Friday, 13 January 2012

(9.30 am)

PROFESSOR VIVIENNE NATHANSON (continued)

Questions by MR GARDINER

THE CHAIRMAN: Good morning. Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Good morning Professor Nathanson. I welcome you back to the Inquiry. Of course, you gave evidence previously, mainly in the context of HIV infection. That's correct, isn't it?

A. It is, yes.

Q. You have provided a supplementary statement for the Inquiry in connection with Hepatitis C and if we could just have that on the screen, [PEN0180419]. I think you have a paper copy in front of you.

A. That's right.

Q. Thank you. You start your supplementary statement by talking about significant developments over the period in question, and perhaps I could just ask you to talk about that a little bit.

A. I think the important issue here is that when you look at ethics, not only has ethics changed during the period in question, or at least the practice of ethics, what we would regard as best practice and what we would expect as the minimum standard but that that has also had to

reflect the change in scientific understanding during that period, and the two things have to come together.

But to say that the development in ethics and best practice has been one of increasing concentration on patients as partners with their doctors, increasing openness and sharing of information, and a more positive way of sharing that information, rather than thinking that only patients who really sought information should be given information, and alongside that, of course, that there is the complicating factor of this increase in scientific knowledge about the medical conditions in question. And that, of course, again changes the dialogue because it's about communicating that change in knowledge as it happens.

Q. Yes. In the first bit of your supplementary statement in one of the paragraphs towards the bottom of the first half of the page, you say:

"Changes have occurred following clear expositions of good ethics and supported by case law, education and in particular training and communication skills to enable doctors to communicate with patients and their relatives in a sensitive and nuanced manner. The developments of key elements of ethical practice and of ethics teaching is outlined in more detail in the introduction to [your] first statement."

I wanted to ask you a bit more about best practice, which you mentioned there again. What would you understand about best practice?

A. Best practice would be the ideal, the thing that you would expect doctors to aspire to reach, some, at least, of the time and increasing most of the time. It's quite clear from looking at the General Medical Council's guidance on ethics that what they have regarded as best practice has not changed enormously over the last, certainly ten years, but their expectation that people will work to that level has certainly changed. The draft that is out for consultation at the moment, which will be the 2012 edition of Good Medical Practice uses an awful lot of "musts":

"Doctors must do the following ..."

And in the past it would have been "should" and before that "would", "might, "may", those kind of words. In other words they are hardening up and making it clear that they expect, almost all of the time, best practice to be reached by doctors, and that again demonstrates that this trend has not just been in showing a trend away from paternalism to a patient-centred approach, but also that they expect more doctors to reach that best practice mark.

Q. Yes. I suppose there must be a level of performance,

which is below best practice but which is still acceptable?

A. Indeed, and it also depends upon the environment. Whenever the General Medical Council, for example, looks at a case brought before it, it will look at the circumstances in which something happened, and it can be that those circumstances make it very difficult to reach best practice. They would also want to look at what the doctor's usual practice was and be looking for evidence of an aspiration and an attempt to reach that best practice wherever possible.

It has to be, again, a nuanced approach, in the sense that they would recognise that the way each doctor treats each patient will be slightly different and should be slightly different, because it should be centred upon what is right for that patient at that time.

I think I have said before -- but I hope you will allow me to reiterate -- that the most important thing is about offering information to patients, not pushing information at them. It's about helping patients to come to terms with information, giving them the opportunity to think and to question, and being open to a repeated set of questions, rather than delivering a measured amount of information each time, which is

identical for each patient, because that isn't right for the patient. It has to be what's right for that patient at that time and judging -- that's the skill of doctors, to judge has that patient understood, are they comfortable and trying to test, which is where the communication skills also come in -- test that they have understood sufficient to be able to make a decision based upon the information that you are offering.

Q. Yes. Thank you. If we could just look a bit further down that page, we see the first question that the Inquiry asked you to consider, which is:

"What is the current approach to testing for HCV? In particular what information should a clinician provide to his/her patients about the disease and the implications of a positive diagnosis? What is the current GMC/BMA guidance on this point?"

In that answer you refer to the GMC's booklet, which I think we could just get up on the screen at the moment, which is [PEN0180430]. I think that's the booklet you are referring to, is it not?

A. Yes, it is.

Q. Then if we just go to the page that you cite, which is page 9 of [PEN0180430].

THE CHAIRMAN: Could we have the date of it, please, Mr Gardiner?

MR GARDINER: Yes, if we go to 0432, so we see that the guidance came into effect on 2 June 2008.

Could you tell us about this document first of all, just generally?

A. Yes, the General Medical Council has been producing versions of Good Medical Practice, which is its general ethical guidance, for some time now but what became clear was that in certain areas it was important to give more detail and consent is one -- there are two areas in fact.

Consent and confidentiality are the two areas in which most queries from doctors arise and most queries from patients. So the GMC put together a more detailed document on consent to help doctors in making decisions about whether or not a patient could give consent, whether it was appropriate for somebody else to consent for that patient and about how to go about the process of giving patients information so that those decisions could be made.

Perhaps the most important part of this is actually the title because it isn't getting consent from patients, this is about patients and doctors making decisions together. And that's a very deliberate decision by the General Medical Council, to stress that consent is not about a doctor deciding to do something

and the patient then agreeing the doctor could do it, it's about that process of decision-making together, and that is very much a change of emphasis from, say, the 60s or 70s, when it would be more about a patient agreeing to what the doctor had suggested.

Q. Yes. Could we go to 0438, please? Could we expand paragraph 5 a little bit?

It's paragraph 5(b), I think, that you particularly refer to. Could you explain why you think this is relevant to this question of HCV testing?

A. The important point about this paragraph is that it is looking at all medical treatments or options for treatment and it is explaining quite clearly that the role of the doctor is to use his or her knowledge, skills, experience and so on, and to understand what the patient wants, to have some understanding of that as well, and using that to identify investigations or treatments likely to result in overall benefit and to set out the options.

Perhaps that's the most important issue here. It's about setting out the options and explaining those options to the patient, and it doesn't limit it to particular types of medical condition or particular types of test or treatment; it is about everything.

That's really important because I think that

sometimes people can get confused and think that there are different standards of consent to different types of treatment and there aren't; the standard is essentially the same.

Q. Yes.

THE CHAIRMAN: Professor Nathanson, I can imagine a rather crusty and perhaps senior medical practitioner somewhere in the provinces dismissing this as the counsel of perfection by a body that's not really in touch with the realities of clinical practice in a busy surgery or whatever, where there are queues of people urgently needing attention. Is there a danger that this might be characterised properly in that way?

A. There is certainly a danger that people might characterise it that way. I don't believe it's proper and I think it's a misunderstanding when people characterise it that way. There is nothing in this that says that you must set out every single detail of every single option; it's about offering information. The key skill here is in understanding the patient's views, understanding the patient and talking to the patient and exploring with them, so that quite quickly some options might be discounted and therefore don't need to be explained any further because the patient says, for example, depending upon what the condition is, "There

are certain types of treatment I wouldn't want." Fine, unless you believe those are to be the only treatment. And it is about prioritising. So you prioritise as a doctor, using your skills and understanding, what you believe to be the most important pieces of information.

Patients then signal, either by saying, "That's enough, I can make my decision on that," or by asking questions, or in many more subtle ways, whether they want more information or not. And sometimes, for some patients in some conditions, or some tests, it can take a long time but very often it takes a very short time. And that's part of the skill of the practitioner.

It's also part of the benefit we have from general practitioner relationships, because most of us know our GP and our GP knows us, and we are able to shorten a lot of this because a lot of our decision-making will be very much the same for many different conditions. And that's helped.

Yes, it's a counsel of perfection but in practice, practising doctors on my committee, for example, ten people who are in everyday clinical practice, say, "This doesn't cause a problem".

THE CHAIRMAN: Thank you.

MR GARDINER: Could we go back to your statement at 0420, please? At the paragraph at the top of the page you

talk about how:

"Doctors are expected to offer the patient all elements of information identified in this guidance."

That's what we have just been discussing. And in the middle of the page you talk about:

"What matters is the offering being made ..."

And again, we have talked about that. In the next paragraph you say:

"Many doctors today back up their information sharing with leaflets or web links."

Could you talk a little bit more about that, please?

A. Yes, we are very much aware that the amount of information that anyone can take in in a one-to-one meeting, and then remember accurately, can be very limited, and in a medical context, that can be affected by people being upset, frightened, worried and so on. So increasingly, doctors will offer short leaflets, web links, links or suggestions of web sites that patients might choose to search, which might be NHS sites but might equally be disease-specific sites, which are often very good, which have information which will allow the patient -- to help the patient to start to look and find out more for themselves.

We know, for example, that people with chronic medical conditions become enormously expert about their

medical condition. One of the problems with people when they first get a new medical condition, particularly a chronic one, is they might have been directed to sites that are unreliable, inaccurate -- I'm trying to be polite about some sites which are really, frankly, quite dangerous because of some of the information on it. The intention is not to stop people looking at sites but help direct them to sites which are likely to have good and reputable information.

And that also helps the patients to ask questions. Many doctors have faced the issue -- which does take up a lot of time -- of the patient arriving with sheets printed out from the Internet or questions, and if you do not know the site and you don't know whether the questions come from a legitimate source, it's quite difficult to start approaching that. So it's an attempt to direct people to what you might call a kite marked type site and information.

For example, I had a slipped disc a few years ago and my rheumatologist immediately pointed me to the Arthritis Council sites on dealing with a bad back. He said, "I'll treat you as any other patient".

And that's as it should be. This was information to help me look after my own back.

Q. Yes. In the next paragraph on that page you talk about

"seeking agreement to tests". Could you tell us what's the contemporary approach to that?

A. Yes. It will depend upon the circumstances, so an individual going to see their GP and saying, for example, they have not been feeling well and the GP looks at them and says, "Well, I think you might be anaemic," may say, "I'm going to have a look and see if you are anaemic." And then they might discuss the kinds of tests that the GP might want to do. Depending upon what else the GP has found out in the question, the history, they may be suggesting that they will do other tests, and some patients will want to know what all of those tests are, and some will just say, "No, don't tell me about the tests now, just tell me when you get the results what the tests mean." So again, it's about offering the information about what you are testing for.

How much you offer, how much information really depends upon what you think is likely to come out of that test, and the reason I used anaemia is there are so many different causes of anaemia. Many of them may be fairly minor, there may be some iron deficiency and B12 deficiency, or something of that sort, but it could equally be leukaemia. The question is: do you have to say to the patient up front, "One of the tests we are looking for in your blood count, it may show that you

have leukaemia," I don't think that that's necessary.

You have to say, "I think you are anaemic and there are many different reasons, some of them more worrying than others". If the patient then says to you, "Could it be a cancer?" then of course, you cannot deny that if that's in your mind, but you have to say, "Well, it could be but the more likely reason is ..." if you think there is a more likely explanation.

So again, it's about giving information that's balanced and is sensitive to that patient's needs. A lot of patients actually don't want to know what the tests are. And that's also legitimate; you do not have to force them to know the details of the tests that they are going through.

There are rare exceptions and those exceptions are tests such as tests for HIV, where you would very specifically talk about the tests because you have to give a very informed positive choice to that, even today, even with the much better treatment and so on, because of the social, economic and so on consequences of that test, as much as the medical consequences.

Q. Yes. So the amount of information that the clinician might give to a patient, clinician to patient, would depend on the suspicions that the clinician has or the doctor has, about the diagnosis. Is that right?

A. It would depend upon the amount of information, the suspicion of the diagnosis, and also about what the test might show and the implications of that test result. If you think the likelihood is, as it were, of a negative test and it's a test for exclusion, then you may not go as much into the likelihood of what that means if the test is positive. But if you think the likelihood is the test is positive, you will probably go more into, or be more open about and more offering, of the implications of a positive test.

Q. Yes. So there is a difference between a general test to see what's wrong and a specific test, which is testing for a particular condition. Is that right?

A. It's partly right. Because the problem is that most tests are -- even general tests have a degree of specificity from time to time. So a very general test, such as a blood count, can actually become a very specific test because of what it can show. So one has to just hedge a little bit on that.

But, yes, I mean, if you are looking for a very specific diagnosis and you are fairly certain that that is a diagnosis you are going to find, then you should be giving some information about that, but generally the amount of information is relatively small because the amount of information that needs to be gone into once

you have a diagnosis will be more detailed but it then is refined by many other test results.

So a single test on its own doesn't necessarily give you all the information that you need to start discussing treatment options or prognosis and so on with the patient, and that's why the amount of information can often be relatively short. So it isn't as scary to give some pre-test information because, relatively speaking, the amount of information that needs to be offered is quite small.

Q. Yes. In the next paragraph you mention the non-medical consequences of a positive result and I think here we are talking about Hepatitis C. Could you explain that a little bit more?

A. Different medical conditions have both medical and non-medical consequences. HIV is the easiest in the sense that one can look at the non-medical consequences, the financial, social stigma and so on. HCV is interesting because there are some social consequences. Some people see it as socially stigmatising. I have never quite understood why, given the nature of the way in which it's transmitted. It shouldn't have a stigma associated with it, and there are of course many conditions which have employment consequences. HCV may, in some circumstances, be one of those, although

relatively rarely, but there would be other medical conditions as well.

So, for example, if you were testing for, say, epilepsy, there are employment consequences for some people and financial consequences in the same way, both because of the employment consequences and for many chronic medical conditions, there are implications particularly for life insurance and therefore for things like mortgage products and so on.

Q. Yes. So it's necessary for the doctor to look at the present social consequences of a positive diagnosis and obviously that changes throughout time?

A. Yes, I mean, one of the most important things is understanding what those consequences are in advising patients about testing but it's also important to recognise that specific testing doesn't necessarily increase financial consequences; they can flow directly from the medical condition, even if it were not diagnosed; in other words, that the symptoms and signs that the patient has might deliver financial consequences such as an inability to work, so the diagnosis may not in fact worsen that and can in fact in some cases even alleviate it.

Q. If I could ask you to be specific about Hepatitis C --

THE CHAIRMAN: Before you go on, could I ask another

question? This relevance to employment and financial and other consequences, does that vary according to the age of the patient? Because I'm conscious that at my somewhat advanced age, life assurance is not something I'm likely to be going looking for now with any prospect of success. So does one have to modulate this according to the patient's age, general circumstances, and if so, how does one go about getting the relevant information to ensure the relevance of the advice?

A. I think that generally you have to modify every piece of information you give according to that patient and their need and again, this is the complicating factor in medicine; it's that you do not have specific information that has to go to every patient in a measured aliquot. If it was, we would just have information leaflets that you just handed to the patient and then said, "Have you any questions on that?" It has to be modified for every individual patient and their circumstances.

It is extraordinarily complicated and there will be patients for whom you are not sure what the consequences might be in some of these areas and where all you can say is, "There could be some issues here."

But that's why doctors doing specific tests, which are likely to lead to, particularly financial, consequences tend to try to find out, roughly speaking,

how these are thought of. And they hear, if they didn't know.

To give you another example, if we go back to HIV, in the early days when people were making that diagnosis, we didn't know how the insurance industry was going to treat it, and what became clear with a relatively short passage of time, to the relatively small number of doctors treating patients and therefore testing, was that even as it became a less immediately lethal diagnosis, the insurance companies were being very hard and were making people effectively uninsurable. And that group of doctors learned that very quickly. So that before they started testing the next group of patients, they had this information and that's really the way in which this sort of information spreads. And GPs who do a lot of testing are very, very knowledgeable on the kinds of tests that insurance companies -- and that's the biggest financial consequence for many people -- treat badly or dislike seeing a positive in, and therefore they are very aware of the ones in which the patients may cause a problem.

But they would also be able to say to the patient. "The reason we need to do this is ..." the following, "That it has a benefit to you, that if we make this diagnosis, it takes us down a particular treatment line,

which is beneficial to you and which we can't do if we don't have that positive test result."

MR GARDINER: Just to follow up that comment, we know that a lot of testing for Hepatitis C was done around about 1992, so would it be fair to say that at that point the testers, the doctors, wouldn't actually know the implications, the non-medical implications of the diagnosis?

A. Absolutely. They wouldn't know the non-medical ones and in fact, to a certain extent, they wouldn't know the medical ones because this is a condition that we have learned about by tracking patients over time, and in fact all that they were really doing at that time, it seems to me, was looking at this very large group of patients who had non-A non-B Hepatitis and trying to identify whether all or just some, and if some, how many of them, actually had this one new one that we could now specifically test for.

Of great advantage to the patient is the long-term advantage that one hopes for, that if you can identify that they fit into a particular subgroup, which became HCV, then you can track that group of patients, learn more about the natural history of the disease and whether it responds to a particular treatment. If you are treating everyone with non-A non-B and some don't

have Hepatitis C, they may react in a completely different way, which would then give you the wrong picture of the response of people with HCV, unless, by chance, all the other non-A non-Bs also responded in exactly the same way, but that would be unlikely.

Q. Just to finish off this first question in your supplementary report, and just to try to be specific to Hepatitis C today, would you be able to tell us what you think best practice is today for testing for Hepatitis C?

A. It comes back to the consent paragraph that I quoted from the General Medical Council's book. It's about giving the patient enough information to make a decision about having that test. That means a short discussion. It is not the most serious chronic illness. It is a serious chronic illness but it is not the most serious. It is not the worst diagnosis you could be faced with. You do need to give patients some information about it, not least to make sure that they are aware that this is something that, if it's positive, you are going to want to follow them up with, and that you would want, therefore, this to be potentially the beginning of quite long period of follow-up, including potentially some quite complex treatment.

Q. Yes. In the mid to late 80s, when there wasn't triple

therapy for HIV, HIV counselling could be really quite extended and the patient would be often given the opportunity to think very clearly about whether they wanted to go ahead with the test. A session could take, you know, quite a long time. Is it that kind of procedure that you are envisaging for a Hepatitis C test today?

A. No, I wouldn't expect it to be. I think the difference is that there are far fewer social and financial sequelae. There is a treatment, which is successful in very many of the patients. The test actually has a reason beyond just understanding the diagnosis for the patient. It actually both helps them to modify their lifestyle, which can be beneficial, but it also means that they can get early on into treatment, which we know we are increasingly able to tailor to being successful.

So in that sense it becomes an easier test to give information about. Or to go back to the HIV test, which itself now takes rather less time to counsel for, that is at least in part because we now have a treatment, which means that the benefits of the test are so much more obvious to the individual patient because there is a treatment that you can get into at an earlier stage, which makes a great deal of difference to the eventual outcome.

In the early 1980s, the test had very limited value to you as an individual until really we got to triple therapy, and now on to HAART, which makes a significant difference. Really then it was more about protecting others and perhaps being part of a cohort that allowed us to look at the natural history of the disease rather than actually benefiting yourself from the test result. With HCV testing, there is a real benefit to knowing the status and to being offered treatment.

Q. So does that mean that today, pre-test counselling for Hepatitis C is not particularly protracted, best practice is --

A. Indeed, I would expect it to be relatively brief. In most patients. There will be some who need a little bit longer simply because they find it more difficult. But for most patients very brief.

Q. And what would you expect to be discussed during that brief session?

A. An understanding that this is a kind of hepatitis that has quite a long natural history and that there is a treatment. It's not the most pleasant treatment but there is a good successful treatment out there and we would want to do, if the test is positive, some further tests and then almost certainly offer treatment.

Q. So there wouldn't be much discussion of non-medical

implications then?

A. Probably not, unless the testing doctor were aware that in that patient there could be specific non-medical implications.

Q. Yes. What would they be? Could you think of some examples?

A. I suppose if your patient is another healthcare worker, you might be thinking about transmission of the virus, slightly complicated because the rules are about to change on the transmission of all viruses and the limits that doctors and other healthcare workers can apply, but I suppose you might be considering that in particular.

Q. Sexual transmission, would you expect that to be discussed before the test?

A. It depends upon the level of evidence that there is. I think this is a virus that isn't readily sexually transmitted. It certainly could be something that would be mentioned and to say that there is very limited evidence that it could be transmitted, in which case it would give you the ability to protect your partner and that's another benefit of testing.

Q. Yes. Thank you. If we could move to the second question, which is [PEN0180419]. This is the same question applied to the earlier period:

"What was the correct approach to testing for HCV

between 1991 and 2000?"

In your answer you refer to a BMA publication "Philosophy and practice of medical ethics". Could you remind us what this publication is, please?

A. This was the then BMA guidance on medical ethics. There had been a variety of iterations of different reports. That was the particular title that we used at that time. It was the first edition of that, published in 1988, and just gave general advice on medical ethics to doctors.

Q. Yes. And I think if we can just have a look at that, I think that's [PEN0180424]. It's the first paragraph there that you have quoted.

A. Yes.

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

Could we just go back to your supplementary report? I think I'll just let you answer in your own way, Professor Nathanson. The question about the correct approach.

A. It was quite clear from the quote from the BMA's report from 1988 and the General Medical Council advice of the same year that the best practice standard was that doctors treat patients only on the basis that the

patients consent, that patients make the decision, that the doctor offers advice, guidance, may even help to lead an individual between different treatments to a particular one, but that it is the patient who decides.

That pre-dated the beginning of the period in question, 1991. So it was quite clear to me from published information that we would expect that patients would be given information to make decisions for themselves, certainly about treatment. The question that always comes then is whether testing is counted as treatment, and the best practice advice, again from the 1980s, is very much that it does, that testing is the beginning of medical treatment. It is the precursor to actually offering a treatment, whether that treatment is surgery or drugs or whatever else it is, that you have to first establish a diagnosis and that testing is part of that process. So you would expect the patient to consent to that test.

Q. Yes. In the next section you refer to the specific HIV infection and AIDS GMC advice that we looked at when you were last here.

A. Yes.

Q. Why is this relevant to the question of HCV testing?

A. I thought this was a particularly interesting paragraph

because this advice from the GMC was looking at HIV infection and AIDS but in paragraph 12, which is the quoted paragraph, it was making it clear that that was the basis of treatment for all illnesses; it wasn't only referring to that. And the particular words make it clear that it has long been accepted and well understood that you should treat a patient only on the basis of informed consent.

I think it's important because sometimes people regard HIV as completely different, in that it and it alone required consent and that everything else didn't require any form of consent, and in practice that's not the case. And what the GMC were saying was that everything requires consent but HIV requires a very specific form of consent to testing because of the non-medical implications.

Q. Yes. Thank you. The next GMC advice that you refer to is the "serious communicable diseases" advice, which is dated October 1997, and that's at [PEN0180494]. We see that that's dated October 1997 on the first page. If we could go to paragraph 4 in that document, please, it's the second half of this paragraph that you refer to:

"Some conditions, such as HIV, have serious social and financial, as well as medical, implications. In such cases you must make sure that the patient is given

appropriate information about the implications of the test and appropriate time to consider and discuss them."

What do you take from that paragraph?

A. This was the first time that I could find the GMC specifically stating not only medical implications need to be considered and discussed with the patient, but other information, and I thought that that was particularly important.

There are many other conditions where you might find some social, financial and other implications and I think that, while many people had understood in best practice that it was implied that those should be discussed as appropriate, this was the first time that the GMC were stating it.

The only argument would be whether they were stating that that was only the case for serious communicable diseases. I don't believe that the wording of the paragraph means that. I think what it says is the particular serious communicable disease it was looking at, it was explicit that there were those consequences but that in other conditions, where there were equivalent consequences, they should also be discussed. There would be many conditions in which there would be no such consequences, and obviously in those circumstances there is no need to even mention the

financial implications because they don't exist.

Q. Oh, okay.

THE CHAIRMAN: Can I ask you about epilepsy, for example? For anyone who drives, a positive outcome of a test for epilepsy has an immediate serious consequence that DVLA will require the surrender of the licence.

A. Indeed.

THE CHAIRMAN: Would that come within this?

A. Absolutely.

THE CHAIRMAN: But it is not a serious communicable disease.

A. It is not a communicable disease and I think that's the important thing, that it's just stressing that the consequences of a diagnosis are not solely medical, that medicine is a holistic calling and that you look at the patient, you look at them within their family, their community, their workplace and so on. And this is particularly true for general practice but not only that. And anyone making a diagnosis of epilepsy knows that they will be discussing with the patient, in the first instance, driving.

They may also be discussing their employment because if it's somebody to whom driving is not necessarily a part of their employment but where operating dangerous machinery is, then it may be that they cannot carry out that work. They will also be giving the good news that

once you have been in treatment and fit-free for a period of time, you can get your driving licence back.

THE CHAIRMAN: Not very good if the period is a year or two.

A. Indeed, but it isn't a life sentence of not driving necessarily. And what that does, of course, is encourages people to take their tablets regularly, which is good for their treatment as well. But it's not only in epilepsy that you might be having that discussion with a patient, there may well be patients on other medical treatments or with other medical conditions where you might have to say the same thing, and we have had recently discussions with ACPO over the surrender of firearms licences usually for people who are suicidal, because that's the usual danger of people possessing firearms -- self-harm.

But again, there are issues that from time to time one has to broach, completely non-medical issues, with the patient. And in all these circumstances the doctor wouldn't write immediately to the DVLA and say, "John Smith has just been diagnosed with epilepsy," the doctor would be saying to the patient John Smith, "You should be telling the DVLA", and encouraging the patient to do that.

If the patient refuses and carries on driving, you may then breach confidentiality, but nevertheless part

of this is encouraging the patient to think it through and to think about what they will do to re-order their life to cope with this diagnosis.

THE CHAIRMAN: Perhaps it's just the sort of residual contact I have with legal practice that I would find it slightly unusual to derive guidance of such generality from a paragraph that's focused specifically on serious communicable disease.

A. I think I would look at it the other way round. I think that this is a paragraph on serious communicable disease that is reflecting what is good practice generally.

PROFESSOR JAMES: Could I ask one question, please?

THE CHAIRMAN: Yes.

PROFESSOR JAMES: I would like to just briefly go back to this paragraph in the GMC advice:

"It has long been accepted and is well understood within the profession that a doctor should treat a patient only on the basis of the patient's informed consent."

I think it had, in 1988, been long well understood, and indeed the practice, that doctors treated patients with their informed consent. Indeed, you know, there had been consent forms for many, many years before that. But as a matter of fact, I wonder if you could comment on the idea that actually this is about treatment and

not about testing. I don't see "test" in there or "investigate"; I see "treat", and as a matter of fact, the way it is framed in respect of "long been accepted" et cetera, implies to me that you really are talking about the practice of getting consent for treatment and it doesn't have a lot to do with testing.

A. Thank you. That's a highly complicated issue. In the mid 1980s the BMA took counsel's opinion on exactly this issue, on whether consent for treatment included consent for testing, and it was over specifically HIV testing, and that counsel's opinion was absolutely as we expected it to be, that treatment included testing, that it was a necessary implied part of treatment.

We had expected that to be the case because you don't do testing if you are not thinking of doing something with that test result and you can't carry out treatment without having done testing, and they are so integrated that treatment is held, and I think in most of medical practice would be held, to include that process of seeing the patient, examining them, taking a history and so on, doing various tests and carrying out treatment and monitoring that treatment and modifying it, and that that is all-encompassed under that word "treatment". And that is how we saw it.

We didn't see it as requiring the written consent,

which is still used predominantly for surgical treatment. We saw that as one example and not actually necessarily the best example; it's probably the one in which often was the least well informed, as it happens, but simply because it was more of a box that was ticked rather than a process of talking to the patient and explaining what you were going to do and making a plan, and that plan being about testing right through treatment and monitoring.

PROFESSOR JAMES: I can't think of a room in Scotland where the words "counsel's opinion" would carry greater weight than this one. So I'm sure you are right, Professor Nathanson.

THE CHAIRMAN: Except for one thing: who drafted the instructions to counsel and did those instructions include the connection through from testing to treatment that you have set out in your answer? Because counsel's opinion is very much conditioned by the instructions counsel receives.

A. We had several counsels' opinions and they all came to the same conclusion, and the questions were drafted by people -- in one case they were deliberately drafted by somebody who avowedly didn't want to make that connection and yet got the answer that they didn't want.

THE CHAIRMAN: That's more persuasive.

A. Which is helpful.

PROFESSOR JAMES: Thank you.

MR GARDINER: Could we have a look back at your supplementary statement at page 0422? Could we have a look at the top of the page? You have just been talking about the 1997 guidance, and in the paragraph at the top of the page you say:

"It is clear and explicit that in 1997 the GMC required doctors seeking consent to have regard to the implications of the test result. This is more explicit than the earlier advice on testing for HIV, but is in accord with it. While the advice relates to HIV, it is important to note that it identifies 'some conditions such as HIV' and is not, therefore, limited only to testing for HIV."

In the next paragraph you mention that there has been nine years from the production of the advice on testing, and you conclude:

"The GMC were almost certainly reflecting best practice and a recognition that not all practitioners were at yet practising at this level."

Just to be absolutely clear, Professor Nathanson, are you suggesting that in this period, 1991 to 2000, the best practice was for pre-test counselling for HCV to be the same as HIV-style counselling?

A. I'm suggesting that it should be the same only in that it should be related to the information that is appropriate to that condition, and that absolutely doesn't mean that it needs to be an hour long and so on, because the nature of the conditions are so different. But all it means is that a doctor doing a test for anything needs to think about the implications of that test and to counsel appropriately.

For a condition with a more optimistic outcome, less social stigma, less impact on finance and work patterns and so on, then clearly that removes an enormous burden from the counselling. It means that the counselling can be relatively short. But it needs to be appropriate to whatever is known about that condition and the effects that it will have, having a test result.

Q. Yes. So from 1997, what process would you have expected a clinician to have gone through before giving one of his patients an HCV test?

A. It would depend, at least in part, upon who the clinician was. If this is a clinician who is a liver specialist and who has been referred -- if the patient has been told, "You have got a seriously abnormal liver function tests, we are sending you to see a specialist," then that specialist will obviously not be starting off by saying, "We need to have a look at your liver

function," but starting off by saying, "As you know, you have got liver function abnormalities, we are trying to find out what it is and there are going to be a battery of tests we are going to do and then we will be able to tell you what that means in terms of treatment options".

Somebody who is seeing somebody who is generally otherwise well but might be at risk, you would expect them to say, "We need to have a look at your liver function because people with your condition are at increased risk," for example, "because of some treatment that they have had, and therefore we want to look for a particular virus", and then whatever else is currently available.

During that period the information that was becoming available about non-A non-B/Hepatitis C, was changing, as we were tracking the patients, and we were better able to identify them, and that would be reflected. That didn't mean you went back to first principles every time you did a repeat test; it just meant that the patients already knew that they had non-A non-B Hepatitis. It might simply have been, "We now have a test for a particular type of non-A non-B and we are going to carry out that test for you. We don't know any more about what it means than what we have been telling you about non-A non-B but at least it will mean we will

be able to specifically type it, and that might help us in the future with treatment."

Q. You said in your answer there it would depend on what was available, and I presume you are meaning what information was available to the clinician about the condition?

A. Indeed, what information is available to the clinician about the condition, which includes of course what future treatment options are beginning to emerge, the success of that, but information about the natural history of the disease is the thing that you are usually thinking about when you are telling patients about a test in the early stages, before you have a good treatment for it. Why is the test important? What do we know about this condition? Will it help us to know whether you have it or not?

Q. Yes. Okay. What I would like to do now is to let you have a look at Dr Hay's report and ask you to comment on that. So could we go to [PEN0181186]? Do you have a paper copy of that?

A. Yes.

Q. So this is Dr Hay's first report to the Inquiry. He gave evidence yesterday. At page 27, which is paragraph 63 of his report, he describes his practice for HCV testing and you have had an opportunity to read

this before. That's correct, isn't it?

A. Yes.

Q. So we see that in paragraph 63 he says:

"It was my practice ... to inform patients that I was testing them for Hepatitis C and to go over (again) an outline of Hepatitis C. Consent and counselling was, and is, not the norm prior to Hepatitis C testing and hepatologists would, and do, routinely test for Hepatitis C as part of an investigation for abnormal liver function test without discussing the test specifically with the patient."

Then in the next paragraph -- I'm not going to read it all the way through -- he says in the middle:

"The idea that a Hepatitis C test should engender prolonged pre-test counselling derives from the practice adopted after 1985 by most centres of counselling prior to HIV testing. The implications of a positive HIV test could be perceived as a death sentence, led to loss of insurance, marriage breakdown, even in some cases suicide. There is no comparison between this and Hepatitis C testing. For that reason there has never been a specific consent process attached to Hepatitis C testing, even though it would be normal practice to inform the patient that they were being tested and to inform them of the result."

Dr Hay's position is that his practice was, as you can see here, to advise his patients that he wanted to test them for hepatitis, give them an exposition of the disease, effectively secure their agreement to the test. Would you take issue with that approach?

A. That is, as far as I'm concerned, pre-test counselling.

Q. Would that accord with best practice for that period?

A. Absolutely, yes.

If I can just say, I think one of the problems is, because counselling was used in HIV for a much more complex situation, people assumed that that complex level of information was necessary for every test and it never was; it was never considered to be so. It was that counselling has to be appropriate to the test; the counselling that he was giving for Hepatitis C was entirely appropriate. It would not have been appropriate -- well, it could have been appropriate even for HIV, provided, when he was going over again his outline of the disease, it meant he was covering all the other implications. But obviously those would be very much longer and more complicated for something like HIV.

Q. Yes. You wouldn't take issue with his contention that the two conditions are very different as well?

A. No, I think they are extremely different. I think that in the context of this Inquiry, they come together

simply because of a group of patients exposed particularly to the two; but they are very different conditions with very different medical outcomes and social outcomes as well.

Q. Yes. Thank you. I should also refer you to the report that Dr Hay produced, commenting on your supplementary statement, and if you would just bear with me, that's at [PEN0181349]. You have had an opportunity to consider this report. Is that right?

A. Yes, I have.

Q. Yes. Before going into the detail of it, could you perhaps give us your broad reaction to this commentary?

A. I think that Dr Hay has looked at my report and considered that I'm writing from an ivory tower without considering the practicalities, and I think that he is missing the nuances that this is about being sensitive to the needs of that patient and the elements of that medical condition. I know that this is the revised report now, so he has now seen my original statement and presumably saw a lot of that nuancing was in that first statement.

But I think also it's very interesting that he is quite resistant to the concepts that I'm expounding on in terms of counselling and yet his own practice, actually he carries out appropriate counselling. So

I think it's just this word "counselling" which in his mind he associates with that incredibly complex process from the mid 1980s for HIV, without actually recognising that counselling, as in consent and so many other things, has many different faces and has to be appropriate to the situation.

Q. Yes.

THE CHAIRMAN: If it can cause that degree of trouble for Dr Hay, then it must have been extremely difficult for patients to hear the word "counselling" and especially now perhaps in retrospect trying to measure what their recollection of experience is against what might be thought to be implicit in such a heavy word, as it were.

A. It is. It is extremely difficult and maybe the word "counselling" is one that we should drop, but our problem is that, because we don't really have in law informed consent for almost any treatment in the United Kingdom, we have what we at the BMA continue to call "real or valid consent", for want of a better explanation, which means that patients must understand enough about the options to be able to make a choice and to make that choice.

It's very difficult and that is what we mean by "counselling", that you are giving patients information, helping them to understand what the choices are and then

to exercise that choice. If we could find a better word -- maybe we need to invent a word, because so many words become laden with other values, and I think that this is part of the problem. But to me pre-test counselling is actually a very simple concept -- it's giving people enough information to make an informed decision.

THE CHAIRMAN: Almost an issue of proportionality.

A. Absolutely, yes.

THE CHAIRMAN: I can't instantly think of a word, Mr Gardiner.

PROFESSOR JAMES: "advice"?

THE CHAIRMAN: That's too positive.

A. "discussion"? "Pre-test discussion"?

PROFESSOR JAMES: We have asked individuals and the Inquiry has written, asking people for their experiences, as you probably know, where from memory the word "counselling" has been used, and perhaps, as Lord Penrose implied, that may have led to a certain amount of sort of misunderstanding over what was expected, because many people's expectation might be that counselling is the same kind of thing that they understand went on before AIDS testing or, for that matter, some enormous event in your life or death, those kind of things.

So it has certainly been borne in on me this morning

that that's, you know, something that might have to be modified.

THE CHAIRMAN: We will have to look at it anyway, yes.

A. There is an even worse form, of course, because the other form of counselling that is required is before genetic testing, and that is even more complicated. That can take days. So maybe "counselling" is, in some ways, a very bad word because, while the values are good, the consequences or the way people look at it, they expect something that is very much more formalised than it necessarily needs to be.

PROFESSOR JAMES: Thank you.

MR GARDINER: I'm very grateful for that intervention because it reminds me that I should ask you to just confirm that in preparing your report, you were provided with statements from patients so that you could get a background to their experience.

A. I did, yes.

Q. That's right, and you also had access to the Preliminary Report, where that was set out as well?

A. Yes, indeed, I did.

Q. Thank you. Just to pick up a comment you made there about in Britain, the UK, it's not informed consent which is required, it's valid consent. One of the things that Dr Hay told us yesterday was that, if you

were to get informed consent or consent for every single test that you are doing, you would be potentially doing that all day and you wouldn't be able to get your work done. And there is a particular section of his revised report that deals with that. Could we have a look at paragraph 19? We see there, he says:

"Professor Nathanson makes the very valuable point that:

'In general the UK, unlike the USA, does not have a legal requirement for treatment to require fully informed consent. Ethics advice over three decades has been that the patient must have sufficient information to understand the choice they are making and to make that choice freely.'

"We tell patients about common complications, not every possible thing ... by the same token, we do not go into chapter and verse about every single test ... if we did, we would do nothing else ..."

If we go over the page, we see at the (a) he is repeating the same message, that he doesn't have time to consent for every test:

"To take full consent for everything would take two or three hours ..."

He then discusses which tests one should obtain specific consent for: unpleasant and hazardous tests and

so on. Perhaps you could let us have your specific response to what he is saying there?

A. This comes back to what we mean by "real consent". The point I would make here is that when one goes to see a doctor as a patient, with a concern, whether that is a chronic illness or a new symptom, for investigation, and the discussion is, "We will do some tests to try to find out what's going on" -- I said before something like anaemia, the doctor may be looking for anaemia or whatever -- you don't necessarily go into all those tests. That's about the skill of the doctor in talking to the patient and helping the patient to understand and to say, "We are going to do a series of tests to see what is the cause of this symptom that you have. Those tests will be blood tests". The patient may say, "Fine, let's do the blood tests". They may say, "What are the tests?" in which case you will tell them what you are looking for.

It's about responding to the patient as well, trying to see what it is that patient wants. Clearly there are some things where there are specific risks, where you would give more information. So, for example, doing things like liver biopsies. There are specific risks associated with it and anyone doing a liver biopsy would explain those specific risks. Would they go into all of

them? Not necessarily. But if the patient indicates that they want to know more, then you give that information. And it's a little bit like the consent for any operation; you talk about the commonest things that the patient could experience first. You would probably also talk about the most serious things that could happen, particularly if there is a relatively high likelihood.

Some patients don't want to know anything, and that's again, fine, although we are back to this issue of, is it legitimate to not force the patient to confront the fact that something is dangerous. And that's really a moot point at the moment, where there is great disagreement. And some patients will want to know more and some patients will want to know very little, and that is consent, because that is valid because the patient has been offered information and the opportunity to ask questions and has said, "That satisfies my need."

Some patients will say, "I don't want to have that sort of a test. Is there something else you could do instead?" I don't know, maybe somebody is told they need to have a liver biopsy and they say, "Do I really need to have that, couldn't you just find it with an MRI or a fancy x-ray of some sort?" and then it's a discussion of the benefits of this test compared to

that.

I think Dr Hay is assuming again, I think, that full consent is almost back to this counselling question, that you have to give every single piece of information, but I'm sure from time to time he has seen patients who want more information and some patients who want absolutely none and he will have adapted to their needs.

Q. Yes. One of the things that he told us was that the testing in 1992, many of his patients already had a history of abnormal liver function tests and had already been told that they probably had non-A non-B Hepatitis, and therefore the Chiron test, the Ortho test, HCV test, was actually a confirmatory test.

A. Absolutely, and that was part of his process. He would be saying, "We are just going to continue to do your liver tests because you have got this funny hepatitis thing and we have a new test which might give us a bit more information." That's consent.

The problem is that people -- it's back again to language, rather like counselling -- that consent is not necessarily a highly complicated process. It just has to be a process that is specific and appropriate for that patient and that test.

Q. I think that's a good point to break, sir?

THE CHAIRMAN: We will have a break at that point.

(11.04 am)

(Short break)

(11.37 am)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Before the break, Professor Nathanson, we were having a look at Dr Hay's commentary. If we could go back to that, please, which is [PEN0181349]. If we could go to paragraph 12. At this point Dr Hay is talking about what is required before HCV testing, and in this paragraph he says:

"I should also point out that hepatologists have never had a policy of taking specific consent for HCV testing. I have discussed this with our current hepatologist and his two predecessors, all of whom told me that it would just be one of a battery of perhaps 15 to 20 tests, conducted as part of the investigation of every patient they investigated for abnormal liver function tests, and that each of these tests would not be discussed with the patient individually. As our current hepatologist said 'everyone checks the creatinine (test of kidney function) all the time and that is never discussed with the patient in advance and yet the prognosis of a patient with an elevated creatinine is very much worse than the prognosis of

a patient with HCV'. He reiterated the point that HCV is potentially curable and even untreated has a generally very good prognosis and that there is no specific guidance."

I think you touched on this earlier, the difference between the kind of discussion that a patient would have with the liver specialist who he has been referred to and other clinicians, but perhaps you could give us your response generally to that paragraph.

A. Yes, I would think that this is absolutely the case with almost every hepatologist, that patients are referred to them because they have got abnormal liver function. They are told, "You have got abnormal liver function, we are sending you to a liver specialist, who will investigate that, try to find out what the cause of that is and what the best plan is for treatment."

And those hepatologists would then carry out those tests. I would imagine that those hepatologists would get consent for a liver biopsy, but I can imagine that for blood tests they would just say, "We are going to do a battery of blood tests to try and identify the cause of your liver disease," as simple as that, and the patient would put out their arm and say, "Fine, that's what I'm here for," and that's, in that sense, consent.

Q. And the context is that perhaps a discussion has already

taken place with the doctor referring, and that perhaps even by going to the liver specialist, there is a form of consent to try to find out what's the matter with the patient?

A. Absolutely. I mean, you can call it "necessarily implied consent". They have gone along to the hepatologist in the knowledge that they have got abnormal liver function tests and they want that investigated to try to find a bit more about the cause and the best treatment plan. They would expect to have a discussion once that cause is identified, of the treatment plan, to discuss that with the hepatologist, what are the options at that point.

Q. Yes. Thank you. Perhaps we could go to the last page of that report, please, page 10. You will see that Dr Hay has produced a table here and he has put "differences between HIV and HCV relevant to counselling are listed below", and he lists the difference: "

"HIV: incurable.

"HCV: curable in 40 to 100 per cent."

He goes down the list. You wouldn't disagree with anything that's in that table?

A. No, I wouldn't.

Q. I think you have told us that you wouldn't disagree with Dr Hay's distinction between the two conditions, and in

particular their relevance to counselling?
A. No, I would think that this was an entirely appropriate background to the way in which you would talk to the patient about consent or indeed about what the diagnosis would mean to them.
Q. Yes. I'm going to leave the commentary now but before I do, is there anything else that you would like to say in response to Dr Hay's evidence?
A. No, I think that's fine. Thank you.
Q. Sir. I propose to move on to a final, separate topic.
THE CHAIRMAN: Yes. I have got one topic I might just pick up.
Professor Nathanson, do you have anything to do with complaints to your body?
A. No, I'm glad to say that's the General Medical Council, not the BMA --
THE CHAIRMAN: So you do not have anything?
A. -- so we don't.
THE CHAIRMAN: My interest is in this perception of the need for counselling and whether it has given rise to a level of activity, let's say, over time that shows that there has been real concern on the part of patients about information they have been given. But if it's not within your area ...
A. We certainly keep an eye on the cases that the GMC

actual hears, which is of course a small minority of the complaints that they receive. So it may well be that they receive complaints regarding that which we wouldn't see, which have been dismissed; in other words, that they haven't felt that there was enough there to go on to a case. But I have certainly never heard from a doctor contacting us for advice, saying that there has been a complaint about them not giving enough information, and we might hear it that way round, where they might come to us saying, "Could you give us some information on what you would expect the normal amount of information to be".

THE CHAIRMAN: I was just wondering whether it might be one index of a level of concern that one could use, but thank you very much for that.

MR GARDINER: Thank you. I just have one final question on look-back, Professor Nathanson. Could we have a look at [SNB0084848]? Could we go to the second page of that? Have you seen this before, Professor Nathanson?

A. No.

Q. This is a letter from Lord Fraser of Carmyllie, and if we go back to the first page, it's dated 22 December 1994. At that point he was the Minister of State at the Scottish Office covering home affairs and health, and it's a letter to Tom Sackville, MP,

Parliamentary Undersecretary of State, Department of Health in London. We will see from the heading that the topic is "Hepatitis C virus look-back exercise", and the letter says:

"Dear Tom, as you will be aware, a number of patients may have contracted the Hepatitis C virus (HCV) from blood transfusions or blood products using blood from infected donors, prior to the introduction of screening for HCV in 1991. Until now there have been no arrangements made to carry out any look-back exercise to identify these recipients of the infected blood and to arrange counselling with a view to treatment. Part of the reason for this lack of any follow up action was a concern that it would be impossible to identify all recipients of infected blood and even if it were possible, there was a lack of accepted treatment which would be beneficial."

It's this next sentence that I would like you to comment on:

"It was accepted that if no effective treatment was available, informing those patients who were unaware of their situation could not be justified, since this would cause further distress and anxiety without any benefit."

Professor Nathanson, I would like you to give us your response to that reason for not going ahead with

the look-back from a medical/ethical point of view?

A. From an ethical point of view, it is a very common reason that's given, and one of the -- I have to go back a little.

It's quite clear that individuals have in one sense, in an ethical sense, a right to know information which is about them, their health, their bodies. It has, however, commonly been argued that where that information would bring them only uncertainty, where there was no treatment available, that you couldn't justify causing distress and anxiety. So that last sentence is a sentences that I would recognise as being one that has been commonly cited.

Against it, however, there is the ethical principle that it's that patient's body and their right to know. There are also practical issues, which is that it gives individuals -- there are in fact things that people can do. With HCV, even if there was no treatment, at least there was the issue of relative abstinence or moderation in terms of alcohol intake. Was the opportunity for closer monitoring and as soon as drug treatment became available, being able to get into that track.

There is also the risk that you could lose patients, you could lose contact with people that you can contact today, if it takes you another three or four years

before you contact them, and then it might mean that when a treatment becomes available, they are not rapidly told.

I think there is the ethical issue that if you do not give people information that you have about them, you can undermine trust and that's a very major concern because if somebody has got a condition which is going to require, at the very least, monitoring and possibly complicated and unpleasant treatment, which requires a lot of cooperation between patient and doctor, then the fact that information was held can sometimes undermine that trust, "Are you continuing not to tell me the full truth?" as it were. And also the issue that if the donor were infected, then there were questions if the donor doesn't know about this continuing. So one is trying to raise the knowledge level in the community, so that we don't have more people coming forward who might be at risk of being infected, not necessarily with HCV by then because of a diagnostic test being available, but other viruses as they become either known about or just new viruses.

So I think there are many reasons for saying I would err on the side of telling people early, and I felt that the pilot research study was a very good study, very useful, because it showed that not only did it work but

it also showed that it didn't cause, as I understand it, undue distress, and I thought that was a very positive thing, which helped us when we came on more recently, for example, to prion disease. Exactly the same discussions had been over should you tell people who had received blood that they might have been exposed to prion.

Q. The pilot exercise that you are referring to is the one that took place in Scotland?

A. Indeed, at the beginning of the next paragraph it identifies it.

Q. Thank you very much, Professor Nathanson.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Professor Nathanson, can I just ask you about testing. I think the position really is that in this field, context, I suppose, matters a great deal in relation to the decisions that are made by the doctor as to what to do. A lot depends on the particular context. Is that right?

A. Absolutely. It's about understanding the patient, understanding the context in which you are seeing that patient, the knowledge base of that patient, what you have discussed in the past. And that's particularly of course the case for people with chronic conditions,

where there is an ongoing relationship and where things have been discussed perhaps on previous occasions.

Q. In the situation with Hepatitis C, the matter is complicated by, obviously, the changing understanding of the disease, and if we have someone who had been a haemophiliac and treated with blood products over a long period of time, if up until the mid 1980s they may or may not have been told that they had abnormal liver function -- they may or may not have been told that they had non-A non-B Hepatitis -- when that person comes to being tested for the first time, say, in the early 1990s, when a test becomes available, is it your view that a doctor should at that stage have told the individual that they were being tested for Hepatitis C?

A. That would have to depend upon the individual patient. I mean, the gold standard, the best practice, would be absolutely you would tell them that but a lot depends on the discussion that you have had prior to that of testing for non-A non-B. And if they know that they have non-A non-B Hepatitis, you are sure that that has been discussed, then all this is is confirmatory test for a specific virus that we now know is one of the causes of non-A non-B, then it's arguable.

I would have preferred people to be told specifically that this is a test for one of the viruses

which appears to cause non-A non-B, but I would expect that at that time there would be some people who would not necessarily tell them that.

Q. There is a difference between what they would or wouldn't have done and what they should or shouldn't have done, and I'm not meaning to criticise anybody in particular here, and we are looking at this with the developments that have occurred since then, and thinking about ethics has presumably moved on. But one of the problems that arise in this area, presumably, is that the person who is treating that individual will have changed over a period of time, so that the person who is then confronted with the decision to give a test won't necessarily know what that patient has been told in the past or the full extent of what that patient has been told in the past. Is that reasonable?

A. Indeed, that does happen and of course, the other thing that also happens is that if you have a test result and don't share it with the patient, then a new clinician coming in, doctor or nurse, doesn't necessarily know what the patient has been told, and so it's impossible -- that's why truth and honesty is always best for many reasons but one of them is not least because it actually helps that everybody treating the patient knows that they will have been told the truth

insofar as we know what the truth is.

Q. What about the situation where blood samples or material is available for testing and, the samples have been collected over a period of time, the new test becomes available and the patient's blood is tested without their knowledge for a specific condition, ie Hepatitis C, should the patient be told before that test is carried out?

A. Normally I would say yes. There is a "but" for this one which comes back again to the individual patients.

If the patients are known to have -- and the patient knows that they have -- non-A non-B, and what is being done by the testing of historical samples is to try to trace what percentage of those patients with non-A non-B actually have this virus that we can now test for for the first time specifically -- and, remember, non-A non-B could have been dozens of different viruses, nobody really knew at the time how many were going to be C. It emerged quite quickly but it wasn't known. I think at that point when it's being done not so much as a diagnostic test for the individual but more about trying to find out what the epidemiological pattern was within this population group, then I think at that point it becomes less necessary to specifically ask the patient.

If you looking at it as a diagnostic test for the individual patient, then certainly, ideally you would get their prior consent. It also depends upon the consent that has been given to testing more generically by the patient.

If the patient has agreed to generally giving blood for routine liver tests, which we will change from time to time as we learn more about the liver disease that we see in your patient group, then one can argue that they have given consent to that. I still believe personally that the ideal world is you go back to the patients and get their permission and if you don't get their permission in advance, you tell them very quickly thereafter, "We have had this new test, we have been able to look historically at your samples and we now know that you have this condition".

Q. You see, one of the problems that arises with Hepatitis C -- and I'm sure it arises with other situations -- we have seen in this Inquiry that the knowledge about this condition changes over time, but there may be many patients who were not taken aside and told -- they may have been told they had non-A non-B Hepatitis -- or there may be situations where patients were not told, "We now realise that non-A non-B Hepatitis is a lot more serious than we previously

thought it was", and of course that would affect their feelings about whether or not they should have been told or not been told. Is that reasonable?

A. Yes, the question is whether they were or were not told about what was known about Hepatitis C. As you know, many patients don't remember things that they have been told, not surprising. That's not a criticism of any individual, either the doctor or the patient; it's just one of those things that we know from research, that people don't remember information, and particularly information that is actually quite frightening, where there is a large emotional load to that information, it's very often blocked by individuals. There is very good research on this.

So that's very difficult. So some people may have been told that. They may indeed have almost dismissed it because a lot of the early information given on Hepatitis C was rightly very reassuring because the early information on Hepatitis C did seem to say, as with non-A non-B, "This doesn't seem to be particularly serious," and then suddenly with epidemiological tracking it became clear that it was a great deal more serious, and then the good news being that they then got a treatment in.

So it has gone through a number of phases and one

would expect, in an ideal world, that patients would be told of the state of knowledge on a regular basis.

Q. Could we have paragraph 64 of Dr Hay's first report? Not the revised one but the original one.

THE CHAIRMAN: Page 27 of [PEN0181186] for the page?

MR DI ROLLO: Yes. Just one matter. I think you have been asked in detail and I don't want to go over this again with you. I just want to ask one matter arising out of your comments in relation to Hay's material. It's paragraph 64, the final sentence:

"For that reason, there has been never been a specific consent process attached to Hepatitis C testing, even though it would be normal practice to inform the patient that they were being tested and to inform them of the result."

I just wondered about the beginning of that sentence:

"There has never been a specific consent process attached to Hepatitis C ..."

Is that right? My understanding of the guidance was that Hepatitis C was a serious communicable disease and therefore there was a need to inform the patient about the test. That seems to have been the position, as I understand it.

A. I think one can argue on whether it is a serious

communicable disease or not, and I think that many people would see it as not a serious communicable disease. I think that nevertheless, consent is necessary and I think that what Dr Hay seems to me to be saying here is that there isn't a consent process in the very formalised counselling that was given for HIV testing; it was never put in place for Hepatitis C.

I would expect that to be true. It would always have been, even when the information about Hepatitis C was at its worst in terms of prognostically, that it would be relatively brief in terms of the amount of information that needed to be shared for the patient to make a decision but that nevertheless it would, of course, require consent if you are taking the test de novo, from the patient for the first time.

Q. If he is to be interpreted as saying that it's not necessary to obtain the consent for the test before performing the test, you would disagree with that? What you would say is that it is not necessary to give counselling of the type, for example, that is required for HIV?

A. Indeed, but I'm reading his sentences as saying that there wasn't a specific set aside process which said, this is the list of things that you need to go through.

Q. And that's correct?

A. That it was just a normal consent as you would for any other test.

Q. You would agree with that, if it is to be interpreted in that way?

A. Yes.

Q. Thank you for that, I understand that. Thank you.

Sir, that's all I have to ask.

THE CHAIRMAN: I wonder if I could just make it a little bit more specific. I think that we know that many virology laboratories will have held historical samples and one can readily envisage that a virologist knowing that and learning of the test might have an academic interest in beginning to develop an epidemiological picture for his place. Does the matter become more definitive in terms of what can be expected where it's a haemophilia clinician who initiates the examination of stored samples?

A. I think that the key is probably whether you can identify the individual patient from when the test is done. So if the tests are anonymous, then normal practice would be, as with any other form of anonymised epidemiological research, that consent isn't necessary. If it's pseudonymous, which means you have applied a code and you can get back to the patient, it's more questionable, and certainly we would see in those

circumstances that you would normally require the consent of the patient, but not necessarily in every case.

So if, whether it is a haematologist who normally is dealing with haemophiliac patients or a virologist, or indeed any other researcher, and what they are doing is that they are getting unlabelled blood samples, even if they know that those blood samples are all from haemophiliacs in Scotland and they are testing to see what proportion of them have Hepatitis C, then I don't see a problem.

The problem is if they know that these are from ... and then they have a list of names and sample A belongs to patient A and so on, at that point you get into the question of when do you get consent; and at the very least in that latter case there is a requirement to inform the patient afterwards and to get ethical approval to do it without consent beforehand and to make sure that, in doing that, you are sure that the patients understand that they have samples stored because of their hepatitis, which might be subject later to further tests as they come along.

THE CHAIRMAN: Do you wish to follow that in any way?

MR DI ROLLO: No, I'm content with that, thank you.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: I am obliged.

Dr Nathanson, good morning. Professor James raised with you about the appropriateness of the use of the word "counselling"; is it possible that a patient might be asked, "When you were tested for Hep C in 1991 or 1992, did you receive pre-test counselling?" that that patient might answer "no", but that same patient, if asked, "Did the doctor say that he wished to do a test for Hep C" and gave you an outline of the disease, that same patient might say "yes"?

A. Absolutely, and I think it comes back to this loading of the word "counselling" and the assumption that that means this very long and complicated process that has to be seen in certain other conditions.

Q. I think I have been guilty in the past of equating "counselling" with grief counselling, for example, a very formal process, but we are to understand "counselling" as a broader church than that. Is that right?

A. Yes, I think that "counselling" in this context basically means -- and indeed from the HIV studies -- giving patients the information that they need so that they can make a choice whether to have the test or not.

When you are talking about a test with the

non-medical consequences of HIV, and particularly HIV in the 1980s, then that is quite a long and complicated process. But if somebody says to you, "I think you have got iron deficiency anaemia and I need to do a blood count. We don't want to give you the iron tablets because they are pretty horrible," then that's enough counselling because you have been given the choice to have the test or not. And "counselling" has many different meanings and Lord Penrose is absolutely right that it is probably the wrong word.

Q. Thank you very much.

THE CHAIRMAN: Mr Johnston?

MR JOHNSON: I have no questions, thank you.

Further questions by MR GARDINER

MR GARDINER: Could I just clarify one point?

Professor Nathanson, you were asked about testing of stored samples. If in 1991 to 1992 blood had been taken from patients and stored and then, when the Hepatitis C test became available, testing had been done without the patient's permission without their consent, do I take it that you would be critical of that practice?

A. We wouldn't regard it normally as ideal but there is a "but" here. When samples are taken for people with chronic conditions, quite often the discussion is had that new tests come along from time to time and that we

would want to carry that out.

So if, for example, part of the discussion had been, "You have got this non-A non-B, it may be that we can go back to some of these samples at some stage in the future if a specific test comes about," and that was part of a routine discussion, then, if you like, you have got consent to that.

So you need to be very careful about that. I think Hepatitis C in the context of people knowing that they had non-A non-B, is rather different. It would be very different if you were treating people for non-A non-B and you suddenly started testing for a disease that had nothing to do with their liver disease. Then I think you would say absolutely you had to have consent but given that it was in a sense a refinement of the test that you were doing, it's much more arguable that it's acceptable and is possibly even consented to already.

Q. Even if the patient has not given consent to future new tests at the time of giving blood?

A. Yes. Well, again it's back to how subtly that question was asked. This is why we say that the ideal and the gold standard is absolutely to go back to the patient and seek permission. But, given again that there is a context within which that blood sample was given and a series of tests performed, sometimes patients would

expect that you would be able to go back and get more results from it. It isn't ideal and indeed, of course, it is the one group of patients in which it is easy to get a second consent because they are patients that you are continuing to see.

Q. Thank you very much.

PROFESSOR JAMES: Could I just ask: in this exact context, what about the question of consent from an ethical committee as to whether those tests could be carried out on stored samples in the kind of context that has just been described? Would you perceive that in, let's say, 1991/1992, which is the, you know, the material time we are talking about, if a lab/group of people in a place was in the position we are talking about, they should have gone to the Research Ethics Committee to get permission to do those tests on stored samples?

A. Ideally, yes, they certainly should have gone to Research Ethics Committee, and I would have expected Research Ethics Committee to have always granted approval in those circumstances, given the nature of the previous testing and what the test was there to consider.

PROFESSOR JAMES: Thank you very much. Thank you.

THE CHAIRMAN: Professor Nathanson, thank you very much indeed. That's very helpful. Mr Gardiner?

MR GARDINER: Our next witness is Mr McIntosh.
THE CHAIRMAN: Is he here?
MR GARDINER: He is indeed.
THE CHAIRMAN: Then we will have a short break to make ourselves comfortable.
(12.11 pm)
(Short break)
(12.26 am)
MR DAVID MCINTOSH (continued)
Questions by MR GARDINER
MR GARDINER: Thank you, sir.
Good afternoon, Mr McIntosh.
A. Good afternoon.
Q. You have previously given evidence to the Inquiry but today we have asked you to come and give evidence about look-back primarily, Hepatitis C look-back. I think it would be helpful just to get an overview of the events surrounding this subject so could we have a look, please, at page 3 of [PEN0172511].
Sir, this is actually a schedule to the letter to Dr Keel but it contains a helpful summary. I'm not sure if you have a copy in your papers.
THE CHAIRMAN: I don't think so but that doesn't necessarily mean I don't.
MR GARDINER: So we see that this is a schedule and in the

middle of the page:

"Snapshots and landmarks."

I'm just going to read this, Mr McIntosh. So we see:

"The introduction of anti-HCV test:

"1. In 1989/1989 the Hepatitis C virus was isolated and an anti-HCV ELISA test was developed...

"2. In September 1991, following advice from the Advisory Committee for Virological Safety of Blood (ACVSB -- predecessor to the MSBT), routine testing of blood donations for anti-HCV was introduced throughout the UK.

"3. From that date all blood donations were tested for anti-HCV. Donors who were confirmed to be anti-HCV-positive were recalled and offered counselling."

If we look at the bottom of the page, in 1990 it says:

"In the summer of 1990, the SNBTS directors set up a working party to advise on policies and procedures of Hepatitis C testing with particular emphasis on counselling and care of donors with positive anti-HCV tests. In a draft report dated 23 November 1990, the authors advised that look-back should be instituted from the onset of testing."

Next paragraph:

"The proposal for look-back underwent further discussion by both the SNBTS and the NBTS directors and was finally rejected after referral by the SNBTS national medical director to the Department of Health, London."

In the next paragraph:

"However, in the Edinburgh and Southeast Scotland regional transfusion centre an HCV look-back was carried out from the commencement of routine donation testing for anti-HCV. The results ... were published in 1994."

Then there is a gap in the chronology in 1993:

"On 15 October 1993, Dr Cash wrote to the SNBTS directors raising the issue of HCV look-back once again."

The next paragraph:

"On 18 November 1993, Dr Cash wrote to Dr Gunson informing him of the discussions at the recent meeting of the ... MSC. He suggested that the issue of HCV look-back should be discussed by the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (ACMSPT). Dr Gunson suggested that the topic be put on the agenda for the next advisory committee on transfusion-transmitted infections (ACTTI)."

Then if we could go on to the next page, if we go down paragraph 11, we see the next significant date on 18 May 1994:

"The committee unanimously agreed that HCV look-back should be implemented."

Then if we could go forward three or four pages to 2518, paragraph 24:

"On 22 December 1994, Lord Fraser (Minister for Home Affairs and Health, Scotland) wrote to Tom Sackville ..."

That's the letter we have just looked at with Professor Nathanson and I think you were here during her evidence --

A. I was, thank you, yes.

Q. Then paragraph 25:

"Shortly thereafter, ministers in England agreed to the submission from ACMSBT and on 11 January 1995, a Parliamentary question announced a UK-wide HCV look-back."

So that gives us a broad overview of the period that your statement looks at, and so if we could have a look at your statement now, please, which is [PEN0180358]. That's your statement, isn't it, Mr McIntosh?

A. It is indeed, thank you.

Q. You have a hard copy with you?

A. I do, thank you.
Q. If we could go to the first page, please, you give a little introduction to the statement, and perhaps you could just tell us about that.
A. Yes. Thank you. I'm very conscious that his Lordship has tried to focus us all and only answer the questions that are asked, and therefore I approach these with some trepidation. I'm very anxious to be clear about what I'm doing with the benefit of hindsight and what I'm doing with the benefit of clear memory. And my introduction here is an attempt to explain the way in which I have tried to structure that, so that his Lordship and yourselves can be warned that maybe some of this McIntosh stuff is too speculative to be worth listening to, but I have tried on each bit to make it clear what I think is true memory and what I think is hindsight.
Q. Yes, thank you. Could we go over the page? The Inquiry wrote to you and asked you certain questions about this topic, and you have repeated the questions there in your statement. Question 1 was:
"What was Mr McIntosh's involvement in the look-back exercise?"
And perhaps I could just ask you to, in your own words, explain this to us?

A. Well, it does occur to me to say this, partly prompted by Lord Penrose's request to me to do the supplementary statement. I have tried to answer the question here and it's a matter of record, so I won't go into it further, but I feel moved to explain the following, that every single thing that one was doing at that time in the SNBTS was against a background of huge cultural change, huge resistance in some areas, and that some of the simply managerial questions like: why are we doing this? Why haven't we done it already? Why aren't we doing it sooner? What is an ACVSB? What has it got to do with it? This sort of question was, for me, routine managerial work, but for a lot of the colleagues I was dealing with, it was outrageous interference with matters that were entirely up to them.

So there is a thread that runs through all of this, which was, "What has it got to do with you, son?" on the one hand and me saying, "Well, it has a lot to do with me because I'm actually responsible for this and in 20 years' time I may have to appear in front of an Inquiry", and I did actually say things like that, and here am.

And with apologies to everybody reading this, it will, in places, appear (a), chaotic and (b), extraordinary naive, but the fact is that none of the

normal management common sense you can take for granted in most organisations outwith the public sector applied, and therefore some of it, where it feels that way, it feels eerie and strange and odd, it is precisely because I was single-handedly appointed as the first general manager of the service and trusted with making it more managerially effective. And every issue that I came across had to be dealt with in that context.

Now, look-back was one which frankly, for me at that time, along with all the other things that we were concerned about, took a relatively back seat, partly for the reasons which I think you have already adequately covered with Professor Nathanson and others, that there was a time when it did not seem to be a big deal, but mainly, frankly, because for me that was one thing that my Medical and Scientific Committee could simply absolutely be thrusted to take responsibility for. So my involvement with it was very much as oversight -- and I don't mean to say that I committed an oversight, I mean, I was overseeing it.

But, as I say in my last paragraph, 1.12, I don't in any way wish to imply by that that it wasn't my responsibility. It happened on my watch. I was responsible for doing certain things to make sure that it went smoothly.

I think the record shows that when I tried to take positive action to make it happen, I was thwarted by the strange, mushy politics of it all, and failed to gain the objective that I sought. However, I think I should say in fairness that it's probably, I think, clear from the evidence that it only happened in the UK as a whole because Lord Fraser kicked the bucket and said "Oi!"

THE CHAIRMAN: An expression we use in a particular way in Scotland.

A. "Kicked the can", perhaps I should say.

So would you like me to say more about my role there?

MR GARDINER: That would be helpful, and I'm particularly interested in your role vis a vis the Medical and Scientific Committee. If you could speak into the microphone in front of you, that would be --

A. On the left?

Q. Yes.

A. Well, again, and with apologies -- and please stop me if I go on too long, because I will, as you perhaps know, if I am left to my own devices.

I joined the blood transfusion service at a time when it had a group of directors, the directors of the SNBTS, which was a group of people, all of whom were either scientifically or medically qualified.

THE CHAIRMAN: Can I ask to you slow down just a little. Remember that we have a small problem in recording it, if you speak too quickly.

A. Sorry. So all of the members of the group known as "the directors of the SNBTS" were either medically or scientifically qualified, and they were, in a way, the sort of representatives of the various components of a federation of blood transfusion services.

I mean, when Dr Ruthven Mitchell went back to Glasgow -- he went to run the Glasgow and West of Scotland Blood Transfusion Service, and what Professor Cash, the medical director in Edinburgh, thought, felt or urged him to do was relevant but not decisive. So Ruthven ran his own ship, so did the man in Aberdeen, so did the man in Inverness, so did the man in Dundee and in Edinburgh and so on. This becomes very clear when you look and tease out things like the fact that Edinburgh and the Southeast was doing look-back in 1991 and others did not do look-back until 1995. We are talking about a very large gap.

That's only explainable when you understand the history of this very diverse, rather diffuse, very loosely-knit organisation. So when I took it over, one of the things -- and you have evidence on this from me in my supplementary report, which is the report I did

after three months in the Blood Transfusion Service in 1990. I can't give you the reference to that but you do have that document -- in which I was saying: well, here we are, it has been in existence for 50 years without ever having any management. I have been appointed to manage it. I have been in post for three months, in an organisation with 1500 employees, about 300 of whom were PhDs, and as Mr Anderson has pointed out, I was a layman. I had three months to look at this organisation and recommend some changes.

Now, in answer directly to your question, one of those changes was to set up a thing called the MSC, which I thought was quite elegant because it is a masters in science. And I tried to think of the right phrase for the managerial side, which would have been the MBA, but I couldn't work out how that would have worked.

The MSC was set up quite deliberately by me -- or, sorry, let me put that another way. I recommended that it should be set up, and that recommendation was accepted, because I wanted to make a clear distinction between the medical and scientific advice that I, as general manager, was looking for and the managerial conduct of the SNBTS as the general manager responsible to ministers for its efficiency and effectiveness.

So the MSC should have been, very clearly, an advisory scientific subcommittee to the board. What its chairman thought it was, as it were, the government in exile of the SNBTS, which, of course, took precedence over these silly little administrative people called "managers", and there was, of course a great deal of tension, in many ways, in many times, and over many issues, and to a certain extent the look-back exercise was one of them.

I don't wish to imply that these were insurmountable problems; they were part of the cut and thrust of the day to day problem of changing an organisation from one mode to another. And though there was a great deal of resistance, and I think John Cash in particular tried very, very hard to make it impossible, it was not impossible and we did in fact make good progress.

But in response to the question, what was my involvement in anti-HCV testing -- in looking at look-back, and what was the MSC's role -- the answer is: the MSC's role should have been to produce lucid recommendations. And of course it's interesting to note that the Inquiry does not have a copy of the final recommendations of that SNBTS working party in 1990, because we are being told by the chairman of the working party and of the MSC, Professor John Cash, that it

unanimously agreed to recommend, in 1990, that it should be done immediately but by 1994, it was still saying, "No, no, no, hang on a minute, hang on a minute, oh interfering manager, we think as professionals that it should not yet happen," and this extraordinary contrast is not actually, I have to tell the Inquiry, as extraordinary as it looks because it was fairly typical of the relationship in areas like that over that period.

Is that helpful?

Q. So the MSC was to provide advice to the board and the board would then implement that advice?

A. That was the intention. And indeed, in many ways that's what happened.

Q. Yes. In the context of your involvement in the look-back exercise, paragraphs 1.5/1.4, you say:

"The subsequent look back at the testing was an SNBTS activity whereas the look-back exercise was not."

Could you just explain that a little bit more?

A. Well, yes, thank you. Because -- and perhaps I didn't expand on that as much as I should. It's a well known thing within blood transfusion services and with healthcare but it may not be that obvious -- the point is that testing something that, if you are a blood transfusion service and you are taking blood from donors

every day, you can do, you just test what you have got. If it's a look-back exercise, you have got haemophilia directors, you have got hepatologists, you've got general practitioners, you've got hospital administrators, you have got a huge job to do to achieve a team effort in a successful look-back. And the point I'm making here is that therefore much of the look-back was not actually my responsibility as general manager of the SNBTS, nor could I expect my organisation to be the sole mover.

We could have all the budget we needed, we could do all the testing that we liked and all the looking back that we liked, but the look-back programme as such is a public health matter involving all the issues you have been discussing with Dr Nathanson and others. I only make that point, not as a "get out clause" for the SNBTS, but to make it clear that actually it was a very different prospect from just a testing exercise and it had a lot more unknowns and ambiguities.

Q. Yes.

A. Sorry, does that explain --

Q. No, that's helpful. You mention the algorithm which I think makes that point very well. Could we look at page 31 of [PEN0172220]?

A. This is the algorithm, is it?

Q. Yes.
A. My memory by the way, for what it's worth, is that this algorithm was actually built and designed originally in Glasgow by Ruthven Mitchell's team, though clearly it was far -- put into effect much earlier by Edinburgh.
Q. Yes. Could we expand the top half? If you could just explain what this is, Mr McIntosh.
A. Right. Without trying to zoom in and go into detail, what we are trying to show here -- and the reason it's called an "algorithm" is because it's a decision tree. When people say, "What is look-back?" this is what look-back is. We have identified that the donor is positive. Can we please now check all the patients who received a donation, either of blood or tissue or blood product, from that person? In the case of haemophiliacs, it would of course be Factor VIII or activated Factor IX, or one of the clotting factors.

So fact 1: donor is positive. Question 1: are there any positive patients? Fact 2: yes, there is a positive patient. Then what do you do about it? First of all you have to make sure that you know that you can actually find them, and Professor Nathanson, I thought, was very lucid on that point earlier. It's not always possible to find them, which is one of the reasons why, of course, you want to do it as soon as possible and why

the delay was pertinent and unfortunate.

But as you can see, if we just wave our hand over this and say, "It's complicated". You have got a lot of people to consult. You have got not only individuals. I mean, the general practitioners and the consultants could be just absolutely on the ball but what about the hospital records department?

I think I remember one general manager of one of the hospitals, a chief executive of the one of the trusts, saying to me, "But do you know, David, it's marvellous, only 5 per cent of our records are missing at any one time," and I'm thinking, but for the patient whose records are missing, that's 100 per cent of my records.

PROFESSOR JAMES: It isn't actually. Sometimes it's only 30 per cent of their records. That's another of the difficulties.

A. I stand corrected, thank you.

But these are real issues and if you, like me -- when I was an MDG I visited almost every hospital in Scotland. You go round some of those old hospitals; they've had fire, they've had floods, they have lost their records. We are talking manila folders here, just great piles of records. This is long before digitisation. I think it's one of the points that it would be good if everybody involved with the Inquiry

were to fully understand the reason why Edinburgh and the southeast did such an exemplary job was not just because they were a very good team, it was because they had the good fortune to be working in an environment where hospitals tended to have better records, better computerisation and so forth.

Q. Yes.

A. So this algorithm highlights that actually you could go down that decision chain and you could get to a blank barrier which just had a big question mark, "Sorry, screen dead".

Q. You make the point that the action below the dotted line is --

A. Generally tends to be outside the SNBTS.

Q. Yes.

A. Yes, in hospitals and healthcare institutions generally.

Q. Yes.

A. And individual practitioners.

Q. Yes. Can we just go back to the statement, please --

THE CHAIRMAN: Sorry, before you do, could we go to the very top and fill in, if we can, the missing line or lines.

A. Back to the algorithm?

THE CHAIRMAN: To the algorithm. I think Mr McIntosh has told us what it was, that there is at least a finding of positivity but we don't --

A. Could we bring that up again?
THE CHAIRMAN: I think it would be very helpful to have the whole document. There is another copy. Right, okay.
A. Yes, the early steps are the ones in which -- absolutely these top four are the kind of thing that you would expect committees of experts -- virologists, hepatologists and others -- to have been deeply involved in. You know, this whole business of whether ELISA screening was enough, what sort of confirmation testing was required et cetera. But then below the dotted line you are into medical administration and all kinds of other skills as well as pure science.
MR GARDINER: Yes. So, just for our records, the reference to the clearer version of the algorithm is [SGH0083098].

If we could go to paragraph 1.8 of Mr McIntosh's statement, please.

You describe here the MSC's responsibility as being:

"To coordinate appropriate research on [all of the issues that you have mentioned] microbiology, immunology, public health and generate recommendations."

How did they go about coordinating research?
A. Well, I mean, to be fair, I'll give you an impression of that and an understanding but it would be worth checking with people who were more directly involved.

My memory actually of this one, because of the

involvement of particularly Dr McClelland and Jack Gillon, Dr John Gillon at Edinburgh, is that there really was a thoroughly good job done on this, and they co-ordinated it in the way that they had always done, which was, "I've got a friend who has written a paper on this, I think he would be good at doing that", "Archie knows more about the other thing", "Jim knows more about the other". It was very, very informal peer group kind of game they played but it got very good results.

So I think in that sense, our rehearsal of the likelihood that one could do this and our subsequent implementation of the doing of it was actually impeccable. The horrifying thing is the gap in the years between 1991 and 1995.

Q. Although it's true, is it not, that Dr Gillon's look-back programme was not something that was co-ordinated by the MSC?

A. Well, it's interesting you say that and I would love to hear you more on that point. Yes, it was actually. As a pilot. And we have all noted, haven't we, that it was still being described as a "pilot" three years later. The extent to which that trial was not to do with the MSC was the extent to which at a given moment it stopped being a trial and just started being a look-back exercise. And I think it's fair to say that Edinburgh

were cooperating fully with the MSC and doing exactly what it says in paragraph 1.8 until the moment when it was conclusively proved that this was a very good idea, at which point that information was taken away for further consideration by eminent committees on the one hand. And Edinburgh, I think, was assumed to have stopped, to have finished its pilot. But Edinburgh just quietly went on and did it. And that was the point at which Edinburgh and the MSC diverged. But until that point, the MSC and Edinburgh -- I mean, I was present at meetings with the MSC with Jack, where he was doing presentations and so forth, and it was a thoroughly cooperative collegiate exercise.

Q. I think I should maybe show you Dr Gillon's statement on this point, just to get your comment on it. Could we have a look at [PEN0180410]? You see, this is Dr Gillon's witness statement on the same topic. You won't have had a chance to see this yet but if we look at the bottom paragraph, it starts:

"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."

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 Southeast Scotland as a routine from the onset of testing in 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 ... )"

A. Agreed, and here is the evidence of it. McIntosh was suitably duped by it being seen as a pilot study. My recollection is that actually there was a period of collegiate cooperation before this split, and I know Jack disagreed with John Cash's position and so did I,

but I don't think I was made aware that Edinburgh was just quite so set on UDI so early.

So to that extent the medical and scientific community managed to imply to the general manager that all was well, when perhaps it wasn't.

Q. Would you be inclined to accept that Dr Gillon's look-back programme wasn't a pilot study?

A. Well, I think in the sense -- this is quite an interesting analysis of the word. It was a beacon and to that extent, whether it wanted to or not, it was a pilot study, and it was used as a pilot study, and it was used as the basis for similar programmes elsewhere.

But from what Jack Gillon says -- and Jack is a very, very reliable witness -- from -- if Jack says it wasn't a pilot study, then it wasn't, as far as he was concerned. If John Cash chose to use it as a pilot study, then I think that's legitimate.

Q. So if you are accepting that it wasn't a pilot study, is that something that you have only learned subsequent to these events?

A. I'm only considering the possibility of not thinking of it as a pilot study because I have now -- thank you very much -- read Jack's evidence. My memory of it was that it had started off as a pilot study and, as those of us who have been involved with medical ethics committees

will know, many programmes start off as trials but are discontinued for ethical reasons because it's felt that we must now give this therapeutic treatment because it's definitely better than the placebo, and my understanding of the Edinburgh trials was that it started off as a pilot but became a reality because it became obvious that it should be. Now, I was wrong about that, clearly. You have just proved to me I was wrong.

Q. And who told you at the time that it was a pilot study?

A. The impression I was allowed to gain came from the MSC as a whole but obviously led by John. Now that we see the evidence from Jack, I suppose it was probably John who convinced me of this. But that's hearsay. I'm only guessing.

Q. Yes.

A. My memory is that I got the impression from the whole community that all was well in the early days.

Q. Yes. Thank you.

Could we go back to your statement, paragraph 1.9? You explain that in your role in relation to the MSC, your responsibilities were: seeking to help your professional colleagues to come to a clear conclusion on appropriate recommendations, intervening in detailed debate if asked to do so, ensuring that an appropriate, practical plan of action was prepared, authorised and

implemented.

Could you just tell us how you did that? Give us some examples of how you did that with the MSC?

A. Bearing in mind that -- I mean, it always sounds kind of pompous, this, and forgive me, but my relationship with the MSC was partly a mentoring one, partly a process consultant, if you like: what are these meetings supposed to be, do they have a beginning, a middle and an end, do we have an objective, are we measuring our performance? All of these things were alien to my colleagues.

So part of the answer to your question is I did it by cajoling and persuading and coaching. Yes? Part of my role with the MSC was clearly as their boss. So I would go into John's office and say, "John, I still haven't had any kind of recommendation from you guys on" -- I don't know -- "blood bag warning labels or optimal additive solution or the volume of blood donations, which was a big issue: did we takes 500 mls or did we take less?

Many, many things that I was looking for clear, specific and lucid guidance from the MSC I didn't get. Why? Because they were not used to committing themselves to clear, lucid and specific anything.

So I would do this by cajoling, or shouting at them

from time to time, but mainly I did it by dropping in on people, persuading people that, "You have got colleagues. If you think this, don't be bullied into not thinking it. Make your case. I'll support you."

So a lot of kind of process activity going on to try and help them get through and use the MSC more effectively.

Q. So you would speak to members privately?

A. Oh, absolutely.

Q. One-to-one?

A. An awful lot of that went on, yes.

Q. But you yourself didn't attend MSC meetings?

A. I did from time to time but I would try very hard not to. Remember, one was trying to coach and mentor one's team into fulfilling their own roles in their own right, and John Cash was moving from having been the head of the service, in titular anyway, to being an active, supportive, real medical director, leading an MSC that was going somewhere. So it was not a good idea to me to go bullying and intervening; I was trying to get the MSC to work as a team. But, yes, I attended some of their meetings.

Q. And they would be chaired by Professor Cash?

A. Always chaired by John, yes.

Q. Looking down the page, paragraph 1.10, you talk about

your personal involvement in Hepatitis C look-back and you say:

"With the benefit of hindsight I find it hard to understand why I took such a hands-off approach to [look-back]."

First of all I wanted to ask you what information is it that you have received that has caused you to look at this again? What's the hindsight that you are referring to?

A. Well, I mean, as the title of my witness statement implies, the biggest blinding flash of the bleeding obvious is Lord Fraser's letter. I didn't see that at the time. It's an extremely sensible, lucid, clear little synopsis of exactly what the issues were. Its only problem is its chronology.

The schedule you very kindly provided me with today is very similar. And this is all based on the Preliminary Report, which, by the way, I found fascinating. Your schedule is very similar to one I already wrote for myself, doing this, and it just screams at you, doesn't it? Here is a expert committee in the summer of 1990 recommending full look-back. In the autumn of 1991 a huge chunk of Scotland does it and everybody agrees it's the right thing to do, and then there is all this immense, meaningless guff about, "We

will have to consider it further and have another meeting and let's advise ... " What?

Finally, in January 1995 -- and I look back and I think, "David, you were involved in all this; what the hell were you doing?" So that's what I mean in my paragraph 1.10.

Q. Yes.

A. With hindsight, it makes no sense at all; it looks the most incompetent, blithering nonsense, whereas at the time, of course, it all seemed kind -- it reminds me of time lapse photography. You know, when you speed it up, it just looks completely ridiculous but, as it slowly unfolded, it all felt quite reasonable at the time.

Q. Yes. You now find it hard to understand why you took a hands-off approach?

A. Yes, I could have written a letter to Lord Fraser in the autumn of 1991 pointing out to him as a lawyer that he was going to be badly exposed. All the facts were there for me. I could have written it, senior civil servants could have written it, instead of which Mr Tucker is quoted as saying that we were resisting attempts in Scotland to do it earlier. Well, there were no grounds for resisting anything at all, other than English interference.

Q. Yes. I think we can tell from what you are telling us

at the moment and also from paragraph 1.12 that you regret not having taken a more hands-on approach?

A. In the context of this specific Inquiry on this particular issue, bearing in mind that there were probably 187 issues that I was dealing with at the MSC and that my overall goal was the health of the service as a whole, Scottish self-sufficiency, the safety of the blood supply and the adequacy of the blood supply.

If I was on trial, as it were, I think I would be defending myself by saying, "Well, you know, I regret this but it's only so much per cent of so much per cent of the wider issues," and maybe the greater good was in not quarrelling more directly with Professor Cash and not completely spoiling the gentle work I was trying to do to change the culture.

But that's very defensive of me. In your context I think I would just have to say what I said in paragraph 1.12.

Q. Sir, that's a good point.

THE CHAIRMAN: We will break there. Thank you.

(1.05 pm)

(The short adjournment)

(2.00 pm)

MR GARDINER: Yes, sir. We are just waiting for a transcript reference to be brought up.

Mr McIntosh, before we return to your statement, I would like to just refer you to some evidence which was given by Professor Cash on Wednesday and if we could go to page 149, please, so at the foot of page 149, if you can see there the question:

"Question: You see, I don't want to go into ..."

Do you see that, Mr McIntosh?

A. Page 149?

Q. Page 149, yes.

A. Yes.

Q. So this is a piece of evidence which is about you. So I'm just going to read it out to you. So the question is:

"Question: You see, I don't want to go into the differences between you and Mr McIntosh too deeply but he did say in his evidence that he essentially had no knowledge of the SHHD policy, that it was all rumours and gossip was the way he put it.

"Answer: I saw all that and I prefer not to get into -- it gets pretty messy. I was just astonished -- I mean, the thing that's haunting me with all this with David was that he was sacked. Now, I was told by a very distinguished lawyer that you don't sack senior health service ministers and he was eventually sent down the road with a hefty package with strings attached, and

I just do not know today, not that he is not telling the truth but what in fact he is able to say. All I know is when I read that, I just couldn't believe it."

The Inquiry has no particular interest in this point but out of fairness and to perhaps correct any inaccuracy, I would like to ask you very briefly about this, Mr McIntosh.

When did you leave SNBTS?

A. Sort of in the middle of 1996, as I recall. Just before my 50th birthday.

Q. Could you try and speak into the microphone?

A. I'm also trying to speak slower.

Q. Thank you. In that passage that we have just looked at Professor Cash asserted that you were sacked. Is that accurate or inaccurate?

A. That is inaccurate and I would like to emphasise, Mr Gardiner, that I'm not asking this Inquiry to believe me or to believe him. What I believe is that the record is very clear that I was not sacked and if further evidence of that is required, I am very happy to furnish it.

Q. Thank you. So is it in fact more accurate to say that your departure was by mutual agreement?

A. Yes.

Q. And is it correct that you entered into a written

agreement at that time?

A. I did, in common with anyone in a senior position leaving most organisations, I signed what is known as a compromise agreement.

Q. And is the content of your evidence to this Inquiry affected in any way by that written agreement?

A. It is not, nor could it have been. There is nothing in the written agreement that would in any way constrain me -- in any way that's relevant to this Inquiry.

Q. Thank you very much. We can put that transcript away.

A. I would, if I may -- given that Professor Cash has taken the opportunity, with the privilege of the Inquiry, to make these comments, I would point out that it's a little sad to see that in answer to the question, he didn't actually address the issue, he launched an attack ad hominem, which it seems to me is only further testimony to the weakness of his argument.

Q. Thank you. Could we just return to Mr McIntosh's statement at page 5 of [PEN0180358]? The question is:

"Why was the look-back not commenced earlier given that a screening test for anti-HCV was available from 1991?"

Perhaps you could just answer that --

A. I love the way you ask me to encapsulate pages and pages. I'm slightly embarrassed by the number of pages

that this took but it does seem to me that it was necessary to peel this like an onion, because the question is a very simple one but the answers are far from simple.

Again, I would assert that nothing I have said is anything other than an attempt to assist the Inquiry with evidence that is already before you. I'm not reporting things that are unique to my knowledge. I'm simply pointing out, (a) that we knew that it was desirable to do look-back, we know (b), that Edinburgh and the Southeast of Scotland did in fact introduce look-back, we know further that look-back was effective, was very well regarded, was thought of as a thoroughly professional and the right thing to do, and yet we failed to do it universally until January 1995.

Now, the reasons why are at many levels. Clearly the simple answer was, well, because nobody fired the starting gun. I'm still in the starting blocks here because I haven't heard the gun. Then the question is why wasn't the gun fired. And I think, going back to John Cash's evidence, it is messy, it's very, very messy indeed, which is probably why he didn't want to go into it. But I think I have set out here, as best I can, the way in which you unpick this one, and if I may, and not ducking this, Nick, but would you like to

lead me a bit and ask me the bits you would like to know more about?

Q. Yes. Perhaps you could explain to us how the procedure should have operated. We know that the committee had been asked to look at the question of look-back, the MSC.

A. I think this is fundamental to my point. I may be wrong. I'm not suggesting that I'm somehow omniscient in this matter but my fundamental point is: there was no way it was supposed to have happened. There was no proper procedure for making it happen. There was an inchoate fudge and fog of highly professional people, some of whom made a splendid contribution, others of whom just bounced around like a big ego in a box.

That's my point when I say it was all rumour and gossip. In managerial terms it was rumour and gossip in so far as it was not properly enunciated, the questions were not properly asked, and had they been, the answers would have been different. Instead, committees were thrown together to create answers, to not any particular question. And of course, they came up with all sorts of fascinating and wonderful stuff about why it may not be perfect, but that wasn't the point, was it? So it seems to me that what should have happened, which is not to say that this was the procedure that existed, but

looking back, what should have happened is the MSC should have sat down in early 1991, and said, "Well, in 1990 we were unanimous that this should happen. Why hasn't it happened yet, chaps? And if there is a good reason why it hasn't happened, can we list those good reasons and can we then do something about each one of them until it can happen?"

But they didn't do that, and it's my failing perhaps that I didn't kind of nail something to their church door and say, "Look guys, I want answers to these questions". And as I have attempted to pull out in my evidence here, the reason why things did not move forward is because there was a complex force field of people who wanted it to happen, who ducked. They left the field of battle. Edinburgh just left the field of battle. They said, "We are never going to persuade that lot. We will just quietly go and do it." That wasn't very helpful to the people of Glasgow was it? But nonetheless, it was understandable.

Now, John Cash in his evidence has said that he didn't have much to do with it expected to encourage colleagues to get on with it. Rubbish, we can see ample evidence that he had a lot to do with it, and what he did with it was to help it postpone, help it delay, stop it ever happening, re-referring it to committees after

committees after committees.

And really, reading that schedule that you gave me this morning, the evidence is just point blank absolutely obvious and completely shameful. You don't go to a committee three years later and ask it to have further thoughts and come back in six weeks. What? I mean, it's just an absurd.

I'm sorry. I shall get overexcited and go too fast for the stenographers again.

Q. How should it have operated ideally? You told us before lunch that the MSC were tasked with making recommendations to the board. If in 1991 and 1992 they had made a recommendation that look-back should start straight away, what would have been the process after that?

A. Well, we do have a little vignette of this, because I did write to the Scottish Office in 1994, in May, I think, and say that it was our unanimous view that it should happen and I was going to implement in June. This is relevant because you asked the question: what would have happened? Well, we know what happened.

Despite the best advice and the best professional facts, and despite the professional ethics, we were told, "No, thou shalt not," for reasons which were never put in writing, never even made clear verbally. It was;

just, "No, no, no, sonny. You just sit down and shut up. We will tell you later."

And we know now , I think, do we? Yes, I think we can certainly assume reasonably safely that this was all because the DOH in England had said, "No, no, no, keep those rebellious Scots quiet, please". Because it's much more difficult in England. The budget situation is much tighter. The complexities of digging in -- the second half of our algorithm that we looked at this morning. Much more difficult in England and Wales. "So please, for heaven's sake, don't let Scotland go it alone.

And nobody, of course, put a footnote and said, "Oh, by the way, half of Scotland has already gone it alone," because we had managed to pretend that that was a pilot study and therefore it didn't count. With the cold benefit of hindsight, the whole thing is just patently a sham.

Q. So the way it should have operated was that the MSC would have made a decision, they would have reported to the board that, "This was our recommendation". What would the board have done with that decision?

A. Well, I mean, what we should have done with that -- and in fact we were in a position to do that in that time in 1990, going into 1991, when there was a consensus

opinion and we had not yet been interfered with. And what we should have done was to lay out very clearly the argument that's in Lord Fraser's letter of three years later. No, it's not true that all you can do is distress them. There are now ways in which we can deal with this. There is Vivienne Nathanson's very lucid description of the medical ethics of it, and I think we could have put an addendum in that had exactly her words in. There was an ethical issue, there was a therapeutic issue, there was a public confidence issue and there was a legal issue.

And had we mustered ourselves in a proper manner, we would have put to ministers incontrovertible recommendation, but what is the role of civil servants? It is to avoid anyone ever putting before ministers such incontrovertible advice.

Q. Scottish ministers?

A. Absolutely. It has to be Scottish ministers -- I think I have made this point in earlier evidence -- that the Scottish health service does not report to the Secretary of State for Health for England and Wales; it reports to the Secretary of State for Scotland. So all of these matters for me are matters which must be seen in a Scottish context. And what Scottish ministers choose to do so in terms of their relationship with England is

entirely up to them, but we Scottish health servants had a responsibility to Scotland.

Q. Yes. Thank you. Perhaps we could move to question 5 in your statement, which is at page 9 of [PEN0180358]. This is in the same area that we have just been talking about. The question was:

"What, if anything, would he have done differently in hindsight?"

A. Yes, in summary the answer to that is I would have paid more attention.

Q. Yes.

A. Because I think it's clear with hindsight that had I really given this the priority that it probably deserved, the only conclusion I could have possibly come to was I needed a meeting with senior civil servants, and if I didn't get what I was looking for, I should have gone straight to ministers. I would have been duty-bound to point all of this out to them and didn't. So that's my short answer to the question. I would have (a) paid more attention, (b) paid less attention to all this guff I was getting from my medical and professional colleagues. Not all of them, a very small number of them actually. And (c) I would have gone much more seriously up the line to try and persuade people to move sooner.

And it's interesting, you see, that for all our differences, John and I absolutely share the same view on this. His evidence says what would he have done differently. He says, he would have pressed harder for an earlier implementation. So I think we are all agreed about that. We should have done.

Q. Yes. In your answer you refer to the letter from Lord Fraser. Perhaps we could have a look at that again.

A. Yes, I do mean my apologies to Lord Fraser here. I'm only using it because I think it's just a beautiful vignette of the whole -- it encapsulates the whole story beautifully.

Q. Could we just all take a moment to remind ourselves of the first page of that?

A. Could we scroll down to the -- yes, that's it. (Pause)

I think the only error of fact in here is the first line of the second paragraph, because whatever you call the Edinburgh activity, whether it be a pilot, research or an actual programme, whatever you call it, it is not true that it was carried out last year. So Lord Fraser was very, very badly advised in that respect.

Now, to be fair, it was only recently published. That's true. So, you know, I'm not saying this is completely out the window, but it is not true to say

that it was carried out last year. That is simply an error of fact. If you change that, and change the date of the letter, it's perfect. It should have been written in 1991.

Q. Yes. Although by that stage Dr Gillon wouldn't have completed his look-back.

A. He wouldn't have completed his report on it but he would have done enough of it that a listening minister would have said, "Right, we had better get on with it then, I think".

Q. Well, it might be helpful to have a quick look at his report.

A. Bearing in mind, Mr Gardiner, that the point that's being made by Lord Fraser here in the first sentence of his second paragraph is that it has been established that a look-back exercise would be feasible and practicable. Not that looking back at it years later, it looks like a fabulous report or we know what the follow-up, the death rates. No, just: was it feasible? Was it practicable?

Because I think we have heard from Vivienne Nathanson that if it's feasible and practicable, then there is a medical ethical reason for doing it. There are other reasons but I think -- we have got a very strong case here for we really should

have done it sooner.

Q. Let's have a look at Dr Gillon's report. It's [PEN0172376]. Have you ever had a chance to read this?

A. No, I haven't. To be fair. But, you know, it was received in November 1993. It was accepted for publication in July 1994. My focus of attention has been not on the reporting of these matters but on the doing of them, and the doing of them greatly pre-dates this report.

Q. Yes. I mean, if we look at the second paragraph of the summary, we see that the report is:

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

So that's the first six months of testing. If we go over the page, we see under the heading "Results":

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

Would you not agree with me that the very earliest that this look-back would be producing results that you could use would be the end of February 1992?

A. I would need to take notice of that question. Let's just think about -- can we think about it together?

I know from discussions with Brian McClelland that there was never any doubt in their minds that as soon as they introduced testing, they would introduce look-back

and therefore, I think -- I'm thinking aloud here -- that in the first week or two some look-back will have been undertaken.

I don't know where those 20 donors fell. Did they fall in week one? Did any of them fall in the first three months? I have no idea, but if any of them -- no, start again.

Whether they did or didn't fall in the first early period, the work that was done to make sure that look-back took place -- the building of the algorithms, the arranging of the systems, the procedures, the agreement with hepatologists -- they had meetings with their haemophilia directors. All of that must have pre-dated the start of look-back. Therefore I'm not sure that look-back has to be seen in tranches of months.

Had I been cross-examining this at the MSC at the time, I think I would have said, "Let's give it a month, guys," and then work comes out of Edinburgh, "Let's decide whether we use it to roll out or not". I don't think any of us thought we would need to wait -- certainly we weren't going to wait three years to see what Edinburgh did, but I'm also querying whether you are right that at least six months would have been necessary. The answer is: I don't know.

Q. Because part of the usefulnesses of this report is that it shows that look-back was feasible and was capable of being done -- well, relatively inexpensively and I would suggest to you that that wouldn't be apparent for at least some time after February 1992 because -- well, first of all you have to take the donations and then you have to start actually tracing the donors and so on. So I'm just wondering whether it's realistic to push the possible date of look-back, you know, back as far as you are suggesting.

A. Well, I mean, I think this is a very, very good point and I would love to hear you discuss this with Jack Gillon but let me say this to you: if practitioners in Edinburgh and the East of Scotland thought it was worth starting straight away and then doing their best to improve as they went along, why would this not also have been the case in Glasgow, Inverness, Aberdeen and Dundee?

I don't think there was any sense in which everybody in those other regions was just waiting with baited breath to see whether Jack could prove it was doable. I think Jack proved it was doable pretty much before he started. He then started doing it and things progressed from there, but I'm absolutely not saying this definitively. I'm suggesting to you that

a cross-examination of Jack might be useful here.

Q. We are going to hear from him next week.

A. Right, and whatever Jack says I will agree he is right, not me. I mean, I'm guessing.

Q. Yes. Thank you. We can put that away.

If we could go back to Mr McIntosh's statement at 0366, the question here is about what you would have done differently in hindsight and are there other ways that Lord Fraser's letter are useful to you in deciding that question?

I see that you separate out the different concerns, the concerns about the impossibility of finding all the exposed individuals.

A. Yes, I mean, again, with sincere apologies to Lord Fraser, it just seems to me that his letter addresses all the key points. Why did we not do it earlier? And there were those three reasons, I think. Was it three or four enunciated? Four. What I have tried to do, just cold bloodedly, is parse the sentences and analyse the facts, and none of those were reasons for delaying as long as 1994/1995.

So what I would have done with hindsight, I think, as I say, is to pay more attention. For a start -- you see, sadly there is no record of my having asked the MSC or having asked John Cash what were their reasons for

postponing. Maybe I asked and I didn't get an answer, but had I got the answer that's written in Lord Fraser's letter, which I think would have been the party line at the time, then I would have been in a position, as a manager, to cross-examine those assertions.

Q. Yes.

A. And I think with the benefit of hindsight, I would have to say that I would have found all of them wanting. And not only would I have found all of them wanting but I would have had no shortage of senior medical colleagues who would have supported that view. But the point I think I'm trying to make throughout all of this is that at no point did anybody sit down to enunciate this as clearly as that, which is why I have leapt on Lord Fraser's letter, because it's beautiful clear, whereas the MSBT or the ATT, whatever they were called, they didn't make anything clear. If they came up with answers, it was not enunciated and explained or justified. It was just "No, no, we are going to have another meeting in six months' time".

So with hindsight I think what I have said here and what I said in my evidence about testing -- and I'm sorry if this sounds terribly naive, but the management principle of: What are we trying to do? How would we know success if it punched us on the nose? What does

failure look like? These are simple things which managers know how to do, accountants know how to do, lawyers know how to do. My experience is that scientists, sadly, are very lacking in this.

John would always go on about scientific method. He was one of the most unscientific people I ever had the pleasure of dealing with. That is my fault. As manager of the service, I should have enunciated these things more clearly: what is it we are trying to do? Why are we not doing it now? Why, for heaven's sake, is Edinburgh doing it and not Glasgow?

I shouldn't have taken "no" for an answer on those things, which is not the point either, is it? The point is: can this Inquiry help future practice by encouraging people to get on with it?

You cross-examined -- sorry, it's not the right word but you were discussing with Vivienne Nathanson earlier about what was the protocol, what should have happened, and she had to give her best English language version of that. What? In the pharmaceutical side of my business there was none of that ambiguity. There was a standard operating procedure for everything, there was a box to tick for everything. You could not get a licence for blood products out of the PFC without a medicines inspector inspection. Did a medicines inspector ever

inspect the MSBT? No, no such clarity existed in that realm. That whole realm was foggy.

Q. In 1991 and 1992, if you had asked the question, you know, what is happening, what are we doing at the moment? The answer you would have been given, from your evidence this morning, was that, "We are doing a pilot study to see if it's feasible". Is that not the answer you would have been given?

A. I'm sorry, I think that is the answer I got and I seem to have accepted it, don't I? That, I should think, is the evidence. I might even have queried it and Edinburgh might even have said to me, "For God's sake, shut up, Dave, we don't want to be stopped". Because they had the Newcastle experience to go on. They might well have been stopped. So it's no wonder they weren't shouting.

Q. Yes. So you think that the Newcastle experience was in their minds?

A. It's very odd for people looking back at it from the 21st century but, yes, that Newcastle experience was harrowing. They practically hounded him out of the profession. Why? Because he did the right thing and showed up the others as not having done the right thing?

Q. So applying that to the "pilot scheme", what do you think might have happened?

A. What I have suggested in my evidence, I have done so very carefully because I don't know. I have spoken to Brian McClelland about this and he says he supposes it might be true but he can't remember -- what I'm suggesting is that, because of the difficulties that people had over HCV testing as such, the fact that they had installed a very successful and very efficacious look-back programme in Edinburgh when the whole of the UK had not yet ruled on the subject, left them very vulnerable to being asked to stop. And they did not -- sorry, I'm suggesting that it would have been very understandable had they kept a low profile in order not to stop. And therefore, though Jack says it wasn't a pilot study, my recollection is that Edinburgh was quite happy for it to be seen as a pilot study, because that was a very good cloak under which to go on doing what they knew to be right when the UK was still adamantly refusing to do the right thing.

Q. Yes. Could we have a look at paragraph 5.13? This is still under the heading of what you would have done differently in hindsight, and you pose the question:

"Why did ministers not authorise look-back in 1991?"

You say:

"Because they were not advised to do so."

And you talk a bit about transfusion professionals

and so on, and then in paragraph 5.14 you say:

"I do, however, believe that our opinion-forming and decision-making systems and procedures were faulty."

Do you think you could expand a little bit more on that?

A. Yes. I don't know how much -- how often you use Excel spreadsheets but occasionally when you use an Excel spreadsheet, a big warning comes up and says, "Circular! You are not allowed to do that. This cell cannot depend on that formula because it depends on itself." That's the problem with the decision-making process that I was living with in the 90s, in that John Cash would say to me, "No, no, the committee has not told us. I would love to go ahead, Dave, but it hasn't told us." Whereas in fact, what he meant was he wasn't ready, he wasn't going to do it and he certainty wasn't going to let a manager do it, so would I please just go away and play with somebody else's football. And when I write my force field analysis, it just seems absurd.

Any professional from any other discipline, whether it be accountancy or the law, would say, "David, don't be ridiculous. You are over 65, I know, but really, your mind has gone faster than most." But the fact is -- and you can see this from the evidence -- where is the written evidence which says, "We have considered

look-back but we have, for the following reasons, decided not to recommend it to ministers. We will be reconsidering it again in six weeks' time."

No, there is no evidence of any systematic approach to that decision-making. And it's a circular -- it's an Excel error. "Does everybody want to do it yet?" "No, not hard enough." "In that case we won't advise that it be done." "Have they manned the barricades yet?" "Well, yes, Minister, they are beginning to." "Oh Christ, then I think we had better take a decision. We will lead from behind but appear to be leading from the front."

I'm sorry, I overdramatise this for the purposes of illustration but am I making my point? If you were to ask me who was officially responsible for taking this decision in Scotland at the time, I would have to tell you it was careful contrived that absolutely no one was specifically responsible. The decisions emerged from this fog of consensus and opinion-forming blah, blah, blah, blah.

So with the benefit of hindsight, what I'm saying is it just would have been a lot better if things had been a lot clearer. If we had been able to say, "Well, everybody in Scotland has formally recommended that it should happen immediately but we have been told by

English ministers that we mustn't because they cannot afford it," managerially that would have been fine. Politically it would have been totally unacceptable. So you couldn't say that, you had to pretend it was because the committee hadn't decided or it was not yet desirable or, "Well, it wouldn't be perfect, you know". All of these arguments are adduced in situations where the real reason underlies them but can't be revealed.

Q. Yes.

A. That's my argument. I'm not arguing conspiracy here. What I'm arguing is total inefficiency in the way these decisions are taken. I hope very much that they are now taken much more effectively in the new Scottish context but if they are not, then clearly his Lordship has a tremendous contribution to make to the future conduct of such affairs.

THE CHAIRMAN: I'm not quite sure I have got that degree of authority.

A. But you see, it's very interesting, my Lord, because -- because this. What's the key thing in Lord Fraser's letter? The key thing is this report has been published. So you do not actually need a lot of authority necessarily. You just freed to blow the whistle. When these things are pointed out to people, they have got nowhere to hide. It just has to be

enunciated clearly. Their defence is the fog they create around themselves.

MR GARDINER: It's published in July 1994.

A. And you can be sure that careful arrangements were made to delay its publication until we could afford to react accordingly, because as soon as it was published, bang, it all happened. So why wasn't it published earlier or why wasn't an interim report published?

Q. How should it have operated then? Just to follow the decision-making process, the MSC should have decided, "We should implement look-back". They report to the board. What do the board do with that recommendation? Who do they then pass that on to?

A. Officially -- and you will have noticed this from various other testimonies, officially we should have notified the Common Services Agency who would then notify the department. But you will find that almost never happens. I would write to George Tucker or I would write to Archie McIntyre or I would write to Rab Panton. We tended to bypass the CSA on anything to do with this kind of issue.

Had it meant a big budget increase, I would have gone through Jim Donald. But most normally these kind of professional issues got handled direct between SNBTS and the department. So in answer to your question, the

MSC would have recommended to the board, the board would have endorsed the recommendation but added -- because this is where, as general manager, I would have had to add the issues, and I would have added the issues that were in Lord Fraser's letter. There is a legal responsibility here. The Secretary of State for Scotland may decide to agree with Mrs Bottomley but does he really want to? He has a responsibility here for Scottish patients and we would have enunciated all that a bit more clearly in the way that management can but medics don't normally want to, and I think that's right. And we would have then shoved it up the department and said, "Look guys, terribly sorry but we really think we ought to be moving on this. It will only cost us X. It has implications of cost Y for you guys, so sort yourselves out."

THE CHAIRMAN: I think you are reaching fifth gear, again.

A. I'm sorry, my Lord.

So we have the money. The point I'm making is we had the budget but there were implications for costs in other parts of the health service, and therefore we would have had to notify the department and asked them to signal back to us when they felt our colleagues, those in the bottom half of the algorithm, would be ready to cooperate.

MR GARDINER: Yes. Can we just take that stage by stage? We get to the stage where the board has endorsed the recommendation of the committee and then imagine it's 1992 or 1993. What do you do next? Who do you speak to?

A. We write to the department.

Q. The department, yes. Who would that be? Was there a particular person?

A. It would have been Rab Panton most normally.

Q. What would you be saying?

A. We would be enunciating pretty much what's in Lord Fraser's letter, but just two years earlier.

Q. What would happen after that?

A. They would phone me and say, "No, David, you won't be doing that". Which is what they did in May 1994. But hopefully, had one pressed a bit harder, they would have had to say "yes".

Q. Right. When you say "press harder", could you explain a bit more?

A. Well, written in stronger terms, asked Rab please not to just let people hide behind him, because he was fairly junior. One would have taken it up the line.

Q. Who would that have been, if you had been taking it up the line?

A. Well, George Tucker, Archie McIntyre and Lord Fraser of

Carmyllie. I would have been perfectly happy to go to Peter Fraser and say, "Look, I think you should know". Quite happy to do that.

Q. Assuming that you got a positive response, what would they do then to take look-back forward?

A. They would have done what Lord Fraser did in 1994. They would have written to the Home and Health Department, because they certainly would not have done anything like this without notifying. But what I like about Lord Fraser's letter of 1994 is that he is warning Tom Sackville. He is not asking him for permission. He is just warning him he is going to do it. That's very rare. The Scottish Office very rarely did that. And I'm proud of him for doing that but he should have done it earlier.

So what would have happened, had we persuaded him, he would have had to write such a letter and, as a lawyer by background, he would have been well placed to do so because ultimately his argument was that this is no longer a health matter; it's a matter of legal obligation.

Q. What's he warning him about?

A. He is warning him that, "We in Scotland are going to go mate, so you had better look to your laurels". Because as soon as we have done it, he wouldn't have had a shred

of -- he wouldn't have had a stitch of clothing to his name. He would have had to have just got on with it.

Q. Yes.

A. Sorry, do I make myself clear? The precedent would be such that were you a learned friend supporting a patient's interests in Wales, and you could say, "Well, patients in Edinburgh are getting looked after in this respect, you are not," I mean, game over. So the English would have had to take note, which is why Scotland would have felt obliged to warn them.

Q. But the decision of Scotland to go ahead with look-back wouldn't be dependent on the reaction?

A. Now you are asking someone who doesn't know. The Secretary of State for Scotland is not outranked by the Secretary of State for Health but they both report to the Prime Minister and if the Prime Minister -- the Secretary of State at that time, I think, was Michael Forsyth. If the Prime Minister had said, "Michael, don't embarrass us, don't do this," one imagines that Michael would have said, "Absolutely, of course, whatever you say". I have no idea what he would have said. You would need to ask him.

But the whole purpose of civil servants is to avoid that kind of crisis decision moment. They try to fudge it round so that somehow it all just happens by

consensus.

Q. So that's how it might have happened. How would it have been better in terms of a decision-making process? Do you have any recommendations that you might suggest to us?

A. When I say "better", I start off with the premise that nobody at any point in this process ever actually got the flip chart out and said, "Right, let's think about this logically. What's at stake? How many patients? What's the likely mortality? What's the cost? What's the incremental improvement in morbidity per pound?" None of that was done. It may have been done mentally and in the back shop, but it was never done clearly.

So what I'm suggesting first and foremost is that when you have an issue like this, you dissect it. If there is a committee that's responsible for this, it's responsible. There are terms of reference, there are rules of engagement. There is a timescale. The chairman has to whip the committee into getting itself together and making a decision, and when a decision is taken -- and remember a decision not to proceed is a decision. So when a decision is taken, reasons should be enunciated, not only for the sake of managerial clarity at the time but for the sake of the record.

And I think Vivienne Nathanson made a very good

point earlier when she said this is about public confidence, it's about trust and the relationship. Why did we not do this earlier?

The fact is, as you are discovering, there is no clear evidence as to why we didn't do it earlier. It is taking you hours and hours of painstaking work to find out. And when I say it should have been a better decision-making process, we should have been able to give you a little folder and said, "Here it is, here is the decision" -- and that schedule you gave me that you did for Aileen Keel should have been two pages long at the most, and it should have been no more than six months apart from beginning to end. And that's what I mean by a sensible decision-making process.

THE CHAIRMAN: Whose decision would it have been in Scotland at that time, in departmental terms, to roll out general look-back?

A. My Lord, there is some evidence on this in Aileen Keel's involvement. I don't know if you recall but there was a meeting with the SNBTS, which she attended, in which she said that she wasn't sure that the Scottish Office actually had a locus here and perhaps the BTS should do it itself. It then became clear, that, "Well, no, Aileen, that is not the way it is. We will tell them when to do it." It then became clear, "Well, and we

will only tell them when the English letters tell them". So when you ask me whose responsibility it was, I'm very sorry, my Lord, I just can't tell you.

THE CHAIRMAN: Let's go down the line just a little bit. When the rollout was announced in England, it was Ken Calman, then in his new position, who would roll it out. At this stage he would be the CMO in Scotland, would he?

A. Yes, he was. I knew him very well.

THE CHAIRMAN: Did he have a similar function in Scotland to what he eventually achieved in England?

A. I'm sorry, I'm thinking about your question and I'm trying to cast my mind back. Ken was not in post very long in that role. He had been in other roles and he didn't last long in that role. He moved on. He was promoted.

I'm trying to think of other examples of that kind of thing. You see, my immediate answer to your question, my Lord, is that actually I don't think he would have been involved. I think we would have just done it. I mean, you know, Edinburgh did it by liaising with key people in the stakeholder community -- the haemophilia directors, the health service trust executives, the GPs, primary care trusts. I'm not sure that we in Scotland would have felt it necessary to get

1 the CMO to send a thing out. I think we would have
2 probably done it on our own.
3 THE CHAIRMAN: But it involved all the hospital services,
4 lots of other practitioners and so on. Do you think you
5 would have had the authority to do that?
6 A. It wasn't an authority by then, my Lord, because
7 a consensus had emerged. We all felt it was a good
8 idea. So both -- it wasn't something that was being
9 imposed; it was, if you like, a kind of spontaneous
10 clinical development. Everybody in Jack Gillon's team
11 and associates thought it was a good idea. So they just
12 did it.
13 THE CHAIRMAN: Just because the team all think something is
14 a good idea, doesn't necessarily bind a manager.
15 A. No, it doesn't, I agree entirely. But I think what you
16 are putting your finger on, my Lord, is the fact that --
17 that's a very good question but there is no
18 organisational answer from the SNBTS and the NHS of the
19 1990s. There was no clarity about exactly who was
20 responsible and if you read Kenneth Calman's witness
21 statement, it is very interesting how little he says and
22 how far he distances himself from all of this.
23 THE CHAIRMAN: Yes, I make no comment on that.
24 PROFESSOR JAMES: Could I make a very brief comment. My
25 personal perception is that actually they were very

lucky and well served in Edinburgh because the blood bank and the blood transfusion service were coterminous, they were in the same corridor. And this is different from all the other transfusion services in Scotland perhaps, certainly from the West of Scotland and many of them, for that matter, in England, the majority again. An initiative of the sort you are suggesting for the whole of Scotland at an early juncture would have involved the goodwill and cooperation of, as Lord Penrose says, every hospital, not just hospital boards, every hospital in Scotland and a great deal of work in tracing patients and so on.

Actually far more work than had to be done in Edinburgh because of its very nice compact nature.

A. I --

PROFESSOR JAMES: So, just to finish, it would have been highly likely, in my view, that at least on the basis of "using his good offices", if, for no other reason, it would be a very appropriate thing for the Scottish CMO to announce that this kind of initiative was going to take place.

And I don't think that goes against a great deal of what you have said; it would have just gone up the medical hierarchy of the medical civil service, medically qualified civil service, in parallel with the

non-medical part of the civil service. That's speculation. But I just want to put to you that this was perhaps a rather bigger undertaking even for Scotland than perhaps you appreciate, for the reasons that I have kind of tried to enunciate.

A. Yes, sir. Your reasons are extremely valid. But I think much less relevant than you suggest. Let me explain what I mean by that.

In Edinburgh and the southeast, it's a big region, it has got some very large hospitals. Only one of them was coterminous with the SNBTS. The Edinburgh Royal Infirmary. Now, in Inverness the Highlands have really only got one major hospital, that's Raigmore, SNBTS blood bank coterminous with hospital. The East of Scotland, Dundee; really the East of Scotland has only got one major hospital, Ninewells. SNBTS blood bank coterminous with a hospital --

PROFESSOR JAMES: Between them there were then half a dozen other little ones, Fortrose and Elgin and so on.

A. Absolutely.

PROFESSOR JAMES: Who were all giving blood transfusions et cetera.

A. If I may just complete my analysis of your point, and it may not be pertinent, so shut me up if necessary.

There is no doubt in my mind at all that the

coterminous nature of the blood bank in Raigmore, in Ninewells and at Foresterhill in Aberdeen, represented a much larger proportion of the total regional blood use than the Edinburgh Royal Infirmary does of the total blood use in Edinburgh and the southeast. I mean, the Western General is an enormous hospital and there are many others also.

So, though I think your point is very valid in relation to England versus Scotland -- because the English are far worse off this way. Their blood transfusion services tend to be far distant from the hospitals. Professor Cash has supplied evidence in which he visited one hospital where there was an eight foot fence between the two of them. Your point is very valid when we are comparing the relationship between blood transfusion services and secondary care and tertiary care in England. With all due respect, I have to say to you that with the exception of the West of Scotland, to which definitely your point applies -- less so now because they are in Gartnavel, but they used to be way out at Law Hospital. They were not coterminous with the Royal Infirmary; they were not coterminous with Yorkhill or any of them. So your point in relation to the difference between Edinburgh and Glasgow is very strong but I have to say that it's not

an argument against the East of Scotland in Aberdeen or Ninewells or Inverness. And those are significant areas in which I'm sure there were patients affected, and where actually it would have been just as sweet as a nut to just do what Edinburgh did. For Glasgow not, I agree with you entirely. I hope that's helpful, with apologies.

MR GARDINER: Thank you. Could we have a look now at page 13 of [PEN0180358]? Figure 1 is something that you have produced for us, a flow chart that shows the forces at play influencing professional opinion and advice in favour of and against early HCV look-back 1991 to 1992. Could you just explain this to us, please, Mr McIntosh?

A. Yes, and apologies if it's clumsy but in answer to a very valid question that his Lordship asked me, like whose decision was it, my answer is it was the decision of this thing, this force field of opinion and ideas and suggestions. The point I'm making here is that at this point in 1991 and 1992, it was fairly evenly balanced. There was a large pressure coming from Edinburgh and others to move to the right, which is the big square arrow on the middle of the left there. There was huge pressure from the right, coming out of the UK solidarity movement and other issues, which was forcing it back to the middle. And then there was a fairly large group, of

which I have confessed I must have been one, who felt, "Well, look, we have got other fish to fry. We have got the Gulf War; we have got all sort of issues here. People are dying out there, for goodness sake, stop fussing us about the finer points of HCV look-back."

So there was a huge force of inertia in the middle. There were activists for action and there were activists for no action. What I'm suggesting is that that's as good a way as any of analysing what was going on and why we didn't move in that period.

Q. If we go over the page to paragraph 5.1, 5.3, you explain your diagram a bit more by saying:

"The block on the right in Scotland is best represented by Professor Cash and the colleagues who followed his lead."

Could you just amplify that, please?

A. Well, yes, I think the best way to amplify that is to refer you to Professor Cash's own evidence, in which there are a number of references to having, you know, just in the nick of time stopped people from doing inappropriate things, stopped McIntosh from having managed to get the thing done earlier. He talks about an MSC in which there were unusual carryings-on. John tended to describe things rather vaguely in a kind of ethereal, theatrical tone. But the whole tone of his

evidence is that he was fighting a rear guard action to try and stop hasty implementation of this thing when it couldn't be done universally in the UK. And my recollection of John's behaviour is now irrelevant because his evidence is very clear: he was trying to stop it.

Q. Yes.

A. I think it's clear but I'm only suggesting to you. It's your own documentation.

Q. We are going to hear from Professor Cash next week but in his statement on this topic, he has told us that when asked what he would have done differently in hindsight, he said that he wished he had pressed more vigorously against the conclusions of the ACVSB in 1991. So --

A. He agrees with me about that but if we read much of the other parts of his evidence, he, what I would call, confesses to having been instrumental in delay. So his various statements on this don't exactly add up for me, I think, but I can only draw them to your attention and you draw your own conclusions.

Q. Yes. If we have a look over the page at figure 2.

A. Yes, my main point in figure 2, and I'm sorry again if this is clumsy, but I hope it's illustrative and helpful. You notice that the big arrow moving from left to right is now gone, because Edinburgh is now at the

bottom there. Having got their own way, they have just quietly left the field of battle, which means that there was no chance of that force field moving to the right until the naysayers had changed their position. Because nobody in the middle block was going to make it happen and there was insufficient weight in the left-hand block to move it.

Q. Yes.

A. Now, that -- I do all of this and then the decision-making process, you know, this is the background to the decisions.

Q. At the bottom of that page you refer to the Newcastle experience and you suggest, as you have already done, that perhaps the Edinburgh team had that in mind in not publicising particularly what they were doing with look-back, but you seem to be saying in your flow charts that Edinburgh were advocating look-back --

A. They had been. In figure 1 they were.

Q. Yes.

A. But by the time we get to figure 2, the heading there is 1992 to 1994. By the time we get to there, they have stopped.

Q. And you think in part the explanation for that is, as you say in 5.16.2, because they had the example of Newcastle and they are concerned that that is something

that might befall them?

A. I do and I say that because I believe that that was the kind of mood and flavour of the relationship. And having shown me -- thank you very much -- Jack Gillon's testimony, I think you have given me a further insight into that. (a), he makes the point that he disagreed very strongly with Professor Cash. And anybody who disagrees very strongly with Professor Cash had better look out. So you duck your head having done that. And (b), he points out that John had decided to disguise it as a pilot. Well, if you have disguised it as a pilot, or at least if you have collaborated in the disguising of it as a pilot, you don't raise your head above the parapet and say, "Come on, we all ought to be doing it".

Q. I interrupted you when you were telling us more about figure 2. What else is different between figure 1 and figure 2?

A. Nothing, sorry, it's very simple. The dates and the absence of the arrow from Edinburgh and then the explanatory footnote that Edinburgh has bypassed the process and is no longer part of the force field.

Q. There is just one more point I would like to draw out in this answer. Could we go to the next page, 5211, that's the bottom of page 16. The context here is that you again are referring to Lord Fraser's letter:

"I consider that I had little choice but to take this forward in view of the position in Scotland."

In that paragraph, 5.21.1, you say that:

"I believe that the experts involved, including the expert advisory committees, often mistook their roles."

Could you explain what you mean there?

A. Well, it's best illustrated, I think, by looking at the scheduled, the one you prepared for Aileen, in which it's quite clear that the professional medical opinions that were relevant to this -- which were about microbiology, they were about testing, they were about the possible therapeutic benefits, they were about medical ethics -- that had all been done. There was absolutely no need to go back to a scientific committee at that point. All the matters upon which light could be shed by a microbiologist had long since passed. But because those committees were eminent committees of high powered professionals -- and don't take anything away from them for that -- because they were very good at one thing, they tended to assume -- and it tended to be assumed about them -- that they would be awfully good at other things. And the other thing that they were mistakenly spending weeks on in 1993, 1994, 1995 were matters to do with politics, to do with public health, to do with the law, nothing to do with microbiology ...

just nonsense.

And it's not their fault. Their terms of reference and the way in which things were referred to them were just totally misplaced. There was no room in 1994, for heaven's sake -- certainly not in 1994 -- to go back to expert committees and ask them for an opinion about implementation. What's it got to do with them? It's about logistics, it's about computers. It's nothing to do with them. And that's what I mean by "misplaced". It's this arrogant assumption by people who are awfully good at one thing that because they are so terribly bright, they must be awfully good at everything else.

Q. Does it not depend on the question that they were being asked?

A. Absolutely, and they were asked the wrong question. In fact I suspect they were asked no question at all. The matter was simply referred back to them.

Q. So a better procedure would be one where the question is more focused, the question that has to be answered?

A. Well, A better procedure would have been, "Dear minister, 87 committees have met 473 times on this. We don't need any more committees. We have come to the following conclusions: it should be done; it can be done. Could we please do it now?"

THE CHAIRMAN: That's perhaps a good point at which to ask

about doing something else. Can I ask about progress? I'm sorry to press you on it but I think it's fairly clear that time is getting short.

MR GARDINER: Yes. I doubt I will be more than half an hour.

THE CHAIRMAN: Yes.

A. Can I keep a left eye on you and if you are telling me to shut up, I'll stop. I'm just trying to respond to Nick's questions but I know I do go on, and I'm sorry.

THE CHAIRMAN: Well, one way or another we have to try and let everyone get away this evening with reasonable confidence --

A. I have nothing to say other than what helps you. So ask me the questions and then shut me up when you have got your answer.

THE CHAIRMAN: Can I ask about the others? Are you being provoked into activity beyond the norm, Mr Di Rollo?

MR DI ROLLO: I think on this particular subject, I'm probably content to hold the jackets rather than ask questions.

THE CHAIRMAN: I can understand that. The other person in the ring is likely to be Mr Anderson. Do you see your questions taking a long time?

MR ANDERSON: I don't think so.

THE CHAIRMAN: Really you should just put up the other

member of the boxing team and let them get at it perhaps.

We will break at this time.

MR GARDINER: Perhaps Mr Johnston will have some questions.

THE CHAIRMAN: I would have thought Mr Johnston's position was likely to be that, from my Olympian heights, this is all rather far down the line and it never got to me.

MR JOHNSTON: I will certainly reflect on that.

THE CHAIRMAN: We will have a break at that point.

(3.07 pm)

(Short break)

(3.30 pm)

THE CHAIRMAN: Mr Gardiner?

MR GARDINER: Yes, thank you, sir.

Could we have a look at [PEN0172550], please? This is the letter that you got from the Inquiry.

A. Yes.

Q. Do you see that? You have got a hard copy as well, have you?

A. Yes.

Q. If we could go over the page, under question 6 -- and this is actually the preface to question 7 -- we have got another short summary of events. We are now at May 1994 and I'm just going to take you through this quickly, Mr McIntosh.

A. Right.

Q. I'll just go through it now for all of us:

"On 18 May 1994. The SNBTS MSC met. The committee unanimously agreed that HCV look-back should be implemented. Dr Keel expressed a view that the SHHD may not have a locus in the matter and that the SNBTS should make a decision on look-back that was based on their professional judgment. However, she asked that no formal action be taken until she had been given the opportunity to discuss the issues with SHHD colleagues."

"On 19 May 1994, Mr McIntosh wrote to Mr Panton at SHHD. The SNBTS MSC had formally recommended that the service should implement a look-back policy without delay. He intended to activate the look-back with effect from 1 June 1994 but would not make any formal announcements until Tuesday, 24 May.

"On 24 May ... Mr McIntosh, Dr Cash, Dr McClelland, Dr Gillon and Mrs Thornton attended a meeting at SHHD. In a letter to SNBTS management ... Mrs Thornton noted that the SHHD were to consult with the DOH before a final decision on look-back was reached.

"On 30 May 1994 Mr McIntosh wrote to the SNBTS regional directors. In that letter he noted that no final decision on HCV look-back had yet been taken. The SNBTS would not be starting a full-scale programme until

1 further consultations had taken place ... agreed that
2 the preferred route would be ... a UK-wide policy ... on
3 21 June 1994, Dr Cash wrote to SNBTS directors
4 clarifying the position 'after the unusual events
5 following our last MSC meeting'. He noted that SHHD
6 approval was now necessary for the SNBTS to commence
7 a formal nationwide HCV look-back programme. As the NBA
8 would not move to consider establishing an HCV look-back
9 programme until it received advice from ACTTI, an
10 extraordinary meeting of ACTTI was to be called."
11 That's the context for the question which comes
12 next; which is:
13 "There appears to have been a significant change of
14 direction following the meeting between SNBTS and SHHD
15 on 24 May 1994. Prior to the meeting, Mr McIntosh
16 advised the SHHD that the SNBTS intended to commence
17 an HCV look-back on 1 June 1994; following the meeting,
18 he advised the SNBTS directors that the SNBTS would not
19 be starting a full-scale HCV look-back programme ..."
20 If we just go over the page, we will see the end of
21 that question. The question to you was:
22 "What was discussed at the meeting on 24 May 1994?
23 Who made the decision not to commence an HCV look-back
24 in Scotland on 1 June 1994, and why was that decision
25 made?"

To get the answer to that, we have to go to your statement, page 21 of [PEN0180358].

A. It would be fair to say, I think, that since that question was put and since I answered it, we have got some quite useful further testimony from others on the subject, including John Cash.

Q. We are interested in your testimony, Mr McIntosh.

A. Yes.

Q. So could you tell us what your answer to that question is, please?

A. Well, as I said, in 7.1 on page 21 of 25, with apologies to the Inquiry, I have to confess I have no recollection of this particular meeting, which is why I do tend to lean on other people's evidence.

I did say however, I think, somewhere, because it certainly is true -- this is absolutely typical. You will notice the timing. I wrote to them on the 19th, telling them that I would move if they didn't say anything by the 24th, following the time-honoured principle of giving them due notice, so that I could not be accused of not having warned them, but not giving them so much time that they really could do anything about it unless they absolutely, desperately needed to.

They responded uncharacteristically quickly. There are very few occasions when they responded that fast to

anything. And it's quite clear to me that they responded that fast because they felt in danger of the SNBTS upstaging the English service. This would embarrass Scottish ministers in the face of English ministers. And therefore they moved very quickly to Scotch this one.

What is interesting to me, though, is the fact that John's recollection of all this is that, ah yes, of course, McIntosh was told to sit down and shut up. There were these usual events at the MSC. He accuses me of misrepresenting the decisions of the MSC, but as your records show quite clearly, the SNBTS MSC unanimously proposed the implementation, and all I did was give effect to that.

But as soon as it became clear that our views might gel into action -- and back to my force field analysis -- the right hand square rallied its troops and we were stopped, bang in our tracks. So in summary, that's the answer to the question.

It became clear that the SNBTS was no longer going to go fudging along pretending it was waiting for the results of pilots. The SNBTS was no longer going to go willingly fudging along, waiting for committees to reconvene. The SNBTS was going to act on 1 June. It was therefore stopped from so doing, because this was

contrary to departmental policy because the department had, I believe, promised the English it would wait.

Q. I was interested to see in paragraph 7.1.1 that you referred to a "default tendency", which ceteris paribus -- I think that's "all things being equal" -- SHHD would want the SNBTS to act in harmony with the NHS in England and Wales.

Could you explain what your experience of this default tendency was?

A. The most shining example, the absolute classic, was when Virginia Bottomley was having difficulty with the Hypergammaglobulinemia Society, the people who suffered from immune deficiency. And there was a shortage of immune -- IVIGG, normal intravenous immunoglobulin in England. Caused by the deficiencies of the English service and their inability to collect enough plasma, among other things. There was a debate going on in England. There was a good deal of acrimony going on in England, and the body representing people with that deficiency was lobbying and asking and demanding.

Now, in the spirit of the point Vivienne Nathanson made earlier of public trust and confidence and particularly reassuring a vulnerable patient group, I drafted a letter to the head of the Hypogammaglobulinemia Society, reassuring him that

Scottish members, that is to say Scottish patients with immunodeficiency, were not at risk because we in Scotland had very adequate supplies of IVIGG. We produced more than we needed. We were exporting to England, as it happens. And therefore I was able to assure him that at least in Scotland he could be assured his members were not at risk. I drafted this note and sent it to the Scottish Office.

Within hours, I think, perhaps minutes, of its arriving, I was telephoned to be told I would not be sending that letter because no such letter could come from Scotland to that body until Virginia Bottomley, on behalf of the English health service, had approved it or authorised it, or in some way agreed that perhaps it would be all right if we sent it. And I duly postponed that letter until such time as I was given authority to send it.

That's the classic example but there were many others less dramatic. And I should say also, Mr Gardiner, that I'm not suggesting that this was the wrong default position. All things being equal, and as long as it wasn't of damage or against the interest of Scottish patients, I saw, and see, no reason why we shouldn't go simultaneously with the English. But the point I'm making here is that that was the knee jerk

default position and I suppose I'm suggesting -- and I think I am, yes -- accusing them of putting that knee-jerk reaction ahead of their local obligation to Scottish patients and their duty of care to Scottish patients.

Q. Are you therefore suggesting that this default tendency that you have identified may have contributed to the delay in introducing HCV look-back in Scotland?

A. I am personally convinced that it is not only the prime reason but it is absolutely the only reason why HCV look-back was delayed in Scotland. It was delayed as long as it was.

The point has already been made from here that clearly there were reasons why it was always going to be more difficult in Glasgow than it was in Edinburgh. So I'm not suggesting that we would have done it in Glasgow in September 1991. But what I'm suggesting is that, if left to itself, the professional opinion-forming, decision-making and acting mechanisms in Scotland would have gone much earlier had it not been for pressure from England, and had it not been for the natural tendency of Scottish civil servants to acquiesce to pressure from England.

And I'm further suggesting that Peter Fraser's letter of 1994 underlines that had he been advised

better by civil servants, he would actually have acted independently.

Q. But to acquiesce to pressure even if it was harmful to Scottish health; is that what you are saying?

A. My contention is that, with hindsight, it is clear that it was injurious to the best interests of Scottish patients. I do not suggest -- perhaps mostly for Mr Anderson's benefit. I do not suggest that at the time there was a deliberate decision to push Scottish patients' interests lower down the priority list. What I am suggesting is that that default position created a cosy acquiescence with England without a full understanding of the implications.

Q. Could you remind us when you arrived at SNBTS?

A. February 1990.

Q. Yes. When you arrived, did you initiate any protocols for the SNBTS communicating with outside bodies such as SHHD? Did you introduce protocols or guidelines that suggested that there should be particular channels followed, particular people speaking to particular people?

A. No, not that I can recall. Not that I can recall.

I think our relationship with other bodies was evolved rather than instructed, and I changed the structure of the SNBTS internally, which had

implications, obviously, on its outside communications. And our relationship, for instance, with the Medicines Control Agency, with the haemophilia directors, with the European Plasma Fractionation Association, with a lot of other bodies, was much more formalised and better managed. But in terms of our relationship with the Scottish Office, no, I think what I tried to do was to fit in with what seemed most comfortable to the Scottish Office.

Q. The reason I'm asking you, Mr McIntosh, is that we did have evidence from Professor Cash that when you started, you introduced a new policy, whereby he would no longer communicate directly with SHHD and that would be done by you; does that ring any bells?

A. I think it would have been the fervent hope of all colleagues in the SHHD that it was the case, but I never recall John feeling in any way constrained on this subject, and there is lots of evidence from him that he talked to Archie McIntyre frequently. No.

There were a number of people in the Scottish Office, and you can take evidence from others on this, who -- I think it was Mr Hamill who said, "McIntosh, you put the genie back in the bottle". He was delighted to deal with me rather than John. But, no, no, there were lots and lots of people who were

still dealing with John, and I didn't interfere with that because, I mean, he was a professional. He was my medical director, for goodness sake. Contrary to appearances, we did, most of the time, get on reasonably well. So, no, I don't recall doing that.

Q. Thank you.

A. He is saying that I stifled him, is he, gagged him or something? This is fairly typical.

Q. His evidence was just as I told you.

A. Right.

Q. Just a final question for you, Mr McIntosh. When we were looking at that chronology, the brief chronology in the letter, which we sent you, there was a reference to Dr Cash writing to SNBTS directors clarifying the position after the "unusual events following our last MSC meeting". Do you know what that refers to, "the unusual events"? Do you have any recollection of that?

A. Again, I would mislead you because I have read his testimony and I would have to accede to his interpretation. It just seems odd to me that the SNBTS MSC recorded a unanimous verdict and then somehow my interpretation of the unanimous verdict was an unusual event. So I'm a bit at sea, I am afraid, on that, I'm sorry.

Q. Professor Cash, in his statement that he has given us

for this topic -- I should in fairness put to you.

He has said that the unusual events following the last MSC meeting were David McIntosh's apparent rejection of the advice given by SNBTS professionals at the 18 May 1994 MSC meeting. So that's his interpretation.

A. Does he specify for us what he thought the outcome was? Because he implies by that, I think, that the outcome was that they decided not to implement look-back.

Q. Yes.

A. So the only interpretation one can draw. So here is the man who said that with hindsight, the one thing he wishes he had done was press harder for early introduction. But the triumph in May was that he had managed to stop McIntosh from encouraging earlier introduction.

Q. I think I had better show you this, in fairness to you. It's page 5 of [PEN0180353]. If you see there, it's question 8:

"What were the 'unusual events' following the last MSC meeting?"

A. This is the MSC meeting of 18 May, which in your schedule is recorded as having unanimously agreed that -- yes, here we are. This is 11 on A40359, page 5 of [PEN0172511]. I'll just read it, it will be quicker

and easier:

"The SNBTS MSC met on 18 May 1994. The committee unanimously agreed that HCV look-back should be implemented."

It goes on to say that Dr Keel expressed a view. So there are other witnesses that there was unanimous decision to implement, which is now described in what's on your screen here, by John Cash, as an apparent rejection of the advice. I'm sorry, I'm lost.

Q. So you wouldn't agree with that characterisation?

A. I can't try and agree with it. It makes no sense.

Q. Sir, I have no more questions.

Thank you very much, Mr McIntosh.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: I think Mr McIntosh has made his position clear, so I have no questions.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: I have no questions.

Questions by MR JOHNSTON

MR JOHNSTON: I actually do have some questions, descending briefly from Olympian heights.

THE CHAIRMAN: I trust not too deeply into the mire.

MR JOHNSTON: Mr McIntosh, as I say, just a few points.

I take it that you would accept that in taking their decisions, ministers, and indeed the department, would

be guided by the advice that came to them from the experts?

A. Yes, this is my circular error in the Excel spreadsheet point. Yes, they would take advice that came to them, but that was an iterative process. And then I would need to ask you: well, where do you think the advice was coming from? Do you see what I mean?

Q. I'm not sure I do actually.

A. Well, sorry. Restate your question and I will have another go.

Q. My question was this: I take it that you would accept that in taking their decisions, ministers and their department would be guided by the advice that came to them from the experts?

A. I need to answer that in two tranches, if I may.

I agree with you entirely that, yes, ministers were acting on the advice they were given. The department was not just acting on the advice it was given. It was generating its own advice; it had its own opinions. So in my experience, while ministers can stay in the Olympian heights, the civil servants can't. They were not acting just on advice, they were part of the decision-making and advising process themselves. That would be my view.

Q. Thank you. Those who would know most about the merits

and demerits of introducing the look-back exercise would not be the medical officers in the department, I take it, but rather those with expertise in the field themselves?

A. Yes, and I think that would have been the view taken by Scottish civil servants, both professional and non-professional, not necessarily in England.

Q. From your own point of view, would you accept that there could reasonably be a view that it was appropriate for look-back to be introduced throughout the UK at the same time, rather than in Scotland at one time and England at another?

A. Oh, absolutely. There was a very strong argument for when you introduce it in place A, you should also at the same time introduce it simultaneously in places B, C and D. What I would refute strongly is that there was any merit in delaying the majority of the population of these islands for nearly four years, in pursuance of this uniform approach.

Q. I see.

A. So it would be nice if we all arrived at once, but not if that meant delaying most people by three years.

Q. I think you made that point last time you were here.

A. Sorry.

Q. Can you tell us in your view when it is that clear

advice was first given to SHHD that look-back ought to be introduced into Scotland?

A. I think it was 1990, was it not, from the evidence? This was before John started to waver. The SNBTS directors made a formal recommendation in 1990, at least in draft form, but it's recorded here that the Inquiry does not have a copy of that final formal recommendation. But they do have a copy of the draft.

Q. Is this before your own time at SNBTS?

A. No, no. I think it's just after I came, just after. I don't claim any part in it.

MR GARDINER: It's here.

THE CHAIRMAN: Do you want the number?

MR JOHNSTON: I doubt if it's necessary, thank you.

THE CHAIRMAN: What's the number of it?

MR GARDINER: Draft number 4, sir, is [SNB0018803]. And that's a report for the national medical director. It's the Gillon report.

THE CHAIRMAN: Do you have the date of that draft?

MR GARDINER: February 1991.

THE CHAIRMAN: February 1991.

MR GARDINER: And the relevant bit, or the bit about look-back, is at page 7 of [SNB0018803].

A. And there is, I think, my Lord, a further reference to the SNBTS directors having accepted that report and

recommended look-back.

I think, for Mr Johnston's benefit, that that's the key point. This is a report from lower down but if the SNBTS directors evinced, not just a prejudice in favour, but a unanimous recommendation, I think that was the first time that this gelled.

MR JOHNSTON: Thank you. I think the document we have just looked at, however, is not advice to the department, it's advice to Dr Cash.

A. Indeed not. That's why I make the point.

Q. That's clear.

A. To be fair, Mr Johnston, it may well be that the department never saw the SNBTS directors' view either. Because that would have been entirely up to John to pass it on or not.

Q. Fine. Just, I think, one other point.

You mentioned towards the end of your evidence that pressure was being put on people by the Department of Health not to introduce look-back in Scotland. Assuming I have paraphrased your evidence correctly, can you give us your evidence about when you say that pressure was exerted?

A. Well, I mean, the smoking gun is this meeting in the department on 24 May.

Q. Right.

A. And Aileen has, I think, given us evidence on the same point and she, thankfully, remembers. I simply don't. I just don't remember it. It seems to me from the record that's the clearest moment when, you know, the chips were down and the gun was out, "McIntosh, thou shalt not".

Q. Thank you very much.

I have no further question, sir, thank you.

THE CHAIRMAN: Thank you very much.

MR GARDINER: No, thank you, sir.

THE CHAIRMAN: Mr McIntosh, thank you very much.

A. Thank you, my Lord, renewed apologies to the team. I have been too quick. And please send me the transcript; I will be happy to work on it.

THE CHAIRMAN: I think you may have to.

A. Thank you very much.

THE CHAIRMAN: Mr Gardiner?

MR GARDINER: That's it for today.

THE CHAIRMAN: I have one bit of housekeeping to raise.

I think it's the first time I have used that expression myself. Counsel should be aware and parties should be aware that next Friday, Friday 20th, may not be free time. If there is a need to make use of it, as matters build up next week, it would be my intention that we should sit on that day, even though there is no

business scheduled at the moment for that occasion.

(3.57 pm)

(The Inquiry adjourned until Tuesday, 17 January 2012 at 9.30 am)

I N D E X