with the PCR testing?

A. The PCR made a big difference, yes. That made sense of the results we had had up to that point and allowed us to understand the natural history better. But the antibody tests were improving all the time. And when we were confident we had got sensible results, we were able to discharge some patients and manage the others better.

Q. I think you said that you had to interpret the early tests?

A. Yes.

Q. And how would you do that?

A. When a test doesn't make sense, you always go back to the laboratory and ask for further help. So you might go back to the virologist and say, "This patient has got a Hepatitis C test that's positive. I can't find a reason why they might be positive. How close to the

cut-off point was this test?" And if it's on the cut-off, you might think that it doesn't make sense and tell the patient accordingly.

Q. Yes. So the cut-off for these early tests, I mean, could you visualise it for us? Could you describe it?

A. When you are doing a laboratory test you have to define a normal range, and that's normally defined as a median plus a stand deviation, or a mean plus a standard deviation. So you give yourself limits wherein the test is positive and outwith the test is negative. And it might be that the particular test was right on the cusp, in which case the sensible thing to do is tell your patient, "Your test is right on the cusp," and don't make a comment about whether it's positive or negative. And we followed 200 of those for a long, long time.

Q. So when you were discussing the results of tests with patients, would you go into that amount of detail to explain the results?

A. Not in every circumstance. I mean, you are guided by the patients, how much the patient wants to know. But I think you can't tell a patient the test is positive or negative unless you think it is one or the other. And if it's in the equivocal area, I think you have to be clear about it, yes.

Q. So it would be positive, negative or equivocal?

A. Or "I don't know".
Q. Okay. At the bottom of that first page, when asked about the correct approach to using the first generation test, you say that was with circumspection and careful review.
A. Yes.
Q. Could you amplify that?
A. I think many of these clinic sessions with patients were couched in exactly those terms: "We have a test that has come back positive. I'm not sure it makes sense to me. Your liver tests are normal. I'm going to follow you in the clinic and see how things evolve," or, "The test is negative but I think you are at high risk of Hepatitis C. We are going to follow you carefully in the clinic for a few months and see how things resolve." And each time you saw the patient in clinic, you would know a bit more about the disease because we were learning very quickly, and the tests were improving fast too.
Q. What sort of patient would you be telling that, "We think you have got a high risk of Hepatitis C", even if you had a negative test?
A. Because we would have had, at that stage, for example, transplant patients -- 50 per cent of our transplant patients at that stage turned out to be

Hepatitis C-positive. We had a lot of haemophiliacs, who were well aware they were likely to have Hepatitis C. We had people who had acquired hepatitis post-transfusion, who were aware they were likely to have Hepatitis C. So there were a lot of people who were very likely to be positive, who weren't always positive on testing.

Q. Yes. Okay. Right. Well, could we go back to the schedule, page 4 of [PEN0181241]? We see that the next question which we asked you was about look-back:

"What was your involvement in the HCV look-back exercise?

"How useful do you think the look-back exercise was?

"What do you think was achieved?

"Would you have done anything differently in hindsight?

"A screening test for anti-HCV in blood donors was introduced in 1991, but the formal UK look-back programme did not begin until 1995. Could you explain why the look-back exercise did not commence earlier."

If we could go back to your statement, page 2 of [PEN0181360], under the heading "Hepatitis C virus look-back", I think over the next two pages you address these questions. Is that right?

A. Yes.

Q. Okay. Perhaps I could just ask you to tell us about look-back, please, doctor?

A. Look-back was something that was discussed by the transfusion services over a period of one, two, possibly even three years before it was actually introduced in 1995, and you might want to come back to the reasons that it was or wasn't introduced at a later date.

When it was set up, there was a project funded by the Government, run through the Colindale service, HPA now, to look to see how many people had acquired Hepatitis C from transfusion and what their natural history was. And a multi-disciplinary group was set up of which I was the chairman.

Since 1995, we met very frequently in the first few years and now once or twice a year to review the data, and it was set up as a resource for research purposes as well as to help the patients. And my role was to make sure that the service was efficient and run within appropriate hepatological guidelines.

Q. Yes. I see that you say:

"There are a number of important points to make when discussing the success or likely success of an HCV look-back exercise."

Could you just go through those with us, please?

A. Yes, one of the reasons that the transfusion services

were keen to do this was that they had done the similar exercise for HIV infection, and it had been quite successful. But I think the epidemiology and the nature of the disease is very different, and I think the "assume that one would work because the fist had worked" was not a correct assumption to make in retrospect. The numbers of HIV were very much smaller, a much clearer homogeneous group of patients who were affected. That was the first point.

The reason we didn't push on with it in 1991 was that we didn't know what to tell patients. You have already asked questions along these lines already. We didn't know what to tell patients the natural history was. So hauling back people in 1991 to tell them that they had got a disease that we didn't understand and didn't know the natural history, and for which there was no treatment, didn't seem entirely rational at that point. But that was easier to implement in 1995.

Q. I suppose there was more of a concern about the infectivity of HIV as well?

A. Yes, I mean, Hepatitis C is much harder to acquire than HIV by many different routes.

Q. Then on that page you also explain a little bit about the English experience and samples from blood donors only being stored for three years. How did that impact

on the process?

A. Well, the question really arises of what other approaches to look-back could you have had. So the approach that was adopted nationally was to identify infected blood donors. But to do that, we had to wait until they came back to the clinic, to the blood transfusion service, to represent for the next donation.

Simultaneously with that people were being discouraged from coming back to give blood if they had a history of drug addiction. So although we wanted to see Hepatitis C-positive blood donors, we were telling them not to come. So there was a contradiction in our approach, if you like. We didn't want them to be blood donors but we did want them to come become. And as time went on from 1985, because of HIV, right through, the number of people coming back who had injected drugs in the distant past was falling each year. So our approach was flawed from the very beginning.

So the alternative approach would have been to go back through the backlog of samples that were stored, and in England that would have been 6 million samples over the previous three years. And we processed at that stage, at that time, 2.5 million donors a year, so that would have been 3 years' worth of work needing doing immediately by a service that was already under

pressure. So the decision was made that that was inappropriate. So those samples were never screened.

The Scottish situation was different in that they had been storing samples for a long time and at that point weren't discarding them. So the potential to look back at more potentially infected donors was much greater but again, the logistics were frightening.

Q. You say that:

"Matching an HCV infected donor with the correct recipient was more difficult than one might imagine."

Why was that?

A. Well, because the transfusion service would have been asked for blood for a particular patient at a particular time on a particular ward at a particular hospital, and that's probably all they would have known at that point. So to track the recipient of that blood down, they would have had to have had the hospital records to ensure that they had been transfused. They would have had to know where that patient now lived. This might be 15, 20 or 30 years ago. That's actually quite difficult; not knowing who the GP is. Not knowing the current address of the patient. Not knowing even if the hospital records are available. And even now we continue to destroy hospital records not long after the patients have been in hospital. So it's difficult to do even

now.

Q. Yes. Earlier on, when Professor Cash was giving evidence, he suggested that one possibility or one possible approach might have been to have had a TV campaign, where you said, "If you had a transfusion between these years, then please come and be tested". What's your reaction to that suggestion?

A. That is one of the things that we discussed at the time, and in fact what happened, most of the people in my profession throughout the UK were invited on to local radio programmes, maybe two or three times over a period of a year or two, often local television programmes, and we would get up and say, "If you have had a transfusion come forward and be tested," and a small number of people did do that. More often with radio than with television. So it was done.

The alternative approach was to ask GPs to haul back everybody who had been transfused from their practice and to refer the patients on. But it transpired that GPs don't have a clear record of who has been transfused. They don't always know that a patient has been transfused. Nor, indeed, do patients. They might have had to have an anaesthetic, been transfused while they were asleep, and not known that they have had a transfusion during the operation.

Q. So that's not routinely reported by the hospital back to the GP?
A. No, not as a routine. It might be mentioned, it might not.
Q. That would probably be a good idea, would it not?
A. I think keeping a record of being transfused in retrospect, with hindsight, would have been an excellent idea, yes.
Q. Okay. If we could go over the page, please, the second paragraph, you say that:

"Perhaps the main issue in the early 1990s was that we weren't fully aware of the natural history of the disease."

A. Yes.
Q. Why was that the main issue?
A. Well, I think when you start out with what appears to be a new disease, you start off seeing the severe end of the spectrum. You see the people who are dying of it. You make a diagnosis. You think it has got a catastrophic outcome. And then you work backwards and eventually find people who have had the virus, in this case for 30/40 years who remain healthy.

And it transpires that they were very often the very people who were our blood donors, who have been coming for 20 or 30 years, who knew they had used drugs in the

past, knew they perhaps shouldn't have been there, but had not had a problem doing so and continued to come forward. And it was not until we were able to tell people that they were actually at risk of transmitting the virus that they stopped coming properly.

Many of those still came in the early 1990s, which is the base of the look-back. They knew they had used drugs in the past but it was a long way back and they had been donors for many years.

Q. At that point you didn't realise the implications of the very short history of injecting drug use?

A. No, I don't think anybody did. I think our experience was based on people who had got post-transfusion hepatitis, defined as abnormal liver tests. So the group of people with normal liver tests were excluded from our definition.

Q. Yes. Later on on that page you say that the points that you have just mentioned really determined how the look-back exercise was undertaken, and donors were tested prospectively. Could you explain what you mean by that?

A. The only donors that were tested were those that came back to donate blood once more after 1991.

Q. Right.

A. So if people had decided to no longer donate at that

point because they knew they might be at risk of infection, those people didn't come forward.

Q. You just told us that on the other hand, those are the sort of donors that you are trying to persuade not to come back.

A. The transfusion service didn't want them back.

Q. Yes.

A. The look-back did, yes.

Q. I see.

A. But they met in the transfusion centre unfortunately.

Q. Okay.

A. It might have been easier if the look-back exercise had been conducted outside the transfusion centre, but that wouldn't have been possible.

Q. Yes.

PROFESSOR JAMES: Can I just very briefly.

Graeme, I'm just not quite clear. Did the look-back actually not start looking back -- obviously it didn't start looking back until 1995, but actually you didn't look at the people who had been HCV-positive on screening and screened out the donors in the end of 1991, 1992, 1993, 1994, you just started with people who were coming through the door for the first time in 1995. Is that right?

A. No, no. From 1991, all people who were positive for

Hepatitis C were recorded, prospectively from 1991.

PROFESSOR JAMES: Were they included in the look-back though?

A. Yes, so the look-back refers to any blood donor who was Hepatitis C-positive from 1991, September onwards.

PROFESSOR JAMES: Although, actually, the first six months' lot, there were probably no stored samples because they were only stored for three years.

A. Exactly.

PROFESSOR JAMES: Thank you. I misunderstood.

A. But a record of that was kept, Professor James. So if they were recorded as positive, they could have been contacted, and there would have been addresses for those donors.

PROFESSOR JAMES: And retested --

A. They would have been invited back.

PROFESSOR JAMES: Fine, thank you. So everybody positive from the inception of testing in England.

A. In 1991.

PROFESSOR JAMES: In 1991, was actually invited back?

A. Yes.

PROFESSOR JAMES: Thank you; thank you. Sorry.

MR GARDINER: Thank you.

So that's the first thing that you would do, get in touch with the donor. But when look-back was introduced

in 1995, there would be the further step: you would go back and look at previous donations and see what had happened to them. Is that right?

A. So when a donor was found to be positive, they were invited back because they now become a patient. So they have to be dealt with as a patient not as an infected donor, and that happened in every case. But then the transfusion service had the task of finding every single recipient of every single unit of the blood that that donor had given, going back sometimes many, many years.

Q. But that wouldn't have started until 1995?

A. Exactly.

Q. I mean, is that what you would call "targeted look-back"?

A. Yes. Poorly targeted, but targeted.

Q. If we could go over the page, you explain at the top:

"Where a recipient was identified of a blood donor who was found to be HCV-positive, a letter was then sent to their general practitioner."

You talk about the discussion that there was. Can you just tell us a little bit about that?

A. Yes, I mean, the premise here is that people who have been transfused by and large are not healthy; might have had an operation for a cancer, for example, and it was felt inappropriate that the transfusion service or

a liver doctor would write to a recipient of blood, not knowing whether that patient was moribund or perhaps had even died. And we felt the only person who would provide the appropriate link for that sort of study would be the GP. And we left the responsibility of pursuing the issue with the GPs. They would know if the patient was appropriate for referral on to a liver doctor or not. And we were aware that some GPs might not feel the need to refer such patients on, so the letters were termed in such ways that would encourage transferral on to a local doctor, and we provided names wherever possible.

Q. Yes. A bit further down the page, you talk about what other countries have done. Have most countries followed the same procedure?

A. Yes, I think they have, and largely for the same sort of reasons: logistics.

Q. And you mentioned France there. What was the approach taken in France?

A. They approached it in a different way by actually trying to target everyone they possibly could. They had better records about who their infected donors were. So they were more successful, not very successful but more successful than we were.

Q. And that was because they had better records?

A. Yes.
Q. Okay. And I think in the next paragraph you are talking about campaigns to inform people who have been transfused. That's what we have just been discussing beforehand.
A. Yes.
Q. And similar programmes have been targeted at injecting drug users. So these are campaigns directed at different areas of the community?
A. Yes.
Q. And if we could go over the page, in the second paragraph, you talk about your involvement in the look-back exercise as chairman of the Hepatitis C virus steering group. Could you tell us a little bit about your experience of that?
A. We met on a regular basis. There was a pathologist present, some of the transfusion service people represented, paediatricians because paediatric liver disease with Hepatitis C was also well reported. So a multidisciplinary group. And we would meet on a regular basis, backing up the team who worked based in Colindale, whose job it was to track down the individual patients. And we communicated with, sometimes the GP, but more often the local hepatologist, to find out what had happened to those patients.

So we took a large amount of demographic details about the patients. We wanted to know what had happened to them. Whether they got liver disease, whether they had had a liver biopsy, what their results were, their blood tests, as much as we could get. And we went back every three years to ask for more and more information, and we continued to do that. So we have been able to define the natural history, and from an academic point of view this was valuable because we knew from these studies exactly which date they acquired the Hepatitis C. So academically it was useful and I think by doing the study, by doing research, you often reinforce good clinical practice.

Q. Yes. From a patient's point of view, has that been a positive programme?

A. I think it has. I think for the patients who were identified, we have done them a service, in that they were probably promptly referred on to a Hepatitis C specialist in the area who would have been up-to-date with their management and treatment and would have treated them at the earliest possibility. I think the look-back has been less successful because the number of people identified was small relative to the number of people who must have been infected.

Q. Yes. I see in the next paragraph you refer to Soldan

et al, who estimated that just 5 per cent of the total number of HCV infections had been identified. In your experience, does that sound reasonable?

A. Those are data based on the look-back exercise, and the data that was coming out of that married up with data on the likely frequency of Hepatitis C at that stage, and I think it's a very fair assessment.

Q. What's the reason for that? Why is it such a small percentage?

A. Because the donors stopped coming back, so if the whole programme is based on a donor coming back and being found to be positive and they don't come back, you are stuck.

Q. Right. Okay. You say:

"In retrospect, one could argue that it would have been more effective to screen all plasma samples that were available from donors ..."

How would that have been done?

A. With an enormous amount of funding.

Q. Right. Okay. In practical, operational terms, how could that have been organised?

A. Put it this way, my laboratory lab does 20 Hepatitis C tests twice or three times a week. You are asking the transfusion services to do 6 million tests in England and many more in Scotland, not more but going back for

many more years. That would have been an enormously difficult exercise, followed by then marrying up all the positive results with the recipients who would have been even further back. Remember, the further back you go, the harder it is to track the recipients.

Q. Yes. I suppose, how long that would have taken would have depended how much resource would have been put into it?

A. Absolutely, yes.

Q. Okay. At the bottom of the page you talk a little bit about the delay in screening testing being introduced in 1991.

A. Yes.

Q. And the introduction of the look-back. Could you talk a little bit about that delay?

A. Yes. That was a response to your very specific question. Screening as a medical concept makes an assumption that you can do something about the disease when you find it. And I think there were concerns that in 1991 we couldn't tell patients what was going to happen to them with any degree of confidence. We didn't have real confidence of the tests that were available to us and we had no treatment. So you can imagine how much distress that might have caused people, to be called back to be told they might have Hepatitis C but they

might not. We do not know what's going to happen to them, and "No, we can't treat you". I can't see that would have been successful.

By 1995 it's clear that we did have a feeling for the natural history. The testing was reliable and there were the beginnings of treatment. So I think the situation had changed. And one might argue that you could perhaps have started it a few months earlier, but I think April 1995 was not a bad time to start. And we didn't lose the 1991 to 1995 patients as Professor James has alluded to, they were still picked up.

Q. Yes. I suppose, because the disease is slow moving, there might not --

A. It's not in everybody.

Q. Yes, indeed. If we could go back to the schedule, the next question is:

"Communication of results and implications of diagnosis.

"What was your practice in relation to telling your patients the results of anti-HCV-positive tests in (a) the early days of anti-HCV testing, and (b) from 1995 onwards? Did your practice change over the period? If so, why did it change?

"What should clinicians have been telling their patients about the disease and the implications of

a positive diagnosis in (a) 1974; (b) 1985; (c) 1991 and (d) 1995?"

If we could go back to your statement, under the heading "Communication of results and implications of diagnosis", you start off by saying:

"In the early 1990s, patients found to be positive for HCV were warned that we didn't understand fully the implications of the test and as a consequence, patients underwent regular testing for HCV, and in our own centre all the patients were offered the opportunity of a liver biopsy."

What would you have said to a patient before you gave them a test? One of the first generation tests.

A. I wasn't in that position very often because by and large I work in the tertiary referral centre, so I'm in an easier position of having the test done before patients get to me. But any patient, for example, undergoing a major haemorrhage being admitted as an emergency, we would test on a regular basis. We would say, "We are going to test you for all causes of liver disease. That includes a test for Hepatitis B, which is standard," and we would say, "We have now got a test for Hepatitis C, which we have less confidence in, but it's a useful investigation".

Q. Would you have told a patient a little bit about

Hepatitis C and what you knew about the disease and so on?

A. Again, that depends on the circumstances and the nature of the patient but, yes, if possible, at all times, yes.

Q. Yes. You say:

"The introduction of testing for HCV RNA was a major step forward ..."

A. Yes.

Q. Could you explain why that was?

A. It divided our patients who were genuinely exposed to Hepatitis C into two groups: those who were carriers of the virus and remained at risk so long as they had the virus in their blood and liver, and the group who had cleared the virus and clearly had a better prognosis, not normal but a good prognosis.

Q. Yes. Okay. In the next section you go through the different periods, and I think in the first paragraph you are talking about the period between 1974 and 1985?

A. Yes.

Q. And I think you are explaining what should have been done in terms of communications with patients. Could you just tell us what you think should have been done during that 1974/1985 period?

A. Should have been done? I don't know. We were aware from 1974 onwards that there was a disease called

"post-transfusion hepatitis", and the investigations in the first decade after that discovery suggested the disease was benign. So I think it would have been reasonable to say to people, "You have acquired a virus infection from transfusion but by and large such patients do well."

And there are plenty of studies from that period which suggest that the mortality of patients who were transfused and acquired Hepatitis C was comparable to those who were transfused and did not.

Q. Yes.

A. And it wasn't really until 1985 when that very first study looking at haemophiliacs with Hepatitis C showed that this was not the benign disease we thought. We used to label them very often at that stage -- "we", my predecessors, used to call this disease "chronic persistent hepatitis" and that was associated in lots of circumstances with a benign prognosis, which we know now is not the case. But that's the nature of following people longitudinally and learning about the disease.

Q. So after 1985 what would a patient have been told about the disease?

A. They should have been told that they had a disease acquired from a transfusion which was likely to be a virus infection and carried a prognosis that was more

guarded than that previously, such that some patients, maybe as many as a fifth, would go on to get serious liver disease.

Q. Yes, okay. Then from 1991 was there a change in the message to the patients?

A. Yes, I think the situation changed in 1991 because we suddenly realised that injecting drug use was probably the major risk factor -- is the major risk factor -- but it was 1991 when we first recognised that, and we recognised in 1993/1994 that co-factors such as your weight, your diabetes, age, your alcohol consumption, were major co-factors in determining whether you got liver disease or not.

So we were learning between 1991 and 1994. But there is other information that became available. For example, in 1991 I would have warned a patient that sexual transmission was a risk. We now know that it is a risk but it's a very small risk. So we no longer, for example, test spouses of Hepatitis C-positive patients because there is no point. But we tested them all in 1991. We tested all the children at that stage and we now know that risk of transmission mother to child was 6 per cent. So we were behaving differently through ignorance.

Q. So vertical transmission?

A. Is about 6 per cent.
Q. Sexual transmission?
A. Hardly ever see it in heterosexual couples.
Q. So from 1991 what would you be telling patients about the disease.
A. In 1991 we would have told patients that we thought they had Hepatitis C but that the test wasn't reliable, that they faced a chance of liver disease, which we couldn't quantify, and we were going to follow them very carefully. If they wanted their partner to be tested, we would test them and if they wanted their children to be tested, we would test them. But we wouldn't know the implications of that test result, either for the partner or for the children, at that point.
Q. But by 1993 would you also be discussing the co-factors that you have mentioned?
A. Yes. I mean, our first study of co-factors, I think, was finished in 1994 and published about two years later. So we were aware of the age, gender and obesity issue in 1994.
Q. Yes.
A. And alcohol had always been known about, from the post-transfusion studies.
Q. Okay. If we just go over the page, you say:
"The advice that [you were] giving in 1991 -- and

I suspect many others in a similar position -- was very cautious."

Is that because you didn't have confidence in the tests that you were doing?

A. I think that was the most fundamental issue, yes; we were aware that the test was unreliable under many circumstances.

Q. Yes.

A. Yes.

Q. Okay. Just moving away from your statement, I would just like to ask you whether you have any more up-to-date information about this cohort of patients?

A. The steering group?

Q. Yes.

A. The transfusion -- yes, I mean, surprisingly, to me anyway, the mortality of the group of patients transfused and Hepatitis C-positive as a consequence is exactly the same, or pretty close, to matched people transfused at the same time for a similar sort of disease.

The difference between the two cohorts is that we have more liver disease, death from liver disease, in our Hepatitis C-related group. We have also shown very clearly that the age at which you acquire the Hepatitis C virus infection is perhaps the strongest

determinant of what happens to you. So the older you are, the worse you do, and we have shown that, with each decade that passes, your response to treatment falls, so that by the time you reach 60-ish, your treatment response is very low, based on current therapies.

So that's a study going right through from children in their first few years through to adults in their 70s and 80s.

Q. Okay.

PROFESSOR JAMES: Is there anything new since 2007, I think, what you last wrote this up?

A. The only new thing, Professor James, is the treatment responses -- falls with each decade. So I think we are beholden to see patients as soon as possible.

PROFESSOR JAMES: Thank you.

MR GARDINER: Do you have a reference for that study that you just mentioned there? Is there --

A. I can provide them for you afterwards.

PROFESSOR JAMES: That would be very helpful.

A. Harris H is the first author on most of our studies.

PROFESSOR JAMES: It's in the preliminary report.

A. Yes.

MR GARDINER: My final question, Dr Alexander, is about something that we noticed last time you were here and that was that patients identified by look-back seemed to

have a better experience of counselling and receiving appropriate information than a patient who has been discovered to be positive just in the normal course of things, not having been identified by look-back. Can you think of a way that that situation could be improved? Is there a programme that ...

A. I'm pleased to hear that is the case. I'm not sure there is evidence to support it but it's reassuring that is the case. I think the reason that might be true, if it is true, is that people were focused on this particular population and the patients were referred on to a group of physicians who were highly interested in the disease.

Q. Right. I mean, specifically what I'm referring to is, if we think of the example of two patients who have both acquired Hepatitis C through a transfusion and one patient is picked up by look-back and the other one is picked up by developing liver disease, the evidence that we have seen does seem to suggest that the patient who's picked up in Scotland by a look-back has had a better experience.

A. Yes, well, I think presenting with liver disease is going to make you fairly resentful in the first instance. I think it's not unusual to be hostile to the medical profession in that context. You have got

a disease, acquired because of medical issues, that has been missed for maybe, 10, 15, 20, 25 years, so I imagine that people don't cope with that well.

And remember, if you are presenting with liver disease, you are presenting with liver disease, whereas most look-back patients are not presenting with liver disease, they are presenting with a test that's found to be positive and they prove not to have liver disease, which makes it easier to cope with.

I think, if you diagnose anything late when you could have diagnosed it early, it's not going to be satisfactory.

Q. I suppose I'm wondering would there be a way to, you know, organise things so that the patient who doesn't present until he or she has got liver disease gets tested earlier?

A. You are looking for a better look-back? I think that opportunity has been missed.

Q. So we are back to publicity campaigns or something like that?

A. Yes: "If you have been transfused, come forward, get tested."

THE CHAIRMAN: You say you think the opportunity has been missed?

A. I do, Lord Penrose. I think -- you know, we are

21 years down the line now. I think the people who are going to get liver disease in that 21-year period have probably got it by now.

MR GARDINER: Thank you very much.

Thank you, sir.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: No, thank you, sir.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: No, thank you.

MR JOHNSTON: No questions, sir, thank you.

THE CHAIRMAN: Dr Alexander, thank you very much indeed.

A. Thank you.

MR GARDINER: Sir, we have no more witnesses today, Dr Gillon and Dr Keel tomorrow.

THE CHAIRMAN: Thank you very much.

(3.46 pm)

(The Inquiry adjourned until 9.30 am the following day)

I N D E X