Thursday, 24 March 2011

(9.30 am)

THE CHAIRMAN: Good morning.

MR MACKENZIE: Good morning, sir. The first witness this morning is Dr Gillon.

DR JOHN GILLON (affirmed)

Questions by MR MACKENZIE

MR MACKENZIE: Good morning, Dr Gillon.

A. Good morning.

Q. From April 1985 to date you have been a consultant physician in Edinburgh and Southeast Scotland Blood Transfusion Service and Department of Transfusion Medicine. Is that correct?

A. Yes.

Q. We looked at your CV last week and I don't propose taking you back through that. As a preliminary matter, doctor, the chairman has raised the question of seeking to pin down the various guidance documents which were in existence in the 1970s, 1980s and perhaps early 1990s, in respect of donor selection, manufacture of blood products and other matters and, doctor, I will undertake to produce a brief note specifying all the documents we are aware of, which I will then send to yourself and your colleagues for revisal or agreement. We can deal with that, I think, in that manner.

But perhaps as an overview or summary of the documents we are aware of to date, doctor, firstly we have seen NBTS guidelines and donor selection, essentially dealing with the collection of blood and the selection of donors, and we saw a 1977 edition. A second category we are aware of are notes on transfusion and we looked with Professor Cash at the 1973 edition, and that category of document, I think, deals with the use of blood.

A third category of document we saw with Professor Cash were DHSS standards for the collection and processing of blood and blood components, and we saw a 1979 edition. Fourthly, I think, there has also been discussion of a Handbook of Transfusion Medicine which came in later, I think, perhaps in the late 1980s or early 1990s. So there are, doctor, at least, four categories which I will specify in my note in due course.

I think in addition, doctor, the 1977 guidelines and donor selection. I think the guidelines are an NBTS document, ie the National Blood Transfusion Service for England and Wales. I think what we are perhaps missing so far in our bundle of documents is any Scottish documentary guidelines, in particular from any of the five Scottish transfusion regions. It may be that we

can both perhaps, doctor, do some further searches and thinking in that regard.

So that's really by way of a preamble, doctor. As I say, I hope the note that I will produce in due course in conjunction with you and your colleagues can try and specify these matters still further.

A. I'm not sure you mentioned the red book which came up in discussion from time to time yesterday and I think that needs to be pinned down exactly, when the first red book --

MR MACKENZIE: Perhaps do that --

THE CHAIRMAN: Before we pin down when, could we please pin down what it was, because it's quite clear that it is a description applied to documents which cannot be the same, if I can put it that way.

A. We can provide a hard copy of the book from its inception.

MR MACKENZIE: In short, what's the title of the red book?

A. The red book is "Guidelines for the UK Transfusion Services". I think that's correct.

THE CHAIRMAN: Just in general terms, is that what I might call the "Dr McClelland book" or is it something different?

A. No. It is a book that Professor Cash mentioned a lot yesterday. His role in initiating it in the late 1980s.

We haven't had time since yesterday to look out the hard copy, but I think it dates from 1989 or thereabouts and we will pin that down. That is guidelines covering the whole of transfusion centres' activities really.

THE CHAIRMAN: But when you do look at this whole issue, it would be a great help if you could interpret the references to the red book at much earlier periods in the documents, because I think that's where a lot of my confusion started.

A. I think -- yes, I noticed those comments. I think they mean orange guide rather than red book, because the orange guide was the guide to good manufacturing process. I expect that sometimes that was the confusion.

THE CHAIRMAN: Perhaps "orange book" is not an expression used much in the West of Scotland.

A. Indeed, maybe in certain quarters.

THE CHAIRMAN: That's perhaps an inappropriate comment.

So it was Dr Mitchell who started it off. Right, Mr Mackenzie.

MR MACKENZIE: Thank you, sir. Could we now, please, doctor, turn to your statement, which is reference [WIT0030129]. The next page, please.

You set out some helpful biographical details. In short you explain that you commenced training in

internal medicine initially and became interested in gastroenterology. Over the page, please, paragraph 1.3, we see that in 1983 through professional contacts with Dr Brian McClelland and Dr Peng Lee Yap you became aware of the challenges facing the blood transfusion services as a result of hepatitis and AIDS. At that time you had almost completed your training and begun the search for a consultant post. The post of consultant responsible for the selection and medical care of donors in the Southeast Blood Transfusion Service was then vacant and after discussion you agreed to an informal rotation to that service during late 1983/early 1984 with a view to deciding whether you might be interested in a career in transfusion medicine. In short, you were.

At paragraph 1.5 we can see you spent three months of a training period abroad. You list the various individuals and bodies and centres that you saw during that period, including, in particular, the community blood centre in greater Kansas City under the direction of Dr William Bayer. You were involved in the question of the introduction of testing for HIV, which was, presumably, being considered at that centre.

In paragraph 1.6 you then, during your final month in the US, you travelled round various centres. We can see in Washington DC. Over the page, you met

Dr Gerard Sandler and Dr Roger Dodd of the American Red Cross and others, and also you spent some time at the National Institutes of Health, where you met the director of the blood bank, Dr Harvey Klein and also Dr Harvey Alter.

Then 1.7, you also travelled to the centres for disease control in Atlanta, Georgia for discussions on epidemiology of AIDS and hepatitis. That must have been an interesting time, doctor, to be travelling round these centres?

A. It was fascinating actually and it was -- I guess the crucial time in transfusion medicine in the United States was just about when HIV testing was about to be introduced and the realisation that non-A non-B was a more significant problem than perhaps had been realised previously. One of the most interesting things then was the visit to the CDC in Atlanta, which was partly to look at HIV epidemiology, because that was the equivalent of HPS in Scotland, HPA in England, as they now are. But what I hadn't realised ahead of time was that they had a major laboratory research project going on there, to look into non-A non-B hepatitis.

I don't know if this is are a digression but it may interest you to know that one of the researchers I spent time with was called Dan Bradley and he described to me

the process that would ultimately reveal the virus which caused non-A non-B hepatitis. And that was the culmination of years of work, when, starting in the late 1970s, researchers in the various parts of the world really established a research community, trying to track down this virus and sending each other samples which they regarded as pedigreed from patients with post-transfusion hepatitis, presumed non-A non-B, and trying to use conventional test methods based on the serum from other patients with hepatitis to show an antibody/antigen reaction. Nobody could do it. It was line wine tasting, it was totally subjective and it was almost always wrong. You couldn't tell using conventional methods which was the real sample and which was the control.

It was after years of passaging the material from patients infected by blood transfusions, through chimpanzees whom they had immuno-depleted, that they arrived at what they thought was a superconcentrated version of the agent causing this condition, which they thought was a virus, it could pass through certain filters, and they were then ultra-centrifuging it.

It was like listening to a Horizon programme. It made no sense to me. They were looking for bits of DNA that matched or didn't match this, that or the other DNA

probe. Four or five years later and a couple of Nobel Prizes later, we saw the result of that in the paper from Houghton and others, from Chiron, in science, which was a description of the virus.

Q. Thank you, doctor, I think that is very interesting background. I think we will come back to that topic in due course, thank you.

We can see that you did produce a paper setting out your secondment to the US in appendix 1 of your statement. We don't need to go to that but I'll provide the court book reference. It is [PEN0100326].

Returning then, to paragraph 2 of your statement, you then address the issue of the acceptance of blood from higher risk donors, in particular prisoners. You explain that you took up your post as consultant in Southeast BTS on 1 April 1985 and that your first attachment to Southeast BTS was an informal rotation for a period of approximately six months from late 1983 to early 1984. Your role at that time was essentially that of an observer but you were allowed to attend virtually all departmental meetings and discussions.

You say:

"In the course of meetings and discussions, I recall that the issue of accepting blood from prisoners, ie scheduling blood donor sessions in prisons and

correctional institutions, was still being discussed at national level, although I was aware that SEBTS had discontinued these sessions some years earlier."

So, doctor, when you were there in late 1983/early 1984 and were aware of discussions about collecting blood in prisons, can you indicate the nature of those discussions?

A. What I can recall with absolute certainty is that during that part of my observational period -- training if you like -- I spent some time in the donor office finding out how we scheduled blood donor sessions, how we went about collecting enough blood from day to day. I'm certain that that's when I heard that we used to go to Saughton. So by then in Southeast it was a dead issue, really. But I think I can recall mention at meetings and so on where Brian McClelland was feeding back to us from what was going on nationally, that there was still a bit of an issue, but more than that I can't recall.

Q. At the top of page 5 of your statement, three lines down, you say:

"I therefore had no first-hand knowledge of the discussions leading to the adoption of this policy, nor the correspondence in other matters referred to in certain paragraphs of the preliminary report."

On to paragraph 3. You were asked to consider

whether the SNBTS accepted the recommendation in the second Maycock report in 1975 in relation to the acceptance of donors with a history of jaundice or hepatitis, who had tested negative for Hepatitis B and whose episode of jaundice was more than 12 months previously. Again you explain you had no first-hand knowledge of that, of course, because you weren't with the service at the time. But you did do some research on the historical position. Then paragraph 4, you were asked to consider:

"The consideration given by the SNBTS between 1975 and 1991 to the exclusion of donors at a higher risk of transmitting NANB including the exclusion of donors with a history of jaundice or hepatitis."

Again you explain that you have no first-hand knowledge of the period from 1975 to 1981 and have had to rely on archive documentation. You explain in paragraph 4.1 there is documentary evidence that the policy of accepting donors with a history of jaundice was implemented in SEBTS by 1982:

"It is apparent from the documents in the archive, the file of donor selection materials compiled some years later, that all five Scottish regional transfusion centres had adopted the policy by 1983 at the latest."

But you also explain:

"The earliest date of implementation is unknown as no such documents exist from the years prior to 1982."

In terms, doctor, of the SNBTS archives of donor selection guidance documents, does the archive really start in 1982? Is that when you were first able to find records relating to these matters?

A. Yes. The archive was compiled retrospectively. I think some time around 1990, when Mairi Thornton was appointed national donor services manager she compiled a historical archive from the individual archives in the five regional centres and that is the file to which I have referred here, and I can find no materials with specifics about donor selection procedures prior to round about 1982.

It is hard to be absolutely precise about dates because none of the forms have dates on them at that time, but we can infer from some of the surrounding materials, for instance, the one that was shown yesterday from Glasgow and the West of Scotland which had a sticker about AIDS on it. Which indicates that was a form which must have been in existence in 1983 and the accompanying comment was that it was about to be revised.

Therefore, we could assume that was in use in round

about 1982 and all of the forms by then -- so what we are talking about is the forms that were used on the blood donor sessions and they all have a statement in all five regions that a history of jaundice in the donor would not disqualify so long as it was 12 months previously.

Q. Yes, and you are, I think, doctor, able to speak to the practice after 1985, after your arrival in the service. In paragraph 4.2 you explain:

"In spite of the intense focus from 1983 onwards on donor selection as a vital safety measure in response to the threat of AIDS, the policy of accepting donors with a history of jaundice seems to have received little discussion between 1985 and 1991, though there was a discussion among SNBTS directors based on a paper presented by Dr Brian Dow in 1986."

You then explain:

"In the draft guidelines on donor selection dated May 1987, the wording had changed to allow acceptance of donors with a history of childhood jaundice, later clarified as before the age of 12, without further qualification."

If we could look at that document, please, the reference is [SNB0066410]. This document is dated in the bottom right-hand corner, November 1987. The title

is "Guidance for the selection, medical examination and care of blood donors". Who authored this document, doctor?

A. I think this was the first attempt by us to produce a single comprehensive document for SNBTS, which would supersede the individual -- it has to be said, similar documents in all five regions, which were in place from the time that I had first come into the BTS.

So from 1983/1984-ish I knew that each individual region had its own guidelines which were present on the donor session for the doctors and nurses there to use and refer to.

So we were trying to bring that together and Professor Cash asked me to review all of that and I produced a report late in 1985, which wasn't a total success, it has to be said. I was a bit green and I think me going into the various centres and trying to suggest that we should pull all this together -- I think perhaps people took the underlying assumption that it was going to be the Edinburgh document that would supersede all others, which was not necessarily going to be the case. But it took a while to get from that point to 1987, when we produced this first draft, and then that went through various further drafts and I think was issued in 1988.

Q. Thank you, doctor. We will come back to look at your report, I think, you made in 1985 in due course, but simply sticking with this document, if I may, if we can go, please, to page 6418, and look at hepatitis, we can see the document states:

"Childhood jaundice/hepatitis with full recovery, accept.

"Hepatitis/Adult jaundice, defer and obtain more information from GP. If not Hepatitis B, accept one year after full recovery. If donor is known to have had Hepatitis B and wishes to donate, should be referred to the centre for individual consideration."

Can you talk us through that guidance, please, doctor? What exactly does it mean?

A. This is fairly strict compliance with the policy that was promulgated post 1975, if you like, which at some point was adopted as SNBTS policy; that is to say that people presenting as donors who had had hepatitis in the past could donate provided it was more than a year in the past and they had no evidence of Hepatitis B.

This implies, however, that the staff on the session could take the donor's word for it that it was not Hepatitis B. I don't think we ever operated that policy and the wording of this had changed, I think, by the 1988 document to make it more explicit that all of these

should be referred to the centre for further consideration. In fact, that was built into this in the sense that when the session staff produced what was known as a GP letter -- in other words they would defer the donor on the day and say we need to get more information from your GP -- that automatically referred the matter back to the doctors in the centre. So it was only once the information came through -- and the system still exists today, from the GP -- that the doctors in the centre could make decisions about the acceptance or permanent deferral of that donor.

Q. If a donor had presented who had a history of jaundice as a result of non-A non-B hepatitis, would this guidance prevent their donation being accepted or would their donation go through based on this guidance?

A. It's quite hard to imagine a situation where we would end up with a history of a donor having had jaundice as a result of non-A non-B hepatitis. That's a very rare event. But if that happened, say in the context of a patient who had a transfusion and then developed jaundice and no other cause was found for it, we would not have accepted that patient as a donor at a later date.

Q. You say that it would be a very rare event for someone to develop jaundice as a result of non-A non-B

hepatitis. If it isn't within your field then please say so, but are you able to tell us approximately what percentage of people who contract Hepatitis C developed jaundice?

A. I have looked at the literature and it is very difficult to get a figure for that in fact. Most papers talking about, for instance, post-transfusion non-A non-B hepatitis don't mention jaundice as a factor. In the very earliest papers from the TTV study, the cohort of post-transfusion patients identified at the NIH and other places in the United States, I think there is a comment about jaundice being infrequent but I couldn't put a figure on it. It is a very small figure and I think most authorities accept that jaundice is an occasional but rare feature in non-A non-B hepatitis.

Q. Thank you.

THE CHAIRMAN: Doctor, can we just pause on the document for a moment. A recurring concern of mine is that the use of the expression "hepatitis" communicates different things at different periods. Now, in this document we have a reference to childhood jaundice/hepatitis and then "hepatitis/adult jaundice". At this time what would have been understood within SNBTS about hepatitis from a reference like this?

A. In this setting, the donor setting, it would be

understood that this was clinical hepatitis, of which the main feature was jaundice.

THE CHAIRMAN: So it is jaundice of which there are clinical signs?

A. Yes.

THE CHAIRMAN: Typically jaundice, which would characterise the condition?

A. Yes.

THE CHAIRMAN: But Hepatitis B, of course, would have been identified in some cases by testing?

A. That's correct, because as we now know, and indeed knew by the late 1970s, I guess, the vast majority of even Hepatitis B is clinically silent.

THE CHAIRMAN: But the person would in fact have had a certificate of some kind from the test, not paper but knowledge from the test that there had been a positive test at some stage.

A. Possibly. This wouldn't be a very frequent event.

THE CHAIRMAN: Mr Mackenzie?

MR MACKENZIE: Thank you, sir.

Doctor, returning, please, to your statement. To complete the end of paragraph 4.2, you say:

"This is likely to have been the outcome of the SNBTS directors' discussion referred to above and will also have been influenced by the data in the letter

published in 1982 by Barr et al".

That reference, please, is [PEN0140067]. While we are waiting for it to appear, doctor, I should say that, if we look at the bottom right-hand corner, we can see the authors are Mr Barr and others, including Dr Dow, and we will come back to go over some of these papers with Dr Dow as he is the co-author of a number of them. If we can look at this one, we can see that is a paper, or rather a letter, in the British Medical Journal of 23 October 1982. We can see that from the very top of the screen. Can we scroll down, please?

Can we then go to the body of the letter, please?

It is headed "Blood donors with a history of jaundice". The authors write:

"The leading article from Dr P M Jones reopens the question of whether blood from donors with a stated history of jaundice are safe for transfusion. In an earlier studies from the West of Scotland we found that these donors were much more likely to have had an infection with Hepatitis A virus than with Hepatitis B virus. In addition, we found that a history of jaundice was no more common among carriers of Hepatitis B surface antigen and hence was of little use as a marker of Hepatitis B activity. A history of jaundice is obtained from 2.8 per cent of blood donors in the West of

Scotland. Alter's American figure is hardly relevant to the UK. We have now studied a group of donors according to the age at which the jaundice occurred. Almost all the episodes of jaundice occurring before the age of 13 years were due to Hepatitis A infection but about 20 per cent of those with jaundice in adolescence or later had no markers for Hepatitis A or B. Other viruses can cause jaundice, for example Epstein-Barr virus, cytomegalovirus, Coxsackie virus, adenovirus and many other agents can cause liver problems. We cannot, therefore, equate unexplained jaundice with infection caused by the elusive non-A non-B viruses. Indeed, it is uncertain whether sporadic non-A non-B hepatitis is caused by the same agent as the form of the disease transmitted by transfusion and it is not known how often a carrier state follows sporadic infection. Furthermore, it is possible that, as with Hepatitis B, clinical jaundice may be an indicator of the elimination of virus rather than carriage."

Just beneath the table:

"The risk of post-transfusion hepatitis at 10 per cent is an American estimate and cannot be extrapolated to European transfusion services. In the last thee years this region as transfused nearly 400,000 donations of blood and derivatives. Only 12 cases of

overt post-transfusion hepatitis, possibly attributable to non-A non-B agents, have been notified. Of these, four were haemophiliacs who had been receiving imported blood products in addition to Scottish large pool factor concentrate. None of the donors involved in the eight cases associated with red cell transfusion have given a history of jaundice."

The final column:

"As the sensitivity and specificity of serological tests for non-A non-B carriers have yet to be proved, we could find ourselves excluding 2.8 per cent of donors because of a history of jaundice, perhaps 2 per cent because of serological findings, and a further 3 per cent on the strength of alanine aminotransferase concentrations. The use of alanine aminotransferase concentrations has not been validated for UK volunteer donors."

We start to see a reference here to surrogate testing. Then the authors conclude:

"The present British policy appears to be correct and any change could cause a serious loss of blood products when some regions are still struggling to make 80 per cent of the blood plasma they collect available for Factor VIII production. We endorse Dr Jones's encouragement to doctors to report all cases of

post-transfusion jaundice."

So that's an example, doctor, of the consideration which was given by the SNBTS to the question of accepting blood donors with a history of jaundice at the time. On the basis of those findings there was certainly not found to be any reason to revisit the policy of accepting donors with a history of jaundice who were negative for Hepatitis B.

A. Except in as much as I think this is what led us to start accepting donors who had jaundice below the age of 12.

Q. Because?

A. Because effectively they had demonstrated that that's all Hepatitis A really.

THE CHAIRMAN: Would that view have been held throughout the SNBTS or does it reflect a particular attitude from a particular region?

A. I don't know that I could speak for all five centres but clearly it was the view in the West of Scotland. It was the view in the Southeast as well. I'm sure that we were operating that policy probably prior to that 1986 meeting of the directors. But I have no documentary evidence of that.

THE CHAIRMAN: And it refers, of course, to overt signs of jaundice.

A. Yes.

THE CHAIRMAN: Which we now know wouldn't have been expected in NANB hepatitis.

A. You wouldn't expect that, no.

MR MACKENZIE: Thank you, sir.

Going back, please, to your statement in paragraph 4.3 you explain:

"Until a test for Hepatitis C became available, the epidemiology of non-A non-B hepatitis, as it was then known, was poorly understood. By far the commonest cause of jaundice in the community was Hepatitis A, the common cause of childhood jaundice, and this was known not to be transfusion-transmitted once the acute illness had resolved (hence the 12-month exclusion from blood donation). In the 1980s, Scottish transfusion centres were receiving very few reports of post-transfusion jaundice/hepatitis. For the most part, the concern in such cases was to exclude Hepatitis B for which there was a test."

To pause there, doctor. It would be unsurprising that Scottish transfusion centres were receiving very few reports of post-transfusion non-A non-B, or as we now call it Hepatitis C, given, as you say, that very few people will develop jaundice as a result of contracting that virus.

A. That's correct. Most post-transfusion hepatitis would have gone unrecognised.

Q. We may come back to look at this question after the summer on surrogate testing.

Then at the bottom of page 6, paragraph 4.3, you say:

"I have no recollection or knowledge of the discussions which led to the amendment to the policy which led to the acceptance without qualification of donors with a history of jaundice occurring before the age of 12."

Paragraph 4.4:

"It is highly probable that the decision to accept the earlier recommendation on donors with a history of jaundice was influenced by the work in the West of Scotland ..."

That's the article we have looked at, the letter by Barr et al in 1982:

"... in which it was shown that 2.8 per cent of donors in the West of Scotland had a history of jaundice. Ninety-nine per cent of those whose jaundice occurred before the age of 12 had anti-bodies to Hepatitis A virus compared with 55 per cent of those with jaundice after 13 years of age. Thus, virtually all jaundice occurring before the age of 13 years was

due to Hepatitis A. About 20 per cent of donors with a history of jaundice in adolescence or later had no markers for Hepatitis A or Hepatitis B. The authors pointed out that many other viruses can cause hepatitis in the community ..."

We have looked at them:

"... and that many other agents can cause liver problems. Therefore, though indirect, this evidence suggested that the putative agents carrying NANB would only likely be present in a small minority of donors with a history of jaundice and this was later borne out by the SNBTS experience after HCV testing was introduced in 1991."

There is then a reference to a paper published in 1994 by Crawford. Again, we will come back to this later in the Inquiry, but in short, of the donors who were positive for Hepatitis C antibodies after the introduction of screening in September 1991, only 5.9 per cent of those positive donors had a history of jaundice, and it is not known what proportion of these occurred in childhood. There is then a reference to the work of Dr Dow in his PhD thesis. Again, we will come back to that perhaps, but Dr Dow:

"... showed that few donors with a history of jaundice had levels of ALT greater than 92 units per

litre. That's 0.2 per cent of donors with a history of jaundice. This compared with prison donors (0.96 per cent), and intravenous drug users (18.4 per cent)."

Over the page, please, question 5 then asked:

"The procedures in place within the SNBTS between 1975 and 1991 for the exclusion of donors at a higher risk of transmitting NANB hepatitis, including the exclusion of donors with a history of jaundice or hepatitis."

You explain in paragraph 5.1 that during your informal attachment to the SEBTS from late 1983 to 1984 you were able to familiaris yourself with the procedures in place for the selection of appropriate donors:

"The process was at that time heavily reliant on the donor volunteering any health or behavioural issues which might have been relevant, prompted by a form which listed the conditions which might debar or defer them from giving blood."

Doctor, I think you referred earlier to having attended donor sessions during this period?

A. Yes, indeed.

Q. Can you just explain what happened in terms of the interaction with donors and what questions they were asked and what leaflets or documents they were given?

A. At that time it all depended on a single form, which was the donor session record, and I'm speaking here for practice within Southeast Scotland. I didn't visit donor sessions in other regions at that stage. But I think the process was broadly the same, given that we have looked at the documentary evidence although the forms look a bit different.

So the donor was presented with a form which welcomed them and outlined the conditions that might debar them from giving blood. That was not presented as something that they had to give specific answers to by ticking a box or saying yes or no. That form also identified the donor and asked the donor to sign. But it contained no specific questions to which they had to give any sort of written answer.

There was no attempt at that stage to ask those questions directly. There were general questions asked about health but it was not until the late 1980s that donors were specifically asked directly the questions that were on the form. Until that time it was always done by a written statement and signature from the donor that they were fit and well.

Q. Yes. So you are talking about the period when you attended sessions in late 1983/1984?

A. Yes.

Q. Essentially, was the donor given a form and asked to read it?
A. They were asked to read it and sign it, yes.
Q. And sign the form as well?
A. Yes.
Q. And was the signed form then given back to those undertaking the donor session or what happened to those signed forms?
A. Yes, the forms then followed the donation and the donor through the process and came back into the transfusion centre, where it was separated into -- well, it was separated at the session into two parts, one part which accompanied the donation back into the laboratory side and the other part, which was the donor's personal details, which went into the donor office. In the case of a new donor, that would give rise to registration in the formal sense on the computer system, as it was by 1983/1984. We had the computer logging all details of donors by then and in the case of a previous donor it would be to update the details and make sure that the details matched what was previously known about that donor.
Q. I'm not sure we have an example of that form, doctor, but we do have this document at [PEN0131395]. This form is from Glasgow in the west and appears to be

dated June 1983. I think you have seen this form before?

A. Yes.

Q. Is this similar to the type of form you have just described or is this a different type of form?

A. It is similar but actually just seeing this and describing the process has jogged my memory. I'm almost certain in the West at the time they had a separate session record form, where the donor signed on a single sheet. All the donors signed their details on this sheet.

Q. In the West?

A. In the West. I think that's the way they did it rather than have the forms signed.

Q. So the form we are looking at now on the screen, is that similar to the type of form you have just described in use in the East?

A. In terms of its content, yes.

Q. Yes. And would the donor sign that page of the form or a different page?

A. My recollection is there were various versions and updates of the forms but by and large the system we used in the Southeast had a detachable bit at the bottom, which was the donor details and signature.

Q. Thank you.

Now, could we go back, please, to your statement from, I think, page 8. We have reached paragraph 5.2 where you explain that:

"At that time I had no knowledge of the procedures in place in any of the other Scottish centres. I was aware that the regions were essentially autonomous, interpreting national guidelines and producing and printing their own materials. Review of the historical archive shows that the system was essentially the same in all regions, though the printed materials look different. The earliest such documents to survive are individual session records from 1982 but it should be noted that many of the official documents from the 1980s are undated; formal document control procedures had not become the norm until 1991."

Next paragraph, 5.3. You explain:

"Although the epidemiology of NANB hepatitis was poorly understood until a test for Hepatitis C appeared in 1989, there was good reason to believe that at least one parenterally transmitted virus was involved ... intravenous drug users were therefore considered to be the most significant group for carriage of NANBH. Recommendations for their exclusion from donor panels first appeared in the late 1970s:"

You refer to a further paper you have produced, we

will come to shortly:

"Evidence of how this was applied on donor sessions is lacking for the period 1975 to 1982 but in June 1983 the first SNBTS ..."

Is the word "AIDS" missing there? Five lines from the top of the page, doctor, after the word "SNBTS", should the word "AIDS" be inserted there?

A. It would be appropriate, yes. It was specifically about AIDS, the next sentence goes on to describe that.

Q. I'm not going to go over the following paragraph because we then come to the question of donor exclusion for AIDS, which will be covered tomorrow. So if we could then, please, go over the page again and go on to paragraph 6. The question there is asked:

"Whether there were national policies in that regard, ie in respect of excluding donors at a higher risk of transmitting NANB hepatitis or whether each SNBTS region had their own practices and policies."

You perhaps, doctor, read from paragraph 6.1 onwards.

A. Do you want me to read out loud?

Q. Yes, save me speaking, doctor, thank you.

A. "As described in appendix 2, there is no doubt that from the late 1970s national policies on these and other issues existed, whether in the form of UK DOH memoranda

or in guidelines agreed by consensus decisions arrived at in meetings of the SNBTS and UK BTS regional transfusion centre directors, or in advisory committees and working parties whose views would require endorsement by RTDs. At the same time, however, regional transfusion centres were essentially autonomous. Thus RTDs might agree high level policy, eg the risk groups on AIDS and how implementation should be approached (eg a leaflet), but regional centres had their own donor session policies, procedures and documentation with different methods for managing donor records and communications. It was only in 1990, when the establishment of the general management..."

The system that Professor Cash described yesterday:

"... was instituted at national level and the appointment of a national donor services manager and a national quality manager that a system of common policy documentation and document control was put in place. The first nationally branded donor selection materials were issued in 1991, if one excepts the successive AIDS information leaflets."

Q. Thank you, doctor, then in the next question you were asked:

"Whether, if all donors with a history of jaundice or hepatitis had been excluded from giving blood, (a),

that is likely to have caused any difficulties in maintaining a sufficient supply of blood and (b), the extent to which post-transfusion Hepatitis C in Scotland is likely to have been reduced."

You then explain:

"There was research in the West of Scotland at around the time of the introduction of the policy to accept donors with a history of jaundice (with strict provisos), showing that 2.8 per cent of donors gave such a history."

A few lines down you pick up:

"It is likely that the impact on the blood supply of reversing the policy of acceptance of donors with a history of jaundice would have been significant, given that 2.8 per cent of the donor population equates to close to 10,000 donors annually."

Over the page at paragraph 7.2 you explain:

"As described previously, Hepatitis A was by far the commonest cause of community-acquired jaundice in Scotland at the time of these events, around the early 1980s. Donors with a history of jaundice were no more likely to have a significantly raised level of ALT (to a level considered possibly indicative of carriage of NANBH in the absence of other potentially causative factors) than 'control' or unselected donors. These

data suggested that a history of jaundice was likely to be a very insensitive surrogate test for identifying donors who might be carrying the putative NANBH agent. It was only in 1991 after a test for HCV was implemented that this supposition could be examined in detail."

Paragraph 7.3 you explain that:

"Questioning of donors found to be anti-HCV positive in the first six months of routine HCV donor testing revealed that 5.9 per cent had a history of jaundice. It is not known what proportion of these cases of jaundice occurred from childhood, but based on the information in Barr and others' 1982 letter, jaundice in many of these donors could have been the result of Hepatitis A or B."

Then at the bottom of page 12, four lines from the bottom, you explain:

"One can, to an extent, estimate retrospectively the effect that exclusion of donors with a history of jaundice might have had on the risk of transmission while at the same time estimating the impact on the blood supply and on blood donors."

Over the page you carry out that estimate and that exercise. Paragraph 7.3 you explain:

"The data on HCV positivity in the Scottish blood cover population post-screening are shown in

appendix 3."

I'm not going to take you to that, doctor, but for the records the reference number is [PEN0100385]:

"Examination of data for the period from the implementation of testing on 1 September 1991 to the end of 1992 can be taken to represent the prevalence of HCV in the donor population in the period prior to 1 September 1991."

You also explain:

"It should be noted that the number of donations does not equate to the number of donors tested since regular donors with negative tests may have donated more than once during the 15-month period (the average rate of donation being 1.5 per annum)."

Can you explain that sentence, doctor?

A. Yes. If you just crudely take the number of donations we take in a year, you cannot assume that that is the number of donors tested because regular donors come back up to three times in a year, and for regular donors a reasonable average, we have found over the years, is about 1.5 donations per annum.

So you have a make an adjustment downwards to get an estimate of the number of donors who were tested during that period.

Q. I understand.

Then you set out a calculation. I think, in short, the two important figures used in this calculation. We can see in the third paragraph a figure of 5.9 per cent. That essentially represents the figure you referred to previously, that after screening for Hepatitis C antibody was introduced, of those donors who were positive for Hepatitis C antibody, 5.9 per cent of those positive donors give a history of jaundice. That's where that figure comes from, I think; is that correct?

A. Yes, that's 5.9 per cent of the 256.

Q. Yes. Then the next paragraph, the figure of 2.8 per cent, that comes, I think, from the Barr and others letter of 1982, being those donors who gave a prior history of jaundice.

A. Yes. And that's the only figure we have for the number of donors presenting with a history of jaundice. So that was putting two bits of evidence together from different time periods, obviously. So that is an assumption.

Q. Yes. And using, in particular, those two assumptions, your conclusion in paragraph 7.5 is:

"Summing up, around 9,000 donors would be lost each year in order to prevent, at best, 15 Hepatitis C virus-infected donations from entering the blood supply, while failing to prevent the vast majority of HCV

infected donations from being made available for transfusion."

At the top of page 14 you explain:

"The exclusion of 15 donations capable of transmitting HCV is clearly desirable but it must be remembered, however, that the significance of NANBH in clinical terms was far from clear in the early 1980s, with most of the evidence suggesting it was a relatively benign condition. Furthermore, the nature of the agent and its rate of transmission were unknown and it was thought (correctly as it turned out) that a history of jaundice was unusual in NANBH."

Then the next paragraph, 7.6:

"In assessing the possible impact on the blood supply of exclusion of donors with a history of jaundice, it is the case that not only would around 9,000 donors be lost annually, the loss of donations would be cumulative as the regular donors in the initial testing period would be lost and a substantial number of perfectly safe new donors, with the potential to donate on average 1.5 times yearly for many years, would be lost to the system."

That perhaps is the corollary of what you explained earlier.

A. Yes.

Q. You also say in paragraph 7.7:

"As stated, these wrongly excluded donors can be described as 'false positives'. In any screening tests applied to blood donations a positive reaction leads to further detailed confirmatory testing, with the purpose of identifying true positive results. Unreactive confirmatory tests define donors regarded as false positives, ie not carriers of the infection. In the unwritten contract established with donors in the mid-1980s we explained the reasons for asking them to refrain from donating as long as the false reaction prevents the use of their blood."

Over the page:

"Most donors accept this without much thought but some do not. To learn that you may or may not be carrying a virus which may or may not be sexually transmissible and may or may not cause serious illness is, in some donors, a cause of great anxiety. In the face of such uncertainty, it can be difficult to provide much in the way of reassurance."

In short doctor, is what you were saying there, that if donors with a history of jaundice had been excluded, say at any point in the 1980s, before the Hepatitis C test was available, you wouldn't be able to tell a donor who had been excluded whether they had the NANBH virus

or viruses or not? So donors who had been excluded on the basis of a history of jaundice would be left in a state of uncertainty, perhaps, as to their true positive or negative status?

A. Yes, most donors wouldn't enquire further about that but some would. They would say, "Why are you doing that? What does it mean? Does that mean I have got a serious disease? Is it going to make me ill?"

Q. It may have been difficult to answer.

A. It is difficult because we had no tests. We had no way of verifying that and it left them uncertain.

Q. In paragraph 7 you also explain:

"The loss of such a large number of blood donations could have catastrophic consequences for all patient groups. Failure to meet the target required for plasma for fractionation into blood products such as Factor VIII could have resulted in importation of products with a much smaller margin of safety than was assumed for Scottish donor-derived products, and this was understood even before the onset of AIDS."

We may come back in a future topic to consider that proposition:

"Also, until heat treatment of coagulation factors sufficient to prevent transmission of HCV was introduced, and due to the pooling of donations,

excluding donors with a history of jaundice would have had no beneficial effect on product safety."

In paragraph 7.9 you come to the question of surrogate testing, which again we will come back to later. On the final page of this statement, the top of page 16, you say:

"In selecting suitable donors there was and remains a constant balance to be struck between maintaining blood supply and ensuring the highest levels of safety as well as minimising unnecessary rejection of donors and respecting the principle of duty of care towards donors."

Can you explain that principle a little, doctor; the principle of duty of care towards donors?

A. By that I was really referring fairly specifically to this situation of effectively surrogate testing. And in thinking about this whole area since writing that, it has become clear to me -- and I have not seen this referred to by other people -- that what we do most of the time in selecting donors is apply surrogate tests. And every time you are doing that, you are rejecting a number of donors who have nothing wrong with them, who are perfectly well and they have come in to volunteer to do something for the good of the community and been turned away, with or without some doubts about their

future state of health.

By "duty of care" I meant that we should be careful not to do that unnecessarily, keep it to an absolute minimum and give the donors as much information about the situation as we possibly could.

To extend the analogy, for instance, if we reject a donor on the basis of having had a tooth out in the previous 24 hours, the reason for that is that there is evidence that something like around 10 per cent of people who have a tooth out will have bacteria in their blood stream within the following 24 hours. That means that 90 per cent of those donors wouldn't have bacteria in their blood stream and their blood would be perfectly fine. The trouble is we do not know which because we don't apply a specific test.

So in that sense it is exactly the same as all of the surrogate testing. You are looking at either behaviour or characteristics or something else about the donor that suggests they might have a slightly increased risk of causing illness in the recipient, which is what it boils down to. But we mustn't neglect the fact that these false positives, if you like, the people who get rejected unnecessarily, can have some impact on them, as well as the whole process having impact on the blood supply and impact, therefore, on patients at the other

end of the line.

Q. So the Blood Transfusion Service, when collecting donations, has to have regard to the interests of the donor as well as interests of the recipient?

A. Yes. And we have always made it clear -- and we make it clear in training staff -- that the interests of the recipient come first but that does sometimes have a knock-on effect backwards on to the donors.

Q. The final paragraph, doctor, paragraph 7.10, you stated:

"These considerations lead me to conclude that the impact on post-transfusion NANBH from an exclusion of donors with a history of jaundice would have been very modest, though undoubtedly a small number of HCV transmissions would have been prevented. The effect on the blood supply and on individual donors and patients, on the other hand, would probably have been highly significant."

If we could then compare your conclusion in that regard, that the effect on the blood supply and on individual donors and patients would probably have been highly significant, with Dr McClelland's conclusion, could we go, please, to his statement, which is [WIT0030072]. Page 0088. The paragraph at the bottom of this screen commencing:

"Assuming that the lower figure ..."

In short, Dr McClelland was asked the same question as you, doctor, in respect of what would have been the impact on the blood supply if there had been a policy of excluding all donors with a history of jaundice or hepatitis.

Dr McClelland's conclusion was that he had looked firstly at what percentage of donors may have had a history of jaundice and he explained that assuming the lower figure of around 3 per cent is correct, the exclusion of donors with a jaundice history would probably not have had a major impact on supply but this is essentially speculation.

So Dr McClelland's conclusion is that excluding around 3 per cent of donors would probably not have had a major impact on supply. Your conclusion is that a similar exclusion would probably have been highly significant. Who is right?

A. Well, it's speculation, isn't it? But the fact is that from the period from about 1983 through 1985 and onwards, there was a significant decline in the number of donations we took, we think related to the adverse publicity about AIDS and so on. When that sort of thing starts to happen, 3 per cent can seem like an awful lot of donations to be losing.

My point is that it could be catastrophic for an

individual. Maybe that overall in terms of blood supply, we could meet targets but for an individual patient in an emergency situation, if you do not get blood of the right type at the right time, it can literally be catastrophic.

So I think we always had to bear that in mind and, yes, you can recover from a 3 per cent loss but it depends how close to the bone you are.

Q. Thank you, doctor. That completes your statement.

I won't be much longer but can I go, please, to another document you have produced, which is number [PEN0100365]. This was the document Professor Cash referred to yesterday. We can see this document is entitled "Donor selection policies and procedures" dated September 2010. Were you the author or principal author of this document, doctor?

A. I was, that's correct.

Q. Thank you. I'm not going to go through it in detail for a number of reasons. Firstly it covers some ground we have covered previously and I don't want to duplicate matters. In addition, the question of donor exclusion for AIDS we will come to tomorrow and also, as I say, between us we will produce a short note listing the various guidance documents during the relevant periods. But there are two pages I would like to go to, please,

to pick up something you mentioned earlier. Can we go to page 12, please, of the document.

Under paragraph 5 there is the heading "Standardisation of donor selection policies within the SNBTS and across the UK."

Could you, please, read that paragraph, doctor commencing:

"It had become clear ..."

A. "It had become clear as the response to the challenge of keeping the blood supplies as safe as possible from the threat of HIV developed that the differences in approach between regions and across borders were difficult to justify. At the request of the SNBTS national medical director, Dr Gillon was asked to prepare a paper comparing donor selection policies in the five Scottish regions. This paper, dated 1 November 1985, was discussed by the co-ordinating group on 30 April 1986".

Q. Can I stop you there, please, doctor, just to look at each of these documents.

Firstly your paper dated 11 November 1985 is reference [SNB0039864]. We can see this document is headed "Report for the national medical director and the regional directors of the SNBTS on donor selection criteria". I think you are the author of this document, doctor?

A. Yes.

Q. The background explains that:

"The guidelines on the care and selection of blood donors issued by the NBTS ..."

So these are the guidelines by the NBTS of England and Wales:

"... have been felt in the SNBTS to require adaptation. The national medical director and the regional directors therefore asked me to prepare a report comparing donor selection practices in the five Scottish regions in an attempt to assess the significance of the existing differences in practice between the SNBTS centres and the NBTS guidelines."

You then explained your method:

"By comparing our present selection criteria in the SEBTS, which are codified by diagnosis and are kept up-to-date with the NBTS document, I identified a list of conditions where differences of interpretation existed and in others where no difference existed, which might prove contentious in other centres. I then arranged with the RTDs to discuss these issues with the most appropriate personnel in each centre and to ask their views on the NBTS document."

It is interesting perhaps, doctor, in the first sentence there you say that:

"By comparing our present selection criteria in the SEBTS, which are ... kept up-to-date with the NBTS document."

I misunderstood the position. Do you know what influence, if any, did the NBTS guidelines have in, for example, the southeast region in Scotland when you were there in 1983/1984?

A. It's hard to be categorical about that. What I inherited from my predecessor was quite similar to the document you showed from 1987 in presentation, and that's where I refer to conditions being listed by diagnosis. It was an A to Z of conditions built up through experience, I presume over years, but possibly influenced by previous guidelines from NBTS. I don't know that for sure but it was a comprehensive A to Z listing of conditions with advice for the session staff.

Q. I understand. You then explain the result:

"There was general agreement that the NBTS guidelines were unsatisfactory in format. The information was felt to be badly presented and in particular there was unanimous criticism of the system of lists and sublists of conditions, and in addition to this, every centre criticised particular items in the NBTS guidelines, although there was no uniformity of topic criticised. Listed below are the most obvious

areas of disagreement in no particular order."

Could we then forward, please, to page 4, which is 9867. Before we look at conclusions, just an issue of tattooing above that. We see that Glasgow would like to see a more liberal view taken in view of the fact that most two-ear piercing salons are now accredited to use sterile techniques:

"At present they use the same criteria as other centres, namely that donors should be deferred for six months after any tattooing but this is perceived as a significant and unnecessary source of deferrals. All other centres use a six-month deferral period."

What was the purpose or point of having a six-month deferral period after having had a tattoo?

A. Essentially that sprang from the fear of hepatitis and six months was chosen as a long enough period to allow the development of Hepatitis B, which would then be detected by the routine screening.

Q. I understand. We then see your conclusions:

"No doubt minor differences exist other than those discussed above but it can be seen that major differences of opinion are few. Many of the differences relate to local factors, eg the call-up interval in Glasgow, and any guidelines could readily be designed to accommodate such differences where no scientific

principles are thought to be at issue."

And the last paragraph. You state:

"I formed the impression that all centres were willing to attempt to reach a consensus. The evidence obtained suggests that this would be relatively easy to achieve. While the information in any such document could be based on the NBTS guidelines with amendments derived from the above data, it would be important to strive for a clear and practical way of presenting the data."

So, doctor, when you examined the practices in each of the Scottish regions in 1985 in respect of their donor selection policies, did you find a wide variation of practice or reasonable consistency or what?

A. There was a core of consistency, which is almost what's missing here. We were by then using exactly the same policies and procedures for hepatitis and HIV and transmissible conditions such as this. For instance, the acceptance of jaundice donors and so on. So really we were working at the margins, largely on issues of donor safety rather than patient safety. By and large I think as far as recipient safety was concerned, there was greater commonality. But for the central core significant issues of patient safety, I don't think there was any significant difference.

Q. Then to complete this document, over the page at page 5, which is reference 9868, we see "Recommendations":

"1. The NBTS guidelines should not be adopted by the SNBTS in their present form.

"2. If the SNBTS directors are unanimously in agreement, a comprehensive set of selection criteria based on the present Edinburgh handbook and taking account of the various points that have been raised during this survey should be prepared in draft form for discussion.

"I feel that the differences between the centres are small enough for this to be undertaken by one person rather than by a working party or committee. Any such document would naturally have to be flexible enough to take account of local factors and also be designed in a way which allows easy updating."

Finally on this point, doctor, could we go to document [SNB0039905]?

Now, these are the minutes of an additional co-ordinating group meeting of the SNBTS held on 30 April 1986. We can see those present included Dr McClelland, who chaired the meeting, Dr Brookes, Dr Mitchell, Dr Perry and Miss Corrie. We can then see under paragraph 1:

"Dr Gillon, Edinburgh, attended for item 2."

Under item 2 we can see donor selection criteria. In short, you introduced the paper we have just looked at and we can see underlined the words:

"Those present agreed that there was a need for an SNBTS set of criteria to serve as a framework for use by medical officers and other team staff. It was agreed that it was for each centre to decide who should take clinical decisions on donor acceptance."

The next words underlined:

"The directors at present agreed to recommend to the full co-ordinating group that the standard guide should be produced and that the Edinburgh document provided a basis for this and could be amended in discussion with the directors. Miss Corrie undertook to send a copy to each director who had not been present and everywhere was asked to send comments to Dr Gillon."

We can put that to one side, please. I think in short, doctor, a common set of guidelines were in due course agreed by the SNBTS transfusion directors?

A. Eventually, yes.

Q. Could we just complete, doctor, the document [PEN0100365]. This was your donor selection policies and procedures document. At page 12, please, returning to paragraph 5 but half way through you say:

"It was minuted at the meeting we have just looked

at that the directors agreed that a standard set of criteria should be produced based on the A to Z guidelines then in use in Edinburgh. The first such guidelines were finally agreed and issued in 1988. A formal comparison of how information about AIDS was provided to prospective donors was carried out at the request of the NMD in November 1987."

Then the next paragraph is to do with AIDS. I'm going to skip that. Over the page for the final paragraph in this document. Could you please just read the paragraph commencing:

"At around the same time ..."

A. "At around the same time, two UK national developments were to have major impact on the service. The introduction of general management to the NHS and the publication of the first guidelines for the blood transfusion services in the United Kingdom, to become known as 'the red book' in 1990. This joint initiative of the regional transfusion centres and the National Institute for Biological Standards and Controls had been set in motion in 1987 with view to complying with the imminent EU Directive which would bind member states to introduce strict product liability by July 1988.

"Since then seven editions of the red book have appeared and the expert group devising the guidelines

which cover all materials produced by the UK Blood Transfusion Services evolved into the joint UKBTS NIBSC professional advisory committee, which is known as 'JPAC'.

"A system of standing advisory committees was established including the SAC on the care and selection of blood and tissue donors. It was some years before the systems for producing common policies were fully in place, and the medical directors of the four UK services retained the right to implement policies as local circumstances demand, but the days of widely varying practice across the country are long gone. More than that, the EU Directive that gave rise to the UK Blood Safety and Quality Regulations 2005 ensures that similar standards of blood safety are in place throughout the European Union."

Q. Thank you, doctor. We can now put this document to one side.

Sir, this may be an appropriate time for a break.

THE CHAIRMAN: A bit of a break at that point, thank you.

(11.00 am)

(Short break)

(11.32 am)

MR MACKENZIE: Dr Gillon, there is one final matter I would like to address with you. In considering the death of

Mr Laing, the question arose as to what guidance had been in place in respect of accepting donors who had a history of transfusion. Doctor, I have gone over the documents we have to try and identify what guidance there was. Perhaps I could simply take you through those documents so they are part of the record.

It also occurred to me, doctor, that I'm not sure we have identified all of the guidance which refers to excluding drug addicts during the last few days of evidence. So I have also taken the opportunity for completeness to try and identify all the guidance that I can find suggesting that drug addicts should not be accepted as donors.

With that background, doctor, could I first please refer you to document [PEN0020462].

I'm taking this short. This is 1971. WHO guidance on the formation and operation of the transfusion service. In particular it appeared to be directed to perhaps developing countries, at least countries which were starting off in creating such a service.

If we could, please, go straight to page 0472, which is original page 15, a chapter, "Recruitment of blood donors". Under "Basic systems" it is explained:

"There are three basic systems of obtaining blood donors: (a), paid donation, (b) the bank system and (c),

voluntary unpaid donation."

Under "Paid donation", midway it states:

"Moreover, there is a danger that donors in need of money will conceal previous illnesses, such as jaundice."

Two sentences on:

"This, together with the indisputable fact that such donors mostly come from the lowest social strata where alcoholics and drugs addicts are often found, has brought paid blood donation into disrepute in many places."

I appreciate, doctor, we have never had a paid system in Scotland. It is simply the reference to drug addicts I bring out for the record.

The next document is [DHF0012672]. Again, we have looked at this document before. It is the 1976 ISBT criteria for the selection of blood donors. If we can go, please, to page 2683 --

THE CHAIRMAN: Before we go there, you have assented to the proposition that in Scotland there have never been paid donors. I understand the position to be that before 1940 some areas did pay donors but it was with the formation of SNBTA that a general prohibition emerged. Do you know anything about the history as far back as that?

A. I am afraid I don't, but it is certainly the case that since John Copland formed the SNBTA there have been no paid blood donors in Scotland.

THE CHAIRMAN: I think it is safe to take it from then rather than forever.

MR MACKENZIE: Thank you, sir.

Dealing with document [DHF0012672], we have gone to page 2638, under "Viral hepatitis" it states:

"Prospective donors should be excluded if it is known that they too have received a transfusion of blood or blood products within the last six months."

Do you know, doctor, what would have been the reason for that exclusion?

A. I'm sure that at that time that would have been in relation to the risk of hepatitis.

Q. Then over the page, please, under 5, another category of donors to be excluded are those who are suspected to be parenteral drug addicts. We can put that document to one side, please.

The next document is [SNB0025348]. We can see from the heading, "The National Blood Transfusion Service of England and Wales, memorandum on the selection medical examination and care of blood donors." Can we go, please, to page 5348, and we can see about half way down the page, "Conditions which necessitate temporary

deferment are as follows", and then subparagraph (v):

"If transfused with blood or plasma within the last six months."

There is a temporary deferment of six months. We can see that, doctor.

Can we then, please, go to page 5352? Half way down the page we can see the sentence:

"Elicit drug taking, if admitted or suspected, should debar."

Again, simply for the record, sir, there are similar provisions in respect of transfusion and drug use in the subsequent NBTS guidance in 1983, which is [SGF0010377]; in 1985, which is [DHF0018931] and in 1987, which is [SNB0066410].

Could we look at the next document, please, which is [LIT0013627].

THE CHAIRMAN: Pause a minute. I would like to make sure I have the correct notes of those references. You gave them quite quickly. Yes. I see that there is one where I may have transposed. DHF0018391 or 8931?

MR MACKENZIE: 8931.

THE CHAIRMAN: 8931. Thank you.

MR MACKENZIE: I should perhaps read them all again just to check. The 1983 guidance is reference number [SGF0010377]. The 1985 guidance is [DHF0018931] and the

1987 guidance is [SNB0066410].

THE CHAIRMAN: Thank you.

MR MACKENZIE: The next document, doctor, is WHO guidance in 1978. If we can go, please, to page 3651. Under "Infectious diseases" we see:

"Donors shall have a negative history of viral hepatitis, of close contact with an individual with hepatitis within the past six months, or receipt within six months of human blood or any blood component or fraction that might be a source of transmission or viral hepatitis."

If one goes over the page as well, at the top, what is, I think, noteworthy in this document is that there is no reference to excluding those with a history of drug use. The document is silent in that regard.

The next document, please, is [PEN0020249]. This document is the 1979 DHSS standards for the collection and processing of blood and blood components, et cetera. If we can go, please, to page 0253, at the bottom of the left-hand column, paragraph 1.5.1:

"The following illnesses or conditions disqualify a person from acting as a donor."

Then the list includes illicit drug taking. If we go to paragraph 1.5.3 at the bottom of the right-hand column, we can see 1.5.3 provides:

"The following illnesses, conditions or circumstances necessitate temporary deferment."

Over the page, please, we can see the words "transfusion within the last six months". Then the second last document in this regard, please, [PEN0131395]. This is the Glasgow donor selection leaflet, apparently from June 1983, which we have looked at before, and I think there is no reference at all, doctor, in this leaflet to either drug use or previous blood transfusion. Is that correct?

A. That's correct, yes.

Q. Then finally can we look, please, at [SGF0010397] if we look at the top right-hand corner, we see a reference NBTS 1105 Rev 1983. So I think this bears to be an NBTS donor leaflet. Does that appear correct, doctor?

A. It does, yes.

Q. I think two things are noteworthy. Firstly, I think there is no reference in this leaflet to drug use but in the second paragraph donors are asked to advise if they have ever received a blood transfusion.

A. Yes.

Q. Doctor, these were the only references I could find to a history of blood transfusion. Have you undertaken your own researches in the past few days?

A. Yes, indeed, and I think it is clear from the historical

archive of donor selection materials that in SNBTS we were excluding donors with a history of transfusion for a year by the mid 1980s. I'm not sure exactly what date. I'm pretty sure that was in relation to reports of occasional late seroconversions in HIV cases, which turned out not to be substantiated. But I'm sure that's why it went from six months -- which had certainly been the case in Scotland prior to that -- to one year, which remained the case until 2004.

Q. Just to clarify that, doctor, there are perhaps two things. The first matter is how long ago did the donor receive the transfusion and the second matter is for how long should they be deferred. So when you say that there was deferral of donors for one year, does that relate to the first or the second matter?

A. I think it's the same thing, isn't it? We would not accept a donor who had had a transfusion within the previous 12 months, from, I think, 1993-ish onwards. Prior to that, we would not have accepted someone with a history of transfusion in the previous six months.

Q. I see. Sir, I have --

THE CHAIRMAN: Could we just pause there? I'm slightly concerned that the dates don't quite match. If you look at line 23 on page 57, we were excluding donors with a history of transfusion for a year by the mid 1980s and

then at 58/13 it is from 1993-ish onwards. Now, I may have got a lot of things mixed up, as often happens.

A. 1983.

THE CHAIRMAN: 1983 it should be? Fine.

MR MACKENZIE: I have no further questions for Dr Gillon.

My learned friend Ms Dunlop has, I think, one or two questions arising from Dr Gillon's evidence last week on statistics, simply by way of minor clarification.

Questions by MS DUNLOP

MS DUNLOP: Sir, you will recall that when Dr Gillon was here last week and was speaking to his statement, [PEN0010043], in one of the appendices there was what looked like a very short interval between the date of transfusion and the date of reporting. It was six months. I think you queried, sir, whether that might be a mistake, whether the 1988, where it appeared as the date of reporting, might be 1998, and Dr Gillon has looked into that and in short, Dr Gillon, the answer is it is not a mistake. Is that right?

A. That's correct. I have looked back at the history of that case, as far as I can, and the patient was transfused in October 1987. Is that the correct year?

Q. Yes.

A. And was identified as having hepatitis in December of that year. This was a patient with chronic renal

failure who was under close follow-up.
Q. Would you like to see the page? Would that make it easier? It might make it easier to see the page. It is [PEN0010043], page 10.
THE CHAIRMAN: So this is somebody who is under surveillance anyway?
A. Yes, receiving regular dialysis treatment.
MS DUNLOP: And it is patient 9 in this table. There we have it.
Sorry, I interrupted you.
THE CHAIRMAN: I think we both did.
A. The first we heard of it was March 1998 which would be a very quick reporting of post-transfusion hepatitis event, but given that the patient had been identified as having had a hepatitic illness in December of that year, it fits perfectly well, and in fact this was when -- I'm not sure that we could really be sure when there was going to be a test for Hepatitis C but I do know that when we were looking at interesting samples to test when we were working with the prototype test, this was one of the samples tested and was shown to be Hepatitis C in fact. So in other words, that was retrospective.
Q. Thank you. That was all, sir. We just wanted, while Dr Gillon was here, to clarify that.
THE CHAIRMAN: That's fine. Thank you very much.

Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Just two matters. One is historical and one is asking about looking back from the perspective of today.

In terms of the importance of targets, can you just tell us who was it that would set the targets for the collection of blood in 1985? How would that actually happen? Who would actually set the target?

A. My recollection is that there were meetings called supply and demand meetings, which were essentially regional transfusion directors and the national medical director, I think with representatives, certainly from PFC, I think also probably from the blood collection side, in other words the regional donor organisers. But primarily these were directors' meetings to set the requirements for red cells, plasma for fractionation for the coming year.

Q. Would they be set on a regional level or a national level?

A. A lot of work was done prior to the meetings saying, you know, "How has it gone for the previous year? How do you see things panning out in the next six months to a year". At the meeting it would be "Well, fine, but could you do it bit more" or, "What would you need to do

a bit more?" That would be the tenor of the discussions as I recall.

Q. Would each region have its own target or would there be national Scottish targets?

A. As I recall there would be regional targets. There is an issue which I don't remember seeing mentioned in the Inquiry before, which is that of hyperimmune plasma, which was certainly one of the issues that was discussed at that meeting and took a great deal of effort. And that was obtaining -- usually by plasma phoresis but not always -- supplies of plasma from donors who had a high level of an antibody that could then be manufactured into a specific immunoglobulin, such as anti-tetanus.

These were complicated procedures. Anti-D was perhaps the major immunoglobulin concerned and there was a lot of work necessary to ensure regular supplies of the source materials for that. So that would have been quite a big part of the discussion at that meeting.

Q. So did the regional director then say, "This is what I need for my region", and he would be responsible for that or would there be an overarching Scottish view of it?

A. I think the overarching Scottish view would have been what was needed for patients. The regional director would be mainly in the position of saying, "This is what

we can supply and this is what we will need if we are to supply more", or whatever it is.

THE CHAIRMAN: Can I follow that just a little bit, Mr Di Rollo?

MR DI ROLLO: Yes, of course.

THE CHAIRMAN: I do have an interest in the nature of that exercise and in the exercises generally that were carried out to forecast the levels of supply that PFC, for example, might be able to achieve.

One of the problems that I might want to look at in due course is what the focus was. If one looks at their needs for surgical procedures, I would have thought that perhaps the level of demand might be fixed by the clinicians who were likely to be in charge of performing those procedures. But I'm not sure that I have seen any input from that quarter being fed through. Rather, the impression is that what one sees in the documents is material coming from the regional transfusion directors as to the levels of material that they will be likely to be able to provide, and we know, for example, that in Glasgow, for quite a long period of time, a lot of the collections went to the production of specific products and material didn't go to Edinburgh at all. One might say there was a certain level of tension coming through.

But where did the information about the demand for

red cells come from, for example? Did it come into this particular group or was it only plasma that came into this group? I don't know at the moment.

A. I think, in effect, red cells did not come into the equation for the simple reason that we were clearly, by the early 1980s, driven by the need for plasma and if we were to meet the needs of plasma for fractionation, which was largely driven by Factor VIII production, we would have an excess of red cells.

THE CHAIRMAN: So far as that is concerned, was there a supply of information about the total demand for the product or only the demand that PFC would be required to meet; in other words, did you know about total demand, including commercial products, at the time of these planning meetings or did you only know what was likely to be required for PFC production?

A. I'm not sure I can answer that. I would not have attended the meetings at national level.

THE CHAIRMAN: Perhaps someone can take it on later because there is perhaps quite a big issue around this.

Now, Mr Di Rollo, I merely want to widen that. I don't think that Dr Gillon is the right person to answer all the questions but if I have flagged up an area for investigation.

MR DI ROLLO: I'm very much obliged.

The other matter I wanted to ask about is that you have obviously conducted an exercise in order to examine, looking back, the position in relation to not rejecting donors with a history of jaundice, and I think you have provided us with a paragraph, paragraph 7.4 in your statement. You have provided us with an indication of how it looks in terms of the position. What I would like to ask you is this: would it be legitimate, knowing what we know now -- and I appreciate that is an important qualification -- to say that it's all right to carry on knowing that you would infect 15 recipients with HCV?

A. Well, I think the point is that nobody knew then.

Q. I understand that. I understand that's a very important qualification. They didn't know. You have made it clear that that is an important feature of what you say. What I'm asking you is: would it actually be legitimate, knowing what we know now, to take that decision?

A. Your use of the word "legitimate".

Q. Would it be an acceptable clinical decision to make?

A. Some people would say "Yes", some people might say "No".

Q. What would you say?

A. I find it impossible to look back and make a decision that would have been relevant to what I would have done at the time. I simply did not know and nobody else knew

what the prevalence was in that particular segment of the donor population. But the evidence we had suggested that the prevalence was likely to be quite low.

Q. I understand all of that. That's not, with respect, what I'm actually asking you. I'm just asking what you would say now?

A. I'm saying it is a hypothetical question I can't answer.

MR DI ROLLO: Thank you, sir.

THE CHAIRMAN: Doctor, I suppose if one applied the protective principle at its extreme, any risk would be unacceptable, would it?

A. Yes. And in fact, if we turned away 10,000 donors in 1986, we would have saved ten transmissions. We would have prevented ten donors with Hepatitis C from coming into the system but we would have had no blood on the shelves.

THE CHAIRMAN: When it comes to the final decision on any of these matters, is there a balance of risk and benefit that has to be struck?

A. There isn't a defined balance of risk and benefit.

THE CHAIRMAN: No.

A. There is no figure that I'm aware of that anybody has ever put on it that you could say, "Yes, at this level this is a risk worth taking".

THE CHAIRMAN: I'm not thinking of a figure, I'm thinking of

an exercise of judgment that has to be carried out.
A. It is just that, sir. But I think the people having to make the decisions at the time have to exercise judgment and some of that is intuitive, some of that is based on experience.
THE CHAIRMAN: Mr Di Rollo, is that the sort of area we are in?
MR DI ROLLO: I think so.
THE CHAIRMAN: Do you want to follow it in any way?
MR DI ROLLO: I'm content. I think the witness has indicated what his position is, as I understand it. Sir, I'm content with that.
THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: If I may, sir, thank you.
Dr Gillon, I think you were present yesterday when Professor Cash was giving evidence. Is that correct?
A. Yes, that's correct.
Q. You will recall that a large part of his evidence concerned what appeared to be the unilateral decisions of the various regional centres in Scotland to stop taking blood from prisons. Do you remember that?
A. Yes.
Q. And we hear, for example, that the Southeast first stopped in December 1981, followed by the Northeast,

East and the North in 1983, and then finally by the West in March 1984. You may recall that Professor Cash was asked for his views on whether there was information available from the mid to late 1970s which might suggest that such decisions could have been taken earlier. Do you remember that passage?

A. Yes.

Q. Were you present when the chairman, quite late on in the afternoon, seemed to suggest that material was available from which it might be inferred that those who ultimately took the decisions might have taken them earlier? Do you remember that?

A. Yes, I do.

Q. That, I think, was a reference to various papers which we will come to look at; that is to say the Wallace paper in 1972, the Prince paper in 1974, the Hoofnagle paper in 1977 and the Berman paper in 1979. Is that right?

A. Yes.

Q. Before we look at those papers, doctor, can you just tell us a little about the nature of Hepatitis B, for example in relation to how infectious it is?

A. Hepatitis B is a very infectious virus and if we look at the issues that we are talking about, there is a gradation from Hepatitis B being highly infectious

through HIV being pretty infectious to Hepatitis C, as it is now known, being not very infectious.

It was known by the mid 1970s that Hepatitis B in any sort of residential setting was likely to spread and in fact, close family members of people with acute Hepatitis B or high level carriers of Hepatitis B are at risk in a way that, for instance, with Hepatitis C family members are not, just through everyday contacts, excluding sexual contacts from this discussion.

Listening to the discussion yesterday, it struck me that the assumption that the reference to social and hygiene issues being code for homosexuality was not necessarily correct. We also had reference yesterday to the outbreak in Edinburgh in 1970, when members of staff were infected with Hepatitis B. They weren't all sticking needles in themselves. It is a highly infectious virus.

I think that in situations like a prison, like a residential school, any institutionalised situation like the armed forces perhaps, Hepatitis B could spread quite readily.

Q. We hear a lot in the press, of course, about the overcrowding of prisons and we know that prisoners share cells, washing facilities, eating facilities, toilet facilities. Presumably on that basis it wouldn't be

entirely surprising if Hepatitis B was more prevalent in such an institution. Would that be fair?

A. I think that's exactly right.

Q. Yes. If we always keep in mind we are talking about the period from the mid to the late 1970s, doctor; standing what was known about non-A non-B hepatitis at that time, do you think there was any basis for an assumption that a greater than normal prevalence of Hepatitis B in any one group, for example prisoners, would necessarily indicate the presence of non-A non-B hepatitis?

A. I don't think it would necessarily imply that but it was realised and the evidence -- which was very recent; non-A non-B hepatitis was only described as such in 1974/1975 in the context of transfusion transmission. Therefore there was, I think, widespread acceptance that there was probably some other agent or agents which was blood-borne. Hepatitis B is a blood-borne virus. You could make that inference but the two don't necessarily follow, I don't think.

THE CHAIRMAN: I'm not quite sure I understand. I'm sure you will appreciate that when I ask a question it doesn't imply that I have a pre-conceived answer to it that Mr Anderson seems afraid about.

My interest at this point is that, with the description of a condition, non-A non-B hepatitis, and

the growing appreciation that Hepatitis B didn't contribute a huge percentage of the overall hepatitis that was identified -- and Hepatitis A could be excluded in a whole range of ways -- there was, I think you have said now, a growing appreciation that there was something else that was causing hepatitis?

A. Yes.

THE CHAIRMAN: And one didn't know what that was.

A. Absolutely no idea what it was, how much of it there was around or how dangerous it was.

THE CHAIRMAN: But those are different points.

A. Yes.

THE CHAIRMAN: Not to know about it might have implied a question as to whether Scotland was doing its bit. To know about it and form a view about its relevance has to involve additional factors.

A. Yes.

THE CHAIRMAN: One would be the geographical question, whether it was local to Scotland or local just to America.

A. Indeed.

THE CHAIRMAN: The next would be whether it was something that had adverse long-term consequences or not. So there is a whole number of strata of information that come into making a judgment.

My interest, doctor, is in finding out whether there was a process of reasoning at the time that led to a particular view about this unknown percentage of unidentified hepatitis or not in the first place, and in the second place, just exactly what the process of reasoning from time to time was. And I would expect it to change. So if you can help me with that sort of approach, I would be very obliged.

A. I'm not sure that I can, sir. My impression, listening to it all and looking at the papers and the evidence and so on, is that there probably was very little reasoning, in the sense of thinking, "Oh, two and two makes --

THE CHAIRMAN: Five.

A. -- five. We must look at prisons." I don't see that that happens. I think the focus on prisons had been largely in relation to Hepatitis B, and the feeling was that testing had reached the level of sensitivity that took that off the radar to some extent.

THE CHAIRMAN: Yes. I know that there is English material in particular, showing the transfusion directors there thinking about cutting prisons out in as early as 1973, which was on the basis of Hepatitis B. But even in that context the confidence that one might legitimately have in the testing procedures would change perceptions over time.

A. Yes.
THE CHAIRMAN: Mr Anderson, it's that sort of history I'm interested in and I hope that with other witnesses you and Mr Mackenzie will be able to help me in due course. I do have to try to get a picture.
MR ANDERSON: I understand that entirely, sir. What concerned me slightly was the suggestion we would return to this. If the exercise is to understand the thinking that went on at the time, it seemed to me that we were in danger of running out of witnesses who would actually assist us with that. So the purpose in exploring this with this particular witness was an attempt to obtain, I hope, a dispassionate and objective, if possibly retrospective, view of the thoughts of those involved at the material time.
THE CHAIRMAN: But unless I have got things wrong, Mr Mackenzie has been focusing on high risk donors at the moment and we are going to come back later to the more general history. But I may have got it entirely wrong, of course.
MR MACKENZIE: Sir, I think to some extent, yes, not in this topic but --
THE CHAIRMAN: No, not in this topic, but that's the point, it is not in this topic we are coming back to it; we are coming back to look at the topic of hepatitis more

generally.

MR MACKENZIE: In particular Professor Howard Thomas has agreed to come along after summer and we can no doubt explore the relevant history with him.

MR ANDERSON: That's encouraging, but, of course, we don't know that.

THE CHAIRMAN: Of course, Mr Anderson, I have set myself apart from it and I don't really know it all either. I'm trying to learn as we go, the same as you.

MR ANDERSON: We are in the same boat then, sir.

Perhaps I can finish this. It won't take long and it may be of some assistance.

I think you may have covered this, Dr Gillon, but again, always remembering that we are talking about the period from 1975 to 1979, what was known of the prevalence of non-A non-B hepatitis at the time?

A. In the UK virtually nothing, in fact literally nothing because, as far as I am aware, the fist prevalence data on transfused patients was published around 1978 by the Newcastle group. I think that was the first information we had.

Q. It may be obvious from that reply, but what was known during that period -- that is to say, 1975/1979 -- about the effect of non-A non-B hepatitis?

A. Again very little indeed. The initial feeling -- and of

course, by "hepatitis", what we are talking about here is recognising liver function test abnormalities in people who were asymptomatic, almost by definition. Nothing much was known about either the chronicity or the severity of the disease for several years. Information came out in a rather piecemeal way, obviously, as it does.

Q. Can we look very briefly at these articles, please. The first is [SGH0029831]. This is the Wallace article in 1972. We see from the summary in the top left:

"Men prisoners have a significantly higher incidence of Australia antigen than non-institutionalised men."

Do you see that?

A. Yes.

Q. If we go over the page to the second column, headed "Incidence", about one third of the way down it tells us:

"The high incidence of Australia antigen of one in 153 in men prisoners has no obvious explanation. Viral hepatitis is not a serious clinical problem in the two institutions concerned and the positive donors are not drug addicts. What is not known is whether or not these men were Australia antigen-positive at the time of their first imprisonment. The high incidence may be related to social habits and to hygiene."

If we just pass from that, we then come to the Prince article, which is [LIT0010363]. We see here in the summary:

"An agent other than Hepatitis B virus seemed to be the cause of 36 of 51 cases of post-transfusion hepatitis ..."

Do you is see that?

A. I do, yes.

Q. And then if we turn to the final page -- that's 0368 -- the authors conclude by saying this:

"The fact that non-B hepatitis cases are less frequently associated with serious acute illness does not imply that such cases are of lesser importance. Long-term complications of acute Hepatitis B infection, such as chronic hepatitis, cirrhosis and hepatoma, have been reported to follow mild anicteric infection more frequently than severe icteric cases. Consideration must thus also be given to the possibility that non-B hepatitis may play a role in the aetiology of some forms of chronic liver disease."

They conclude:

"Our findings imply that an substantial proportion of post-transfusion hepatitis cases is caused neither by HB virus nor Hepatitis A agent and suggest the existence of an additional virus(es), hepatitis type C."

Is this the first public dissemination, as it were, of the possibility of a virus other than A or B causing hepatitis?

A. I think it probably is. It's certainly the publication I have in mind in reference to that. But I have also seen reference to Harvey Alter having coined the term "non-A non-B hepatitis". But it was around exactly the same time.

Q. It may be axiomatic but this article doesn't mention prisons at all, does it?

A. Not to my knowledge. It was based entirely, as far as I remember, on post-transfusion hepatitis cases, which were identified by prospective follow-up.

Q. The next that my friend Mr Mackenzie referred to yesterday is the Hoofnagle paper, and it is [LIT0013657], if we could have that on the screen, please.

I suppose the first thing one notices about this is that, unlike the Prince article, this actually makes reference specifically to non-A non-B hepatitis. Is that right?

A. Yes.

Q. We see the title, "Transmission of non-A non-B hepatitis".

A. Indeed.

Q. Whereas Prince simply said there seems to be something else that isn't B or A. Is that right?

A. Yes.

THE CHAIRMAN: Could we get the date of that?

MR ANDERSON: Yes, sir, it is 1977. We see that in the very bottom right-hand corner.

If we return to the rubric, as it were, we see again what is said, eight lines up from the heavy type:

"Testing of serum samples from these recipients with hepatitis showed no evidence of Hepatitis B virus or Hepatitis A virus infection. This study and other recent evidence suggests that there is a third type of human viral hepatitis, non-A non-B hepatitis, which is due to a transmissible agent and may well be associated with a chronic carrier state."

Does that in effect tell us any more, doctor, than the Prince article did? The language seems to be remarkably similar.

A. It is very similar and, no, it is telling us nothing that in any way amplifies what the Prince articles tells us, as far as I can remember.

THE CHAIRMAN: What does the language tell us? You see lawyers tend to think of "may" as indicating a very low level of probability in any circumstances. Is scientific language rather different in its intent and

effect?

A. I think it takes into consideration the overall context, yes, I think in a different way. It is not purely hypothetical at this stage. In other words, they have found people who have evidence --

THE CHAIRMAN: That's the point --

A. -- of hepatitis.

THE CHAIRMAN: I would not want you to be associated with the thought that, because this says "may", it is an indication of a very low probability or nothing more than a possibility. It is not that, is it?

A. I would think not, no.

MR ANDERSON: I certainly didn't mean to suggest that and in fairness to the authors of the Hoofnagle article, we see that they actually say:

" ... may well be associated ... "

I think that may give an answer to the chairman's question itself.

A. But the statement obviously implies also that we don't know if it does.

Q. Finally, I think in this catalogue we have the Berman article. It is [LIT0010189]. Again there is a specific reference to non-A non-B hepatitis but this concerns itself with the chronic sequelae of that hepatitis. Is that correct?

A. Yes.
Q. What is said there -- and this is half way through the rubric, as it were:

"Chronic non-A non-B hepatitis was symptomatically mild and unaccompanied by physical signs or laboratory evidence of autoimmune disease or severe chronic liver disease."

It concludes:

"Thus chronic active hepatitis is a common sequelae of acute non-A non-B hepatitis but it may have a better prognosis that chronic active hepatitis of other causes."

Whether the question, Dr Gillon, is whether it was reasonable to take no action or whether the investigation is as to the thinking behind it, can you help us with the impact that these articles cumulatively had upon the profession, particularly in relation to the question of the efficacy of continuing to take blood from prisoners?
A. Well, I think this was accumulating evidence that there was a problem, the magnitude of which was not at all clear. This is very important evidence in the sense that it was based on liver biopsies. So when they are talking about chronic persistent hepatitis and chronic active hepatitis, they are talking about findings on

pathological examination of a biopsy. But this is in the context of patients who are not experiencing symptoms to any significant extent and who have no physical evidence of chronic liver disease. These are patients who have been followed for quite some time, for greater than a year at least.

So there was evidence that there was something going on in these patients but it was far from clear what the ultimate significance of that would be.

Q. And these papers would be known or ought to have been known not only in Scotland but presumably in England, Europe and indeed the rest of the world. Is that right?

A. Indeed, and Professor Sheila Sherlock's textbook in 1983 -- I think this was mentioned in the preliminary report -- was still describing non-A non-B hepatitis as essentially benign.

Q. Can we look briefly at the final article in this catalogue? This is the Barr, West of Scotland, one. It is [PEN0140068]. This is 1981. So this, of course, is very close to the time that the practice began to be discontinued. We have looked already at the second paragraph, which says:

"Despite the high incidence of HBsAg in male prisoners, viral hepatitis is not a serious clinical problem in the institutions surveyed and the positive

donors are not drug addicts. This incidence is probably related to social habits and hygiene."

And so that appears to echo the very first of these articles, the Wallace one. Is that correct?

A. Yes, that's correct, yes.

Q. But they share a common author, do they not, because we see the lead author, apparently, or at least the first-named author, in the one we looked at in 1981 is A Barr. Is that right?

A. Yes.

Q. And he is one of the three authors of the Wallace paper as well. Is that correct?

A. Yes, he was one of the senior laboratory personnel.

Q. Now, we have heard some evidence about the increase in drug use, and the chairman in particular has been interested in the possible accuracy of the assertion that these donors were not drug addicts. But on the face of it both the Wallace article and the West of Scotland article say that the incidence is probably related to social habits and hygiene. Is that right?

A. Speaking about Hepatitis B?

Q. Yes.

A. Yes.

Q. So whether it is right or not, that's what any reader of the article would take from it, I assume. Is that

right?
A. Yes, and I think readers interested enough to read this would know about Hepatitis B and its mode of spread.
Q. Finally, doctor, on a quite separate matter -- and this concerns the cumulative effect of deferrals -- I think you have produced very recently -- indeed, I think I saw this for the first time last night -- a chart, which might assist visually in the understanding of this.
I regret this is not in the court book, sir, and I have a limited number of copies but it may be helpful and I simply put it up for such assistance as it gives. I have got copies which I can disseminate.
THE CHAIRMAN: If you can let us see it, perhaps you might actually try to convert it into narrative that will make sense.
MR ANDERSON: I was rather hoping the witness would do that, sir.
THE CHAIRMAN: If you tender it, Mr Anderson, I expect you to understand it. (Handed)
There are quite a few bits. Do you want to leave it to your witness?
MR ANDERSON: Your expectation may be disappointed, that's all I can say, sir, so I'm going to ask Dr Gillon.
We have a very colourful chart here, headed "Cumulative Effect of PTD Deferrals". Can you --

THE CHAIRMAN: I'm sorry, Mr Anderson, before you go any further, I think that a document like this must be identified for the future. How shall we do that? Shall we attribute it to you, "Mr Anderson 1", or would you prefer it was attributed to SNBTS1 or something like that?

MR ANDERSON: Whatever is easier for the Inquiry team. I don't mind.

THE CHAIRMAN: Is there any nomenclature that would be confusing. If we do call it "SNBTS1", are we going to get into a mess or ...?

What would be best? I would like consistency once we start on these things.

I'm sorry, Dr Gillon, but getting this right may seem a matter of no importance but I can assure you, many months down the line, when we go back over these things, it takes on a significance that you can't identify at the time.

What should we call it?

MR MACKENZIE: Sir, one possibility may be to use the prefix "HNR", to show that at least it has been produced during the hearing and it may be that some further details could be --

THE CHAIRMAN: That would be fine. That would mean we didn't have to distinguish among the various

contributors of documents and we just have a numerical list.

Are you quite happy with that, Mr Di Rollo?

MR DI ROLLO: Yes, thank you.

THE CHAIRMAN: So we will call it "[HNR0010001]".

MR ANDERSON: Thank you, sir.

Dr Gillon, can you look at the paper [HNR0010001] and explain to us in language that even lawyers can understand what it is that we can see here.

THE CHAIRMAN: Don't try to cover all lawyers, Dr Gillon.

A. This document is a fairly recent document provided to me by Dr Moira Carter, who is the national donor services manager for SNBTS.

I think I would like to restrict my comments to the first sheet. I'm not sure what the supplementary information behind would add to it.

The first sheet illustrates the point I made in my witness statement, sir, in that this derives from the decision in 2004 to permanently defer any donor presenting with a history of transfusion since 1980. This was done in response to the fear -- well, the knowledge that variant CJD had been transmitted by blood transfusion and this allowed us to follow prospectively the effects of banning a cohort of people in the sort of manner that I described in my witness statement, which

would apply to any, in broad terms, surrogate test, which in effect this is. You can see that implementation -- and that, I think, was a seventh-month period -- resulted in the loss of 6,735 donors.

Then, following the red columns, these are the annual total but cumulative numbers of donors deferred. So, in other words, that's the 635 from the first seven months and then the additional amount from the next year and the next year and so on, following the red columns. So by 2010/2011, based on year-to-date figures, because obviously we are still in that year, the loss of donors so far as has been 16,315.

The blue columns refer to an assessment -- this is based on an assumption of the frequency of donation that would have occurred from those donors -- of the number of donations lost over that period.

MR ANDERSON: But it is based on historical evidence?

A. This is based on real evidence of the number of donors deferred.

Q. Yes.

A. And it is quite clear, I think, that when you do ban a large swathe of donors, your loss is cumulative and that has to be made up for in some way.

I might add that the service did successfully make up for this loss of donors but at the cost of

1.3 million, I think, in the first year. So it is not easy to turn round this particular tank.

Q. Thank you very much, doctor, I have no more questions?

THE CHAIRMAN: Could I just understand your last answer? The service did make up for the loss of donors at a cost of £1.3 million. That was the cost of commercial practices or what?

A. No, that was the cost of advertising, primarily, in various ways and scheduling extra sessions, making sure that enough donors come through the door to make up for the loss.

THE CHAIRMAN: So it is generating more donations at domestic level?

A. Yes, and a large slice of that was taken up with television adverts.

THE CHAIRMAN: Right. The donor base figures, what are they?

A. One of the ways that Moira Carter and her colleagues tried to prepare for this was to look at what had been happening in the donor base; in other words, the number of donors known to our system who are active, who had attended within -- I can't remember if it was the last year or last two years, and that constitutes the base number of donors that we know are active and can be called at any given time.

THE CHAIRMAN: And we can see a relative increase in the rate of growth in the numbers in the first period and then it flattens off a little as time goes on.
A. Yes, and that probably reflects the impact of the --
THE CHAIRMAN: Of the advertising, yes.
Mr Sheldon?
MR SHELDON: I have no questions, thank you.
THE CHAIRMAN: Thank you very much again. I expect we will be seeing you yet once more, if not more often than once, but thank you so far.
MR MACKENZIE: Sir, the next witness will be either Dr Perry or Dr Scott. I wonder, if I may, sir, request a very short adjournment just to clarify that.
THE CHAIRMAN: I think we can't call them both in the hope that one will turn up, so, yes.
(12.34 pm)
(Short adjournment)
(12.37 pm)
MR MACKENZIE: Thank you, sir. The next witness is Dr Perry.
DR ROBERT J PERRY (affirmed)
Questions by MR MACKENZIE
MR MACKENZIE: Good afternoon, Dr Perry.
A. Good afternoon.
Q. Could we start, please, by looking at your CV, which

will come up on your screen. Our reference number is WIT0030410.

A. Yes.

Q. And can we start with the qualifications, please, doctor? We can see you are obtained a Bachelor of Science honours degree in chemistry at the University of London in 1971. In 1975 at Manchester you obtained your PhD in chemistry. You are a member of the Royal Society of Chemistry. We also see you are the holder of "qualified person" status as defined by EEC Directive 75/319/EEC. What does "qualified person" status mean?

A. It is a professional qualification, which is an experience-based qualification, but it is basically part of the EU regulations on pharmaceutical manufacture. Manufacturers of pharmaceutical products have to have people that have the appropriate qualifications for batch release, distribution of products to the market and so on. So it is a qualification which is, as I say, an experience-based qualification, which I actually received as a result of my experience in previous employment.

Q. I see. When did you become a qualified person?

A. I think, from memory, it was in the early 1980s, probably 1980/1981.

Q. Thank you. Turning then, please, to your employment

history, I would like to do this is chronological order, starting at the earliest date. So could we perhaps go to the next page, please?

We see that between 1971 and 1972 you were a biochemist in the Department of Chemical Pathology in Hammersmith, London, and then, in particular 1975 to 1977, you were an analytical chemist with Severn Trent Water Authority. Briefly, doctor, what were your duties there?

A. In the Severn Trent Water Authority?

Q. Yes.

A. I was a member of a team that did analysis of water samples and various other materials that the water authority dealt with. It was an analytical role in a central regional laboratory.

Q. The next job up from that. I think between the years 1977 and 1981 you were chief analyst at the regional Sterile Supply Unit, the West Midlands Regional Health Authority. What did that job entail?

A. The regional Sterile Supply Unit was a National Health Service pharmaceutical manufacturing unit set up by the West Midlands Regional Health Authority and its purpose was to manufacture sterile fluids, not blood products but injectable solutions, topical solutions, for use in the regional health

authority in the Midlands of England.

I was appointed as part of a team that was appointed to this new facility and my main role was to set up the laboratory, to set up the analytical procedures and to develop quality assurance systems for the manufacture of the products that the unit was there for. So it was my introduction to pharmaceutical manufacture. That's where I became involved in the business of pharmaceutical manufacture.

Q. Thank you. Could we go back to the first page of your CV, please? We then see at the bottom of the page between 1981 and 1984 you were quality control inspector at the protein fractionation centre. Is that correct?

A. That's correct.

Q. So you joined the SNBTS in 1981?

A. Yes, I think it was January or February, yes.

Q. Can you give us an indication of your main duties and responsibilities at that time?

A. Yes. This was a new post, that had been developed by the SNBTS and the protein fractionation centre. My understanding at the time was that the post had been created largely in response to the first of the medicines inspectors' reports of the protein fractionation centre, where the inspectors identified deficiencies in some of the procedural aspects,

documentation and so on, and the SNBTS and indeed the PFC felt it wanted to bring on board to its staff somebody with experience of basically setting up quality systems and quality procedures in a pharmaceutical environment. I was effectively employed and appointed to that role on the basis of my experience with the West Midlands Regional Health Authority.

Q. Thank you.

A. But I had no prior experience of blood or plasma products. This was a completely new area of endeavour for me.

Q. Yes, and then in 1984 I think you became director of the protein fractionation centre and you held that post until 2003?

A. That's right.

Q. Dr Perry, did you succeed Mr Watt in 1984?

A. I did. Obviously, I worked very closely with Mr Watt from 1981, and at the end of 1983 Mr Watt left the service. He had already indicated his intention to leave. I had applied for his job. He left slightly earlier than was anticipated and I was asked to, technically speaking, become acting director. So I was appointed as acting director in 1984 and that was made substantive in 1985.

Q. And between, say, 1984 to the end of the 1980s, can you

indicate your main duties and responsibilities in that post?

A. My responsibilities were effectively the operational management of the fractionation centre of the SNBTS, and my responsibilities covered everything from financial control, operational management to production, quality control, not single-handed, obviously -- I had a staff of about 200/250 people -- and also the research and development of new plasma products that the service wanted to bring into use.

I think the preoccupation at that time -- and there was absolutely no doubt in my mind that this was the case when I joined in 1981 and certainly strengthened as the 1980s moved forward, that the dominant goal and target was self-sufficiency. It was very clearly evident to everyone who worked in it that, in terms of plasma products, the goal and the aim was to make Scotland self-sufficient in plasma products and in particular coagulation factors.

Q. Thank you. Then from August 2003 until April 2004 you were seconded as personnel director of the SNBTS.

A. Yes.

Q. On the face of it that seems an odd move but perhaps you can explain that.

A. I think the organisation was going through change and

I had expressed an interest in this and my previous boss suggested that I might want to do this on a short-term basis and I did that. Yes.

Q. And presumably as director of the PFC you would have had organisational responsibilities, including the management of staff?

A. Yes, absolutely.

Q. And just to complete the CV, we see that between May 2004 and May 2005 you were Director of Pharmaceutical and Technical Projects, National Services Scotland. Where was that job based?

A. Well, National Services Scotland, the office that I was based at was in The Gyle, which is the headquarters of the National Services Scotland or the CSA. The role was to look at the possibility of rationalising throughout Scotland some of the small-scale NHS manufacturing units that exist. I think there were three or four of these small units and the view was that it might be much more effective, and cost-effective, if they were rationalised into a single entity. So I did a study on that and presented it to NSS as a single, discrete project.

Q. Thank you. Then between June 2005 and January 2007, again with NHS Scotland and the SNBTS, you were director of the Better Blood Transfusion programme. What was that?

A. It was a programme that had a long genesis in SNBTS but it was effectively a systematic approach to looking at what some organisations in the world called "optimal use of blood components". It was about creating good practice in transfusion, creating training systems for transfusion. I think a particularly interesting part of the project was putting in place systems for measuring specific use of blood components -- red cells and platelets -- where the blood is actually being used. So it was a whole range of activities, which were designed to create, as I say, an optimal use programme for Scotland.

Q. Thank you. I think you left the NHS in January 2007.

A. That's correct, yes.

Q. And since then and still you are a self-employed independent consultant. Is that correct?

A. Yes.

Q. And what matters do you consult on?

A. Well, my main role is -- although I am an independent consultant and employed as an independent consultant, my main area of activity at the moment is as executive director of an organisation which rejoices in the title of "International Plasma Fractionation Association", which is a trade association representing the interests of not for profit plasma fractionation organisations

throughout the world. It has a fairly modest but international membership and it's based in Amsterdam.

Q. When was that organisation set up?

A. It started in about 1991, and indeed the SNBTS was one of the founder members of that organisation. At that point it was an European organisation but it has subsequently expanded to take on board members from other countries, including Japan, South America, South Africa and North America and so on.

Q. I think at one point I read that it comprised 11 member organisations from ten countries and is based in Amsterdam. Is that still correct?

A. That's roughly correct, yes.

Q. I'm grateful. Thank you, doctor.

Turning then to page 2 of your CV, could you please simply read out the membership of the key committees, please?

A. Sure. Well, going from the top to the bottom, I was a members of the SNBTS management board and directors' committee for the Scottish National Blood Transfusion Service from 1984 to 2004.

I was a member of the European Plasma Fractionation Association, sitting on their board. Each member organisation had a member on their board and they had two effective forum for European Plasma Fractionation

Association members; that was the general assembly and the executive board.

I was a chairman of the EPFA standing committee on quality assurance, which was a subcommittee of the European Plasma Fractionation Association board.

I was a member of the UK Committee on Safety of Medicines -- commonly known as the CSM -- biological subcommittee from 1986 to 1990.

I was a member of the British Pharmacopeia Commission, specifically its committee K on blood products. I apologise, I don't have the specific dates for that. It was a fairly short-lived appointment.

I was a member of the UK Government advisory committee on microbiological safety of blood and tissues. That has taken two forms really: the Advisory Committee on Virus Safety of Blood, which I think was convened in 1991, which then subsequently emerged to become the Microbiological Safety of Blood and Tissues Committee.

I was a member of the UK BTS and NIBSC working party on blood and blood products, a member of the SNBTS medical and scientific committee and a membership of various ad hoc national and SNBTS committees and working parties.

Q. What is the difference between the EPFA and the IPFA?

A. The EPFA was its original manifestation. It was the European Plasma Fractionation Association. I think around about 2003 it became the International Plasma Fractionation Association.

Q. Thank you, doctor.

You have provided a statement, please, if I can next go to that. It is [WIT0030050]. We can see that you were asked to provide a statement in respect to the topic we are looking at today and you were also asked the matters to be included in the statement and particularly the question was asked:

"Whether in the 1970s or early 1980s Dr Perry or, to his knowledge, any of his colleagues at the Protein Fractionation Centre ever (a) considered the practice of collecting blood from penal institutions and the increased risks of hepatitis, including non-A non-B hepatitis, from such donations; (b) considered whether the practice of collecting blood from penal institutions should continue; and (c) made any recommendations in respect of that practice."

Can you go to the next page, please? We see:

"Introductory comments."

Could I ask you, doctor, please, simply to read out what you have written?

A. Under the introductory comment?

Q. Please:
A. "Prior to my appointment within SNBTS I was employed as chief analyst in the regional sterile supply unit of the West Midlands Regional Health Authority. This new NHS unit was established for the large-scale pharmaceutical manufacture of sterile injectable preparations for the region, and my role included the development and management of quality control systems and procedures necessary for the commissioning and operation of the unit within standards of good pharmaceutical manufacturing practice applicable to the industry in general."
Q. To pause there, doctor, your reference to "good pharmaceutical manufacturing practice", were these standards contained in documentary form?
A. I was trying to think this morning at what point this -- and I think other colleagues have mentioned the Orange Guide. I think this was around about 1976/1977 and these were guidelines really in the course of being developed by the Medicines Control Agency, the UK regulator of pharmaceuticals under the Medicines Act. So I think they did exist but they were very early on in their development. But I think the principles and practices of quality management within a pharmaceutical industry were fairly well understood then and this

centre was expected to -- although it was a National Health Service unit technically, probably operating under Crown immunity, it was the expectation that it would operate to current standards of pharmaceutical manufacture.

Q. And these standards would be written down somewhere?

A. Yes.

Q. Could you read on, please?

A. "In March 1981 I was appointed in SNBTS as quality control inspector in the protein fractionation centre. This was a new post. Its role inter alia was to develop and implement quality assurance systems and controls as part of a programme to bring the centre into compliance with modern standards of good pharmaceutical manufacturing practice. I reported to the PFC director, Mr JG Watt."

THE CHAIRMAN: Please carry on.

A. "In January 1984 I was appointed acting director of PFC, following the departure of Mr Watt. This appointment was made substantive in 1985, reporting formally to the committee of management of the CSA and responsible for all activities of the centre -- subject to the responsibilities and duties of the SNBTS national medical director."

Q. You also said that clearly you had no involvement in or

knowledge of discussions, actions or decisions on the above or other issues prior to March 1981 when you joined the PFC?

A. Absolutely. I had no knowledge of the plasma fractionation industry or blood establishments or blood transfusion services prior to my emigration to Scotland.

Q. I understand. Then, under the heading "Background information relevant to the issue", you set out the organisational framework, accountabilities and responsibilities in place at that time and you explain that:

"Throughout the period in question, the SNBTS was (and remains) a centrally financed division of the CSA. Although widely regarded as a national service providing blood components, plasma products and services for Scottish patients, the management arrangements and accountabilities within the service provided a high degree of professional autonomy for its constituent regional centres and the PFC. Effective leadership and co-ordination of policies and strategy for the service was provided by the national medical director, although the ultimate professional responsibility and independence of regional centres was always respected and observed. Within this arrangement, which was typical of the UK and some other European countries, the

national medical director exercised managerial control through persuasion, consultation and ultimately consensus, when seeking to establish a collective national position.

"It was, therefore, clearly evident and understood at that time that the responsibility for the recruitment, selection and testing of donors rested with the regional transfusion centre directors, who, it was understood, would take account of appropriate and contemporaneous UK guidelines. So far as PFC was concerned, therefore, plasma supplied to the centre for processing was accepted on the understanding that donors had been recruited and blood had been collected, tested and processed according to appropriate UK standards and under the ultimate supervision and responsibility of the regional director, and accordingly the donor selection and epidemiology did not arise as issues for PFC intervention. However, during this period PFC did have a pressing interest in plasma quality, but primarily concerning Factor VIII content, methods for separation and freezing and transport, and a number of studies were carried out in an attempt to improve and optimise the yield of Factor VIII from plasma.

"Latterly, during this period ..."

Which period is this, doctor, you refer to?

A. I think this is the early 1980s.
Q. Early 80s, I'm grateful:
"Latterly, during this period PFC and regional centres worked more closely on the development of quality systems and standard operating procedures for the processing and testing of plasma but this did not extend to issues of donor selection, which at that time would have been accepted as the exclusive responsibility of the regional directors and their medical staff. This situation remained largely unchanged until reorganisations of the service in the 1990s. In its original licence applications to DHSS medicines division for Factor VIII information on donor selection practice or policy was neither supplied by PFC/SNBTS or requested by the UK licensing authority."
Do you recall, doctor, when PFC/SNBTS made its original licence application for Factor VIII?
A. I don't personally recall because it was prior to my joining but I believe it was in 1976 or certainly the late 1970s the first applications for licences were submitted to the Department of Health --
Q. I'm grateful, doctor.
Sir, we next turn to --
THE CHAIRMAN: We will be stopping at that point. Before we leave altogether, in your narrative of the general

background, you do point to regional autonomy.

A. Yes.

THE CHAIRMAN: I can understand regional autonomy where senior people have to have a great deal of professional discretion. Did the accountability of regional officers vary according to their responsibility directly or inversely?

A. I'm not sure I fully understand the question.

THE CHAIRMAN: Was there any system of accountability that was applied to RTDs, for example, for the exercise of their autonomous powers?

A. Certainly in the early 1980s I think it's a fair statement to make that I think this was a largely self-regulating activity and I think the individual directors were held accountable as senior doctors, as senior consultants, for their activity. I'm not an expert on the accountability systems within the medical profession but there was no formal process of audit or inspection, which is commonplace today.

THE CHAIRMAN: Thank you.

(1.01 pm)

(The short adjournment)

(2.00 pm)

MR MACKENZIE: Dr Perry, could we return to your statement, please? We had reached page 0052. In the middle of the

page we see you were asked:

"Whether in the 1970s or early 1980s Dr Perry, or to his knowledge any of his colleagues at the PFC, ever considered the practice of collecting blood from penal institutions and the increased risks of hepatitis, including non-A non-B hepatitis, from such donations."

You replied:

"I have been unable to find any documentary evidence of any formal (or informal) consideration of this topic within PFC either before my appointment in March 1981 or subsequently. However, the letter from Dr Cash to Mr Watt dated 5 July 1982 clearly seeks his view on the topic of prison donors."

Could we have that letter up on the screen, please? The reference is [SNB0056703].

I think we can see, Dr Perry, that this is a letter from Dr Cash to Mr Watt, who was the director of the PFC at that time in July 1982. From the stamp at the top of the letter we can see that the letter was received on 7 July 1982 and we can see your name, I think, Dr Perry, there, and I'm coming to that very shortly. Under item 7(a) Professor Cash states:

"We need to consider formally in the not too distant future the question of sessions in prisons et cetera. I would very much welcome your comments as to whether we

should abandon this practice."

Dr Perry, do you have any recollection of that letter?

A. No, I don't have any recollection of that letter, which doesn't mean to say I didn't see it, as evidenced by the annotation on the top of the letter. But, no, I don't recall having seen this letter. But clearly I did.

Q. Well, when you say clearly you did, if we can look at the top of the page again, please, is that your handwriting, Dr Perry?

A. No, that's Mr Watt's handwriting. The system was that letters would come into the addressee and then Mr Watt would annotate them with people that he wanted to see. He would have copied it to me and scribbled a note on saying basically, "Bob, we should discuss this". And there is a tick on it which presumably indicates that he had either moved on from that or he did actually discuss it with me, but I have no recollection of that discussion, I am afraid.

Q. I understand. Do you have any recollection of Mr Watt having ever expressed any views about the practice of collecting blood from prisons?

A. No, I don't. I don't.

Q. Thank you. So really you can't help us any further with that letter?

A. No, except to note that it wasn't a letter directly to Mr Watt. I think, from the content of the letter and the subject matter, that was a letter that would have been addressed to all directors of the service at the time. I think the convention was that the so-called round-robins, or these letters that should go to all directors, would have been individually headed with the recipient's name, but I think, given the content -- much of which is not related to PFC -- I suspect this was a general call for comments from regional directors.

Q. I understand. Perhaps we can just scroll down --

THE CHAIRMAN: Before you do that, can we take anything from the annotations at the top? There is:

"Bob, we should discuss", and that's you?

A. That's me.

THE CHAIRMAN: And that's ticked.

A. Yes.

THE CHAIRMAN: And then if we look at "Action taken", the only entry is "File".

A. Yes.

THE CHAIRMAN: Does that help you to guess?

A. Not really. This was very commonplace. Most of the transactions in the SNBTS were carried out by letter and formal letters between not just directors but staff generally, and that would have been very commonplace.

Mr Watt would have received the letter, refered it to me, suggested we might talk about it. That could have taken the form of a very formal discussion or an incidental conversation in the corridor. So regrettably I don't recall the discussion but I can't say with any certainty that I did not have a conversation with Mr Watt about that particular --

THE CHAIRMAN: I'm assuming you did but one can't infer from the "Action taken" being limited to filing, that Mr Watt didn't do anything else in response.

A. No, I don't think we can assume that. It is quite possible that he might have asked for something to happen but I have not found, from any of the research I've done into my files, any correspondence between myself and Mr Watt that either suggested a specific request for me to do something or a specific course of action that he may or may not wish to take.

MR MACKENZIE: Just to finish that point, Dr Perry. If Mr Watt had written a letter in reply to Professor Cash, would that fact have been noted on this letter on the screen?

A. Not necessarily. Not necessarily. It wasn't a rigorous and robust system, I think. Sometimes he might have noted that he had replied. But there wouldn't be a chain of evidence, as it were, from the original

letter, you know, linking that to a reply and so on. The documentation system wasn't like that.

Q. Yes, thank you.

You also, I think, indicated that we shouldn't assume that this letter was only written by Professor Cash to Mr Watt; in fact you suggested there were other indications in the letter, that it was a round-robin-type letter sent by Professor Cash to each of the transfusion directors. Can you perhaps indicate briefly the content of the letter which perhaps applied to PFC and the content which didn't?

A. Yes. I think -- firstly, the letter refers to a letter from Mr Haythornthwaite who was the medicines inspector at that time, and I think this post-dated his suggestion that collecting in prisons was not desirable. But that primarily was targeted at regional transfusion centres.

I think item 4, designated QA post, I don't think that was particularly relevant to PFC. We already had a designated QA post. That was myself. I was the QA manager in PFC. That, I think, was an issue surrounding the suggestion that each regional centre should have a specific person who was responsible for quality assurance, because at that time there was no such post in each individual centre.

So I think that was a question that was probably

targeted at regional centres rather than PFC. I think item 7(a) could apply to both regional centres and PFC obviously. And 7(b) is a specific comment that he has asked Ewa Brookes to explore that further.

Item 10, I think, is really an issue more targeted at regional centres who were involved in the process of screening blood. PFC didn't routinely screen individual donations. That was a responsibility that was very clearly an operational and management responsibility. It was very clearly designated to regional transfusion centres. So item 10, I think, is certainly targeted at regional transfusion centres.

Q. Can we then look over the page?

A. Yes, I think that's probably directed at the collegiate body, as it were. I think individual centres did a lot of local printing, and there was a suggestion that PFC as a central national facility could take that up and do it on behalf of all regional centres.

Q. Perhaps the clincher, doctor, if one looks at Professor Cash's final words:

"I look forward to your responses."

A. Again, I can't be absolutely certain but, yes, it certainly indicates to me that he would be expecting responses from more than one person. Equally he could be expecting responses to one than one question from one

person, so I don't think it is absolutely -- it is not a clincher for me.

Q. I understand. If one then does look back at the previous page again, finally, in the second paragraph in the letter, Professor Cash stated that:

"There are one or two items which emerge from this letter which I believe deserves our collective national attention."

A. Yes.

Q. Is that perhaps another indicator --

A. That's a clear indicator, yes.

Q. -- that collective or national attention --

A. Yes, the collective national attention would almost certainly imply to me that Professor Cash at that time was suggesting that this was something that we collectively needed to address and come to a position on.

Q. I understand. We can then leave that letter to one side, thank you, doctor. If I may return to your statement, please, at page 0052. Picking up the reply to the specific question about half way down. We have dealt with that letter. You go on to say that:

"I am aware of the references cited in the preliminary report, which describes the discussions and actions of SNBTS directors in relation to prison donors

which took place during the above period."

Could you, please, read on, Dr Perry?

A. "Mr Watt will have participated in these discussions but I have no recollection or record of having been briefed or consulted on the content of these directors' discussions. I have been unable to find any record of an instruction or request to myself or other PFC staff to take any action in response to these discussions. Indeed, since the directorial discussions were, in any event, inconclusive, it is unlikely that any action would have been requested."

Q. Please read on?

A. "Finally, following the departure of Mr Watt at the end of 1983 and my appointment as acting director in January 1984, I do not recall any further consideration of collecting blood from penal institutions, either between directors, which by this time I would now be party to, or elsewhere. Probably because the practice ceased in Scotland in March 1984."

Q. Thank you. Could you just then complete that passage over the page, please?

A. "It is, of course, possible that throughout this period, PFC staff generally would have been aware of the SNBTS practice of collecting blood from prison donors as part of their background knowledge of SNBTS activities. It

is equally possible that many would have held personal views and casual discussions on whether or not this was appropriate practice. However, I'm not aware of any substantive or formal consideration of the issue in PFC between 1981 and 1984."

Q. Thank you. Just to complete your statement, at this point, please, doctor, you were also asked:

"Whether in the 1970s or early 1980s you, or to your knowledge any of your colleagues at PFC, ever considered whether the practice of collecting blood from penal institutions should continue."

And you replied:

"It followed from the above that [you] had found no record and also have no recollection of any consideration of whether the practice should continue or cease. However, again I would expect a number of staff held personal views and periodic casual discussions on the subject, although again this is conjecture."

Finally you were asked:

"Whether in the 1970s or early 1980s you, or to your knowledge any of your colleagues at the PFC, ever made any recommendations in respect of that practice of collecting blood from penal institutions."

You replied:

"I can find no record and have no recollection of

any recommendations from myself, Mr Watt or any other staff on this practice. I cannot exclude the possibility that the topic was discussed periodically between Mr Watt and other SNBTS directors, but I can find no evidence that such discussions produced substantive recommendations or proposals."

Doctor, that was the end of your statement at that stage. If we can then, please, go on to the next page. What I think then happened was that the Inquiry team's attention was drawn to Dr Wallace's paper in 1972 and also Mr Barr and others' paper in 1981 in relation to the higher prevalence of Hepatitis B among prison donors. I think these papers were sent to all of the witnesses, including yourself, for any comments you may have, and in particular you were then asked this supplementary question. It stated:

"Dr Perry should be provided with a copy of the undernoted papers and asked whether he was aware of these papers at the time of the publication and what, if any, conclusion he would draw from them, either at the time or now, about the appropriateness of collecting blood from Scottish prisons, including any possible or likely increased incidence of any non-A non-B hepatitis from such donations."

You provide a full response, doctor, on this page

and the following page but I have to say it did then occur to me when reading this and having now seen your CV, doctor, I think others are better placed to speak to what happened in the 1970s and also what should have happened in the 1970s. In particular those who were working in transfusion at the time. Professor Cash, Dr McClelland and Dr Mitchell have all essentially given evidence on these matters. It did seem to me that they were better placed to do so. So if you genuinely agree with that proposition that you would defer to their views on this question, I don't propose asking you anything more on it.

A. I'm very happy with that proposition.

Q. Thank you, doctor. I have no further questions for you.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Dr Perry, can I just ask, it does appear that as far as PFC at Liberton was concerned, there was clearly an importance attached to the drive towards self-sufficiency in the period that you were there. Is that correct?

A. Oh, yes, indeed. It was a dominant theme from the day I started, yes. That together with responding to medicines inspectors' criticisms and so on. So there was a drive towards improvement of quality systems and

developing modern pharmaceutical approach to -- but also the organisation, I think, as a number of other witnesses have indicated, the dominant goal in the early 1980s was to make more Factor VIII to meet the increasing demand for treatment of haemophilia.

Q. Who was it that was setting the targets for the Factor VIII or the amount of blood that was needed to make the Factor VIII?

A. I think the targets primarily came from discussions between people like Professor Cash, the senior haemophilia doctors; colleagues from the Scottish Home and Health Department were involved in this, and I can't remember exactly the date on which the precise target evolved but I remember it quite clearly. It was 2.75 million units per million population. That was considered to be the organisation's goal for self-sufficiency, judging the increasing demand for Factor VIII for an increasing haemophilia population, increased prophylaxis and so on.

Q. So presumably the PFC would say, "In order to make so much Factor VIII we will require so much blood"?

A. Absolutely. We would convert that into a volume of plasma that would be required to meet that demand and those targets would then be cascaded down to the regional centres whose job it was to go out and collect

the plasma.

Q. The drive towards self-sufficiency was motivated by what? What was the importance, did you understand, in relation to self-sufficiency?

A. My understanding at the time when I joined the service, as a new person to the blood service, was that this was a goal or a policy that had been set by the Scottish executive at the time, that we wanted to meet the WHO recommendations for self-sufficiency. But I think also it became very clear that one of the prime justifications for self-sufficiency was a belief, which was based on fairly good evidence, that imported products from the USA, which were the alternative source of products, were much higher risk products than those that would be produced from voluntary non-remunerated blood donors from one's own community. So it was a target which was aimed at creating a sufficiency of supply from our own community but also a target which sought to reduce the risk to haemophilia patients of transmission of disease from other countries.

Q. The risk arises from United States' products because of the source. If it's a commercial product, if it is bought from paid donors, then there are certain risks attached to that, and you understood that?

A. At that time, yes, I think that was a well-known part of

the SNBTS culture, that locally sourced plasma from voluntary donors in Scotland was going to be a much safer raw material than the product made from paid donors in the US.

Q. Concern would arise because the people that were donating blood, they would be unreliable in relation to their medical history, for example, or that they would be at increased risk of infection or that they were from the lower socio-economic background. That kind of --

A. That kind of thing. I think there was also a belief that there were not rigorous systems for the control of the raw material, primarily because there was payment involved and so on.

Q. Did it never occur to you that there might be a similar problem with donors coming from prisons in this country?

A. I think I have answered that in either this supplementary question or another, that from a PFC perspective, firstly the whole activity of donor selection was a very clearly demarcated responsibility for regional centres, and we assumed, rightly or wrongly, at the time that the senior directors in charge of the regional transfusion centres would be following appropriate guidelines to make sure the plasma was as safe as possible.

But even if it were the case that there was a higher

risk of infectious disease, particularly non-A non-B -- this is in the early 80s -- from prison donors, removing that source of plasma from the supply to PFC wouldn't have made a difference to the safety of the products that we were manufacturing, and the reason for that is that the -- our belief at the time was that the background level of non-A non-B hepatitis in the 1980s was roughly, I think, from memory, 0.5 per cent or some figure around that.

So even if we removed a few donations by removing prison donors, each pool of plasma that was used to make the clotting factor products, the Factor VIII and the Factor IX, would still have been contaminated from the infective donations which were in the general blood donor pool.

Q. Was that a consideration that played a part in the thinking at the time?

A. It was a factor that led PFC not to consider this to be a major issue.

Q. Can you explain because we haven't seen any documentation to that effect. Nobody so far has given an indication to that effect, as I understand it, but is that the reason for carrying on with prison donors, should we understand, longer than perhaps might have been appropriate, because it wouldn't have made any

difference in relation to PFC?

A. Absolutely not, no. Really, for the reasons that I have described, the FPC wasn't directly involved in formulating policies and proposals for selection of donors, either from prisons or elsewhere. But I think in the informal discussions and views that took place, we were aware that there was a background level of non-A non-B hepatitis that couldn't be reduced below the level that it was at. And removing a small number of donations, which would have been the effect of ceasing collections in prisons, wouldn't have made a difference, but it didn't drive the policy, I think it just led us to conclude that this wasn't a major issue as far as --

Q. You say "us"; who is "us".

A. I think the individuals in PFC, in the manufacturing facility.

Q. Did that include the other individuals, the regional directors and the director of the SNBTS at the time?

A. No, I don't think the thinking would have been related to PFC. I think the thinking in the regional transfusion centres was usually dominated by the safety of the red cells and the platelets. I don't think the fact that it would make no difference at PFC would have influenced the evolution of discussions on this topic by regional transfusion centres.

Q. You can see obviously that clearly if PFC is setting targets at a certain level in order to meet a target for self-sufficiency, then that would obviously put pressure on the system in order to produce that amount of blood?
A. Hm-mm.
Q. That's fair, isn't it?
A. It is a reasonable proposition. I don't believe it was true. I think if your question is, did we collect plasma or blood from any location simply to meet a quantitative target, I certainly don't think that was the case. I would argue very strongly against that. And I think the contribution of prison donations to the volume of plasma supplied to the PFC at the time was really quite small.
Q. You have mentioned guidelines; you mention that in your statement. I think you mentioned it in part of your answers to my questions just now. Do you know what these guidelines were, or do you have any understanding of them or do you know which guidelines you are referring to, or are you just assuming that there were guidelines which were being followed?
A. I think, as I described earlier, my assumption at the time, and indeed the assumption of the director at the time, and indeed the operational practices that were in place and the allocation of responsibilities, were quite

clearly that the whole business of selecting appropriate donors -- both for production of blood components, red cells and platelets, and also plasma -- to feed the manufacturing process at the PFC was very clearly the responsibility of regional transfusion directors and their expert medical staff.

At that time that was a very clear demarcation. PFC had quite a passionate interest in quality of plasma in other respects, but that was primarily to do with its biochemical condition, the level of Factor VIII, the speed with which the plasma was separated and frozen, so that we could maximise the amount of Factor VIII that we could get out of each donation.

Q. So you were concerned with yield, I suppose?

A. We were, we were concerned with yield.

Q. Getting as much material out of the material you had?

A. Of course.

Q. And that involves an assessment of quality with a view to producing as much as you can. Is that right?

A. We had a number of research projects that sought to identify the best conditions for separation of plasma, for freezing it quickly, the way in which you froze, its storage condition, its transportation and so on, and it was those elements of plasma procurement that dominated our activities.

Q. Just coming back to the question about guidelines, in your statement -- this is in background information relevant to the issue -- you say:

"It was therefore clearly evident and understood at that time that the responsibility for the recruitment, selection and testing of donors rested with regional transfusion centre directors who, it was understood, would take account of appropriate and contemporaneous UK guidelines."

I'm just reading on:

"So far as PFC was concerned, therefore, plasma supplied to the centre for processing was accepted on the understanding that donors had been recruited and blood had been collected, tested and processed according to appropriate UK standards."

It is the reference to UK guidelines and appropriate UK standards. Were you yourself familiar with these or did you just assume that there were such guidelines and standards and that those would be followed?

A. I knew the existence of such standards but I didn't spend much time, if any, at that stage in the process of understanding what they were because I had no locus or influence in changing them. These were seen as primarily medical matters for expert transfusionists to work out the risks associated with certain categories.

Q. Presumably it follows from that that whether they said anything about prison donations or not, it was not something that you were familiar with?
A. No.
Q. Thank you, sir. That's all I have to ask.
THE CHAIRMAN: Mr Anderson?
MR ANDERSON: I have no questions, thank you, sir.
THE CHAIRMAN: Mr Sheldon?
MR SHELDON: Nor I, sir, thank you.
THE CHAIRMAN: Dr Perry, thank you very much.
A. Thank you.
MR MACKENZIE: Sir, the final witness today is Dr Graham Alexander Scott.

DR GRAHAM ALEXANDER SCOTT (affirmed)

Questions by MR MACKENZIE

THE CHAIRMAN: Dr Scott, if you have any trouble hearing, please make sure you mention it right away and we will try and do what we can for you.
MR MACKENZIE: Dr Scott, good afternoon.
A. Good afternoon.
Q. Dr Scott, you have provided a statement to the Inquiry. I would like to bring that up on the screen in front of you, please. The number is [WIT0030019] and if you have a hard copy, doctor, feel free to use that. I certainly use the hard copy myself.

A. I will use it, yes.
Q. I'm grateful. I'll just go through your statement, if I may, please, doctor.
In paragraph 1 you explain your qualifications. You have a bachelor of medicine, also FRCPE. Is that perhaps a fellowship of the Royal College of Physicians in Edinburgh?
A. Yes.
Q. Also FFPH. I think that is a fellow of the Faculty of Public Health?
A. That's correct.
Q. And DPH. When does that stand for?
A. Diploma in public health.
Q. Thank you. We see that between 1951 and 1956 you did your national service with the Royal Australian Army Medical Corp?
A. Yes.
Q. And you joined Stirling County Council as a senior assistant medical officer in 1957. In 1962 you were promoted to deputy county medical officer. Then in 1965 you joined the Scottish Home and Health Department as a medical officer. That presumably, doctor, was based here in Edinburgh?
A. Yes.
Q. Then you were promoted to senior medical officer in

1968, and in 1975 you were promoted to deputy chief medical officer. You explain you had been a principal medical officer for around a year before being promoted to DCMO. You explain that between 1965 and 1974 your work primarily related to medical manpower matters, for example, control of the number of medical students, control of training grade and consultant numbers, and negotiating with the profession in relation to conditions of service of medical and technical staff.

You explain that during that period you did not have any involvement with either scientific or blood matters. You also explain that when you became deputy chief medical officer in 1974, you were one of two deputies. The other being Dr Ian MacDonald. You explain that the reason for that was that the chief medical officer at that time, Sir John Reid, was often absent from the department as he was much concerned with WHO matters, which took him out of the office a lot of the time and that was why it was felt appropriate for there to be two DCMOs. Was that relatively unusual, doctor, for there to be two DCMOs?

A. That was the first time but at that time, yes, it was usual.

Q. Thank you, doctor. I think the one thing you don't tell us is when you retired?

A. I retired in 1962. I was supposed to retire in 1960 but Kenneth Calman was made chief medical officer. He had no experience of departmental matters at all. So I was asked to stay on for two years to hold his hand.

Q. Was that the early 1980s, doctor?

A. That was -- well -- I was supposed to retire when I was 60; that would be 1987. I stayed on for two years until 1989.

Q. Thank you.

Then in paragraph 2 you explain that when you became the deputy chief medical officer you took over responsible for all matters relating to the SNBTS.

A. Yes.

Q. And you spent around 5 per cent of your time on SNBTS matters. You explain that you used to sit on the Common Services Agency management committee and in that capacity was involved in discussions regarding funding et cetera. The committee had wide membership. There were health board representatives and the departmental assistant secretary was also a member. You explain that you cannot now recollect the level of your input, although -- over the page -- you suspect your opinion carried a fair bit of weight and you cannot recollect the detail of any discussions you had in that capacity.

You say:

"This is true in relation to all issues covered by the witness statement request. I stand by my past actions but cannot now remember why I did what I did or why I advised in the way that I advised. I should say that I was heavily reliant on my colleagues, Dr McIntyre and Dr Forester. I had the highest regard for them both, particularly Dr McIntyre. He would really only come to see me if he was in doubt about something."

In paragraph 3, doctor, you explain:

"This statement relates to a request received by the Scottish Government legal directorate in October last year."

You remind us that the events and documents mentioned took place up to 35 years ago, and you say again:

"While I would stand by any actions I took or advice that I gave, I cannot now recall the specifics of the reasoning process I employed at the time."

The first question you were asked, doctor, was:

"The consideration, if any, given by the Scottish Home and Health Department between 1975 and 1984 to the practice of collecting blood from penal institutions, the risk the non-A non-B hepatitis from such donations and whether the practice of collecting blood from such institutions should continue."

You answered, doctor, that:

"I do not know whether SHHD gave any consideration to this issue; I do not recall being asked to consider it. In any event, I would not have considered it appropriate to interfere with SNBTS practices."

Can you, doctor, please explain that sentence a little, where you stated:

"In any event, I would not have considered it appropriate to interfere with SNBTS practices."

What do you mean by that?

A. Well, I wouldn't have considered it appropriate to question their decisions about taking donations from prisons. I considered them to be excellent scientific individuals and well able to judge what they were doing in their individual circumstances and their individual reason. And in their areas, they would know what was going on. I would not have interfered with that.

Q. They, after all, were experts in transfusion medicine. That, doctor, I take it, isn't your particular expertise.

A. Oh, none. None whatsoever.

Q. And you go on in paragraph 4 to say that:

"I have been provided with a copy of a minute from J G Davies to Mr Mackay dated 6 May 1983, which records that this issue was under constant consideration by

SNBTS."

I would like now, doctor, to bring that minute up on the screen, please. The reference is [SGH0026764]. Doctor, in the top left-hand corner we see the reference "PS/Mr Mackay". Was Mr Mackay the Secretary of State for Scotland at this time?

A. No, I think he was the Minister of Health.

Q. I see. What do the letters "PS" stand for?

A. Private secretary.

Q. I'm grateful. Then there are copies of this minute to PS/SHHD. What do the letters "PS" stand for there?

A. I think they are private secretary to the secretary of SHHD.

Q. Could that perhaps be a reference to permanent secretary of the SHHD?

A. No, it wouldn't be permanent. Permanent secretary was over -- Scottish officers would be the secretary of the health department of SHHD.

Q. Thank you. Mr Walker, who was that?

A. He was the assistant secretary.

Q. Dr Scott; is that yourself --

A. Yes.

Q. -- the reference there. Then a director SIO.

A. Scottish information officer.

Q. Thank you. We can see the title of the minute is

"Acquired immunodeficiency syndrome."

If we can go to the very bottom of the minute, please, we can see the author is J G Davies and the date is 6 May 1983. Who was J G Davies?

A. I'm pretty certain he was an assistant secretary.

Q. In the SHHD?

A. Yes, division IVD.

Q. Thank you. If we go back to the top of the memo, please, we can see it states:

"Mr Mackay may have seen comment recently in the media about AIDS. He might find it helpful to see some briefing material on the matter prepared earlier in the week by DHSS for the Prime Minister. We agree with the general line in the briefing. There are, however, a few Scottish points to be made."

I should pause, doctor, and ask you: do you have any recollection of having seen this memo?

A. No.

Q. I'm grateful. Then if we go down, please, to paragraph 3, "Donation policy", it states:

"The blood transfusion directors in Scotland are very aware of the problem and have it under constant consideration."

To pause at this point, doctor. The reference to "the problem which is under constant consideration", do

you agree that appears to be a reference to AIDS?

A. Yes.

Q. And we can see then in subparagraph (d) one of the options being currently considered was:

"Avoiding collection in high risk locations such as prisons or where there is known to be a high proportion of homosexuals or drug abusers in the population."

If I could then, please, doctor, return to your statement. In answer 4, paragraph 4, where you say:

"I have been provided with a copy of a minute from J G Davies to Mr Mackay, dated 6 May 1983, which records that this issue was under constant consideration by SNBTS."

Would you agree -- I think you just have -- that the issue which was under constant consideration by SNBTS was the question of AIDS, rather than the question of collection from prisons?

A. Yes.

Q. I'm grateful. Sticking with your statement, please, doctor, the next question you were asked is:

"The communications, if any, between the SHHD and the SNBTS between 1975 and 1984 on the subject of the collection of blood from penal institutions."

You answer that you have no recollection of any communications which may have passed between SHHD and

SNBTS. Doctor, simply to pause here. We have seen reference in 1983 department and social security internal minutes to the Home Office in London having been in favour of collecting blood from prisons from a rehabilitational aspect of prisoners. Are you aware whether the SHHD ever held a similar policy; that is of being in favour of collecting blood from prisons?

A. No, I'm not aware that they had expressed any views on favouring collection from prisons.

Q. In short --

A. It was a matter for the SNBTS directors.

Q. I understand. If I could then, please, return, doctor, to your statement, to the bottom of page 2. You were then asked:

"The communications, if any, between the SHHD and the Department of Health between 1975 and 1984 on the subject of the collection of blood from penal institutions."

At the top of page 3 of your statement in paragraph 6 you answer:

"I have no recollection of any communications which may have passed between SHHD and DHSS. I do not recall whether the subject was discussed at meetings of DHSS, medical staff, which I attended."

Doctor, do you have any recollection of having ever

discussed with the Department of Health and Social Security the question of collecting blood from prisons?

A. No recollection.

Q. The next question, doctor, you were asked was the extent, if at all, to which the chief medical officer or the deputy chief medical officer and the permanent secretary of the SHHD were aware of and were involved in any consideration by the SHHD between 1975 and 1984 of the practice of collecting blood from penal institutions. And the answer:

"I cannot recall being involved in any consideration by SHHD of the practice of collecting blood from penal institutions. As I mentioned previously, Dr McIntyre would only refer matters to me if he needed my assistance."

Is it a reasonable inference from that, doctor, that if the question of collecting blood from prisons in Scotland did come to the attention of the SHHD, it would firstly have been considered by Dr McIntyre?

A. Probably, but I don't think it ever came to him. Maybe it's not for me to say that, but I don't think it came to him. But if he had any doubt, he would come to me, if he had any doubt.

Q. I understand. The next question, doctor, about the middle of page 3. You were then asked whether yourself

or the SHHD were aware of the evidence produced by the National Blood Transfusion Service for England and Wales around July 1974, that the incidence of Hepatitis B in donors from prisons was approximately five times greater than the incidence in donations from the general public. And you answered that:

"I do not recall being aware of this evidence or of taking any steps in response to it. I do not recall whether SHHD took any action."

In paragraph 9 you explain that you had been provided with copies of papers by Dr Wallace and others in 1972, or rather the paper was published in 1972, and also you were provided with a paper by Barr and others, which was published in 1981, and you state:

"I do not recall having been aware of these papers. I do not feel it is appropriate for me to offer any comments on these papers or their relevance to the practice of donor selection, as the subject of donor selection was not within the province of SHHD. SNBTS directors were in the best position to make informed decisions based on local circumstances."

To pause there, please, doctor. Dr Wallace's paper in 1972 and also Mr Barr's paper in 1981 reported a higher prevalence of Hepatitis B in prison donors in the West of Scotland when compared with non-prison

donors. Were you, doctor, aware, or can you recollect, whether you were aware in the 1970s of there being evidence that prison donors in the West of Scotland had a higher prevalence of Hepatitis B compared to non-prison donors?

A. I don't think I was aware of it. I don't recall but I don't think I was aware of it.

Q. Thank you.

THE CHAIRMAN: Before we leave paragraph 9, could you help me, please, Dr Scott, with the statement that the subject of donor selection was not within the province of SHHD? Had a question arisen in Parliament at that time about collection of blood from prison, who would have answered the question?

A. Probably SHHD.

THE CHAIRMAN: It would have been the Minister of State in the Scottish Home and Health Department, responsible for SHHD?

A. Yes.

THE CHAIRMAN: Well, what do you mean by saying that the subject of donor selection was not within the province of SHHD, please?

A. It is a loose phrase. The subject of donor selection was being left to the directors.

THE CHAIRMAN: But you do appreciate that's a very different

matter?
A. I think that is loosely worded, yes.
THE CHAIRMAN: Thank you.
MR MACKENZIE: Thank you, sir.
So, doctor, I think you would accept that the question of donor selection was within the province of SHHD to the extent that SHHD, or at least the relevant minister, was ultimately responsible for the health service.
A. Yes.
Q. But is your position that essentially the question of donor selection was something which was delegated, at least on a de facto basis, to the SNBTS directors?
A. I don't know about the word "delegate". It was their responsibility and whether it is delegated to them, I don't know, but it was left to them as their responsibility, which they accepted.
Q. If, doctor, in the 1970s you or your department had tried to suggest to the SNBTS directors which donors they should or should not take blood from, what do you think the response would have been?
A. To mind their own business, to an extent, whatever you want. They would have said, "We are doing it. It is our responsibility as consultants to do this and we are doing it."

Q. I understand. At the bottom of page 3, doctor, the next question you were asked is whether you or the SHHD were aware of a letter, dated 6 January 1975, by Dr Garrot Allan of Stanford to Dr William Maycock of the blood products laboratory warning of the increased risk of hepatitis, including non-A non-B hepatitis from blood collected from prisoners. Over the page, doctor, you say:

"I do not recall being aware of this particular piece of correspondence or of taking any steps in response to it. I do not recall whether SHHD took any action."

To pause there, doctor. Did you have any knowledge in the 1970s of the work of Dr Garrot Allan in America?

A. No.

Q. I think we have also heard reference to Dr Garrot Allan having published a book of his studies in perhaps the early 1970s, where the point, I think, essentially he was making was that blood collected from commercial donors in the United States had a far higher incidence of either post-transfusion hepatitis or perhaps Hepatitis B -- I think it was probably the former -- than blood collected from non-commercial donors. Do you have any recollection of that book or that point?

A. No.

Q. Moving on to a different matter, doctor, you were also asked whether you or the SHHD were aware of a letter dated 1 May 1975 by Dr Yellowlees, the chief medical officer for England and Wales to all region medical officers on the subject of blood donation and hepatitis.

We will come to some documents in this regard shortly, doctor, but, firstly to read your answer in paragraph 11, you replied:

"[You] have been provided with certain papers and that it is clear from these papers that the letter from Dr Yellowlees was copied to me and that I gave some consideration to the issue of whether SHHD should endorse the introduction of a more specific test for Hepatitis B. The reverse passive haemagglutination test, RPH. My handwritten notes from Dr McIntyre's minute of 13 May 1975 record that SHHD had no objection to the introduction of RPH testing. The question of donor selection is a separate issue and one which was dealt with by SNBTS."

I would like, doctor, to pause at this stage and take you to a number of documents around this period, which I think help provide the context for Dr Yellowlees's letter. In particular, doctor, I think you may be able to help us with interpreting some of the handwriting on the minutes at the time.

A. I'll do my best.
Q. The fist document, doctor, is [SGH0030186]. Doctor, we can see this is a minute dated 2 May 1975 by Dr E M Warwick, addressed to you, Dr Scott. Who was Dr Warwick?
A. She was a senior medical officer involved in infectious diseases.
Q. We see the minute is addressed to yourself, doctor, and also copied to the DCMO. At this point would this be the other DCMO as well?
A. No, that would be Dr Smith, I think, at that time.
Q. Dr MacDonald and Dr Gordon, the heading is "Blood donation and hepatitis". It stated:

"Dr MacDonald left the attached teleprint ..."

What's a teleprint, doctor?
A. It was a kind of fax.
Q. I wondered, yes:

"... with me this morning and Dr Gordon and I subsequently had a word with Dr McIntyre who had already received the copy (also attached) of the actual letter sent out by DHSS to all the regional medical officers. It seems that this is primarily a blood transfusion matter, though we should be glad to be kept informed of any action that you may be arranging to take."

What did Dr Warwick mean by saying:

"It seems that this is primarily a blood transfusion matter."

A. As I say, she was a senior medical officer with responsibility for other things, infectious disease, and any question relating to infectious she should be kept informed. That was my understanding of her minute.

Q. When she said "this seems primarily a blood transfusion matter", did she mean by that it was a matter for you and your particular part of the department?

A. Yes.

Q. I understand. The next document, please, is [SGH0030185]. We can see, doctor, this is a minute written by yourself, I think, if we scroll down the page a little. Is that your signature and name there, Dr Scott?

A. Yes.

Q. To the left of that we can see the date is 8 May 1975?

A. Yes.

Q. If we go back up to the top, please, doctor, we can see this minute is addressed to Dr MacDonald and Dr Smith and also a copy to doctors Warwick, Gordon and McIntyre. The heading is "Blood donation and hepatitis, DHSS/CMO letter of 1 May."

I think that's a reference to Dr Yellowlees's letter

of 1 May 1975. Does that appear correct, sir?
A. Yes.
Q. I should pause, doctor. Do you have any recollection of this memo at all?
A. No, I don't have any mental recollection of it. As I say, I obviously saw it.
Q. You set out in this minute that:
"The position, as I understand it, is that the Maycock advisory group set up a small working group to consider geographical and racial factors and they produced recommendations in the form of an appendix which appeared in an early draft. It was our view as soon as we saw it, and indeed finally the view of the whole advisory group, that the inclusion of such an appendix could be inflammatory and the appendix was therefore dropped."
I should pause, doctor, and ask: what was your involvement with the Maycock advisory group in the mid 1970s? I don't think you were a member, were you?
A. No, I wasn't.
Q. But obviously you were aware of the work of the group, given your position in SHHD?
A. Yes.
Q. And then in the second paragraph, the minute provides:
"DHSS seemed to have interpreted the decision of the

Maycock group as being that although the appendix had been dropped, it had been agreed that a letter should be sent out drawing the attention of RMOs and regional directors to the recommendations of the small working group."

The next paragraph:

"All I intend to do at present is to ask Dr McIntyre to discuss the recommendations with the national medical director ..."

That will be the national medical director of the SNBTS?

A. Yes.

Q. "... and establish the practice in Scotland now and when the more sensitive methods of antigen screening have been instituted, I would have little doubt that the practices recommended is what Scottish centres are doing or are intending to do."

Finally you say:

"If they are not, then all that would require to be done would be to send a letter from the department, drawing the attention of the NMD to the recommendations of the small group and asking him to take it up with regional directors."

I think we have seen, earlier in the Inquiry, that's in fact what happened. I don't think the various

handwriting on this minute matters much, apart from perhaps at the very bottom where we can see, I think, your initials again, in the bottom right-hand corner. I think those are your initials, doctor?

A. Yes.

Q. And the date, 13 May?

A. Yes.

Q. And I think you say:

"Dr McIntyre, you may now proceed as outlined at X."

And we can see the second last paragraph of that minute, you have marked a "X"?

A. Yes.

Q. The next document --

THE CHAIRMAN: Before you go on.

Dr Scott, who would have been responsible within the Scottish Home and Health Department for the health of prisoners at this period? Not necessarily the individuals but first of all the officer?

A. I don't think SHHD was involved in the health of prisoners.

THE CHAIRMAN: Well, there would be a prisons division, I take it, even then, but I'm looking for information about the medical aspects of prisoners. You don't think SHHD would have been involved at all?

A. The question of the -- I'm sorry, if I'm thinking. The

question of the prison medical service -- I'm not sure it was within the SHHD. I think it was in the department as a whole but I don't think it was specifically within SHHD. I may be wrong. I just have no recollection.

THE CHAIRMAN: You have no recollection. If we look up to the top, to the list of people who received copies of this document, we now have six names including your own.

A. Yes.

THE CHAIRMAN: None of them would have been involved with this topic so far as you can recollect?

A. With ...?

Q. With health of prisoners?

A. No, none of them.

THE CHAIRMAN: Thank you.

MR MACKENZIE: Yes, doctor, the Scottish Home and Health Department, presumably the home part of the department, would have been responsible for the running of prisons generally.

A. Yes.

Q. But in particular the health of prisoners, you can't recollect which part of the SHHD would have been responsible for that?

A. The home side.

Q. The home side?

A. Yes.
Q. The next document, please, doctor, is [SGH0030184]. If we scroll done the page, please, we can see this is a typed minute by Dr McIntyre dated 13 May 1975. Then if we go to the top of the page again, please, we can see this minute was sent to yourself, Dr Scott, with a copy to Mr Roberts. Is that correct?
A. Yes.
Q. Who was Mr Robertson?
A. He was either a principal or an SEO. I don't remember his exact grade, but he was on the administrative side involved with such matters.
Q. Again, the minute is still on the subject of the advisory group on the testing for HBsAg. There is a discussion of the particular type of test. Dr McIntyre writes:

"There is now no doubt that the advisory group will recommend RPH for routine screening of blood for HBsAg. It is also likely that following representation from this department, the passive inhibition agglutination test will be accepted as being perfectly satisfactory for the detection of antigen. From a the draft text of the report it would appear that they are approximately equally sensitive. There would seem therefore to be no reason why a gradual change should not be made at an

earlier date to one or other of the more sensitive methods."

Then the next paragraph states:

"This subject will be sure to come up at the Scottish transfusion directors' meeting on 11 June, and if the NMD knew in advance that we were agreeable in principle to the introduction of a more sensitive test, they could perhaps ask the directors to come prepared to discuss at that meeting the test they were likely to adopt and the financial implications thereof. I agree that the question of money will be up to the NMD but I feel sure that he will eventually come to us for additional money for this purpose. It is just possible, however, that some of the centres, eg in the West, have already built in some additional staff, part of whose duties will be to carry out these new tests. I doubt if all Scotland will use the inhibition agglutination test. While Dr Wallace has no reason to doubt its sensitivity, he is still to be convinced by a large reported comparison."

I think, doctor, you have previously been sent a copy of this document and asked to help us with the handwriting?

A. Yes.

Q. If one goes to the handwritten passage, just under the

date, 13 May 1975, I think firstly there is a handwritten note by yourself, doctor, dated perhaps 13 May?

A. Yes.

Q. You have previously advised that the handwritten note said as follows:

"Mr Roberts, NMD was at me again today on giving Wallace go ahead. Could we at least say the department has no objection to Wallace using RPH? As I said in my minute (and NMD has also made the point) the tests to be used are largely a question of clinical practice. If we say we have no objection, it is easier than saying we recommend -- this can only ..."

I think the final words, Dr Scott, you weren't entirely clear what they said but you suggested they appear to say:

"This can only further publication and consideration."

But you appreciate that may not be the correct interpretation of the final words.

A. I can't read my own writing. That word beginning with an "F", I don't know what it is. Maybe -- probably "follow". "This can only [probably follow] publication and consideration. Sorry, I can't make out my own writing.

Q. To be fair, we are asking you some time after the event, to be fair to you.

Then simply to complete the handwriting, the interpretation thereof. I think underneath that Mr Roberts has written a note to you, Dr Scott, which I think states:

"I agree what you say. I think that having no objection puts us less at risk to appeals for financial assistance, which would be unlikely to go [or be] forthcoming anyway than 'recommending'."

Or "recommendations."

Finally to compete the next note, I think you, Dr Scott, then write a note to Mr Roberts saying:

"I told NMD that we had no objection to Dr Wallace going ahead and using RPH. I drew attention to the form of words. As the request was verbal, no letter seemed to be indicated."

But I think, just to complete this line, we will see, doctor, in the event, it wasn't RPHA which Dr Wallace sought additional funding for, rather it was an RIA test?

A. Yes.

Q. In particular, if we can, please, go to document [SGF0012836]. It's a letter dated 22 June 1976 by Dr Wallace to Dr McIntyre. We don't have to look at the

content of this letter, doctor, but in short Dr Wallace explained that RIA testing was more sensitive for Hepatitis B antigen than RPHA testing, and Dr Wallace sought funding for RIA testing. Have you had a chance to look at this letter previously, doctor?

Perhaps I should just take you through the main parts, doctor?

A. I think there is more of it.

Q. Yes.

A. Where it came to, as it were, the crunch.

Q. If we look, doctor, in perhaps in the middle paragraph commencing:

"You attended meetings ..."

In that paragraph we see:

"It was acknowledged that radioimmunoassay was the most sensitive method available for the detection of HBsAg but in practical terms, both expert groups recommended that reversed passive haemagglutination, RPHA, should be introduced as the method of total screening because RPHA could be introduced much more rapidly than a more sophisticated RIA technique."

If we can go over the page, please. Dr Wallace, who I think, it would be fair to say, was at the forefront of the issue of screening of Hepatitis B in the UK in much of the 1970s, had been carrying on using RIA and

had found it to be more sensitive, rather than RPHA. And in the final paragraph on page 2 he states:

"There is, in my opinion, substantial evidence in favour of total screening by RIA rather than by RPHA."

Then over the page, please, at page 3. In the first paragraph Dr Wallace stated:

"The cost of RIA screening at the commercial rate would be £50,000 per annum. This sum allowed for HBsAg testing in the current year as £24,000 which would allow us to undertake total screening by RPHA. Since we are already in danger of overspending under the head of medical supplies, there is insufficient money in our present allocation to allow us to undertake total screening by RIA after the middle of August 1976."

Then in the final paragraph, Dr Wallace states:

"As I have indicated above, copies of this letter are being sent to Miss Corrie and to Mr McPhee. I have not, at this stage, informed either the Scottish legal office or my own Defence Society of the position because I am hoping that something can still be done to maintain a sensitive method of testing donations."

I think in short, doctor, Dr Wallace wished to continue screening with RIA rather than RPHA because it was more sensitive and he wished extra funding to enable him to do so. Does that seem a fair summary of the

letter?

A. That's what he says in that letter, yes.

Q. Yes. That really, doctor, is a precursor to looking at the next document, which is [SGF0012834]. Doctor, this is the typed minute by Dr McIntyre, dated 28 June 1976, addressed to yourself; do you see that?

A. Yes.

Q. The passage I'm interested in, doctor, is about half way down, the paragraph beginning:

"Dr Wallace has been involved in the problems of hepatitis right from the beginning and knows that the problem is complex and that Hepatitis B is only the tip of the iceberg."

Do you see that sentence, doctor?

A. Yes.

Q. What do you think Dr McIntyre meant by saying that "Hepatitis B is only the tip of the iceberg"?

A. Well, we knew that there were other hepatitis agents involved that hadn't emerged then. Non-A non-B. Nobody had developed a test for the other forms of hepatitis.

Q. I understand. Then simply for completeness with this minute, the handwritten passage beneath Dr McIntyre's typed minute, is this in your handwriting, doctor?

A. Yes.

Q. I think it is dated 29 June, addressed to Dr McIntyre

and I think you say that:

"I have suggested a few minor amendments leaving out ..."

A. Present financial situation.

Q. Thank you:

"We should rest on the Maycock report advice, which took into account sensitivity and cost."

A. Yes.

Q. Could you perhaps read on, doctor.

A. "They knew that RIA was marginally more sensitive but did not recommend as a routine."

Dr Wallace, (inaudible) he was a member and a signatory to the report, Dr Wallace was.

Q. Thank you. I think we know that in the event, Dr Wallace was unable to continue using RIA screening, at least for a period, and we have previously seen a letter Dr Wallace then wrote to his medical colleagues in the West explaining that fact and that he was going to have to use a less sensitive screening test. I don't think we have to take you to that letter, doctor.

THE CHAIRMAN: Is that a letter of 26 July?

MR MACKENZIE: It is indeed, sir, yes.

Doctor, can I now, please, return to your statement and complete that? At page 4 of your statement, about half way down the page, the question is asked:

"Whether the witness or SHHD were aware of the internal correspondence within the DHSS in July and August 1983 on the practice of collecting blood from prisons."

I take it, doctor, you were shown a copy of these DHSS minutes when you prepared this statement?

A. I was not aware of the correspondence.

Q. Yes. Doctor, when you prepared this statement we are looking at, I take it you were shown a copy of the DHSS minutes?

A. I believe I was, yes.

Q. I'm sorry, doctor?

A. I believe I was, yes.

Q. Maybe I should take you to them again for completeness.

The first one is reference number [SGH0010575]. We can see, doctor, this is a minute from J B Brown to a Mr Parker, dated 27 July 1983, entitled "The use of blood from prisons". So were you shown a copy of this minute when compiling your statement?

A. Yes.

Q. And you say you don't recall being aware of this minute. And for completeness, can we please have [SGH0010574]? Again, doctor, this is a DHSS minute. The author of this minute is a P A Winstanley, dated 23 August 1983, and it is addressed at the top of the page to

Mr J B Brown again, and headed "Use of blood from prisons". So you had an opportunity, doctor, to read that minute when compiling your statement?

A. Yes.

Q. Again, I think your position is that you don't recall having seen that previously?

A. No.

Q. Thank you. Finally, please, doctor, to complete your statement. At page 4, just above paragraph 12, you were asked. You were then asked:

"In the 1970s and early 1980s, did the Scottish Home and Health Department or ministers encourage donations in prisons ..."

You reply:

"Neither SHHD nor ministers encouraged donations from prisons."

Then the final question you were asked, doctor, was:

"What was the view, if any, of yourself or SHHD between 1975 and 1984 on the practice of the collection of blood from penal institutions?"

And you say:

"I don't have a view on this. In my opinion, this was a matter for SNBTS."

Doctor, looking at matters today and with the benefit of hindsight and all that we know, do you have

any view today on the question of collecting blood from prisons in Scotland from the 1970s and 1980s?

A. I don't believe in answering questions with the perfect vision of hindsight. I just don't believe in it. If you had the perfect vision of hindsight about the whole of your life, would you have done anything any different? I don't accept the premise of the perfect vision of hindsight. I'm sorry, that's the way I feel about it.

Q. Thank you.

Sir, I have no further questions for Dr Scott.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Dr Scott, we heard yesterday from Professor Cash, who was, as I'm sure you are aware --

A. I was.

Q. -- the director of the Scottish National Blood Transfusion Service, I think, at the time where you were at the Home and Health Department.

A. Yes.

Q. It is unavoidable for me to summarise his position but I do want to ask you one or two questions. It seems that there is a contrast in relation to what you have said today, perhaps, and what he told us yesterday, in

that it appears that his position was that it was really a matter for the Scottish Home and Health Department or beyond, the DHSS in London, to direct the transfusion service in Scotland as to what should happen in terms of whether blood should be taken from prisoners or not.

A. Did he say that?

Q. He perhaps didn't put it quite in that way but what he did say -- I can quote. He was asked:

"Who had the power to tell the directors what to do?"

He said:

"I would have to say in the environment we worked, it would be none other than the Scottish Home and Health Department, and in terms of individuals, I would have to nail poor old Dr Graham Scott, deputy chief medical officer, because it was one of his many responsibilities at the Blood Transfusion Service."

So that's what he said yesterday. Do you have anything you want to say about that?

A. I would have said if I had told the SNBTS directors what to do with regard to the donors selection, I would have been told to mind my own business.

Q. Would it have been put in those terms or would it have been put more colourfully?

A. Probably more colourfully in private, yes.

Q. So your position is that it was a matter for him and them to decide what to do in relation to from whom they took blood?
A. Yes.
Q. The other thing, I think it is fair to say, that Professor Cash indicated to us was that he certainly thought -- or gave the impression of thinking -- that they were waiting for a lead from somewhere else, ie either from Edinburgh or perhaps from London. In other words, there should have been a UK policy in relation to these matters; that it was a UK issue whether to collect blood from prisoners or not. It would have been part of a UK policy. Are you aware of whether there was a UK policy in relation to that or was it something just for the Scottish National Blood Transfusion Service to decide upon?
A. As far as I was aware, it was for the national blood transfusion directors to decide individually, in light of their own experience and in the light of the region they were operating in, what they should do and they did -- they didn't do it altogether, they were spread out in time as to when they stopped taking it in prison.
Q. I take it, if they were waiting for a lead from you or from beyond you, they weren't going to get that lead from there?

A. I considered it to be their responsibility individually.
Q. So they wouldn't get a lead from the Scottish Home and Health Department?
A. No.
Q. And they wouldn't get a lead from London either?
A. No.
Q. Thank you.
THE CHAIRMAN: Dr Scott, do you appreciate that if I were to accept as reliable the evidence of Professor Cash that has just been read to you and at the same time accept as reliable your recollection of affairs, one inference might be that no one in Scotland had any input into the decision as to whether or not to take blood from prisoners? Do you appreciate that?
A. The only people in Scotland, as I saw it, was the SNBTS, the directors individually or collectively.
THE CHAIRMAN: That was not my question.
A. Sorry.
THE CHAIRMAN: I'll repeat it. Do you appreciate that if I accept as reliable the evidence of Professor Cash as to his attitude towards your role and SHHD's role and at the same time I accept your evidence as to your understanding of the position, one inference could be that no one in the governmental structures in Scotland had any particular interest or influence over the

collection of blood in prisons?
A. I was not aware of the collection of blood from prisoners.
THE CHAIRMAN: If I formed that view, it might suggest that there was rather a big gap in the governance of this issue, mightn't it?
A. I don't think so. I think when you take the view that it was up to the SNBTS directors to make the decision on their own and they would not have appreciated any interference from anybody else as consultants in the NHS, they were in the position to make their own decisions.
THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: Dr Scott, good afternoon to you. You don't appear to accept the proposition that the SNBTS directors were waiting for some sort of guidance from either the Scottish Home and Health Department or the DHSS in London. Is that correct?
A. That's correct.
Q. Can we look together, please, at this letter of 1 May 1975 that Mr Mackenzie referred you to. It is [SGH0030187]. Do you see that?
A. Yes.
Q. I think this is a letter that forms the basis of one of

the questions that was put to you and you deal with this in your statement, but you see there that this is a letter from the chief medical officer from the Department of Health and Social Security?

A. Yes.

Q. And it is addressed to all regional medical officers. Do you see that?

A. Yes.

Q. And if we go over to page 2 of that document, do you see under the heading of "Prisons" it states:

"There is a relatively high risk of Hepatitis B being transmitted by the blood of prisoners. But there is probably an equally high risk in other groups of the population, eg drug addicts, who are not so easily identified in advance as prisoners, if they can be identified at all. The advice we have received is that it is not necessary to discontinue the collection of blood at prisons and similar institutions provided all donations are subjected to one of the more sensitive tests referred to above."

Do you see that?

A. Yes.

Q. What do you think the purpose of that paragraph is within that letter? It is a letter from the chief medical officer to all regional medical officers.

What's the purpose of it?

A. The advice we have received -- where did we receive it? Who was it from?

Q. Would you agree with the fairly straightforward proposition, Dr Scott, that the purpose of this letter is essentially the dissemination of advice, isn't it, to the regional medical officers?

A. Yes, that's essentially what it's doing. Yes, undeniable.

Q. We know that that letter or a copy of that letter was sent by your colleague, Dr McIntyre, to Major General Jeffrey, the national medical director of the SNBTS. Do you know that?

A. Yes.

Q. Why do you think your colleague Dr McIntyre was sending copy of that letter to the SNBTS?

A. Presumably for their information.

Q. It is not just for their information, is it; it is the advice that is contained within that letter this is being specifically forwarded to the SNBTS, is it not?

A. Yes, I suppose that's correct. I have never seen this letter.

Q. Members of the Scottish Home and Health Department attended the meetings of the directors of the SNBTS from time to time. Is that not correct?

A. There was usually somebody there in attendance, yes.
Q. Yes. And did you ever attend any of these meetings?
A. No.
Q. Was that largely your colleagues, Dr McIntyre and Dr Forrester?
A. Yes.
Q. Dr McIntyre, I think, is currently GRO-A GRO-A. Is that right?
A. I haven't seen him for years.
Q. What about Dr Forrester; is he still alive?
A. No idea.
Q. But in any event, any representative, whether it be Dr McIntyre or Dr Forrester, that attended the meetings of the directors of the SNBTS would be aware of the discussions at those meetings and would consequently be aware of any discussion that there had been in relation to the question of collecting donations from prisoners. Is that not right?
A. Should be, yes.
Q. Thank you very much, sir.
THE CHAIRMAN: Mr Sheldon?
MR SHELDON: Thank you, sir.

Questions by MR SHELDON

MR SHELDON: Doctor, the chair asked you some questions about whether the question of donor selection was within

the province of the Scottish Home and Health Department; do you recall that a little bit earlier today?

A. Yes.

Q. And I think it is clear that in terms of political accountability, all matters relating to the health service in Scotland were within the province of the Scottish Home and Health Department and the relevant Scottish minister; would you accept that, in terms of accountability to Parliament?

A. Well, there is this question of the status of a consultant, which is rather unique. A consultant -- and the SNBTS directors were consultants -- you interfere with them at your peril. They are, in terms, responsible to their patients and at the end of the day through the MDA(?) to the courts.

Q. You perhaps anticipated where my line of questioning was going but in terms of political accountability, I think you would accept that politically, in terms of Parliamentary accountability, health matters in Scotland were within the province of SHHD?

A. Yes, generally.

Q. I just want to explore a little what you meant when you said that the selection of blood donors wasn't within the province, or what you saw as the province of SHHD. I think we have some evidence from Dr McClelland of

SNBTS that in the 1970s and early 1980s, the concept of clinical freedom was sacrosanct?

A. Yes.

Q. And I really just wanted to ask you how, if at all, that concept or that idea informed your view of the province of SHHD at that time?

A. It was always there, in terms of consultants. Their decisions were their decisions. I was involved in that side with the rest of my job. And consultants made their decisions and were responsible for them. And in the end only to the GMC, or, if there was negligence, to the courts.

Q. So would you distinguish then between matters of policy and matters of clinical judgment?

THE CHAIRMAN: I'm sure he will now, Mr Sheldon. Please.

A. I don't know how clinical consultants would take it if they were informed of anything that limited their ability to make decisions they wanted to. It would be in terms of what money was available to them and all the rest but not the actual decision they made on an individual patient.

MR SHELDON: Just to put that in a more general context, would you regard the question of whether it would be appropriate to continue to accept blood donations from prisoners as a matter of clinical judgment or a matter

of policy?

A. Clinical judgment.

Q. We also heard evidence from Professor Cash yesterday. Well he was asked by Inquiry counsel: would it be fair to say that medical and scientific matters relating to transfusion were primarily for the SNBTS, whereas wider policy matters may involve government? And he agreed with that proposition or that characterisation of matters. Would you also agree with it? That medical and scientific matters relating to transfusion were primarily for the SNBTS, whereas wider policy matters may involve government?

A. Yes.

Q. You would agree with that?

A. Yes.

Q. We understand, of course, that the Scottish Home and Health Department combined certain functions, really the functions of the Home Office and the Department of Health in England. I really just wondered if you can help us a little bit with the extent to which the DHSS was involved at that time in informing and guiding health issues in Scotland. We have seen numerous references to the DHSS in the correspondence and so on. How did that fit in with the Scottish Office and the SHHD?

A. Well, we would listen to what they had to say.
THE CHAIRMAN: I didn't hear that.
A. Sorry.
THE CHAIRMAN: I didn't hear that, doctor.
A. We would listen to what they had to say, of course, but not necessarily take it fully. We regarded ourselves as separate from DHSS on certain matters.
MR SHELDON: But you would look to them for guidance and assistance on certain occasions; is that fair to say?
A. We would look at what they said.
Q. If I can ask you a hypothetical question -- I understand that you are perhaps not a fan of those -- but if the transfusion directors had asked SHHD for guidance on an issue related to the selection of blood donors -- I think there is no suggestion that actually was done -- but if they had done so, how would that have been handled? How would you have handled it?
A. We would just discuss -- if DHSS had made any statements on it, we would have looked at what they had said or we would have discussed it internally within the department with our administrative colleagues. Our official position is we advise the administrators and they take the action. It doesn't always just follow through as simply as that, but that's the official position.
Q. Would you also look to the question of whether there

were any groups, advisory groups, working on the matter?
A. Yes, if we had an advisory group in Scotland that was looking at a thing, we would refer it to them.
Q. What about DHSS advisory groups or UK advisory groups?
A. If they had given advice which they had sent to us, we would look at it.
Q. Perhaps we could look again, please, at the letter [SGH0030187]. Perhaps just see the first page, please. We have seen this letter already briefly. This is the letter from Dr Yellowlees to all regional medical officers. We see that the first paragraph reads:

"The department has recently received advice from a group of experts on the use of blood donations from certain categories of donors."

There is a little asterisk and if we look to the foot we see that the experts in that context is the subgroup of the advisory group on testing for Australia antigen.

A. Yes.
Q. Do you see all that? So can we take it that the letter from Dr Yellowlees proceeds on the basis of advice received from a working party or an advisory group?
A. Yes.
Q. Would that be your understanding of it?
A. Yes.

Q. All right. Just thinking more generally then about this type of advice, or this type of circular from a medical officer, what would the basis of such advice generally be if and when the chief medical officer sent out advice?
A. In the light of all information available from whatever source.
Q. Which might include, of course, a working party, a group of experts or whatever?
A. Yes, whether from the DHSS or within our own orbit.
Q. Thank you, sir. Nothing further.
THE CHAIRMAN: Dr Scott, thank you very much indeed.
MR MACKENZIE: Sir, there are no further witnesses today.
In fact tomorrow, a different topic of B1 with Dr McClelland, the question of donor exclusion in AIDS, and then revert finally on Tuesday next week to C1 with Professor Leikola.
THE CHAIRMAN: Mr Sheldon, I make it clear that I have no objection generally to leading questions. This Inquiry will never finish if we don't have them. Just occasionally I have to be sensitive to the position of the witness and I don't want to be put in a position of making adverse comments if it is unnecessary.
MR SHELDON: I appreciate that, sir.
THE CHAIRMAN: Until tomorrow, ladies and gentlemen.

(3.49 pm)

(The Inquiry adjourned until 9.30 am the following day)

I N D E X