Tuesday, 22 March 2011

(9.30 am)

THE CHAIRMAN: Good morning.

MR MACKENZIE: Good morning, sir. We continue with the topic of C1 today and we have two witnesses, Dr Brian McClelland and then later on, Dr Mitchell. So the first witness, please, is Dr McClelland.

DR BRIAN MCCLELLAND (sworn)

Questions by MR MACKENZIE

MR MACKENZIE: Good morning, Dr McClelland.

A. Good morning.

Q. Could we start, please, by looking at your CV, which will appear on the screen. The reference for that is PEN0020593.

Now, I think that's your CV?

A. Yes.

Q. If we look at your professional qualifications, we can see that you obtained a bachelor of science in 1965, a bachelor of medicine in 1968 at Edinburgh. I think 1971, you obtained membership of the Royal College of Physicians. You then completed a doctorate of medicine in 1977 and then in 1986 you became a fellow of the Royal College of Physicians in Edinburgh, and in 1990 a fellow of the Royal College of Pathologists, is that correct?

A. Correct.
Q. Then looking at your employment history, we can see between 1968 and 1969 you were a house officer in surgery and between 1970 and 1977 you were a Medical Research Council research fellow and registrar in the department of therapeutics and clinical pharmacology at the University of Edinburgh. You then became a research fellow in the Netherlands between 1975 and 1976 and then 1977 to 1979 you were a consultant in the Edinburgh and Southeast Scotland Blood Transfusion Service?
A. Correct.
Q. And then we can see between 1979 and 2001 you were the regional director of that service. I think that's a 22-year period in that post. Is that some sort of record, doctor?
A. Possibly, yes.
Q. If we can go over the page, please, we see further details. Between 1977 and 2009 you were a senior lecturer in the department of medicine?
A. I should say perhaps some of these dates are a little confusing because things were running concurrently. It is difficult to find a very clear way of presenting it.
Q. There is some overlap, obviously, in different posts and different duties.
A. Yes.

Q. In 2001 to 2003 you were a consultant in SNBTS transfusion medicine service. 2001 to 2004, you were a strategy director of the SNBTS, and then 2004 to 2008, you were a professional director of the joint professional advisory committee for the UK Blood Transfusion Services. Can you explain briefly, doctor, what is the joint professional advisory committee?

A. Yes, indeed. It is a committee which produces -- one of its main products is a book which is colloquially called "the red book" which is formally entitled the guidelines for the blood transfusion services in the United Kingdom, which is a compendium of guidelines and standards for practice in all aspects of transfusion.

This originated back in, I think, 1995 as an initiative of Professor John Cash and some other colleagues in England to lay the findings of a common set of guidelines and standards for the United Kingdom Blood Service because that had not existed in the past.

Q. When did you first become involved in these guidelines?

A. Oh, quite some time before this because this parent committee, which we have just referred to, developed a number of subgroups, which were called specialist advisory committees, one of them dealing with transfusion-transmitted infections. So I was a member of that and of some of the other subgroups in the time

before I became chair of the main committee.

Q. I see. We will perhaps come back to some of these activities in due course, thank you.

THE CHAIRMAN: Dr McClelland, I think from the answer you are giving, the impression might be taken that the red book began in 1995. Did it not have a much longer history?

A. The working group -- it had a different name when it was set up. I can't actually remember for the moment what it was, but the group of people started to work to develop common guidelines. The first edition of the red book, I think actually was 1995. So the committee started a few years before that, sort of putting this together. I know we did provide a copy to the Inquiry of the first edition of the actual publication and my recollection is that that was dated 1995.

MR MACKENZIE: I think we will come back in due course, sir, to some of the particular guideline documents and the particular years.

THE CHAIRMAN: It may be that there was another red book that was the subject of discussion in the 70s.

MR MACKENZIE: Yes, I think that's right.

A. Certainly not the one that I'm referring to. There is no question; it did not exist and hadn't been conceived in the 1970s.

MR MACKENZIE: Thank you.

Returning to your CV, doctor, we can see between 2007 and 2010, you were the lead clinician in the European Union optimal blood use project, promoting safe and effective transfusion practice in the European Union and then we can see your current status, 2009, you retired from the SNBTS.

A. Correct.

Q. And do you remain retired?

A. Yes.

Q. You then set out in your CV experience and activities in previous posts. I'm not going to take you through that, doctor, in the interests of time. I think we will simply take all of that as read and if we can perhaps, please, go two pages on. It is page 4 of the CV and we can see a subheading "Contributions to developments and patient care". Two paragraphs below that, we can see, between 1983 and 1985 you say as the spread of HIV became recognised in the UK, you worked with Dr Anne Smith and later Dr Jack Gillon to pioneer the development of the donors' selection and screening procedures, now universally used in the UK. And following the start of donor Hepatitis C testing in 1991, you supported Dr Gillon and Dr Yasmin Ayob in carrying out the first comprehensive regional

Hepatitis C look-back in the UK?

A. That's correct.

Q. If I may then go on to page 6 of your CV, please, and we can see membership of various advisory committees, and you say:

"Over my career I have been an active member of various UK advisory bodies related to transfusion and AIDS, including the expert advisory group on AIDS, the UK advisory committee on the microbiological safety of blood, tissues and organs, the UK BTS, NIBSC joint professional advisory committee and its subgroups."

When is the NIBSC, doctor?

A. It is the National Institute of Biological Standards and Control, the director of which was Professor Geoffrey Schild and he was one of the co-motivators, with Professor Cash and Dr William Wagstaff, of the group which established the standards and guidelines for transfusion.

That organisation was an important part of this group because they are the organisation for the United Kingdom that deals with the issue of standardisation of reagents used in a whole variety of tests, biological tests, because that's a large part of the blood services work. It has been extremely important to have them as partners in this enterprise.

Q. Thank you. Then over the page at page 7, the top of the page, we see you were chair of its specialist advisory committees on clinical transfusion and were editor of the UK Blood Services Handbook of Transfusion Medicine. Is that the red book you referred to earlier?

A. No, it is not. This has been a confusion and I think it is dealt with more fully in the second statement.

The red book covers, if you like, the guidelines and standards for the collection, processing and testing of blood and relates to donor selection criteria. So it's essentially to do what one might call the manufacturing side of the blood chain.

The Handbook of Transfusion Medicine is expressly directed to the clinical practice. It is intended for doctors, nurses and other people who are directly engaged in the use of blood in the clinical context. So there is a minimal degree of overlap but purely to sort of provide some explanatory information in the clinical handbook.

Q. I understand, thank you. Also I think we can see at the top of that page that you were a member of its SAC, its specialist advisory committee on transfusion-transmitted infections. Do you recall when you became a member of that group?

A. I haven't got those dates in my head. I'm sorry, I left

them out in the interests of brevity.

Q. Would it be 70s, 80s or 90s?

A. No, it would have been later than that. It would have been 90s.

Q. I see. Just carrying on, we see you were also a founding member and steering group member of the Serious Hazards of Transfusion reporting system, SHOT?

A. Correct.

Q. When did that begin approximately?

A. SHOT is now about 13 or 14 years in operation and I guess the steering group -- the initiating group would have been set up for about two years before, so starting about 15/16 years ago, and I was involved with it very actively for two or three years and subsequently I have remained on the steering group.

Q. Thank you. And we also see you were chair of the BCSH?

A. British Committee for Standardisation in Haematology.

Q. A working group on blood administration procedures. Again, can you give us an approximate guide to the dates?

A. That was for a fairly short period. I think I did that for about one year in about 2000/2001.

Q. Thank you. But moving on, doctor, to your international work, we see you were a member of the World Health Organisation panel of experts on

transfusion. Again, can you give a clue as to the period?

A. I'm still a member of that group and have been for about 12 years.

Q. We can also see you were a founding member of policy and steering groups for WHO Global Collaboration On Blood Safety, including a member of the WHO working group on national policy and guidelines for clinical use of blood. So again that would be within the last 12 years?

A. Yes.

Q. I understand. Over the page, please, to page 8. At page 8 we can see further group memberships and projects. About half way down, member of European Committee On Blood Transfusion. What is that?

A. Yes. It is a committee that was established originally in the Council of Europe and remains formally within the Council of Europe. It advises European health ministers on policy issues relating to transfusion. It prepares what is, in effect, an European version of our red book, which is guidelines and standards for primarily, again, the "manufacturing" part of blood transfusion. That has been issued in annual revisions and I think it is now in its 16th or 17th edition. I was a member of that group and actually of the editorial group that produced the book for three years up until about the time of my

retirement as the UK representative of that group.

Q. Thank you.

Then we see teaching and training, tutoring medical students, undergraduate medical lectures, supervision of PhD and MSc students and frequent lectures at educational meetings et cetera. Under "Awards" we see various awards you have been given, including in 2006 the International Society of Blood Transfusion award for teaching and research in transfusion medicine. Can you explain briefly what the ISBT is?

A. It is the International Society of Blood Transfusion, which is the sort of global professional association and has large international meetings involving all countries every two years, and regional conferences every alternate years, which will be European, Southeast Asia, whatever.

Q. Who are the members of the ISBT? Is it open to anybody or only certain organisations?

A. Its membership covers people involved with blood transfusion both at the production side and the utilisation side from virtually all countries in the WHO book, as it were. So it is a very international group.

Q. Thank you. If we could then, please, go forward to page 10, this is the start of your publications. I'm not going to go through them, just to say that we see

that between 1979 and 2007 you have produced, as author or co-author, many publications over a wide range of matters arising in transfusion medicine. I think, in fact the publications take up about 40 pages of your CV. Have you ever counted them, doctor?

A. Not recently.

Q. No. Many, many publications. I think in fact we can then fast forward to the second last page of the document, page 51. The publications had ended the page before but on page 51 you then set out a number of invited lectures and meetings organised between 2005 and 2010. Is that correct?

A. That's correct.

Q. Thank you, doctor. I think we will leave your CV now.

A. Thank you very much.

Q. Please go to your statement, which you have kindly provided. The number is [WIT0030072].

Doctor, what I intend doing, if I may, is to take certain passages as read in the interests of time but to focus on certain other passages and ask you questions about them. So if we could start, please, on the first page. The first paragraph I'll take as read. The second paragraph, you explain it as background to your response to some of the questions in the schedule. You have included an appendix giving a short account of your

training and experience before joining the SNBTS, your recollections of your own knowledge about hepatitis at the time and your recollections of the attitude to hepatitis in the SNBTS:

"I joined the service in 1977."

I will come on, doctor, to ask you specific questions about some of these matters but if you could perhaps just go to the appendix now. This is page WIT0030090. We can see appendix 1, "Background". I propose simply taking all of this as read, doctor, so I won't take you through it just now but it does, I think, provide an interesting account from a personal perspective of some of the matters that we will come on to discuss today. If I could ask you one question, doctor. Over the page, please, and about half way down the paragraph, the paragraph beginning:

"I was familiar with the studies of Krugman and Giles."

The next sentence states:

"I was well aware of the risks of hepatitis among residents of institutions."

What do you mean by "institutions"?

A. This particular paper related to work carried out in the Willowbrook School in New York State, which is for people who would now be described as having learning

difficulties, and the other type of institution where there was, you know, a great deal of evidence of spread of hepatitis was various forms of children's homes. In relation to prisons, I have to say, I don't think that at that time I was particularly aware of that as an issue in the United Kingdom. But I was very much aware that in the United States there was plenty of evidence of hepatitis being a major issue in prison populations.

Q. Yes. I just wanted to clarify, doctor, when you used the word "institutions" on that page, does that include prison institutions?

A. When I wrote that sentence, I wasn't particularly thinking of prisons.

Q. Yes. You meant the homes which you discussed?

A. Yes.

Q. Thank you.

THE CHAIRMAN: Did Krugman and Giles write about a prisoner population or another population?

A. It was another population.

THE CHAIRMAN: At a school?

A. It was a school for the mentally handicapped.

THE CHAIRMAN: And there were some experiments carried out?

A. Correct. It would not, I think, get medical committee clearance today.

THE CHAIRMAN: I think "today" could stretch back a long

time -- at least hopefully it could.

MR MACKENZIE: I think the experiments were back in the 1950s, perhaps.

A. The 50s, yes.

Q. Where I think some residents were deliberately injected with serum containing Hepatitis B to see what would happen essentially.

A. The purpose of the experiments and the reason I referred to them was that they were probably the definitive experiments that delineated that there were almost certainly two forms of infectious hepatitis, which had very different characteristics in terms of the course of the infection in the individual.

Q. Yes, thank you.

If we could, please, return, doctor, to the first page of your statement and carry on going through that, please. In the second last paragraph, you say:

"For some of the questions in the schedule that relate to the activities of the SNBTS rather than those of the individual regional transfusion services, I have been unable to provide information. This reflects the degree of independence of the regional services and their directors during the 70s and into the 1980s. I feel it is important, by way of background, to offer a personal view of my recollections of the

organisational relationships among the regional directors and the SNBTS headquarters in the years following [your] appointment."

You then go on to explain that the organisation known since 1974 as SNBTS has its origins in several distinct organisations that were rooted in individual hospitals and had a strong sense of local identity, and that, despite the re-assignment of management of SNBTS from the SNBTA to the Common Services Agency, the regional transfusion centres remained largely autonomous entities; and that in respect of blood donor selection, the region transfusion director and his or her consultant colleagues determined their own local policies and issued guidance to medical and nursing staff.

You go on to explain that certain documents were designed and printed locally. You say discussions between RTDs at national level were just that and they often agreed to disagree. Moreover, the concept of clinical freedom was sacrosanct and every donor session was overseen by a doctor who had the final say in all matters of donor selection.

Doctor, we will come on in due course to look at national guidance on the selection of donors. Is it the case that any national guidance would be interpreted and

applied locally?

A. That's absolutely right.

Q. Then at the very bottom of page 2 you say that:

"It may also be worth mentioning that during the late 1970s, the headquarters of the SNBTS was a tiny organisation. My recollection is that it was staffed by the national medical director, one national administrator, a secretary and a clerical assistant."

Just completing this introductory passage you say:

"From the mid 1980s a number of changes, notably the appearance of AIDS, the commencement of regulatory inspections of the transfusion services, the enactment of the European Directive on consumer protection and the development of the guidelines for the transfusion services in the UK led to progressive convergence of practices among the UK transfusion centres."

A. Yes, I would simply like to explain that the reason that I wanted to include this passage in my statement was that looking at it now, it does seem rather odd that an organisation which calls itself a national organisation did appear to be behaving in many respects as a series of regional organisations. And you know, the truth is that at this period, at the time that I joined it, it very much was a series of regional organisations and that was where it had come from and the level of sort of

autonomy that at that time rested with the regional directors was not actually particularly unconventional. The health service in its totality was a very different place in the 70s and 80s from what it is now.

Q. I understand. Thank you.

I'm going to skip the next question and table in the statement because we will come back to fuller figures on the amount of blood collected from prisoners in due course, but over the page I think we do see a helpful table for today and table 2 shows the total donations collected by the Southeast of Scotland Blood Transfusion Service between 1975 to 1991, including the per cent contributed by donations from penal institutions. I think in short, doctor, the Southeast Scotland BTS collected from Saughton Prison but no other prisons.

A. That's correct.

Q. We can see the table shows that between 1975 and 1981 the total donations are set out. I won't repeat them but we can see the percentage of the total donations collected from Saughton Prison range from 1.3 per cent before falling down to 0.27 per cent in 1981?

A. Correct.

Q. And I think, the last collection was in 1981?

A. Yes.

Q. I'm grateful.

Could we then go over the page, please, doctor? And we can see -- this is page 5 of the statement -- table 3 then provides the date of the last blood donor session held in a penal institution for each of the Scottish blood transfusion regions and we can see, I think, in the Southeast of Scotland, the date of the last donor session was 18 December 1981?

A. That's correct.

Q. At the bottom we can see for the West of Scotland the date of the last session was 25 March 1984?

A. Yes.

Q. Just pausing there, doctor, before we go on to question 4 to look at why the practice stopped, could you just explain to us how donor sessions at, for example, Saughton Prison were conducted? Can you talk us through what would happen?

A. Well, the sessions were arranged through a member of staff in the prison, usually through the director of the prison, who would delegate to the prison medical officer. The dates were obviously set well in advance. They were part of our routine donor programme, which was usually set anywhere between 12 and 15 months ahead to allow all the necessary planning.

The conduct of the donor sessions in the prisons would be, as far as possible, identical to that of the

conduct of a donor session anywhere else. The same, you know, personnel who attended would be the same mixed people. There would be a doctor in those days, the doctor was always present at the session, the senior nurse or team leader and a group of what were then called "donor attendants".

Between them they would, as I say, operate the session very much according to the same processes as any other session. Essentially, the donors would attend. Obviously our staff would work on the premise that the donors were volunteers when they attended, and then there would be a discussion -- which you may wish to explore -- around the nature of volunteering when one is in a penal institution. But, for the purpose of the sessions it had to be accepted that the donors were volunteers.

They would then be welcomed to the session. In this period they would have been given an information card which was pretty standard across the UK, in fact, which gave a series of criteria which, if they had any of these particular features, they would be asked not to donate. Then they would go to the sort of station where there was a clerical person, who would sort of walk them through that card again and ask them a few questions to sort of confirm that they had read it, record some of

the information about the donor and then they would pass to a separate person who would take a sample of blood, using a finger prick technique, which was tested for haemoglobin. Provided the donor passed that test, they would then be moved to another waiting area from where they would lie on the couch and have their blood taken.

That was, in very brief outline, the procedure.

I think one thing that is perhaps helpful to add is that while this appears to be a sort of stepwise process, in fact most of the staff, particularly in these days had -- the donor would be seen, talked to and observed by our staff throughout the whole process, so if something struck a member of staff, you know, perhaps even when the donor was giving blood that they felt uncomfortable about the donor's suitability, that issue would still be noted and acted on.

So there was a fair amount of sort of observation of the donor through the whole process of donation.

Q. What sort thing might strike a member of staff about the donor's suitability?

A. Take some very obvious examples, someone who was heavily tattooed, which, for some reason might not have been noticed at an earlier stage. When you expose the arm to take a sample, anybody who had evidence of needle injection tracks, anybody who appeared to be inebriated,

which was fairly unusual in the prison sessions but not unheard-of elsewhere.

I think it is important to say that at that time quite a lot of donor selection, despite the existence of certain pieces of paper that said, "You must do this, this and this", there was almost certainly a fair amount of individual variation in the sort of way that individual members of staff would assess a donor and to be honest that remains to this day something that is extremely difficult to control with a very large team of people operating peripatetically in a whole lot of different situations.

So while we have always striven for consistency in the application of these standards, it is, I think important to realise that that's actually very difficult to achieve.

Q. Doctor, I think from an early stage in the 70s the Blood Transfusion Service wanted to exclude donors who injected drugs because of the obvious risk of transmitting diseases. Is that correct?

A. Yes.

Q. What steps were taken at donor sessions outwith prisons to seek to exclude donors who had a current or previous history of injecting intravenous drugs?

A. Looking at the donor selection documents, which exist

from this period, which I have been able to access -- and that certainly is not a comprehensive sample of all the documents going back to the 60s and early 70s -- it was clearly a feature of those documents that a history of injecting drugs or evidence, physical evidence of having injected drugs was seen as an exclusion criterion.

Q. Again, sticking with donor sessions outwith prisons, would the donor have been asked about whether he or she had ever injected drugs in the 70s and early 80s? Would that question have been asked?

A. I think it is important to realise that at some of these earliest stages, there was relatively little interviewing of donors in the sense of actually face-to-face questioning. A lot of this was done by providing the donor with information, asking him to respond to that information if they felt they had any of these features.

So I think actually in the majority of donor sessions, the majority of the staff, I think, would have asked that question, but in the period before sort of routine questioning of the donor was part of the procedure, one cannot be certain that it would have been asked to everyone.

Q. So can you help us with approximately when you think the

majority of staff may have asked a question about current or past drug use?

A. Well, I think that the point at which it becomes really possible for me personally to make confident statements about what happened is really at the beginning of the 1980s when, as I think I have said in my statement, there was awareness of AIDS as being a new and dramatic problem. There was the beginning of a really sort of step change in the rigour of the donor selection procedures in the desire to have a sort of national consistency in proper documentation of the procedures as they evolved with document control.

I think in the period prior to that -- first of all I wasn't working in or around the transfusion service at all so it is impossible for me from personal experience to say what the details of the procedure were -- I think there was probably a fair amount of heterogeneity among the centres as to what was done.

Q. It may be helpful to look at a couple of the donor selection leaflets at this stage. If we could go to [PEN0131395]. This is a leaflet from Glasgow, not from Edinburgh. I think if we go to the very bottom right-hand corner of the leaflet, down again, we can see somebody has written on the date 16 June 1983. If we go back to the top of the leaflet, please, we can see

a list of questions about various matters but I don't think there is any reference to drug use, whether current or previous. Is that correct?

A. That's certainly correct. I'm familiar with this document and it does not refer to drug use, the date is probably correct because it has the little addition at the bottom about AIDS, which was the very first action taken by the West of Scotland BTS to introduce something about AIDS into their selection.

Q. Does that look like a sticker that has been added onto this donor selection leaflet?

A. It does, yes.

Q. If we could also for completeness just go to a similar document, document [SGF0010397]. I think, if we look at the top right-hand corner of this leaflet, doctor, we see "NBTS 110A (Rev. 1983)". So on the face of it this would appear to be an example of a donor leaflet from the National Blood Transfusion Service of England and Wales. Is that correct?

A. That's correct.

Q. It appears to have been revised in 1983, and again I think there is no reference in this leaflet to asking the donor whether they have ever injected drugs. Is that correct?

A. That's correct and I think that this NBTS110 was quite

widely used as a sort of template because I think the wording in the Glasgow document is very similar to this.

My recollection is that there was, as it were, issued concurrently with this what is called a memorandum or a guide to donor selection procedures which was a kind of instruction to staff, which went further than this and did make reference to drug injection. But what is not entirely clear was how that particular instruction was to be implemented and, as it were, quality controlled at the donor sessions. And as I have I have said, I think it was probably quite inconsistently done.

But that is something I really cannot comment on from personal experience and I'm giving you an impression which is partly based on, you know, subsequent experience of trying to explore the extent to which written guidelines are adhered to as a generic issue and I suspect that there was a fair amount of inconsistency in how this was applied, but I would stress that is not from my personal experience because I don't have any personal experience of that period.

Q. I think, doctor, you first joined the service in 1977 and became the regional director for Edinburgh in 1979.

A. That's correct.

Q. So between, say, 1977 and 1981 or 1982, did you actually

go out to donor sessions or was that not something you would do, or what?

A. I went to a few donor sessions. I didn't probably go to as many as I should have done but I would have been maybe half a dozen donor sessions.

Q. Thank you. That's very helpful background. Thank you, doctor. Could I just turn now, please, to your statement?

THE CHAIRMAN: Mr Mackenzie, are you coming back to the procedure in prisons?

MR MACKENZIE: I think I should actually, sir, yes.

Just perhaps to complete this passage, doctor, I should ask perhaps firstly: are you aware whether any specific steps were taken at sessions in prisons to exclude those who had ever injected drugs?

A. I'm not aware of any, as it were, written documentation that refers to special procedures. I'm not aware. I'm not saying they don't exist but I certainly have not seen any documentation which I could draw on to answer that question. So I would have to say to my knowledge there were, as I have already said, no sort of unique, explicit measures for sessions in prisons.

THE CHAIRMAN: The reason I ask, Dr McClelland, is that there is material -- and you may be referred to it, I don't know -- from Glasgow dealing with testing, which

proceeds on the fairly confident statement that none of the donors in prisons were drug addicts.

Now, whether that confidence was justified is a different matter but to be able to say that it appears that there must have been some sort of pre-selection of the group. Are you aware of any steps involving prison doctors that might have had that effect?

A. I'm aware obviously of the documents from Glasgow that you refer to. I'm not aware of what steps may have been taken in the West of Scotland sessions to establish that fact.

THE CHAIRMAN: Thank you.

MR MACKENZIE: Thank you, sir.

I think we may come back to explore that with Dr Mitchell this afternoon. Could I ask one final question on this matter, though, doctor, please.

A. Yes.

Q. Are you aware whether prison donors received any reward or inducement to donate blood?

A. I'm quite certain that they did not receive any material, financial or remission of sentence or any material award. I think, particularly from statements that I recall being made by Dr Ewa Brookes, many years ago when the transfusion directors were discussing this whole question of should donations be taken in prisons,

Dr Brookes said -- and I remember this because it was quite a graphic statement -- she had actually taken the trouble to roster herself when she worked in London as the doctor for, I think, half a dozen prison sessions. At that time she had already -- and she voiced this quite strongly to the directors -- felt that prison sessions were not a good idea and one of the reasons was that there was an incentive, which was to get out of wherever you were as a prisoner, presumably locked up, to get somewhere else, to see some girls, young women -- or not so young women -- actually to talk to somebody who wasn't one of your fellow inmates or a warder. So that actually could -- and I think in Dr Brookes' view, who had more experience of this than I have had, was actually quite a powerful incentive. That and other reasons which she articulated. I think she was of the view that this was not a suitable place to be collecting blood.

Q. So perhaps an intangible benefit perhaps to donating?

A. Absolutely. But in terms of any sort of overt material, you know, type of benefit, no, there is no question that has never been a practice for any donors in the United Kingdom, to my knowledge.

Q. Thank you.

If we could, please, return to page 5 of the

statement. I think it is 0076. Thank you. Question 4, the doctor was asked why the practice of collecting in prisons stopped. You say that for Glasgow, Dundee, Aberdeen and Inverness:

"[You] do not remember discussions of the reasons that led these centres to stop donor sessions in prisons."

And you have been unable to find documentation as to that reference in the preliminary report. You then refer to the medicines' inspectors' report on the Edinburgh centre. I think it might be helpful to look at that now, please. That document is [SGF0010351]. Can we go over the page, please, to page SGF0010352.

I'm sorry, I should have prefaced this by saying this was a report by the medicines inspectorate following, I think, visits to Edinburgh BTS in March and May 1982?

A. That's correct, yes.

Q. And at the top of page 0352 in paragraph 12(b), there is a comment by the inspectors:

"The location of bleeding and type of donor, for example whether prisons and borstals were really appropriate or necessary as a source material."

Doctor, you became director in 1979. This report was produced some time after, May 1982, which raised the

query regarding whether prisons and borstals were appropriate or necessary. Do you recall whether you gave any consideration to the practice of collecting blood in prisons between, say, 1979 and the arrival of this report?

A. Well, yes, we did, and I have dealt with that elsewhere in my statement. By 1982 -- I mean, the last occasion which the Edinburgh centre teams went to Saughton Prison, I think it was December of 1980. It is in the table.

Q. 1981, I think.

A. Yes. So we had considered it and I have gone into a little bit of sort of background elsewhere in my statement and decided that we weren't going to do it. The Edinburgh teams never went back to a prison session after that.

Q. We will come back to look at that shortly, doctor, but in short, is it the position that when this report arrived, some time after May 1982, you were already or had previously considered the question of whether it was appropriate to continue the practice?

A. We had considered and acted on it. This was a rather unusual medicines inspector's visit. It was one of the very first and I think as is apparent from reading the report, the inspector was ranging quite widely over

a number of issues. I assume, but I actually don't recall this, that they had already inspected other centres, either here or south of the border, where there were prison collections, and I think he was sort of speculating out loud as to whether this was a good idea. But it is a documented fact, and we have very carefully rechecked this, that December 1981 was the last time that we collected blood. I have taken the trouble to try and reconstruct the basis of that decision. So, yes, as I say, not only when we considered it but we had stopped it before we met the medicines inspector.

Q. We will come back to that, doctor, but could we just look at the report of the visit to Ninewells Hospital in Dundee. This is document [SGF0010086]. We can see at the top of this document that it is a report following a visit, I think, on 25 March 1982 by the Medicines Inspectorate to Dundee. If we go down to paragraph 10, we can see a little more detail than we saw in the Edinburgh report. We can see in paragraph 10:

"Brief discussions were also held on sources of donated blood. At the time of this visit the Inspectorate had not visited donor sessions with mobile teams. However, it would seem most unlikely that we could continue to endorse the continued collection of blood from such places as prisons and borstals."

Paragraph 11 states:

"This recommendation is based on the following:

"12(a). Prison medical officers are often not involved in assessing the suitability of donors.

"13(b). The increased risk of infection associated with prison populations and the increased risk of transmitting disease through such donations."

Over the page, please, 14(c):

"The unreliable answers to the pre-donation questionnaire that can occur in such environments, as well as the motivation of some of the donors."

Now, doctor, the reasons set out by the inspectors for querying the practice of collecting blood in prisons, are those the sorts of reasons which were in your mind when you considered the practice prior to these visits and reports?

A. Yes, they were. I think actually our concern -- I did, in trying to provide as full as possible a response to why we stopped the prison sessions -- I actually spoke briefly to the person who was then our regional donor organiser, who was responsible for all the planning and organisation of the sessions, who was a new recruit to the organisation, who started shortly after I had begun, and she had certainly raised concerns with me, which echoed my own concerns, not least because she actually

felt it was just an unsuitable environment in total.

It was almost more that concern, plus the specific concerns that really, for lots of very good reasons, we could not rely on getting completely clear transparent answers from prisoners, not least because the sense was that the prisoners weren't so much afraid of authority or of the transfusion staff, but it was very difficult for a prisoner, possibly within earshot of other inmates, to admit any form of illness or something that might be seen as weakness because of the nature of the sort of social environment in the prison.

So it would not be correct for me to say that we were worried about hepatitis in the prisons. We were worried about the totality of the environment and I was certainly aware that infection with hepatitis and related viruses was a problem in prisons. I was certainly aware of that information in the United States. So it was a sort of complex of things that led us to this decision.

Q. Yes, and the concerns of the member of staff you mentioned, were they to do with it wasn't fair to put members of the BTS staff into prisons conducting the sessions?

A. I think the BTS found it quite a threatening environment.

Q. Yes, I understand that.

Returning to paragraph 15, before we leave this document, I think we can see reference to something you mentioned before. Paragraph 15:

"While it is understood that the questionnaire used for donors is a fairly standard one, its interpretation appears not always to be consistent."

Is that along the lines of what you mentioned earlier?

A. Absolutely. I think it is a very fair description of the situation.

Q. Simply completing this line of documents, if I could, please, then look at the Edinburgh response to the Medicine Inspectorate's report, and this is document [SGH0035059]. Could we, please, go to page 5063. We can see "Blood donation", paragraph 1.11.a. Just continuing what we have just looked at in terms of the interpretation of the guidance varying and Edinburgh's response -- I should say this is dated 12 January 1983 -- it states:

"We share the inspector's concerns. The following actions have been taken and a new comprehensive guide to donor selection has been prepared and is in routine use by donor selection staff."

And other steps are set out there as well.

The paragraph below is the Edinburgh response in relation to prisons and borstals, and we can see:

"Prisons and borstals. We do not visit these regularly. No such sessions have been held for two years. These donors will only be used in an emergency."

So was the position of Edinburgh at this stage in January 1983 that you wouldn't routinely visit prisons to collect blood but you wouldn't necessarily rule it out if an emergency dictated or required that?

A. That must, I think, be the interpretation. We never did go to prisons again. Having tried to reconstruct this, I find no evidence that we recorded a policy decision that we will stop collecting blood in penal institutions; we just stopped doing it. We informed the contact person, who I think was the Director of Saughton actually, or whatever the correct title was at the time, that we were not making any further appointments, and in fact we had several representations from them subsequently to come back and run sessions and we did not do that.

I honestly cannot remember now why we did not, as it were, make it a formal policy. I have tried very hard to find any evidence of that, but, as I say, the actions are that we did not ever return and we did not book any

1 further sessions and we never felt any need to do so.
2 Q. Thank you. If we could now return to your statement,
3 please, I think we have covered some of the ground which
4 follows.
5 A. Yes.
6 Q. So if we go back, please, to WIT0030076, under
7 "Edinburgh" you explain why the practice stopped but you
8 have given oral evidence on that, without having to take
9 you through your statement. Over the page again,
10 please, at the top of page 6 of your statement you do
11 say:
12 "I cannot recall if I was specifically concerned
13 about hepatitis risks in donations given by prison
14 donors but in view of my study, training and experience
15 before joining SNBTS, I think it is likely that I would
16 have been aware of this as a risk."
17 A. Yes.
18 Q. You say you may have read the 1972 paper by Wallace and
19 others in the BMJ, although you do not remember doing
20 so. I think you then speak about matters you have
21 already spoken to. In particular, Mairi MacLeod,
22 I think, was the individual who played a part as well in
23 no longer visiting prisons?
24 A. Quite definitely, yes, absolutely.
25 Q. I think half way down page 6 you say:

"I think it is unlikely that the question of risks related to homosexual behaviour was raised since up to 1983 it was not the practice in any blood collection practice, as far as I'm aware, to take actions to exclude donors on the basis of sexual behaviour."

That changed rapidly with the arrival of AIDS, and we will come on separately to look at that in a separate topic.

A. Correct.

Q. Before we leave this page, doctor, can I refer to one further document, which is number [SNB0143030]. This is to do with minutes of a meeting of the UK Working Party on Transfusion-associated Hepatitis. If we look at paragraph 4, there is a discussion of AIDS, and I think if we go towards the end of the document -- perhaps start at the last page and scroll backwards. If we look at paragraph 7, we can see that is headed "Donor sessions in prisons" and states:

"Members asked if the chairman could provide details of which centres took donations at prisons. They realised that the definition of prison ranged from closed to open prisons. The working party felt that prisons should be considered in the context of a high risk population in terms of several of the transfusion-transmitted infections and as such should be

avoided as a donor source."

If we go back to the first page, please, we can see the members of the working party included, I think, Dr Bruce Cuthbertson from Edinburgh -- "PFC" -- and also I think yourself, you were a member, and Dr Mitchell.

A. Yes.

Q. Would it be fair to say that's a fairly eminent body of transfusionists at that time, putting modesty aside?

A. Dr Craske was a biologist, as you know.

Q. Yes. Certainly, the view of the working party at that time in September 1983 was that prisons were not an appropriate place to collect blood?

A. Yes.

Q. And of course AIDS had come on the scene by that stage as well?

A. I honestly can't recall whether that comment about prisons was a conversation that raised concerns about AIDS rather than hepatitis. I think it probably was the latter because, as is evident from this minute, although it is called "Transfusion-associated hepatitis", the big issue, AIDS, had taken over completely in people's pre-occupations.

Q. If we go back to paragraph 7, in the second last page of the minute I think there was a reference to several transfusions-transmitted diseases.

A. Yes, there was, absolutely correct.
Q. We can see that there.
A. Yes.
Q. Thank you. Could I then, please, return to your statement? We are now on to page WIT0030078. At the top of this page, question 5, you were asked:

" ... the consideration given between 1975 and 1984 by those from the SNBTS to whether blood collected from prisons carried a higher risk of hepatitis, including in particular non-A non-B hepatitis, and whether the practice of collecting blood from penal institutions should continue."

You explain that you were not involved in SNBTS discussions before your appointment in 1977 and you would not have attended meetings of the SNBTS directors until 1979, and you say:

"I do not recall that the matter of donation by prisons was discussed during meetings of SNBTS directors before the May 1983 meeting."

You then go on to say that:

"Both the Edinburgh and Glasgow centres had started research on hepatitis by 1970."

You state:

"The Glasgow studies demonstrated a higher prevalence of Hepatitis B surface antigen in prison

donors."

You refer to two papers we have looked at, the 1972 Wallace paper, the 1982 Barr paper and also a textbook by Dr Wallace, which I think was 1977. We will come back to that. The next paragraph goes on to say:

"Prison donations were discussed in Dr John Wallace's book."

I think Dr Wallace was the director of Glasgow at the time?

A. That's correct.

Q. "His book 'Blood Transfusion for Clinicians' published in 1977."

A copy of that book was given to you by Professor John Cash on his appointment in Edinburgh in 1977 and you read it at the time. You helpfully set out a passage from this book on this topic. This is at page 279 of the book. We don't have to go to the book because you have helpfully set out the passage, but for the record using the Inquiry numbering system, it is [LIT0013058] at 3106. You say that Dr Wallace described the issue of collecting blood in prisons as controversial. He also stated that:

"It has been established that within any potential donor population, certain groups have a higher than average incidence of HBs antigenemia, in particular HBs

antigenemia is more prevalent in male prisoners and in volunteers from tropical areas. Some transfusion services have declined to accept volunteers in prisons and among immigrant populations. This ultra-cautious approach may be doubly undesirable. Visits to prisons can often be arranged when the general intake of blood is low because of the holiday season. The incidence of HBs antigenemia among male prisoners in Scotland is less than 1 per cent using the most sensitive technique of testing, thus generous offers of useable donations would be lost by placing a total embargo on prison donations."

In short, I think Dr Wallace was in favour of continuing to collect blood from prisons and he has set out his reasons there for holding that view.

I think, in particular, would it be fair to say that it was the fact that visits to prisons could often be arranged when the general intake of blood was low because of the holiday season or perhaps other reasons. You mentioned earlier, doctor, that visits were often arranged a year or move in advance but did donations sometimes also take place at short notice?

A. My comment before was referring to the way the sessions were organised in the centre that I was responsible for. I honestly can't respond to whether there were short-notice sessions organised in the other centres.

But I suspect that what happened was that they were aware, you know, from experience, that there were certain times of the year, Glasgow trades or around Christmas or New Year time, when their ability to organise other donor sessions was reduced and possibly attendances tended to be below what was hoped for. So they may well have actually scheduled sessions in prisons at those times because they could predict a shortfall.

Q. I understand.

A. Dr Mitchell, I'm sure, will be able to give you --

Q. It may be predictable in advance, perhaps well in advance, that there may be certain periods in a year when the donation figures may be low.

A. That's my hypothesis. I don't know whether that is actually correct.

Q. Indeed, yes. You say:

"Reading this passage again after many years, I can only interpret it as implying (a), a higher level of confidence that testing donations with a very sensitive test for HBsAg and removing all donations with positive test rules would virtually exclude the risk of transfusion-transmitted Hepatitis B, and (b), a belief that, provided Hepatitis B transmission was avoided, the blood would be safe. This seems somewhat at odds with

the statements on pages 273 and 274 of Dr Wallace's book that refer to 'other infective agents that might transmit hepatitis, such as the predicted virus C' and to the fact that Hepatitis B screening may only detect 25 per cent of cases of post transfusion hepatitis."

"I think this apparent inconsistency must be a reflection of the prevailing sense at the time, that hepatitis not due to Hepatitis B virus was not a serious condition and Dr Wallace also makes the case that it is socially and psychologically undesirable to exclude prisoners from the donor population on the basis that acceptance of prisoners as donors helps them to rehabilitate."

I do intend turning to a number of publications to look at the knowledge of non-A non-B hepatitis at the time. It may be, sir, this would be an appropriate stage to have a short break?

THE CHAIRMAN: I think that would be.

Dr McClelland, if we look at the large passage. Reading this passage again and in particular the views expressed towards the end where you say:

"The apparent inconsistency must be a reflection of the prevailing sense at the time."

At that stage would you have shared the views you referred to here?

A. I have found this very confusing when I read it again because it seemed to be saying several conflicting things. I would not have shared that view. I do think that, lying in back of this is something which I think came through to me in reading a lot of this material again, that there was a very strong sense within the UK that non-A non-B hepatitis wasn't a big problem in the UK.

There was clearly awareness that it was a big problem in the United States, that is in spite of the fact that the only prospective study of transfusion-transmitted hepatitis that was done for many years was organised by the Medical Research Council in the UK and published in 1974. The data, we are actually interpreted as saying that it wasn't a problem apart from Hepatitis B. Non-A non-B hepatitis wasn't a problem but actually, if you look at the data for five minutes, it actually clearly is a problem and that, you know, coming from a group of eminent academics seems -- again, I had real difficulty understanding that when I looked at it again.

It does seem to me that there must have been a very strong received belief that somehow non-A non-B hepatitis just wasn't a problem in the UK sufficient to cause highly intelligent people doing research study to

actually really ignore their own findings and interpret them quite inappropriately, in my view. So I think that sort of attitude, the power of that sort of attitude must underlie this statement of Dr Wallace.

It's speculation.

THE CHAIRMAN: Yes. There are two possible aspects to it, from what you have said, I suppose. One is that non-A non-B hepatitis was not a significant problem in the United Kingdom because there was not a high prevalence, and the other is that such non-A non-B hepatitis as there was did not present a high risk. Do you have any view as to which it might have been -- or both?

A. Well, there is possibly a third interpretation, which was there was non-A non-B hepatitis but it wasn't recognised as such because it's typically, as you will now know very well, in the course of this infection, the classic feature, you know, the sort of hallmark feature of jaundice is unusual in the early stages. So unless individuals were being actually checked and monitored for evidence of disturbance of liver function tests, there could be nothing to really draw attention to the fact that an infection had happened.

THE CHAIRMAN: I think we will see that from time to time. The problem here that I have, I think, is that, looking back now with the benefit of a great deal of developing

knowledge over time, some issues become questionable because of hindsight, but I think I have to try to penetrate back to what the perception might have been at the time.

A. Yes.

THE CHAIRMAN: And that's why I'm trying to get your feel, as it were, for what might have explained this. It could be quite important to understand. Anyway, we will have a break now and if you come up with anything in the break ...

A. Okay.

(11.00 am)

(Short break)

(11.34 am)

THE CHAIRMAN: Yes, Mr Mackenzie.

MR MACKENZIE: Thank you, sir.

Dr McClelland, I would like now to look at some publications illustrating the knowledge of non-A non-B hepatitis in the late 1970s. Could we start, please, with an extract from Dr Wallace's 1977 textbook. It is number [LIT0013058]. Can we go in particular, please, to page LIT0013100.

THE CHAIRMAN: Which page in the book is it, Mr Mackenzie?

MR MACKENZIE: It is page 273, sir.

THE CHAIRMAN: Thank you.

MR MACKENZIE: And at the bottom of the page we see the subheading "improved selection of donors." I think this is the passage which you had earlier referred to in your statement, Dr McClelland, and I'll simply read this passage. It states:

"The recognition of Hepatitis B surface antigen as a marker for the infective agent of type B hepatitis, introduced the possibility of testing every blood donation of the presence of HBsAg. Considerable discussion ensued as to the benefits resulting from the costly and time-consuming procedure of total screening. Some authorities stated that the exclusion of HBsAg-positive donors would, at best, reduce the incidence of post-transfusion hepatitis by only 25 per cent. The inability to prevent 75 per cent of cases of transfusion-transmitted hepatitis was considered to be multifactorial."

Over the page at page 274 of the book:

"1. The methods of detecting HBsAg by large scale screening with a relatively insensitive immunodiffusion and CIEP techniques.

"2. It was suspected that HBsAg was not homogeneous and that different subtypes would make detection difficult.

"3. Other infective agents might transmit

hepatitis. These included virus A, CMV, EBV and viruses not yet identified, such as the predicted virus C.

"For the use of absolutely fresh, untested donations, some clinicians considered that fresh blood had clinical merit and insisted on its use.

"5. A route of transmission other than transfusion was recognised that various hepatitis viruses could be transmitted by parenteral routes other than transfusion and by close contact."

There is a reference there to the predicted Hepatitis C at page 283. That's our reference 3110. At the top of the page we see, it states:

"The difficulties in establishing the diagnosis and incidence of post-transfusion hepatitis have already been discussed. For similar reasons, it is difficult to assess the benefit of total screening of donations for the presence of HBsAg but careful studies from USA have provided valuable information. Prince et al (1974), in a detailed prospective study of 204 cardiovascular surgery patients, found that an agent other than virus B seemed to be the cause of 36, 71 per cent, of 51 cases of overt post-transfusion hepatitis. The sera of these 36 cases of hepatitis showed no evidence of the presence of HBsAg or of anti-HBs. Incubation periods and clinical and epidemiological features were inconsistent

with the diagnosis of type A hepatitis, while the serological evidence indicated that it was unlikely that CMV or EBV infections had caused the post-transfusion hepatitis in these 36 cases. It was concluded that another infective agent, virus C, was involved and that complete control of post-transfusion hepatitis would require identification of this postulated hepatitis virus."

It may, for completeness, be helpful to go over the page to page 284 and about two thirds of the way down the page the paragraph commencing:

"Evidence from the USA indicates that a long incubation form of hepatitis, other than type B, exists and this has been named type C or non-A non-B. Present evidence on this infection in Britain is scanty but most cases of post-transfusion hepatitis seem to be type B, although some cases with relatively short incubation periods are associated with type A or CMV or EBV infections. It may be that at present, type C infection is rare in Britain. More evidence on this subject will emerge as RPHA and RIA are introduced as the method of testing donations for HBsAg."

And to complete this passage; the next page at page 284, again about half way down the page, a sentence commencing:

"While type B hepatitis seems for to be the form of post-transfusion hepatitis most commonly encountered in Britain, it would be ..."

I'm sorry, we are on 285, please.

THE CHAIRMAN: Where is it, Mr Mackenzie?

MR MACKENZIE: It is about half way down, sir.

THE CHAIRMAN: Yes, about seven or eight lines down.

MR MACKENZIE: "While type B hepatitis seems to be the form of post-transfusion hepatitis most commonly encountered in Britain, it would be advantageous to recognise markers for the infective agents of non-B hepatitis, such as type B and type C if the latter really exists."

The comment at the end, "if the latter really exists," does that tell us anything, doctor?

A. I think, you know, the whole sort of set of passages that you have read, really underscores what I said just before we broke, that this certainly reflects an underlying attitude that this wasn't a big problem in this country. Which again is slightly difficult to understand when in the first paragraph that you read I think it is suggesting that only 25 per cent of cases of post-transfusion hepatitis can be explained by Hepatitis B testing, given that there are a number of reasons explained for that, like insensitive tests and Epstein-Barr virus and so on. It is somewhat

inconsistent with the sort of conclusion that he moves on to, that maybe it is not a problem and maybe it doesn't exist at all. So I think it just again shows us a sort of attitude that was clearly quite prevalent at the time, that somehow non-A non-B hepatitis, which is due to virus C, isn't a big problem in the UK.

Q. Was there a sufficient evidential basis in the UK in 1977 to say that non-A non-B hepatitis didn't seem to be much of a problem?

A. No. I mean, there wasn't. The one study that I can remember as preceding that was the one we have already touched on, the MRC study, which was interpreted and then reported and recycled, as it were, as basically concluding that non-A non-B hepatitis was not a major transfusion problem; whereas in fact, the data could be interpreted as indicating it was actually quite a large problem in this particular population.

It was a bit confused, that study, because the patients were enrolled over the period when Hepatitis B testing was just beginning and that does make the findings a little bit more difficult to interpret. But even stripping that out, I would have thought being, you know, a proper prospective study, that was actually quite strong evidence that there was something going on.

There were subsequent studies, which I have reviewed

in another paper -- I haven't got them all in my head. But there was a study in 1983 in Newcastle of, I think, 100 or 200 post-cardiac surgery patients, in which the incidence of persistent elevation of Alanine Aminotransferase was very low, which would be consistent with the view that this maybe wasn't a big problem because these patients have received quite a lot of blood.

Then later there were further studies, particularly done around the north London transfusion service, which also were interpreted that the incidence was low. But the difficulty was the studies were really all too small to get the numbers that would allow you to estimate the size of the problem.

Q. I should perhaps say, doctor, I think we will come back to look at all these studies in a separate topic after the summer, the surrogate tests.

A. Sorry.

Q. No, it is helpful to know that.

A. Your question was date limited, and 1974, I cannot from recollection think of any other studies that were designed in such a way that would have given us very useful information about the size of the risk of non-A non-B, whatever agent was causing it.

Q. It may be helpful just to compare what is said in

Dr Wallace's textbook in 1977 with a report from North America on the question of transfusion-transmitted NANBH. So if we could, please, look at document [LIT0013657]. This is a paper entitled "Transmission of non-A non-B hepatitis", written by J A Hoofnagle and others, including Gerety and Purcell and Feinstone; names we see quite regularly in this field.

If we go to the bottom left-hand of the paper, we can see these authors were employed at the Bureau of Biologics of the US Food and Drug Administration and also at the National Institutes of Health in Maryland. In short, what are these bodies, doctor? What are these bodies, the Bureau of Biologics and the National Institutes Health?

A. The Bureau of Biologics was essentially the United States health service regulatory agency for biological medications, biological treatments, as part of the Food and Drug Administration. The laboratory of infectious disease. The NIH, the National Institutes of Health was probably the prime medical research institute in the United States. So these are the heavy hitters, these guys.

Q. Thank you. We can see on about the right-hand page of the paper, this report is published in the Annals of Internal Medicine. What journal is that?

A. It is an important, longstanding, respected American medical journal.

Q. If we go forward, please, to page 3662, the right-hand column, a little bit down the paragraph beginning:

"Several clinical and epidemiological features of non-A non-B hepatitis have become clear from studies such as the present ones."

I think this paper is quite helpful in perhaps summarising knowledge in America at this time:

"First, non-A non-B hepatitis closely resembles type B hepatitis. The incubation period, the clinical symptoms and signs and the potential for chronicity appear to be similar to type B hepatitis. Undoubtedly, what was once referred to as 'serum hepatitis' included both type B and non-A non-B hepatitis.

"Second, non-A non-B hepatitis appears to be spread predominantly by the paraenteral route. Most cases have been described in association with transfusion, intravenous drug use or serum inoculation. However, as in type B hepatitis, the importance of non-paraenteral routes of transmission -- by saliva, sexual and intimate contact, biting insects -- needs to be assessed. Third, non-A non-B hepatitis appears to be associated with a chronic carrier state in chronic liver disease."

Skipping the next sentence:

"These implicated blood donors were, for the most part, asymptomatic. Both the liver function tests and liver biopsy examinations frequently showed evidence of underlying chronic hepatitis.

"Finally, non-A non-B hepatitis appears to be common. Previous studies on post-transfusion hepatitis have shown that 40 to 71 per cent of such hepatitis is non-A non-B. Currently all blood donations are screened for HBsAg by radioimmunoassay or a method of similar sensitivity. Data generated from post-transfusion hepatitis studies done since the institution of such sensitive screening methods suggest that at the present time, more than 90 per cent of post-transfusion hepatitis is due to non-A non-B hepatitis."

To pause there, doctor, I think most or perhaps all of the evidential basis for what is said here results from studies carried out in North America. Is that correct?

A. I believe so. I mean, the literature that probably first sort of engaged my interest in this was actually a conference report, which included an early report of something called the transfusion-transmitted viruses study, which some or all of the authors of this paper were involved in. That was an observational study, as opposed to a trial but it was a very big and very well

done observational study which demonstrated that there was substantial incidence of disturbance of liver function tests in individuals being transfused.

This was built on earlier work by, I mean, notably -- I have blank for the name. Sorry, it will come back to me in a minute.

There was a surgeon in the United States who had been actually publishing a great deal of work on the incidence of post-transfusion hepatitis prior to that, including a book on the subject.

But I was personally aware of the reports of the TTV study, and of course, that and a subsequent study also somewhat serendipitously identified the issue -- which we were then able to come on to -- that possibly some form of testing that wasn't actually a direct test for a virus had the potential to mitigate the risk to blood recipients.

Q. We will come back to the testing.

A. I'm sure.

Q. Thank you, doctor. Simply to complete this line of what was the knowledge of non-A non-B H at the time, could we go next, please to [LIT0010189].

THE CHAIRMAN: Doctor, was it J Garrot Allan?

A. Allan, thank you.

MR MACKENZIE: This is another publication in the Annals of

Internal Medicine, this time in July 1979. This is entitled "The chronic sequelae of non-A non-B hepatitis". The authors include Berman and Alter. Again, we can see from the bottom left-hand side of the page is from the National Institutes of Health in America. Again, I think there is quite a helpful summary at page 0192. The bottom left-hand column, essentially five observations or points are made which I think are consistent with the paper we have just looked at but perhaps developing the previous paper a little.

So towards the bottom of the left-hand column:

"Several interesting features of non-A non-B hepatitis and its relation to chronic liver disease derived from this study. First, although it can be clinically severe, acute non-A non-B hepatitis after transfusion is usually anicteric, mildly symptomatic disease and probably goes undetected in most patients not prospectively followed. A very large number of non-A non-B hepatitis cases may occur each year but an accurate assessment of its incidence will not be possible until tests are developed that will detect specific serologic markers. Second, many cases of non-A non-B hepatitis are associated with prolonged elevations of serum transaminase."

The next paragraph:

"Third, the predominant histologic lesion of chronic non-A non-B hepatitis appears to be chronic active hepatitis."

The start of the next paragraph:

"Fourth, among patients with acute anicteric, non-A non-B hepatitis in this study, the tendency to develop chronic hepatitis could be predicted by the peak SGPT elevation; anicteric patients with an SGPT in excess of 300 IU/L were much more likely to develop chronic liver disease than were those with lesser elevations."

At the bottom of the page:

"Fifth, although one of our patients with chronic non-A non-B hepatitis and one in a previous study had histologic evidence of cirrhosis, patients with non-A non-B hepatitis, including those with chronic active hepatitis, usually show gradual improvement in abnormal serum biochemical indices."

We can then leave that paper there. Is that the sort of paper or knowledge you were aware of at the time, doctor?

A. Probably, yes. And what -- the date of date of this paper is?

Q. This was July 1979.

A. No, probably not in 1979, I have to say. I have been

working on quite different things for a while then but I certainly was aware of the substance of this information within quite a short time after joining the SNBTS. Certainly by 1980.

Q. Just out of interest, doctor, you, I think, joined the SNBTS in 1977 and became regional director in the southeast in 1979?

A. Yes.

Q. During the 1970s and perhaps early 1980s, how was knowledge distributed among transfusionists? What periodicals did you read? How did you know about updates in knowledge?

A. Well, there were a small number of journals. There was then an American journal called "Transfusion". There is an European journal called "Vox Sanguinis", which were both published at that time and I think were both quite widely read, certainly among my medical colleagues in transfusion.

The British Society of Blood Transfusion probably was formed after this date. So one was probably dependent in terms of meetings on some very sort of, you know, ad hoc organisations, gatherings of professional staff and blood transfusion services. Certainly pre sort of Internet type exchange of information.

So I would have thought that actually the primary

route of acquiring new information would have been from reading either the transfusion journals or others, who may have had an interest in another specialty as well, may have looked for transfusion-related topics in, for example, journals of surgery, or anesthesia or intensive care. But I think in the 1970s there probably wouldn't very much in those journals.

Q. Thank you. To complete this line of literature and to come back to Scotland, could you, please, look at [PEN0020511].

THE CHAIRMAN: The original reference was 0511 and I don't think we are there yet.

MR MACKENZIE: Yes. Could we go back to the [PEN0020511], please?

This, doctor, takes us back to Scotland. It is an article, "Viral hepatitis in Glasgow, 1976 to 1977" contributed by Dr Chaudhuri and another, and Dr Follett in Glasgow. The reason I refer to this article is that it appears to be one of the first reports, I think, of non-A non-B hepatitis in Scotland. In the summary we can see that:

"During the two-year period from January 1976 to December 1977, 164 patients with a viral hepatitis were admitted to the infectious diseases unit at Ruchill and Belvidere hospitals Glasgow. Of these 52, 32 per cent

of patient had Hepatitis B, as they were found to be HBsAg positive. In 112 patients who were HBsAg negative, a diagnosis of non-B hepatitis was made; however, in a majority of these patients, epidemiological findings and clinical course suggested a diagnosis of Hepatitis A."

In particular, if one goes to page 0513, one sees the heading at the top "Non-A non-B hepatitis". The author of this report says:

"In four patients with non-B hepatitis, hepatitis developed within two to six months of transfusion of blood products. Three male haemophiliacs and a female patient with Christmas disease had received numerous transfusions of Factor VIII and cryoprecipitate. These four patients and also two drug addicts with hepatitis had no evidence of Hepatitis B infection, nor of Hepatitis A infection, nor of infection with cytomegalovirus, nor EB virus. At present they are classified as cases of non-A non-B hepatitis.

"Evidence from other countries suggests that a virus or viruses may be associated with this type of hepatitis and that a carrier state is possible. With laboratory tests now permitting definitive diagnosis of Hepatitis A virus infection as well as Hepatitis B, in 1979 it should be possible to determine the prevalence of non-A

non-B hepatitis in the general population of West Scotland."

Again, the next article, please, is [LIT0010395]. This is an article by Galbraith and others, including Professor Zuckerman, entitled "Non-A non-B hepatitis associated with chronic liver disease in a haemodialysis unit". An article in the Lancet of 5 May 1979.

I think, doctor, this article is interesting. If one looks at the summary, the authors state:

"To clarify the aetiology of an outbreak of HBsAg negative, acute hepatitis in the renal unit at Fulham Hospital, 1968 to 1970, serological tests for antibody to Hepatitis A virus were done retrospectively on serum samples obtained at the time of the outbreak."

A few lines down:

"These findings do not provide evidence for the involvement of Hepatitis A virus in the outbreak of hepatitis and effectively exclude a role for this virus in a chronic liver disease which developed subsequently in eight (28 per cent) of the patients. This outbreak is therefore probably non-A non-B hepatitis, which has not been reported previously in Great Britain in a haemodialysis unit. The results confirm that this form of hepatitis may be related to a high frequency of persistent hepatic dysfunction."

This report is perhaps quite interesting in that the actual outbreak was in 1968 to 1970 but it wasn't until 1979, I think, that the authors were able to identify non-A non-B hepatitis as the likely cause.

A. Yes it required a specific Hepatitis A assay to be able to make that classification.

Q. Indeed. And just for completeness on this paper, if we could very briefly, please, look at [PEN0131426].

THE CHAIRMAN: Before we go there, the paper before, [PEN0020511], there appears to be a very high incidence of Hepatitis A recorded. Do you know how the population came to be selected in that case or what the distinguishing characteristics might have been?

A. That was the paper from CDS?

THE CHAIRMAN: Yes.

A. No, actually I couldn't see the age structure of the population. So I'm not familiar with that paper. I don't know whether the details are in the text but it looked like a pretty young population, so I would suspect that it probably included samples referred from some outbreaks, possibly within an institution because Hepatitis A is highly contagious. You can get a lot of infected patients very quickly.

THE CHAIRMAN: So a lot of people who were showing jaundice, who were yellow in a group or what?

A. Or who might not have been, you know, particularly jaundiced but would have been unwell. But acute Hepatitis A, the patients tend to get an elevated bilirubin. They tend to get quite yellow, unlike Hepatitis C, where it is typical to be maybe a bit unwell but not to actually develop jaundice in the early stages.

THE CHAIRMAN: I have a difficulty at the moment in seeing where that paper does fit in, which is why I was asking about it.

MR MACKENZIE: It is simply that I think it is one of the first reported references in Scotland to non-A non-B hepatitis here.

THE CHAIRMAN: I see. Just from that point of view?

MR MACKENZIE: Yes.

THE CHAIRMAN: Yes.

MR MACKENZIE: Before, I think, if we remember back to the Wallace 1977 textbook, the reference to how, if Hepatitis C exists and it didn't seem to be a problem in the UK, I think it is one of the first reports saying it is; that it appears to be here in Scotland in 1979.

Doctor, going back to the Galbraith investigation of the outbreak in Fulham in 1968 and 1970, if you could also simply, for completeness, have [PEN0131426]. This is a previous report on the same outbreak by the same

authors, reported also in the Lancet.

I think we can see this is a report in the Lancet in 1975 by the British authors of the previous paper. I'm not going to go into it in any detail, doctor, but in short when one reads this report, there is no suggestion of non-A non-B hepatitis having been considered as a possible explanation for the 1968 to 1970 outbreak and that's perhaps quite interesting, that even in 1975 that possibility didn't appear to have occurred to the authors, or if it did, they certainly didn't put that in their paper, which may be one indicator, for what it's worth, of the awareness, the state of knowledge of non-A non-B hepatitis in the UK at the time.

A. Yes.

Q. Finally, to complete this line of literature on knowledge, if we could go, please, to two paragraphs in the preliminary report. The reference is [LIT0012453] and paragraph 6.110 is a reference to a 1981, the sixth edition of "Diseases of the liver and biliary system" by Professor Sheila Sherlock. There is reference there to non-A non-B hepatitis that had accounted for about 75 per cent of post-transfusion hepatitis."

Although that may be a reference to America; we would have to be cautious about that. Then:

"It is also noted that the NANB hepatitis agent had

not been conclusively identified and its identity remained uncertain. In terms of the clinical course of the disease, it indicated that a mild chronic hepatitis develops in about a quarter of patients but this usually improved with time although cirrhosis could develop."

If we could go over the page, please, to paragraph 6.114, there is then a quote from Professor Sherlock that:

"Non-A non-B hepatitis often progresses to a mild chronic hepatitis. The prognosis of this is at the moment uncertain but probably benign."

So, doctor, does this paper capture perhaps the British knowledge and thinking on NANBH in 1981?

A. Well, all I can really say to that is that Professor Sherlock was obviously the doyenne of hepatology in the UK at the time. I would assume that in preparing the various successive editions of her textbook, she would have firstly read the literature pretty well and secondly have consulted experts internationally. So I mean this has to be considered as an authoritative view, which may not be the same as being a correct view.

Q. I think we might come back at different stages of the Inquiry to look at questions of developing knowledge, doctor. So I think I'll leave that at this point and if

I could return to your statement, please, at page 8.

We moved on to question 6, a slightly different point. The question was asked whether the cessation of the practice of collecting blood from penal institutions led to any difficulties in maintaining a sufficient blood supply in Scotland. You say that you can only comment on the situation in the southeast RTC and you have no recollection that stopping prison blood collections caused supply problems in that region and you think it is unlikely that it caused shortages since the only prison session provided 0.3 to 1.3 per cent of all southeast donations of the total collections in the region.

So, doctor, when you did stop collecting at Saughton, that didn't lead to any problems in the southeast region, at least in supplies?

A. It did not, and we would not have expected it to do so because our blood collection programme at that time was firmly driven by the requirement for plasma to be used in the preparation of Factor VIII, you know, in the effort to achieve self-sufficiency with an ever rising utilisation of Factor VIII.

So we actually had a superabundance of red cells. The reason for that is that the majority of the plasma which was provided from our centres to the fractionation

plant was collected, at that time, in the form of whole blood from which it was then separated. So we had a lot of red cells and we shipped the plasma off. Over this sort of period we quite frequently supplied red cells to centres south of the border. We regularly supplied them to one of the London centres for quite a period because we were concerned about, you know, inappropriate wastage of cells that had been donated.

So it didn't cause a problem in the southeast region.

Q. Did supplying red cells south of the border occur in the late 70s or simply the early 80s or ...?

A. I think probably the early 80s. I would have to go back and try and establish the precise dates but I think probably early 80s.

Q. Thank you.

Returning to your statement, please, to page 9. A number of particular questions are then asked and reference is made to particular documents. We can perhaps try and take this reasonably shortly. Question 7 asked whether you were aware of the evidence produced by the NBTS 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 reference to

document [SGH0017095] is made. You say that you have no recollection of being aware of that report before receiving a copy from the Inquiry. But, of course, you didn't join the BTS in Scotland until 1977, I think?

A. That's correct. I mean, I'm surprised that I wasn't aware of it but I wasn't.

Q. In any event, the English findings around July 1974 are fairly similar to the Wallace report in 1972 of an approximately five times higher incidence of the prevalence of Hepatitis B antigen in prison donors.

A. It is possibly just worth mentioning that one contributory reason for that is almost certainly the fact that almost all the donors in prisons will be first time donors as opposed to donors from the community, 80 per cent of which have given before and therefore the population of those with positive tests has been screened out and excluded.

So we see a higher rate of any infectious markers in first time donors. I'm not suggesting that accounts for the whole phenomenon. It would be a contributor to it.

Q. So to get a true comparator, one would have to compare the prevalence in prison donors with non-prison first time donors?

A. I think that would be correct, yes.

Q. Thank you. Going back, please. Question 8 then moves

on to a separate matter. It asks whether you were aware of a letter dated 6 January 1975 by Garrot Allan to Dr Maycock in England warning of the increased risk of hepatitis including non-A non-B hepatitis from the blood of prisoners.

I think you say you have no recollection of having been aware of that letter but you had read Dr Garrot Allan's book. I think we should bring the letter up because we haven't looked at it yet. It is [SGH0046061]. We can see from the top that Dr Garrot Allan was a professor of surgery at Stanford University in California. On 6 January 1957 he wrote a letter to Dr Maycock at the blood products laboratory in Elstree in England. Who was Dr Maycock at this time?

A. Well, Dr Maycock was the director of what was called the blood products laboratory, which was the predecessor to the new bio-products laboratory and essentially a fractionation facility. I think Maycock was also a very senior figure in the transfusion world and I think he was adviser to the Department of Health on transfusion matters around this time.

Q. Thank you.

We can see Dr Garrot Allan's letter, the first paragraph. The context is in relation to factors VIII

and IX. Then about half the way down the page, Dr Garrot Allan states:

"The other imponderable which has troubled most of us is the ineffectiveness in screening for the Hepatitis B antigen. This failure, of course, dates back to at least 1971 and suggests that half, if not more of the cases of post-transfusion hepatitis are caused by an agent other than Hepatitis A or B. Whatever this agent or agents may be, it still seems to be more frequently encountered."

There is a missing word, I think it may be:

"... [in] the lower socio-economic groups of paid and prison donors. It is ..."

There is an indecipherable word:

"... among volunteer donors. It seems that the most certain method we have for reducing the number of carrier donors at the present time is still to determine whether or not the donor has been paid in money."

The missing word may be "or":

"... in reduction of his prison sentence."

You say you weren't aware of this letter at the time but you were aware of Dr Garrot Allan's book published in 1972. What was the general thrust of the message or the findings in Dr Allan's book?

A. I think there were two. There is a huge amount of data

in there for a start, so it is an extremely difficult read, but I think the sort of dominant message that came through from his work was exactly what he said here: to improve the hepatitis safety of transfusion, the best thing was to stay away from paid donors and particularly from paid prison donors. But his data also shows, you know, quite clearly, as do other quite early papers, the very high rate of post-transfusion hepatitis in many parts of the United States. I mean, spectacularly high.

So there is no doubt that at the time a lot of blood was collected in commercial centres, as he says here -- you know, transfusion centres were businesses, commercial blood banks -- then the overall risk of contracting hepatitis from transfusion in the United States was much higher than it was here. I think, going back to obviously earlier discussions about the prevailing attitudes, that was very important.

I think people in the UK were extremely proud of the voluntaryism and the voluntary system and they knew it was morally better and they probably felt also that it was microbiologically safer. It was safer. The rates of post-transfusion hepatitis in the UK never, I think, reached anything like the very high rates described in the USA.

Q. So in the early 1970s it was known that paid donors

resulted in a much higher prevalence of post-transfusion hepatitis?

A. Absolutely.

Q. Was any consideration given, either in the UK or the US, as to the underlying reason or reasons for that?

A. I'm not sure that a great deal of attention was given to it in the UK because paid donations was not a phenomenon that we had ever had in the UK.

I think, as Dr Allan says in his letter here, the donors who were receiving payment tended to be motivated by the importance of receiving that payment, which, you know, discourages the disclosure of any sort of potential behaviour or other bar to donating. And also from essentially low income groups, who would, for, you know, sort of environmental, sociological reasons, have a higher prevalence of infection anyway.

So everything militates against blood safety if you are using paid donors, and precisely the same issues come up with paid plasma donors, as you will come on to later on. You just have to see it to understand what the problem is.

Q. Yes. Going back to your witness statement, please, doctor, at page 9. This is another new document we haven't looked at yet, I think.

You were asked whether you were aware of a letter

dated 1 May 1975 by Dr Yellowlees, the chief medical officer of England and Wales, to all regional medical officers in England and Wales on the subject of blood donation and hepatitis. We should perhaps look at this letter. It is [SGH0030187]. This is a letter of 1 May 1975. It is headed "Blood donation and hepatitis". It starts:

"The department has recently received advice from a group of experts ..."

If we look at the footnote at the bottom:

"Being a subgroup of the advisory group and testing for Australia antigen on the use of blood donations from certain categories of donors. Geographical factors --"

I think the point is that it had been noted that donors from what was termed "tropical areas" had an higher prevalence of Hepatitis B antigen. If we can go over, please to the second page, the other point which is noted concerns prisons. Dr Yellowlees states that:

"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 that all donations are subjected to one of the more sensitive tests referred to above."

So at this time in May 1975, the advice of the chief medical officer in England and Wales is that it is acceptable to collect blood from prisoners provided a sensitive Hepatitis B screening test is used. Is that correct?

A. That's what he says.

Q. Albeit you weren't aware of this document --

A. I wasn't aware of this.

Q. -- at the time. If you are not able answer this, Dr McClelland, please say so but do you think that was appropriate advice at the time?

A. I think it is very surprising advice from a CMO, from a public health doctor. That seems to me to be very strange advice. I don't know from this letter where his expert advice on transfusion came from. I suspect it may have been from a committee chaired by Dr Maycock.

Q. I think it was a subgroup of that advisory group, yes?

A. I have never been privileged to see any of the deliberations of that group. I think it is a very surprising letter actually.

Q. Given this is dated May 1975, why do you find it surprising?

A. Because I would have expected, you know, someone who really would have had an overview of some of the basic issues in public health to have paused and thought, "Hang on, prisons can't be a very good idea". It has been known for a long time and common sense would tell you that, you know, prison is a place where living hygiene standards aren't very good, where there would be people who have got, you know, difficult lifestyles and so on. All gathered together. It just doesn't make sense to me, really.

Q. This is dated May 1975; you in Edinburgh continued to collect from prisons until 1981. So why do you find this advice surprising, if in fact you continued to follow it until 1981?

A. I think that we should have stopped. I think we should have stopped sooner. I think it was a matter of focusing on, you know -- you come to a complicated new job, you have to decide on which bit of it you are going to focus on and there were many, many preoccupations, like -- as will be evident from the medicines inspector's report, the facilities in Edinburgh were deeply unsatisfactory. There was a huge pressure within the organisation. Really the driving pressure in the organisation was collecting plasma to meet haemophilia requirements, and I think that I, as a director there,

was slow off the mark in realising this.

I don't wish to defend that but, as you say, you end up not paying attention to all the potential problems simultaneously. This was one that came a little bit later but I think we responded to it. I think once we sort of started to think about the issue, it became quickly very obvious that we were going to stop.

Q. If we can perhaps deal with this in this order, doctor. Firstly, I think, from what you have said, it seems clear that, with what we know now, with everything we know now looking back and from what you have said, your view would be that blood should not have been collected from prisons between 1975 and 1981. Is that correct? With the benefit of hindsight?

A. With the benefit of hindsight, absolutely.

Q. Let's then, if we can, unlearn what we now know and go back to that period, 1975 to 1981. If I had asked you to think about the question at the time, between 1975 and 1981, and if I had asked you then, is it appropriate to continue the practice of collecting blood from prisons, what do you think your answer would have been, if you had applied your mind to it?

A. I think that's almost impossible to answer. I can't unlearn. I mean, what may have happened at that time was I would have consulted my colleagues, as transfusion

directors, many of whom had been in post for a long time and were highly experienced, and I would have perhaps consulted what, you know, the recommendations from the CMO, or whoever, were. And I might have concluded that, because it was normal practice, because everybody else was doing it and because the CMO said it was fine, I might well have continued -- I can't put myself back 25 years in any meaningful way.

Q. I appreciate it is difficult, doctor. Another way of looking at it is this: you did say a little earlier that you thought the advice in Dr Yellowlees' letter of May 1975 was wrong, was incorrect, and also I think you said that you should have ceased the practice of collecting --

A. With the wisdom of hindsight, yes.

THE CHAIRMAN: Can you remind me when Mrs Thornton became the regional donor organiser.

A. I was appointed in 1980 ... sorry, I was appointed director in 1979. I think she was provided in 1980, very shortly after my appointment.

THE CHAIRMAN: Did I understand correctly that she had a significant part to play in alerting you to this?

A. Absolutely.

THE CHAIRMAN: So before that, had it been a real issue for you, do you remember?

A. I don't think it had. I think I had probably accepted it as the way things were done and probably not directed a great deal of attention to it because I was probably directing my attention to other things.

THE CHAIRMAN: Mrs Thornton wasn't a medical person in any way.

A. No, she was not, that was possibly one of her great strengths.

THE CHAIRMAN: I think it has been her great strength in other jobs since.

A. She cast a very fresh eye.

THE CHAIRMAN: So really it is speculative to be asked to try to answer --

A. I am afraid it is, sir.

MR MACKENZIE: Because in short, would it be fair to say, doctor, you hadn't really applied your mind to it until Miss Thornton raised it as an issue when she arrived?

A. Yes.

Q. I see. Reverting to your statement, please, doctor, at question 10 the question was asked why the SNBTS continued to collect blood from penal institutions following the Medicine Inspectorate's adverse comments on that in March/May 1982.

I think you have explained already that of course the Edinburgh Southeast Scotland section had stopped in

any event by March/May 1982 and you have referred already in your evidence to the main argument in favour of continuation, that a collection of blood in prisons made an important contribution to blood supply at times such as holiday periods when collection from the general public was more difficult. We have looked at that already.

Then question 11 refers to a meeting of the SNBTS directors on 29 March 1983 and asks why the directors were unable to agree on a future policy in respect of collecting blood from penal institutions. Over the page you explain you do have a recollection of this matter being discussed at the directors' meeting but you don't recall any specific points and you think that it is likely that opinions differed about the impact on the blood supply for the different regions of using prison blood collections.

A. I have to add to that actually, I didn't remember when I wrote this, but I think it may well have been at that meeting that Dr Brookes made the comments that I referred to earlier, in which she expressed a view that collections in prisons were not a good idea. I think it may well have been part of that discussion.

Q. I see.

A. The minute is singularly uninformative.

Q. But in short, I think in 1983 there was some discussion of the question of collecting blood from prisons at at least some of the SNBTS directors' meetings.
A. That's correct, and there was clearly a difference of opinion for the reasons which you have just reviewed.
Q. Yes. Question 12. This refers to a meeting of the National Institute for Biological Standards and Control on 9 February 1984 to discuss the infectious hazards of blood donors, and you advised that certain policies had been adopted in Scotland to minimise the risk of transmission of infection:

"The main strategies were stated to include the avoidance of high risk communities such as prisons."

The question was asked:

"When was the strategy referred to at the meeting of avoiding high risk communities such as prisons adopted and implemented and why?"

Et cetera. I don't really, I think, doctor, want to go to the document in the interests of time.
I appreciate that we do want to get through this.
I think for the record the reference is [SNB0048628].
I think you explain that you haven't found any notes of your contribution to that meeting so you are not sure how accurately the meeting reflects what you said but you think your remarks would have related to donors'

selection in relation to both AIDS and hepatitis. Of course, by that stage, 9 February 1984, AIDS was, I think, very much on the scene.

A. Yes. I mean, the use of the term "high risk groups" or "high risk communities" really, I think, began with the discussions about AIDS, which is why I think, if that's what was minuted, that's probably what I was talking about. It was on top of everybody's mind at that period.

Q. Well, we may come shortly, doctor, to some international documents which do use the same term, "high risk group", in relation to hepatitis. But it may be nothing much turns on that perhaps.

A. Probably not.

Q. Yes. Then, doctor, question 13. The answer, I think, we will simply take as read because that relates to surrogate testing, which we will come back to after summer.

Question 14 asks about any discussions between the SNBTS and officials from the SHHD on the question of the practice of collecting blood from prisons. In short, doctor, are you aware whether the SHHD, the Scottish Home and Health Department, ever sought to influence or encourage the SNBTS in the collection of blood from prisons?

A. I'm not aware of the Home and Health Department expressing a view either way, either for or against. The view, I think, that has been expressed in a number of documents from the English Department of Health was it is up to the regional directors at this time; the responsibility lies with the transfusion directors to decide. But I personally wasn't involved at this time in any discussions with the department. As I have said here, though, the transfusion directors' meetings were regularly attended by a senior person, a medical person, from the department and they received all the papers and so on. They would have been party to any discussions and would have had ample opportunity to express a departmental view, had they wished to do so.

Q. Yes. Who do you consider was best placed to decide on matters of donor selection policy: the Scottish Home and Health Department or the Scottish National Blood Transfusion Service?

A. I think it probably was primarily an issue for the Scottish National Blood Transfusion Service. Had there been a view that there was, as it were, a non-medical, like a sociological or welfare reason, to encourage donation in prisons, which certainly is the strand that emerged from the consultations in London, that, I think, would have been an issue for the Department of Health

because it is certainly not a health issue for the transfusion service.

Q. And I think we have seen reference in some of the documents to the Home Office in London being in favour of prison collections for prisoner rehabilitation reasons but are you aware --

A. I'm not aware of that having emanated from the SHHD.

Q. Thank you.

Returning to your statement, please, doctor, question 15 we have dealt with. Question 16 moves on to a separate topic, or rather issue, the question of donors with a history of jaundice. Again I would hope to take this reasonably shortly because I think it is all fairly well documented.

Question 16 refers to the second report of Dr Maycock's advisory group on the testing for the presence of Hepatitis B surface antigen, where, in short, a recommendation was made that blood from donors with a history of jaundice or hepatitis could be accepted if the donor tested negative for Hepatitis B surface antigen.

You say in your statement you do not remember being part of the discussions for this report. Again it would be before 1977, before you joined the SNBTS, and certainly before 1979, when you became regional

director. You do, however, refer to, in the final paragraph on page 13:

"The National Blood Transfusion Service memorandum on the selection, medical examination and care of blood donors in 1977 appears to embody the Maycock recommendation."

I think it may be sufficient, doctor, to simply give the references for these documents. Sir, I don't want to take up too much time on all of this but if other parties have any issues over them, they can no doubt be raised.

The Maycock report: the reference number for that document is [SGH0030079]; the 1977 guidance is [SNB0025348], and I will, sir, be coming back to look at this question with Dr Dow in due course because Dr Dow, in his statement, refers to a number of published papers on this question of accepting donors with a history of jaundice.

But, in short, there was a change in 1975 or 1977 towards now accepting donors with a history of jaundice or hepatitis, so long as, I think, the attack had been more than 12 months previously and the donor was negative for Hepatitis B --

A. That's correct.

Q. -- using a sensitive test.

At page 14 of your statement, doctor, you revert a little to the question of evolution of knowledge about non-A non-B hepatitis and you say:

"This period was early in the evolution of knowledge about non-A non-B hepatitis."

You say, "This period". Is this 1975 to 1977, or about 1975?

A. I think I was probably referring to the time when that recommendation came out.

Q. Which was 1975, thank you.

A. Yes.

Q. And you quote from a paper by Gerety and others. You say:

"The first solid indication that an additional form of hepatitis existed came from the analysis of post-transfusion hepatitis after it had become possible to show that a large percentage of post-transfusion hepatitis was neither Hepatitis A nor Hepatitis B".

And you refer to three papers there. You go on to say that:

"The importance of the condition had not at this time ..."

Again, is that 1975 you are referring to?

A. Yes.

Q. "... been fully appreciated by many concerned with these

decisions. Because no causative agent could be identified, there was no specific test for non-A non-B and knowledge of the natural history and the epidemiology was lacking, it was not possible to know that individuals could become infected without having evidence of jaundice or indeed any clinical features. Nor could it be known that once an individual was infected, their blood could continue to contain the infectious agent for many years in the absence of any symptoms or that some forms of chronic liver disease would eventually be discovered to be caused by chronic infection."

To pause there, doctor, that passage I have just read out, where you seek to capture knowledge in 1975, if one puts the advice by Dr Yellowlees in May 1975, if one considers that advice, about the collection of blood from prisoners, if one puts that advice against the background of your summary of knowledge in 1975, does that make the advice any more or less appropriate?

A. The change, obviously, here was all about suddenly having a test for Hepatitis B. I feel that the advice about prisons surprises me because it's wider than just hepatitis. You know, as I say, I would have expected an experienced public health expert to have been concerned about essentially the whole gamut of infection risks

among prison donors and also about possibilities of, you know, prisoners being poorly nourished perhaps being rendered iron-deficient. There would be quite a lot of reasons why what is essentially a pretty underprivileged community, one should think very carefully about asking them to donate blood, both from the safety of the patient and possibly also for the safety of the donor. I do find it surprising, despite that statement.

Q. So in 1975, if one was considering the practice of collecting blood from prisoners, should there have been any consideration of whether there was a higher risk of prisoners transmitting infection?

A. I think that's what I'm saying. The focus here was on -- again hindsight is a dangerous thing. The focus here was on Hepatitis B, and I think there must have been a period after the discovery of the Australia antigen by Blumberg et al, which moved very rapidly on to having some really rather insensitive tests, when, you know, there was a sense that we have cracked the problem of hepatitis, and in the background these guys, particularly in the States, were very rapidly realising that they probably hadn't cracked the problem of hepatitis. Then, when the Hepatitis A tests became available and the importance of examining liver enzymes perhaps became more widely realised -- and you showed

some of the early original papers in the last half hour or so -- it very quickly became evident to people who were looking at all the facts that there was something else going on.

Q. So again trying not to look back with the benefit of hindsight, do you think that any consideration between, let's say, 1975 and to the end of the 1970s, the second half of the 1970s, of whether it was appropriate to continue to collect blood from prisoners, ought any such consideration to have included consideration of the question of non-A non-B hepatitis?

A. I think to put it in those specific terms is probably asking for an incredibly quick knowledge transfer, to be quite honest. I mean, we are talking about these earliest inklings that there was another entity which are referred to here. It is perhaps a little unreasonable to expect that to move instantly into a completely different context and be considered carefully and reflected on and applied. Life's not like that.

Q. So not even between 1975 and, say, 1979?

A. That's a matter of opinion. This is conjecture, not evidence.

Q. Thank you. An important distinction.

Returning, please, doctor, to page 14 of your

statement, question 17, the answer again we will take as read, if I may, because we will return to that with surrogate testing.

Question 18 asks about the procedures in place within the SNBTS between 1975 and 1991 for the exclusion of donors at a higher risk of transmitting non-A non-B hepatitis, including the exclusion of donors with a history of jaundice and hepatitis, and then, two paragraphs down, you say:

"During the first period, 1975 to 1983, [you] believe that the measures taken by SNBTS were essentially those described in the 1977 guidance ..."

Which we referred to earlier, although to date you say you have not located donor selection guidance documents used by SNBTS earlier than 1982. Have you since managed to find anything further?

A. There has been a further search and I know documents were submitted to the Inquiry relatively recently. Whether they yielded anything additional or not, I don't know at the moment.

Q. Thank you.

At the top of page 16 you say your recollection is that:

" ... some of the SNBTS services modified this policy ... "

That's the policy in the 1977 guidance:

" ... restricting acceptance to donors with a jaundice history under the age of 12 years. The rationale for this was that in that age group, where there was any evidence of infection with the hepatitis virus, it was almost always found to be an antibody to Hepatitis A virus."

Can you explain what, briefly, that refers to?

A. I think this was based on work done by Dr Brian Dow, who I'm sure could give you a more expert read on this than I can. But in one of his studies, or a study carried out by Dr Follett's lab, I can't remember, but it became clear that donors who reported that they had had jaundice in childhood, many of them had Hepatitis A, evidence of past Hepatitis A infection, and Hepatitis A is effectively not transmissible by transfusion. It is essentially a transient infection, where the virus is cleared and is for all practical purposes not considered as a threat in terms of transfusion.

I suspect -- but I have to say I have not found the evidence for this and it is possible that Dr Jack Gillon -- in fact it is probable that Dr Jack Gillon could expand on this point -- that the decision to restrict the acceptance of a donor with a jaundice history was related to a concern that

jaundice occurring in later life may not be due to Hepatitis A but due to something to do with non-A non-B. This is a slightly vague recollection of something a long time ago and I would hope that perhaps Dr Gillon can enlighten the Inquiry.

Q. That's fine. We may pick that up again with Dr Dow in due course.

Question 19, doctor, asks about the question of national policies and/or whether each region had its own practices and policies, and you reply that you are not aware that was a national policy:

"My understanding is that all the SNBTS regions had based their procedures on the 1977 guidance document."

Question 20 is really the final question to do with donors with a history of jaundice or hepatitis, and it is asked (a) if such donors had been excluded, is that likely to have caused any difficulties in maintaining a sufficient supply of blood and (b) the extent to which post-transfusion hepatitis in Scotland was likely to have been reduced.

In relation to (a), I think your answer in short is that if such donors had been excluded, that is unlikely to have caused any difficulties in maintaining a sufficient blood supply. Is that correct?

A. It is, but the answer to that hinges on the proportion,

the number, of donors who would be labelled as having a history of jaundice and, as I tried to point out, that's actually an extremely difficult thing to determine in an any reliable or standardised way.

Q. If we turn page 17 of your statement, you do address this, to be fair. Under "Impact on blood supply" you refer to various papers which report varying incidences of a past history of jaundice amongst donors, and just below that paragraph you explain that, assuming that 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.

Then, finally, the question asked:

"If such donors had been excluded, would that have had an appreciable difference in reducing post-transfusion non-A non-B or Hepatitis C?"

If one then goes, I think, to page 18, again trying to take your answer in short, or reasonably shortly, under the table you say:

"With respect to antibody to Hepatitis C virus, Crawford et al in 1994 ... "

Our reference is [PEN0020582]:

"... found that only 5.9 per cent of the donors who had been found to be HCV-positive gave a history of

jaundice, suggesting that the result of this questioning would not be an effective screening test. This is consistent with observations that the natural history of Hepatitis C infection does not typically include early episodes of jaundice. The infection can be asymptomatic for a long period after exposure. So it cannot be assumed that donors carrying the virus would recall any episode of jaundice or hepatitis."

In short, doctor -- and if I'm being overly simplistic, please say so. But in short, with Hepatitis C is it the case that a minority of people who contract Hepatitis C display jaundice? Is that correct?

A. I think that's correct, yes.

Q. And those people who do display jaundice are the ones most likely to clear the virus?

A. I'm not really professionally qualified to comment on that second question.

Q. I should perhaps ask a hepatologist?

A. My knowledge may well be out of date on that.

Q. I'm grateful.

In the final paragraph, page 18, of your statement you say:

"From the above information I am unable to estimate the size of any possible impact of an exclusion of donors with a history of jaundice on the incidence of

post-transfusion hepatitis but I think it is unlikely that any effect would have been large."

Doctor, thank you. That completes your statement. I am afraid, sir, there are some international documents I would like to take Dr McClelland through but it may be that 2 o'clock may be a better time to start that.

THE CHAIRMAN: I think better than 1 o'clock, yes.

After lunch.

(12.58 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Dr McClelland, could I bring you back to the start of the day and the red book, please?

A. Yes.

THE CHAIRMAN: The note I had related to a meeting of the SNBTS directors on 13 September 1983. We won't look at the minute but it is [SNF0010072], and I think it was at that meeting that Dr Brookes expressed very strongly her feeling that blood should not be taken from prisoners.

The discussion proceeded and the minute notes that:

"Dr Mitchell in particular felt that it would be unfortunate if a recommendation to cease collecting in prisons was to be included in the red book of good manufacturing practice."

Which is considerably earlier than your book and is

the source of my confusion at the moment. Can you help?
A. I think so, yes. I think what I said about what is now called "the red book" was correct. I think its first edition was mid 1990s. There was a thing called "The guide to good manufacturing practice", which was usually known as "the orange guide", and I suspect that this slight colour confusion may be the source of it.
THE CHAIRMAN: That might explain a lot. If I just give you a little of my impression of what happened thereafter, perhaps you can tell me.

My impression is that in the mid 1980s there was an attempt to revise whatever that was then known as, and that certain documents were issued by the DHSS that didn't find universal approval in Scotland. And Dr Urbaniak in particular prepared quite long list of corrections to it and soon after that you seem to become a member of a group that had in mind the preparation of quite a different document. Is that correct?
A. I did actually write a short sort of statement about this.
THE CHAIRMAN: I have not been party to what you have not given in evidence. So maybe it is not explained.
A. I have expected to have been examined on that today. There still is confusion and what I tried to make clear in this other document was that there -- the document

that you have just referred to was prepared by the then director of the Oxford Regional Transfusion Service, with one or two colleagues.

As I recall, there were two parts to it. One was a revision of the guide to donor selection, which we discussed previously, an update of that. The second was a revision of something called "Notes on transfusion", which was neither orange or red; it was actually white. It was a successor to a previous document which was directed at the clinical users of blood. So it was a hospital-focused document.

What you recollect is absolutely correct. When this document arrived, it was discussed extensively by the Scottish directors and we had a number of problems with it, most important of which was that actually it was full of mistakes. So it was issued along with a whole lot of sort of stick-on erratum pieces, including several complete pages. And we felt this was really not a very business-like way to do business. The outcome of that was that it was decided not to issue it in Scotland and in fact I think -- I'm not sure -- it was possibly not issued in England either. For my sins I got landed with the job of producing something which was supposed to be better, which ended up as the Handbook of Transfusion Medicine, which has survived through and

I think you had evidence early on this week from my successor as editor of that.

So that was addressing the clinical practice bit of the business.

THE CHAIRMAN: It doesn't seem that my limited researches have actually cast any light on matters.

Mr Mackenzie?

MR MACKENZIE: Thank you, sir. I think we can return to the question of the guidance for selection and notes on transfusion a little more with Dr Gillon perhaps tomorrow afternoon.

Dr McClelland, I would like to finish my chapter of questioning, if I may, by referring you to six documents which I think set out matters from an international perspective, the 1970s, and there are really two questions I would ask you to bear in mind while looking at these documents. The first question is whether these documents support the practice of collecting blood from prisons or rather point away from that practice. Similarly, the second question will be whether these documents support the practice of accepting donors with a history of jaundice or hepatitis, or rather point away from that practice.

So with that preamble, could I ask you to look first, please, at document [PEN0020462]?

If you go over to the next page, please, we can see this document is entitled "Blood transfusion: a guide to the formation and operation of a transfusion service". It is edited by C C Bowely, K L G Goldsmith and W d'A Maycock on behalf of the World Health Organisation International Society of Blood Transfusion and the League of Red Cross Societies. At the bottom of the page we can see it was published by the World Health Organisation in 1971.

We know that Dr Maycock was from England and in fact if we go to page 8 of this document, please, we can see the contributors. We can see Dr Bowely was the director of the NBTS in England, based at Sheffield. Dr Goldsmith was at MRC in London, and Dr Maycock we have looked at already. We can see essentially, I think, a fairly international and particularly European set of contributors.

If we can then, please, go to page 0474, which is page 17 of the document, we can see the subheading "Recruiting methods". If we then go over the page, please, we can see a few lines from the top:

"Initial steps to form a panel of donors are best taken within such groups and communities as the armed forces, the police, large industrial or commercial undertakings, universities, prisons and social or

religious foundations. The advantages are that information about the need for donors and the speed and ease of donation can easily be given directly to the members of the community or group in question and blood collection can be arranged and carried out without delay."

Then half way down the page we see the paragraph:

"Recruitment among the general public may be started once experience has been gained with special groups or organisations."

So while we see the reference to prisons, I think we have to be slightly cautious in looking at that. If we go back, please, to the preface, which is at page 0466.

I apologise, I should have come to this initially. At page 0466 we see from the preface that the guidance in this document is really directed towards developing countries who are starting up a blood transfusion service:

"We can see in many developing countries, blood transfusion services are still insufficiently organised or wholly lacking and the present book is intended to help physicians and pathologists who, after receiving a basic training in blood transfusion, are entrusted with the responsibility of establishing and developing transfusion services in their own country."

So I think we have to look at the guidance in this document perhaps with some caution when seeking to apply it to Scotland, which I think in 1971 had a relatively mature blood transfusion service. Would that be fair?

A. Yes.

Q. Thank you. We can put that document to one side, please. The next WHO document is in 1973. If we can, please, go to [SGH0029746], we can see from the front cover this is a document again by the WHO technical report series, number 512, with a title "Viral hepatitis". That is the report of a WHO scientific group.

Can we then, please, go to page 9749. We can see the members of the group, that they met in Geneva in 1972 and the members include Professor Marmion, I think is the fourth name down, from the department of bacteriology at Edinburgh University. We see other international members across the world, and under the secretariat, underneath that, again we can see it is an international group with Professor Zuckerman of London as part of the secretariat. Is that correct?

A. Hm-mm.

Q. If we can then go two pages on, please, and this is page 9751, which is the original page 9 of the document. The very last two lines in the right-hand column state:

"There is substantial historical epidemiological and experimental evidence to suggest that these two types of hepatitis ..."

That's A and B:

"... are caused by antigenetically distinct agents."

This is the next page, I should say. At page 9752 it states:

"It is appreciated it is not possible to allocate every patient with hepatitis to one of these two groups and that viral hepatitis infections exist that are due to other agents, only some of which have been recognised. This is a problem frequently confronting epidemiologists, clinicians and pathologists that will only be resolved when the different aetiological agents of hepatitis have been identified."

Is that some reference to there perhaps being hepatitis other than A or B; the possibility at least of that?

A. Oh, yes. Viral hepatitis infections exist that are due to other agents.

Q. Thank you.

Then at page, please, 9754 just to pick up on that point. This is page 15 of the original document the right-hand column, at the very bottom:

"Hepatitis type B and medical care."

"It is generally agreed that not all cases of post-transfusion hepatitis are caused by Hepatitis B infection, the proportion due to Hepatitis B or other undesignated agents probably varies with the circumstances, however, as more Hepatitis B carriers are eliminated from serving as blood donors, the proportion of cases due to other types of hepatitis will increase."

In particular, please, doctor, over the page again at 9755, which is page 16 of the original document, the paragraph in the left-hand column headed "Changing patterns of infection in certain developed countries":

"At this stage, during the past decade, marked shifts in the age and sex-specific rates for hepatitis have been observed in the USA and some European countries. These changes were subsequently found to be due to an increase in the number of Hepatitis B infections, particularly among males in the 15 to 29-year age group. The infections were not related to blood transfusion or other medical procedures. These features, together with the loss of seasonal peaks and the increasingly large proportion of urban cases suggested a likely association with the illicit use of drugs. It is quite possible that in addition to the increased risk of paraenteral transmission, the mode of life of drug abusers may increase the level of non

paraenteral transmission ..."

I think there we see at least a reference to a link between drug use and a higher prevalence of Hepatitis B, in particular among young males, albeit the commentary is at a fairly general level. It simply talks about in the USA and some European countries. Is that fair?

A. There is no sources referenced for this statement, which is slightly surprising but I'm sure that's perfectly fair.

Q. If we could look then, please, at page 9761, which is original page 28 of the document, under the heading "Prevalence of Hepatitis B antigen and blood donors" it provides that:

"Great variations in the prevalence of Hepatitis B antigen in apparently healthy blood donors have been found in different parts of the world. The prevalence also varies with such factors as the socio-economic status and sex of the donor, whether he is a volunteer or paid and whether he lives privately or in an institution.

"The antigen has been detected most frequently in males in the younger age groups and the limited surveys have also shown that the prevalence of Hepatitis B antigen is no higher amongst donors with a past history of jaundice than in those without such a history ..."

Again, it is a fairly general commentary. The use of the word there "institution" there, doctor, do you think that is similar to your use of the word "institution" we discussed at the outset this morning or are you simply not able to say?

A. I really couldn't say.

Q. We have to look at the papers?

A. I think to me that would imply living in a place where other people are living and presumably sharing facilities, but I can't say more than that.

Q. I appreciate that.

Then on page 29 of the original document, the use of donors with clinical evidence of prior hepatitis infection. It provide that:

"Policy regarding the exclusion from blood donation of individuals with a clinical history of hepatitis varies from country to country."

The start of the next paragraph:

"Studies --

A. I haven't found you.

Q. It is page 29 of the original document, the top of the right-hand column.

A. Yes.

Q. "... use of donors with clinical evidence of prior hepatitis infection."

I read out the first sentence of the first paragraph and the paragraph beneath that commences:

"Studies of Hepatitis B infection among volunteers and those naturally infected with the virus suggests that a greater proportion of individuals who have had a mild or inapparent infection become chronic carriers of the antigen than those who have had a more severe illness. For this reason, the exclusion from blood donation of individuals with a clinical history of Hepatitis B infection but who do not have detectable antigen may not materially reduce the frequency of hepatitis among the recipients of blood."

Again just beneath that:

"Furthermore, prospective studies of recipients of antibody containing blood reveal that such recipients do not have a higher frequency of post-transfusion hepatitis than do recipients of blood free of detectable Hepatitis B antigen or as antibodies."

So I think we see there perhaps the beginnings of a move away from the exclusion of donors with a history of hepatitis and reasons are explained in this paper. Is that fair?

A. Yes, that's absolutely right.

Q. Finally, please, for completeness, over the page, if I may, at page 9762?

A. Actually, before you change pages, just, sorry, looking at that paragraph again -- sorry, I don't know what's the last page -- here we are. Yes.

In the first paragraph, the last couple of sentences:

"The rationale for exclusion was based upon evidence that some of them remained infectious long after apparent resolution of their illness. In retrospect it would seem that most of these carriers were former Hepatitis B patients."

Which I think sort of feeds into the point that came up this morning, that there was a strand of belief that was saying: once we have dealt with Hepatitis B we have kind of solved the problem. That's interesting, that statement. We have seen that most of these people who had the ability to transmit an infection were Hepatitis B patients, which we now know obviously was not correct.

Q. I see. And then finally in this document, over the page at 9762 -- and this is original page 30 of the document -- the left-hand column the first paragraph at the top:

"The present widely employed techniques for detecting Hepatitis B antibody in blood are thought to be capable of preventing approximately 30 per cent of cases of post-transfusion hepatitis. The effect of the

introduction of more sensitive techniques will have on the rate of post-transfusion hepatitis is not yet clear but preliminary evidence suggests it will not be great."

The end of that paragraph:

"Cases not due to virus B are thought to be due to a variety of causes, including Hepatitis A virus, cytomegalovirus and other as yet unidentified agents."

So that's the 1973 document, doctor.

A. Just a comment on that. I think the second sentence:

"The effect of introduction of more sensitive techniques."

Which I assume relates to techniques for detecting Hepatitis B surface antigen -- it is not likely to be great. I think there are two issues here. One is to what extent were these techniques missing Hepatitis B, and the answer is quite a lot because they were actually very insensitive. So the earliest techniques failed to detect many cases of Hepatitis B. The second issue is, having detected all or the great majority of Hepatitis B cases, then was there something else. So the two things are slightly confounded in that paragraph.

Q. I'm grateful, doctor, and we should bear that in mind when considering documents from this period. Thank you.

Putting that document to one side, please, the next document is a 1975 WHO document. The number is

[LIT0013272].

The front page is not copied well but if we could go on to the next page, please, we can see the top right-hand corner of page 3273. This again is from the World Health Organisation technical report series, number 570, and it is reported at a WHO meeting on viral hepatitis. If we then go, please, to page 3276, we can see from the left-hand page that this meeting took place in Geneva in October 1974 and if we look at the membership, I think we can see it's an international membership but the USA dominates and Professor Zuckerman from London was also present.

If we could then go straight to the recommendations, which followed this meeting, it is two pages from the very end of the document. The reference is LIT0013298. Can we look firstly, please, at recommendation 6, originally page 49 in the document:

"Recommendation 6 provides that at present blood donors should not be excluded on the evidence of previous hepatitis alone, whether it is based on a past history of infection or on the findings of Hepatitis B surface antibody, provided that they have had no attack of hepatitis during the previous year and their blood has been found negative for Hepatitis B surface antigen by a very sensitive test."

Pausing there, doctor, I think that essentially is consistent with the recommendation in the Maycock report of 1975?

A. Entirely consistent.

Q. Which in turn is consistent with the 1977 guidance. The reference for that guidance being [SNB0025348]. Simply for the record, to follow that through, a similar provision is found in the 1983 guidance, which is [SGF0010377], the 1985 guidance, which is [DHF0018931] and the 1987 guidance, which is [SNB0066410].

The paragraph beneath that, doctor, paragraph 7, states that:

"There can be no categorical designation of high risk blood donor groups. The situation is likely to vary from country to country, from time to time and within countries. Any subpopulation with specific characteristics shown to have a continuing carrier rate of HBsAg at least three times that of the total potential blood donor population may be considered for exclusion. However, such decisions should be made on a local basis with due regard to the needs and availability of blood."

Does recommendation 7, doctor, have any relevance to the question of collecting blood from prisoners in Scotland?

A. Well, what it does is give a proposal for a definition of a high risk blood donor group, and I stand corrected, the term has been used much earlier than I realised it had been used.

Yes, I think it is relevant. I think it is probably written in the context of a growing awareness at this sort of time that among different populations -- I mean populations of other countries -- there are huge differences in the prevalence of Hepatitis B. Surface antigen carriage. And therefore, to put an absolute, as it were, prevalence rate could cause enormous problems. Some parts of Africa and Southeast Asia have 10 or 15 per cent of the population carrying surface antigen. So the implications of excluding all of those from donations is a huge hit on the available supply of donors. I think that may be part of what's at the back of the mind of the people who drafted this paragraph. But in answer to your question, yes, it is relevant to the assessment of the suitability of any population, I would have thought.

Q. And in particular we know that in the 1972 document, Dr Wallace's paper, there was found to be an approximately five times greater prevalence of Hepatitis B among prison donors than in non-prison donors. I think there were also English statistics in

the early 1970s to a similar end?

A. That's correct.

Q. In light of that known higher prevalence in Scotland and the UK in the early 1970s, do you think the recommendation in paragraph 7 ought to have at least led to reconsideration of whether it was appropriate to continue collecting blood from prisoners in 1975?

A. Well, I think, if I understood it correctly, the view taken by Dr Wallace, who is like our representative protagonist at the time of continuing blood in prisons, I think he was very determined to make use of the very best available sort of state-of-the-art radioimmunoassay techniques for detecting surface antigen which were, and are, extremely sensitive. As we touched on this morning, I think his belief must have been that as far as Hepatitis B was concerned, provided the use of those tests was guaranteed, he had effectively eliminated the risk of Hepatitis B.

And seeing this paragraph is about Hepatitis B, I could see that were Dr Wallace with us today, he could probably make an argument that would say his policy was consistent with that. What it does not take account of is other forms of hepatitis.

Q. Thank you. Just on this point, doctor, to sidetrack slightly and shortly, the question of different

prevalence among different populations, could we look, please, at document [DHF0028014]? These are the minutes of a meeting of the NBTS directors in England and Wales on 20 September 1972. If we go to page 7, please, of the minutes, if we could go down a little bit, please, we see the paragraph:

"AU-positive donors in prisons."

There is then:

"[Blank] said that RTC's Edinburgh and Glasgow are collecting blood from prisoners. In Edinburgh the incidence of AU-positive tests in prisoners is no higher than among the general population. In Glasgow the incidence in prisoners is significantly higher."

So certainly in 1972 it seemed to be that there wasn't a higher incidence of Australia antigen in Edinburgh prisoners. Are you aware of any results since 1972 on that question?

A. I certainly don't have them in my head. There almost certainly will be data more recently than that because there have certainly been studies of HIV prevalence, and I think it is likely that Hepatitis B markers may have been determined also in those studies. But I would have to look for data over the years on these markers in prison populations in the east of the country.

Q. So certainly, off the top of --

A. Not in my head --
Q. -- your head you are not aware of what the prevalence of Hep B in Edinburgh prisoners was from 1972 to 1981, for example?
A. No, I would have to look that up, sorry.
Q. Thank you.

The next, doctor, international document is again one from 1975. The reference number is [DHF0030764]. This is a much shorter document. To do with self-sufficiency I think. We can see at the top of the document it is headed "World Health Organisation, World Health Assembly Resolution 28.72 of May 1975: utilisation and supply of human blood and blood products."

In numbered paragraph 2 member states are urged:

"(1). To promote the development of national blood services based on voluntary non-remunerated donation of blood."

Presumably, doctor, your position is that that is exactly what Scotland was doing at the time?
A. That's what the whole of the UK has done all the time.
Q. If, however, there is on one hand a category of voluntary, non-remunerated donors and on the other hand a category of paid donors, do prisoners in Scotland share greater characteristics with the non-paid group or

the paid group?

A. I'm not sure that that's really a question that I can answer. I think it's a sort of, you know, an apples and oranges question really. I mean, I think you have to put some terms on that. If you say "in terms of the prevalence of Hepatitis B" --

Q. If one seeks to identify particular factors, for example, the higher incidence of Hepatitis B, do prisoners fit better into the non-paid group or the paid group?

A. I would be very reluctant to give any sort of general answer to that question. I think really you would have to say, "Here is a population of paid donors with a prevalence of X. Here is a population of prison donors with a prevalence of Y." The one with the higher prevalence is the one that is less desirable as a group of donors.

Not particularly because of their Hepatitis B prevalence, because in fact, with modern tests, you will effectively interdict Hepatitis B transmission, because the presence of a high prevalence of Hepatitis B in a population will tend to be indicative of the prevalence of other infectious agents that are transmitted by the same sort of routes as Hepatitis B. If you like, it's a surrogate marker that should make

you worry about other infectious agents. The same argument exactly applies to HIV, which I'm sure we will return to.

Q. So perhaps it is not so much a matter of terminology, whether a donor is paid or not paid, but perhaps rather looking at specific factors which may apply to a particular group, for example, one may ask oneself, "Do prisoners, for example, as a group tend to have a higher prevalence of Hepatitis B?" One would ask that sort of question.

A. I think I would put it slightly differently. I would say that there are a number of classifications which you can put around a group of people and say that experience would suggest that those people will probably have a higher prevalence of Hepatitis B than the totality of the community. And those two groups would include, for example, prisoners in general, paid blood donors, assuming all the other donors were non-paid, and equally it would include people from certain ethnic groups.

So, you know, there are a number of classifications which can be used which take one into greater and greater levels of difficulty when you come to the practicalities of recruiting blood donors but which can define a statistically greater likelihood of a higher prevalence of Hepatitis B. I'm sorry, I'm not sure if

that's clear or not.

Q. I think to be fair, doctor, I'm not formulating the question very well either. If I can perhaps be more specific: in the late 1970s, would it be reasonable to assume that prison donors were less likely to be truthful or reliable in their response to questioning at the donor session compared to non-prison donors?

A. I think that's a reasonable inference and certainly was a concern, as has been expressed by many people and that I would share, and I would say, coming back to your initial question, that's probably a characteristic that would be shared by donors who were motivated by the desire to receive payment because they will have a motivation to conceal things that might come between them and donation. So in that extent there probably is a commonality.

Q. In the mid to late 1970s, would it be reasonable to assume that there may be a higher incidence of past or previous illicit drug use among prison donors compared to non-prison donors?

A. I think that's probably a reasonable assumption.

Q. Even in the mid to late 1970s?

A. That's why I'm not giving you a completely unequivocal answer because I don't actually know the statistics. I don't even know if there were reliable statistics for

injecting drug misuse in UK prisons as against the general population for the UK at that time. Those data may well exist but I'm not familiar with them.

Q. So one would really have to try and search for these reports or data before being confident of the answer to that question?

A. Yes. I think the answer is, if data is there, it will probably point to a yes but I think one would need to see some data.

THE CHAIRMAN: I'm not sure how far I might necessarily want to follow the comparison of these groups.

A. I'm slightly uncomfortable with it.

THE CHAIRMAN: I do have information that in the summer of 1974 information collected by NBTS showed that the incidence of Hepatitis B antigen in donations from new general public and factory donors in 1973 was 0.09 per cent, while the incidence of Hepatitis B antigen in donations from prisons, borstals and similar institutions was approximately five times greater at 0.47 per cent. I think I feel reasonably comfortable with that, having regard to what you have told me earlier, but I don't know that I am prepared to move from that to a comparison with people who might have been prepared to take money for blood, since that might imply that the same people who would take money for

blood would be the same people who would find themselves in prison, and I'm not sure about that. I don't know how far you want to take it, Mr Mackenzie.

MR MACKENZIE: I have no further questions on that particular point, sir.

Other than this, perhaps, Dr McClelland, that it does seem to me that one should look beyond terminology of simply assuming that if a donor is unpaid his blood is more likely to be safe, and rather try and look at the underlying reasons why a paid donor's blood is less likely to be safe does that seem a fair comment?

A. I'm not sure that I quite understand where you are going. From the point of view of the workings of the blood service in the UK, in terms of blood that was collected and supplied by the Scottish Blood Service, for example, the question does not arise. Where it does arise, of course, and very profoundly, is in relation to the use or non-use of blood derivatives that are made from blood or plasma that has been paid for; which is a totally separate issue. I'm not sure that I have the drift of your question, I'm sorry.

Q. It is my fault, doctor. Let me have one last final attempt to ask the question properly.

Was there an element that in the 1970s in the UK it was thought that the problems with paid donors was an

American problem because in the UK we didn't have paid donors, and really the query is whether in the UK transfusionists should have been asking themself: why, what is the cause of the safety problems in paid donors and could any of these underlying problems apply in the UK, in particular when collecting blood from prisons?

A. Yes, I understand where you are going now.

I think that would have been a perfectly reasonable line of questioning. I'm not aware that that sort of logical jump was actually taken by anyone to say, are there common factors, are there common features? I don't recall anybody actually writing about this or researching it. But clearly, as we have already said, there is potential for there to be certain common features between a population that's motivated by a desire for payment and a population that perhaps has quite different motives for being less than frank about their health status.

Q. Thank you, doctor. I have only two further documents. The second last one, moving into 1976. This is [DHF0012672].

THE CHAIRMAN: While you are looking at that. Do you know the policy of prosecution services and judges in the 1970s as to sending people even caught in possession of drugs to prison?

A. I don't.

THE CHAIRMAN: If the policy was to send a far higher proportion of people in those categories to prison, then one might expect to find a certain concentration of people with a history of drug abuse behind bars.

A. It seems an entirely reasonable line of speculation because drug use and the behavioural consequences of drug use tend to lead to criminal actions which will presumably get people into prison, really regardless of the precise policy for prosecutions and so on at the time. I think it is a perfectly logical argument.

THE CHAIRMAN: I'm quite worried about going beyond the basic facts here. We know that there was, certainly in the English, for example, in 1973, five times as many cases of positivity in the new prison population than in the general, but I just wonder if we are getting into sociological and other factors that are really quite beyond my remit.

MR MACKENZIE: It is also very difficult to put oneself in the shoes of people who were there at the time. Even people who were there at the time, I'm sure find it very difficult to step back into their own shoes and that perhaps does emphasise the need for hard factual data or contemporaneous documentary evidence one can point to at the time.

THE CHAIRMAN: Yes.

MR MACKENZIE: Yes, doctor, the next document is [DHF0012672]. This is a document from the ISBT. We can see its title:

"The criteria for the selection of blood donors".

Dated 1976. Over the page we can see a little about the ISBT at that time. We can see the executive council comprise an international and a particularly European group. We can then see the regional councils are an international group and the councillors below that are again, I think, an international group.

I think we can see in the executive council the past president is Dr Tovey of the UK. Who is he?

A. Geoffrey Tovey was a regional transfusion director in Bristol and was particularly known for his work on the prevention of rhesus disease of the newborn using anti-D immunoglobulin. Retired for many years, obviously.

Q. Essentially I think what is set out in this document are criteria for the selection of blood donors. If we could then, please, go to page 2683, which is originally page 10 of the document, under paragraph 9, "Viral hepatitis", the document provides:

"In spite of recently developed tests for the detection of HBsAg, only a relatively small proportion of carriers can presently be detected. No routine and

screening test is presently available for the detection of Hepatitis A virus or of other viral agents that cause transfusion-associated hepatitis. It follows, therefore, that some general precautions should be taken in an attempt to reduce the risk of such viral agents being transmitted from donor to recipient. Prospective donors should be excluded if it is known that they, 1. Give a history of viral hepatitis at any time except during the first months of life. This rule may not be acceptable in all countries and may have to be modified where viral hepatitis is endemic."

Just to pause there, doctor. That recommendation, or suggestion at least, does that seem inconsistent with the 1975 WHO recommendation about accepting donors with a history of hepatitis or jaundice if they were Hepatitis B-negative?

A. It is inconsistent with it, clearly; it is saying something different.

Q. It specifically recognises that this rule may not be acceptable in all countries, I suppose?

A. It also -- yes, yes.

Q. So that stands as it is.

Then over the page, please. Other donors who should be excluded are:

"5. If they are suspected to be parenteral drug

addicts."

Number 6 is tattoos within the past six months. "Are inmates of a correctional institution."

I think that, doctor, seems to be a recommendation not to collect in prisons. I think, as far as the Inquiry team have found through their researches, I think that's the only express international guidance suggesting that collection should not take place in prisons. Does that accord with your knowledge and understanding?

A. I think so, yes.

Q. So certainly this document by the ISBT -- because you started in Edinburgh in 1977. Had you any knowledge or recollection of this document at the time, do you remember?

A. I don't even know what the date of the document is.

Q. It is 1976.

A. I may well have seen it. I certainly did receive ISBT publications. Whether I read this in 1977 or 1978 I honestly can't remember.

Q. You are certainly not aware of whether this document prompted any fresh consideration of the issue in Scotland in the late 1970s?

A. Absolutely no knowledge of that.

Q. The final document, doctor, if I may move back to the

WHO in 1978 and the reference is [LIT0013627]. We see this is a document produced by the WHO expert committee on biological standardisation. It is the 29th report. From 1978. If we then, please, go to page 5 of the document, which is page 3630, we can see this followed a meeting in Geneva in December 1977. We can see the membership and the secretariat is set out and again I think no representation from Scotland but we can see it is an international group, including some representation from England. If we can go two pages on, please, at page 3632, to see the purpose of this document. We can see the WHO expert committee on biological standardisation met in Geneva in 1977:

"The committee considered that one of the most useful documents made available at the meeting was Guidelines for the preparation and establishment of reference materials and reference reagents for biological substances."

In the next paragraph:

"Another important matter was the Requirements for the collection, processing and quality control of human blood and blood products (see annex 1). It was agreed that it would be most useful to have a single set of requirements applicable to all organisations and laboratories involved in the collection or fractionation

of blood and blood products."

So that forms part of the background to why this document was produced. If we then, please, jump to page 3640, which is originally page 28 of the document, we see this is the annex 1 referred to. If we go to the footnote 1, we see it has been prepared by a team of WHO consultants and staff members whose names are given in appendix 1. I think we don't have appendix 1 in the court book but the names include Dr Harold Gunson, a well-known English transfusionist, and also Mr Watt of the PFC who was part of this group. Over the page, please, page 3641, the introduction provides:

"In the past, a number of documents of the WHO have been concerned with whole blood and its components but each one has concentrated on guidelines mainly concerned with blood transfusion services, and except for human immunoglobulin, none has dealt with the requirements applicable to the control of blood and blood products. A WHO working group on the standardisation of human blood products and related substances considered that there was an urgent need for international requirements for the processing and control of whole human blood and blood products. It emphasised that as the quality of the source material played an important part in the quality of the final products, such requirements should

cover all stages from the collection of source materials to the quality control of the final product. In the compilation of these international requirements for human blood products, advice and data from a number of experts have been taken into account. The names of these experts are given in appendix 2."

Again, we don't have that appendix I am afraid but the names did include Professor Cash and Dr Wallace from Scotland.

If we then, please, go to page 2644, which is page 32 of the original document, roughly half way down we see the paragraph:

"The parts are divided into sections, each of which constitutes a recommendation. Text printed in type of normal size is written in the form of requirements so that if a health administration so desires, these parts as they appear may be included in definitive national requirements. Paragraphs printed in small type are comments and recommendations for guidance."

We have to, I think, bear that distinction between recommendations and other requirements and guidance in mind when we come to look at what follows. If we then, please, look at page 3651, which is page 39 of the original document, if we look at infectious diseases, this document provides:

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

So that's a recommendation or requirement. What then follows in the indentation is by way of guidance and provides that:

"Acupuncture within six months may also present a risk. In some countries donors with a history of viral hepatitis or of a positive test for Hepatitis B surface antigen are permanently excluded. In other countries such donors are accepted providing that recovery occurred longer one year previously and that the reaction for Hepatitis B surface antigen was negative and tested by a sensitive technique."

Pause there, doctor. The guidance contained in that indented paragraph is consistent with the Maycock 1975 recommendation and what followed in the UK in terms of accepting donors with a history of jaundice?

A. Yes, it is.

Q. Thank you.

Over the page, please, finally, at page 40 of the document, which is also page 3652, this again is still

in the way of guidance rather than recommendation and requirement. It provides:

"Donor populations showing a prevalence of acute or chronic hepatitis higher than that found in the general population should be avoided for collection both of single donor products (whole blood and its components) and of plasma for pooling for the manufacture of plasma fractions known to be capable of transmitting hepatitis, such as clotting factor concentrates."

Is the guidance contained in that indented paragraph of relevance to the question of whether blood should have been collected from prisons in Scotland in the late 1970s?

A. I think it is. I mean, in any instance where there is evidence, as there clearly is in some cases, of a higher prevalence of Hepatitis B, well, acute or chronic hepatitis -- the evidence was essentially for Hepatitis B -- it falls within the meaning of that paragraph, yes.

Q. Yes. Doctor, simply to try and now conclude, I will summarise matters in this series of six international documents we have looked at and if my questions are too general, please just say so, but firstly if one considers the practice in the UK from 1975 onwards in terms of accepting donors with a history of jaundice or

hepatitis, in general is what is contained in the international documents we have looked at consistent or inconsistent with that practice?

A. It is consistent with the practice in the UK.

Q. In respect of the practice in Scotland of collecting blood from prisoners during the 1970s and up until the early 1980s, in general is what is contained in the international documents consistent or inconsistent with that practice?

A. I think it certainly calls the practice into question, that some of the guidance in these documents would, I think, fairly clearly identify prison population as potentially at least a population from which it is inadvisable to collect blood donations.

Q. Thank you, Dr McClelland.

Thank you, sir.

THE CHAIRMAN: Thank you.

Mr Di Rollo.

Questions by MR DI ROLLO

MR DI ROLLO: Sir, we have had a very comprehensive examination of this witness and I'm extremely grateful for that. I'm also extremely grateful to the witness for the contribution that he has made. There is just one matter that I would like to ask and it's really to ask, having spent much of your professional life trying

to drive up standards, do you see any particular lessons that can be learned from the fact that it does seem to be the case that collecting blood from prisons was inadvisable in the 1970s to the 1980s? And there does seem to have been material available at the time which, if someone with an overview had considered the matter, might have thought that it was inadvisable. Are there any lessons that can be learned from that that can be used going forward?

A. Oh, I think there undoubtedly are. They are not necessarily easy lessons either to articulate or to put into practice.

The sort of overwhelming reason why this problem was not sort of focused on even in the presence of quite good evidence in England, you know, in the early 1970s, from Scotland in the mid 1970s, I think one has to ask why did that not get through to people who were concerned with the policy of blood collection and influence them to take some actions sooner than they did.

You know, it's very easy to propose some mechanism where there shall be some wonderful oversight grouping with a clearer vision than anyone else, and we have had various attempts in the UK to do that with, you know, the expert advisory group on AIDS or the advisory

committee for the microbiological safety of blood, tissues and organs which has got a new name now, ASBT or something.

Those represent the best attempts to put in place, if you like, a sort of governance body for these sort of issues, and within the organisation that I was involved in, the joint professional advisory committee, by far the most active of the committees was the standing advisory committee on the transfusion of transmissible infections, which in recent years has worked extremely hard to be aware of information about either new or emerging infections or new examples, new knowledge about populations at risk of infections and to push for action to be taken quickly. So I think some of the lessons probably have been learn learned and implemented by putting these sort of mechanisms in place.

Those probably have improved the situation to some extent.

What I think is much more difficult is to deal with the problem where you have within a community, a professional communal, a sort of very powerful sort of dome of received opinion, which is sitting over everybody and they have a belief system that this isn't a problem. And therefore even when perhaps some individuals sort of stand up and make a noise and say,

"I think it is a problem", there is a very good history of you know, people who actually do see a little bit further ahead, clearly not being -- actually they seem to be a nuisance because they get in the way of what we are doing at the moment, and that's really a sort of sociological problem, I'm sure not unique to blood services and it is actually very difficult to deal with.

So I think that the best that we can do, and a lot of efforts, I think, have been made to do this is, you know, is wherever possible to encourage attitudes that permit and encourage questioning of things that "everybody knows" and more specifically to look at the mechanisms that we have now and that would include the ASBT -- somebody help me with this -- the advisory committee on the safety of blood. It is the successor to the MSBT. Which is the national body charged with informing the ministers of health for UK countries about precisely this type of issue, and try to see that that group is well supported, well resourced, has access to the best intelligence, the best connections for picking up, assessing the importance of things and then making a big noise about it so that somebody does something.

I think these are not exactly revolutionary mechanisms but I don't know that I'm in a position to invent any better solutions. Challenging the received

wisdom -- because no doubt the received wisdom in the UK was that these things weren't a problem. We were okay because we didn't have paid blood donors and somehow that just made everybody feel -- I think it would not be unfair to say that there was a slight sort of sense of superiority because we didn't have paid blood donors in the UK. And that may well have been a factor that sort of blinded people to the fact that we need to look at the totality of our donor populations and be sure that we were sensitive and aware of where perhaps there were risks that were greater and should be seriously questioned.

MR DI ROLLO: Thank you.

A. Not a very specific answer, I am afraid but it is the best I can do at this hour of the afternoon.

Q. Thank you, sir.

THE CHAIRMAN: It is of interest. I think that our terms of reference require me to look at Hepatitis C and HIV and consider what lessons might be learned from that. It occurs to me to be a different exercise to look at what's done now, which may have developed out of a very much broader spectrum. But it could be that one lesson is that one should never rest on one's laurels, and that whatever structures are set up should be subject to constant review in the light of developing knowledge or

emerging risk.

A. I would suggest that the other one is never believe the experts. At least not unreservedly.

THE CHAIRMAN: As a judge I sometimes have to. But I think that might be going a little bit far. But it is quite difficult, isn't it, at this point in time to comment on existing structures, which may have developed for very many reasons other than those that I'm particularly required to look at. I think I may have to resist that.

A. I think there are some good example, sir, but I won't --

THE CHAIRMAN: I have no doubt there are good examples of very prominent people who had very fixed ideas from which they couldn't be budged.

A. Yes.

THE CHAIRMAN: I don't require you to disclose them here today, some of them may have been disclosed already. Is there anything else you want to follow, Mr Di Rollo? I'm slightly concerned not to go too far from what I can legitimately do.

MR DI ROLLO: I'm content with the matters and I appreciate that we are obviously under certain constraints but I'm grateful for the opportunity of asking that question.

THE CHAIRMAN: The terms of reference are constraints, yes.

Mr Anderson, do you have anything to ask.

MR ANDERSON: I'm obliged. I have just one or two

questions. I'm conscious of the time and we have another witness waiting so I'll try to take this as quickly as we can.

Good afternoon.

A. Good afternoon.

Q. You will recall the letter that we looked at this morning from Dr Yellowlees, the chief medical offer, which, for the notes, is reference [SGH0030187]. We see that that is a letter from the Department of Health and Social Security directed to all regional medical officers, and we have looked at that already but the first full paragraph on the second page says:

"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."

I take it that that represented Government advice and thinking at that time. Is that right?

A. Yes.

Q. And can I ask you this, doctor: was that express advice or guidance ever expressly rescinded or retracted?

A. I'm certainly not aware of that ever having been formally retracted.

Q. If we look at the government position as it were, we

have looked at the Medicine Inspectorate's reports, do you remember, this morning?

A. Yes.

Q. One in relation to their visit to Dundee and the other in relation to their visit to Edinburgh, and although they are described, I think, in the questions as adverse comments, if we look at the report in respect of the visit to Dundee, which is a reference [SGF0010086], what it says there is:

"It would seem most unlikely that we could continue to endorse a continued collection of blood from such places as prisons and borstals."

In respect of the visit to Edinburgh, and the report is reference [SGF0010351], it suggested that:

"Whether prisons and borstals were really appropriate or necessary as a source material is questionable."

Do you remember that?

A. Yes.

Q. What was to be taken from those comments, do you think, at the time, as regards some insight into government thinking on the question of taking donations from prisoners?

A. I'm not sure that the Medicines Inspectorate who looked after these reports would necessarily consider

themselves as representing Government thinking. They were representing the views of a group of people with quite a long experience of inspecting the pharmaceutical industry, who were coming into a very different sort of manufacturing involving, first of all the fact there was an NHS organisation operating under Crown immunity as it was at the time, it was involving human tissues and so on. So they were learning on the job, and I think, particularly from the Edinburgh inspection, some of the issues that were raised were almost more sort of musings on the part of the inspector than firm statements of a "thou shalt... "

One could compare these with other reports, where they said, "This is unacceptable; if you don't do that we will close you down". And they are quite capable of doing that. So these are of a different nature.

Q. All right. Can we have a look at a document which I don't think we have looked at so far but it is referred to in the questions and that is a letter from the Department of Health and Social Security, although again it appears to be from the Medicines Inspectorate. The reference is [SNB0087582]. This appears to be a letter from David Haythornwaite, Medicines Inspectorate, on notepaper of the Department of Health and Social Security. It is addressed to

Professor Cash, who was then the national director of the Blood Transfusion Service. Do you see that?

A. Yes.

Q. Have you seen this letter before?

A. I'm sure I have.

Q. All right. Can you turn with me, please, to the second page and paragraph 7. You see there that the author states:

"Source material: I have not observed donor sessions under the worst conditions, however, I wonder whether certain high risk areas are necessary or desirable. Prisons and detention centres would seem to come under this category and I would be interested in your views on this."

A. Yes.

Q. I don't want to put words in your mouth, doctor, but again is that simply the musings, do you think, of the Inspectorate?

A. Well, it is what it purports to be, I think. He is saying, "As an inspector I'm not very happy about this. I'm asking you to comment." It falls far short of saying that, "We have made a judgment as pharmaceutical regulators that this is unacceptable". It would have been in fact extremely difficult for them to do that because you know, this practice of collecting blood in

prisons continued in the United States until the late 1990s. And the same organisation, the MHRA, was involved in the inspection of those facilities and the licensing of the products that they made, on which the UK haemophilia patients were dependent, particularly those in England. So it was necessary, I would think, for them to choose their words really quite carefully.

Q. During the 1980s was information ever sought from the Department of Health on its policy on the practice of collecting and using blood from corrective institutions?

A. 1980s? It certainly was sought by the -- and the Inquiry has correspondence about this by the English blood service, and the Department of Health sought views from the Home Office about this in possibly the end of the 1970s or early 1980s. I'm sorry, I can't recall the date of that. But the correspondence I think is probably in the court book or certainly in the hands of the Inquiry, on the basis that the Home Office had -- I think it was the Home Office -- as did other countries -- had promoted the concept of blood donation as a sort of societal duty which prisoners could discharge.

Q. Can I suggest to you that in fact it was in July 1983 that information was sought from the Department of Health?

A. Okay.
Q. You wouldn't quibble with that?
A. No, I won't quibble with that because I can't remember the date.
Q. And the response through the Home Office was that they were very much in favour of blood donation from prisoners but they had no particular departmental policy.
A. That's the correspondence I'm thinking of, yes.
Q. During the 1980s was there ever any published guidance on the question of prison donors from any governmental advisory committee or statutory or regulatory body in the United Kingdom?
A. I don't believe there was. I cannot recall it at the moment, sir.
Q. We have learned of the dates upon which the various regional centres ceased taking blood from prisons; various dates, I think, between 1981 or 1982 and 1984?
A. That's correct.
Q. You have alluded to a practice elsewhere in the world. Can you help us just a little with that? Do you know what the position was, for example, in the rest of Europe in relation to taking donations from prisoners?
A. Well, this was a major issue in France and actually the government, the French government, the Department of

Health, I think, did issue guidance in the 1990s but it was -- sorry, again I can't remember precise dates, I'm hopeless at that, but certainly France did collect blood in prisons and eventually, when it became evident there that HIV was a major issue in some parts of France and particularly in prisons, there were, I think, two attempts made by the Ministry of Health to instruct the blood transfusion service in France to stop this practice and it eventually was stopped. But it was in the 1990s some time.

As I have mentioned, I think the FDA did not issue guidance or instructions that collections in penal institutions should stop in the United States until, I think it was, 1995. So considerably later than this. Other European countries, unfortunately I cannot comment on at the moment. I would have to research that.

Q. Right. Just for the avoidance of doubt, the FDA was the Food and Drugs Administration in the USA. Is that right?

A. Yes, that's correct.

Q. If I suggested to you that that guidance that was disseminated from that body in 1995 was in fact the first guidance anywhere in the world on the question of --

A. The only other example I'm aware of is one that we

looked at earlier which was not government guidance but from professional associations, which I think was the International Society of Blood Transfusion in about 1979. It is the document with the green cover, I think, that you asked me to comment on earlier, which --

Q. I think in fairness that document is actually dated 1976. The one we looked at a few minutes ago.

A. Yes, that was the only one, as I said earlier, that I'm aware of which makes a specific reference to donations in prisons and it is certainly not a governmental document, it is a professional recommendation.

Q. Doctor, thank you very much, I'm obliged to you.

THE CHAIRMAN: I wonder if I could follow that just a little. I think that I do have a note of a letter dated 27 July 1983 when a Mr J Brown of the DHSS wrote to Mr Parker about the use of blood in prisons, asking departmental advice on whether there was any policy. That was followed by a reply on 23 August 1983 by Mr Winstanley.

A. That's right.

THE CHAIRMAN: He commented on the difficulty of finding a particular departmental policy and said it was for individual regional directors to make up their own minds. Do you remember that? At the end of that note he said:

"We shall obviously need to liaise closely with Home Office also since they have in the past been very much in favour of blood donation by prisoners."

Starting earlier than that, I think you have shown that in Scotland actually taking blood from prisoners began to be phased out, first of all in Edinburgh, a couple of years before that, and I think that the indications are that although in the 1970s some English regions depended heavily on prisons, the information from there also was that it began to be phased out. Do you know when the English stopped taking blood from prisons?

A. The only specific information I can recall was a report by Dr Ewa Brookes, when she was asked in 1983 by Professor Cash to consult with colleagues in England -- because she had worked in England -- and she reported at that time that there was still two centres out of the, I think it was, 12, who were collecting. I cannot tell you which those two centres were or when they ceased collection.

THE CHAIRMAN: I know that Dr Brookes wrote to Professor Cash on 23 August 1983 -- that's [SNB0026554] -- following on the request that she should speak to the working party in England and that at that initial stage her impression was that all sessions in

England and Wales had been stopped, but I think that there is later information suggesting that that wasn't quite accurate and that it lingered on a little in the particular places thereafter.

A. I think there is a subsequent document which I think indicates that two centre were, as it were, collecting and I don't know exactly when they stopped but England was on the same trajectory.

THE CHAIRMAN: On 8 September 1983 she reported to the SNBTS directors on her later findings. I think that completes the history, as I have it, Mr Anderson.

Mr Sheldon, do you wish to ask any questions?

MR SHELDON: I'm grateful, sir. Your questions, sir, have largely headed off at the pass any questions I might have had. There is one question to clarify with Dr McClelland.

Doctor, would I be correct in saying that officials such as the CMO, as I think you characterised him, would be largely public health doctors and not specialists in, I think, for example, haematology or hepatology?

A. I was specifically referring to Dr Henry Yellowlees, who, my recollection may be wrong, but I think he was very definitely a public health person.

Q. Indeed.

A. Not (inaudible) as you know, in Scotland we have had

CMOs who were surgeons and strange characters like that, but it is very much a public health function in any case.

Q. Yes. One wouldn't expect the CMOs or regional medical officers and so on to have expertise in every field or each field of medical expertise?

A. Well, I would expect them to get the right advice.

Q. That's really my point. But in taking a position, and it has been characterised, I think, by my learned friend as the government's position. The government is really then dependent on expert advice from what will hopefully be appropriate places and bodies?

A. Yes, except, as I said earlier, it is not always wise to believe the experts implicitly.

I was asked a question this morning, which is an extremely difficult question to answer, and arguably I should have answered it differently. But I was asked if, looking at the text of that letter, written as it was by the then CMO, who was an eminent public health doctor, I found it surprising that he would not have had some reservations about making such an unequivocal recommendation on this topic. That is a personal view. It says absolutely nothing about what I might or might not have thought about it had I read it 30 years ago but I was attempting to answer the question as I understood

it.
Q. Yes. But it seems plain from that letter that Dr Yellowlees was in fact relying on advice from, in this case, the advisory group on --
A. He probably had a few other things in his in-tray.
Q. Yes, indeed. Would you agree that the advisory group on Hepatitis B testing, taking that short, was itself a somewhat eminent group, a group of experts?
A. They would have been chosen on that basis by somebody. Quite the mechanism for their choosing of course is another question.
Q. Indeed, but as you very fairly said, one is then perhaps thrown back on the issue of what the prevailing views among the experts were at that time?
A. Certainly that and certainly there is always, you know -- within any small group of this kind, there may be one or two individuals whose views are particularly influential.
Q. I'm grateful, sir, thank you.
THE CHAIRMAN: I suppose whether a CMO had other wide-ranging experience would just depend on the individual. Someone like Sir Kenneth Calman might not be thought of as a public health doctor in the first place.
A. Absolutely not, and there have been other distinguished

examples.

THE CHAIRMAN: Thank you very much for the time being.

We will have a five minute break.

(3.36 pm)

(Short break)

(3.45 pm)

MR MACKENZIE: The next witness is Dr Ruthven Mitchell, please.

DR RUTHVEN MITCHELL (sworn)

Questions by MR MACKENZIE

THE CHAIRMAN: If you get uncomfortable, make sure you let us know. Mr Mackenzie.

MR MACKENZIE: Dr Mitchell, good afternoon.

A. Good afternoon.

Q. I apologise doctor for having kept you waiting most of the day but in light of that I'll try and be short, but also because Dr McClelland has covered a lot of the ground as well, I think that will enable us to take things reasonably shortly.

Doctor, firstly I think you have provided a statement to the Inquiry, and if we could see that, please, it is reference [WIT0030106]. I think that is the statement you provided, doctor?

A. Yes.

Q. Doctor, I propose to take this statement as read, which

means that I won't take you through it in detail; rather, I will put the statement to one side and ask you one or two of the main questions which I think arise from it if that is okay?

A. Hm-mm.

Q. Doctor, could we firstly, please, look at document [PEN0100003]? This will come up, doctor, on the screen shortly.

We are looking, of course, at the question of donations collected from prisons. So I would like to see how many donations were collected from prisons in Glasgow and the West. This document should show us that. If we go, please, to page PEN0100008.

Doctor, these statistics have been provided by the SNBTS and helpfully set out the number of donations from prisons. We can see that in 1975 the percentage of donations from prison donors in the West was 2.83 per cent. If we go down to 1984 when collection from prisons stopped, the percentage from prisons was 0.23 per cent. Do you see that?

A. Yes.

Q. I think, doctor, it is also correct to say that your region collected approximately half of the total donations collected in Scotland. Is that correct?

A. Yes, that's right.

Q. I'm grateful, doctor. We can put that to one side.
A. The only problem is the 1976, 501 donations in that year.
Q. Yes. That's the figure that has been supplied to us.
A. Well, sorry, I can't check it.
Q. No.
A. It seems strange.
Q. It did seem strange and I did wonder if there may have been some reason for that?
A. I don't think the prisons were closed.
Sorry, I don't know the answer.
Q. No. I see.
THE CHAIRMAN: But it seems unduly low to you?
A. Yes.
MR MACKENZIE: I think what we can see, doctor, is that there is at least a range within which the percentages fall. So the highest figure is 2.83 per cent and the lowest is in 1984, it is 0.23 per cent.
If we can put that document to one side, please, doctor, and now look at a paper published in 1981, please. This is reference [PEN0140068]. If we can magnify this, please. I think, doctor, we can see this is a publication in 1981, where Mr Barr, I think, was the lead author and your name also appears as well. The publication is "Hepatitis B virus markers and blood

donors in the West of Scotland."

A. Yes.

Q. Is this paper familiar to you?

A. Yes, I remember.

Q. And I think in short this paper reported that male prisoners in the West had a higher prevalence of Hepatitis B than non-male donors. Is that correct?

A. Yes, that's right.

Q. Do you we see, doctor, the paragraph beginning "The incidence of Hepatitis B ..."?

A. Yes.

Q. Half way down, the words:

"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 high incidence is probably related to social habits and hygiene."

The statement, doctor, that the positive donors are not drug addicts, do you know the basis for that statement?

A. Yes. Dr Crawford was one of my consultants at that time and he, of course, had a close interest in this work. And it's over a period of ten years, as you can see. And Bob actually made a point of interviewing some of these people at the Prison Service, and saying, "Have

you had any cases of hepatitis among the inmates since they were screened and do you have any evidence of any of these men being addicts?"

The regulations, as I understand them, for the collection of blood from any institution is that the donor shall not be a drug addict. In donor care and selection from WHO and others, it is quite clear that no known drug addict should be bled as a donor.

Q. Yes.

A. So I think that's what Bob was covering.

Q. Doctor, in the late 1970s or early 1980s what steps were taken at donor sessions, whether within or outwith prisons, to try and exclude people who had ever injected drugs?

A. I think some of the donor leaflets actually mentioned that -- if I can remember, I'm not sure. I haven't seen them for some time -- may well have said, "Have you ever had an injection?" "Have you ever received an injection?" In other words, "Have you ever had an needle inserted into you."

Q. I think if we can have one leaflet, please, it is [PEN0131395]. I think this is an example of a Glasgow and West of Scotland leaflet. If we go to the very bottom right-hand corner, I think someone has written by hand 16 June 1983. Take a minute or two, doctor, just

to read the leaflet from the top of the page.

A. Hm-mm. (Pause)

Q. It may have to be magnified and scrolled down a little perhaps.

A. No, it was sent to me about three or four days ago. I have seen it.

Q. I'm grateful. I don't think there is any reference in this leaflet, doctor, to the question of drug use.

A. Hm-mm.

Q. Would that be correct?

A. It is not referred to directly, no. Many donors will not tell the truth on these particular matters and much of it is left to the medical officer at the time, who is treating the donor, to decide if there is any possibility of the individual showing needle stick injury or any other sign that might indicate that.

Q. Yes. In short, doctor -- and if you can't remember, please simply say so -- but in the late 1970s and early 1980s was it the practice at donor sessions whether within or outwith prisons to ask a donor if they had ever injected drugs?

A. During what time, sorry?

Q. The late 1970s or early 1980s.

A. I think -- no, I don't think so in the 1970s. I can't remember it being there. It might have been later in

the consideration of AIDS. I notice this one says:

"Do you understand what's meant by AIDS."

At that time.

Q. Certainly when we looked --

A. Clearly -- sorry, I beg your pardon?

Clearly at that time other information was being given to donors about AIDS and the method of transfer and so on; the leaflets and so on that were available, asking people if they were in a risk category. So I mean, I think that would be covered in the 1980s certainly, and I did check before coming to this meeting from one of my senior medical officers at sessions -- she has now retired -- it was quite clear that when this statement arose at the bottom of that document and around that time, when the donor actually booked in, the nurse who was booking them in, said, "Have you read this statement at the bottom here? Do you understand what it means? Does it apply to you?" before they were allowed to go on and give blood.

It is quite clear, as I think we all know, 4 per cent of people can't read. So it is important not to rely just on the written word but to actually say, "Do you understand what this means, yes or no?"

Q. I see.

A. That's all I can remember about that but I did check

with one of the senior medical officers.

Q. Thank you, sir.

Doctor, if we could, please go back to the document [PEN0140068], which is the 1981 article again. Back to the paragraph we looked at, the statement:

"This high incidence is probably related to social habits and hygiene."

What is meant by that sentence?

A. I think this is just the way of life of some of the particular prisoners that are in the establishments in and around the city. I think it refers more to sort of chronic alcohol abuse, not injectable drug abuse but other forms of self-injury, if I can put it that way. Not so much diabetes or obesity and so on but more to do with these other examples of the kind of way that people live, the way they behave, and I think that's what we meant by social habits and hygiene.

Q. I see.

A. Tattooing, for example. People in those days, there was no question of worrying about tattooing artists being registered and tattooing equipment being cleaned, and prisoners tattooing one another is reasonably well-known among these groups.

Q. So might that sentence include a reference to tattooing then perhaps?

A. Pardon?
Q. Might that sentence include a reference to tattooing, the question of social habits and hygiene?
A. Well, it could have related to other forms of needle stick injury. Like, for example, tattooing or scarification and so on. Tattooing is one of them but, as I say, most of the social habits were to do with drug abuse orally. I think I did say in one of my other papers to the Inquiry that it was said, I think in the late 1980s, that the Scottish prisons were well becoming a treatment agency for drug addiction. That was intravenous drug addiction and it had increased by something like 12-fold. Now, in the days of early blood transfusion that really wasn't much of a problem, as far as I remember. Intravenous drug abuse was something that came in much later.
Q. You mentioned there the late 1980s.
A. I think it was at that time. I can't be -- I'm sorry, the article I referred to in my other paper was from the place where most people get a lot of medical information, which was the Sunday Post. I think I referred to that in one paper but it made it quite clear that there was a scale of intravenous drug abuse over a period of time which gradually became worse and worse and worse, until it became almost epidemic and was

a major cause of concern for the prison staff, governors and medical staff. Treatment was being offered in the prisons.

Q. Doctor, I am afraid I should have taken you to your CV but I think you became regional director for Glasgow in 1978. Is that right?

A. That's right, yes.

Q. And then you retired in 1995?

A. Yes.

Q. But from your appointment in 1978 through to 1984, being the last collection from prisons in the West, did you give any consideration at all to whether it continued to be appropriate to collect blood from prisoners?

A. I think there was a certain amount of discussion about it at that time. I think we were dealing with Hepatitis B, and good tests, very reliable, robust, very sensitive tests were available for virus B at that time.

So clearly virus B was not a worry. It wasn't worrying that we had virus B, we all knew that. We had that in the population. We had that in the prison, we had that all over the West of Scotland. Indeed, every other transfusion centre had that. So that wasn't a problem, virus B was well organised and easy to diagnose at that time. So therefore the question that tipped the balance, as far as Glasgow was concerned, was

the advent of an incurable disease at that time, called HIV.

Q. Yes. And I think the --

A. And that came in about the end of 19-whatever it is. Just at that time. So that's what tipped the balance.

Q. I'm grateful. I think the question of whether it was appropriate to continue collecting blood in prisons was raised by the Medicines Inspectorate, at least in relation to the Dundee and Edinburgh reports in 1982. I think that then led to some discussion among the SNBTS regional directors, in particular, if I can take you to the minute of a meeting, please. The reference is [SNF0010072].

We can see these are the minutes of a directors' meeting on 13 September 1983. If we can go, please, to page 0077 and scroll down the page. If we can stop there, we see on the matter of collection in prisons and borstals, it was noted that the medicines inspector had expressed concern at this practice owing to different circumstances in the transfusion regions. The directors have been unable to reach a consensus.

Dr Brookes had a particular view on it because of the uncertainty about replies to questions concerning health. Reference to the medicines inspectors, referring it to the DHSS, and at least down south, the

Home Office. Then:

"It was acknowledged that prisons and prisoners differed greatly from one place to another and some directors felt that a blanket decision to cease visiting prisons would be a mistake. Dr Mitchell in particular felt that it would be unfortunate if such a recommendation was to be included in the red book."

Can you explain, doctor, if you can remember, what you meant there?

A. Well, firstly, the medicines inspector didn't mention prison donors in the West of Scotland, as you well know. The Medicines Inspectorate initially, as I understood it, their job was to look at the processes of processing blood, its handling, sterility, that sort of thing, the actual mechanics of using donations when they got into the centre and looking at the available facilities there.

Of course, they made many recommendations about that. The remit was not really to look at the question of collection of the donations, as I understood it; and they never mentioned this with me at all. We had a discussion with them after they had done their two or thee days' discussion and certainly I knew -- and I was at this meeting, as you can see -- and the question of whether that shall be included in the so-called red

book, which is colloquially called the red book -- it was standards written for the benefit of laboratories and blood transfusion -- and it covered many, many different aspects of laboratory work.

I, for example, wrote the chapter on sterile fluids because I had some experience from Africa of doing food, water, milk, ice cream testing.

So I knew about that. Therefore it was also, at that time, quite clear -- and I think you will see from some of the other documents -- that the Department of Health and the Scottish Home and Health Department were constantly being asked: what is the position of the department? Quite clearly, the decision of the department was: yes, it is accepted that people will collect blood from sessions at prisons and that has gone on and on and on.

I think I already mentioned that in my statement here, if I can refer, sir, to one of the paragraphs which I wrote. I said that some of the information was clearly -- yes, on page 6. I mentioned at paragraph (a) this meeting you are talking about. All were avoiding -- that's not true. And it went on to explain why that's not true.

Then it also goes on to explain that on the very day that the report from the Entwistle committee was being

considered and put to the Scottish directors, on that same day there was discussion in another working party on 23 August, where it was in conflict with the actual statement. Again, beyond that, if one goes into other documents, for example DHSS, recently the one -- I think it was from one of the ministers -- it was quite clearly there, it was mentioned.

Q. Excuse me for interrupting, Dr Mitchell. In short, is the point you make here in your statement that in 1983 you perhaps looked for guidance or a view from government on the question of the practice in prisons, but no such view or advice was forthcoming?

A. I think I already said that in one of my other statements.

Q. Can I ask you this, please, doctor: who do you consider was best placed to decide on whether donations should be collected in prisons or not? The Blood Transfusion Service or Government?

A. The question of whether or not donations should be collected in prisons was in fact available -- was departmental policy. It was in the departmental files and therefore, if they had to be corrected, it was up to them to correct it based on whatever evidence they had, and they had evidence that was available.

I had made up my mind at the end of 1983 to go ahead

with this, to avoid prisons. And again, trying to stop the Queen Mary is not easy when you are making up venues, perhaps anything for three, four five -- a year in advance to arrange where you are going to go for your sessions.

Given that there were three small sessions in 1984, by that time no decision had been made and yet we were faced then with this other thing called HIV, which was quite clear then at that time: no, this was a much different kettle of fish.

Q. What was the particular benefit to the West of Scotland in collecting donations from prisons?

A. Well, it depended at what time of the year. Clearly, every transfusion centre that I have ever worked in has shortages. There is no question that that does occur. It occurs for a variety of reasons. Sometimes it is due to, as I said in my statement, holiday times, especially festive seasons, certainly around the West of Scotland. It may also be due to problems with transport, problems with weather and so on. These can easily upset a session or a set of sessions.

So when people are going away or things don't happen then you are left with a major problem and that's one of the reasons that one went to prisons during times when you could anticipate that there might well be shortages.

Q. Doctor, we know that in March 1984 the West did stop collecting in prisons. Did that in fact cause any difficulties in respect of shortages of blood at particular times of year, so after the practice had stopped?

A. I think the answer to that is: yes from time to time.

Most of the time one could cope. In fact, pretty well all of the time you could cope. The reason being that we knew all the haematologists in our region. Many of them had been taught by me and some of my colleagues. They had attended courses at the centre and so on. I was the chap that actually wrote the definitive, up-to-date article on the use of red cell concentrates. I was able to go to the haematologists meetings in Glasgow where we met regularly with the consultant haematologists.

So we all knew one another. We all knew how to deal with things and we knew -- for example, you have evidence later on of some correspondence between Professor Cash and Dr Crawford concerning a particularly difficult time in one particular winter, where things really just almost collapsed on us. Not because there were no sessions organised but we couldn't get to the session and the donors couldn't get to us because of weather.

Q. Would it be fair to say, doctor, that because of the efforts of you and your colleagues, stopping collection from prisons didn't cause any insurmountable problems with blood supply?

A. That's right, I would agree with that. I think most haematologists knew that and had been educated to accept that. But there were other ways of dealing with these problems, which they did. But usually if there was a problem, they would phone us directly. We knew them by name. They were able to discuss particular things and so they could make the necessary arrangements in their hospital. They are responsible for their own hospital.

Q. I'm grateful. I simply have two last questions. The first question is this: with the benefit of hindsight, so knowing everything we know now, do you think blood should have been collected from prisons in Scotland in the late 1970s and early 1980s?

A. I don't think there was any major reason not to do it. Can I put it that way? It was quite clear that prisoners are human beings. They have a right to give blood like anybody else. It is a civic duty. Many of them felt that it was important that they should do that. Many of them continued when they left prison. Some had been giving before they went into prison.

Nothing very much had happened in the interval to suddenly decide against one particular group, it would be difficult to sustain that against the idea "Well, why are you discriminating against us?"

Q. Even if that group had a higher prevalence of Hepatitis B and a combination perhaps of, at least the initial testing for Hepatitis B may not have detected all positive donations, and then, come the late 1970s/early 1980s, the question of non-A non-B hepatitis comes on the scene, so to speak, and there are no tests to exclude that, could these factors influence or change your views at all?

A. No, not really. I think the question of the advent of non-A non-B was something which was badly understood in the UK. Something which wasn't entirely -- the whole epidemiology of it wasn't understood. And whether it would be confined to prisoners who we already knew were not in the drug addict class and so on, like anybody else, we had no reason to believe that they were any different, except for the statement that's made that there were social differences perhaps among prisoners, for reasons of close contact with others, incarceration and so on.

These things had their own tale to tell. But non-A non-B was a diagnosis of exclusion in most cases. There

are very few cases in the UK that I was aware of at that time. We seldom got reports from hospitals, "Oh, we have got a case of post-transfusion hepatitis" of any kind. That was unusual. They knew to report that. It was not a question of not knowing. They knew to report it. It was quite clear in notes on transfusion and so on, every medical student that I ever lectured knew that. They all had copies of the booklets.

So I'm sure they would have let us know but they didn't and you would take it, well, it wasn't all that important. Dr Collins, a member from Newcastle, did a study of post-transfusion hepatitis, looking for non-A non-B in patients who had undergone cardiac surgery using blood that had been tested and found negative for HBsAg and antibody. She said -- and there was some rise in ALTs, transaminase levels, after surgery which rapidly subsided, and it seems to her that non-A non-B was not a serious problem.

Q. Thank you, doctor, that answers all my questions, thank you.

THE CHAIRMAN: Dr Mitchell, there is one aspect of drug addiction in prisons that interests me at the moment. In the late 1970s and into the 1980s, it seems to have been reasonably well established that drug addiction was a growing problem in Scotland and Glasgow and

surrounding areas would not be exempt from that problem.
A. Yes.
THE CHAIRMAN: So at first sight it might seem rather strange if there were drug addicts in the general population but none in Barlinnie. Was there a procedure that excluded those who were suspected of being drug addicts before they got near the donor session?
A. It's difficult. I can't really answer that. I don't honestly know. I don't know how they would be excluded, except asking -- the first thing about donor care and selection -- remember, it is donor care and selection. It should also include donor maintenance, that is they come back. In these cases, if it's the case that a person is being asked, "Are you healthy?" because that's the question: "Are you healthy? Do you think you are unwell at the moment?" And they say, "No, I'm fine." So how do you say, "No, I don't believe that you are not unwell. I think you are unwell." I suppose the doctor at the session or the sister at the session would say, "You do not look very well." I don't think you can ask a donor to self-exclude. They only would self-exclude on the basis of, "I'm not going to go because I don't feel very well today."
THE CHAIRMAN: Perhaps in Barlinnie many people don't look terribly well, but wouldn't the prison doctor have

a fairly clear idea about his constituency?
A. Yes, I think that was one of the features of donors giving blood in prisons, that the prison governors -- I think I've read somewhere there was a statement that said that drug addicts should not be allowed to give blood. That's what it says.
THE CHAIRMAN: That's what I'm interested in. It may be that there was a pre-selection process --
A. There may well have been among the wardens and among the prison staff. But that wasn't for us. I mean, as Lord Glenarthur said in one of his papers, we are not there to police people's private lives.
THE CHAIRMAN: We did send them to prison for using drugs --
A. I know what he meant by that. It was a different -- I'm sorry.
MS DUNLOP: I should explain, sir, that, to spare Dr Mitchell from having to come back again, we thought that, while he was here, we would just ask him one or two questions about his statement on topic B1, which is to do with leaflets in relation to AIDS. Dr Mitchell has been warned about that. I don't know whether you would prefer to ask the other parties if they want to ask their questions at the moment or whether I should proceed and ask my questions before giving the other parties their chance.

THE CHAIRMAN: Gentlemen, does anyone have any strong views about this?

MR DI ROLLO: I don't have any strong views about it.

THE CHAIRMAN: Just go ahead, Ms Dunlop.

Questions by MS DUNLOP

MS DUNLOP: Thank you, sir.

Dr Mitchell, I think you have been warned that we have one or two questions for you as well about another statement you provided, which is in relation to AIDS, more particularly in relation to leaflets and other public information measures that were adopted.

A. Hm-mm.

Q. We shall ask to see that statement on the screen in front of you and it is [WIT0030033].

A. Yes.

Q. That's another of your statements, isn't it?

A. Yes.

Q. Right. Have you had a chance to look at our preliminary report at some point as well?

A. Yes.

Q. Good. Perhaps we could keep the statement but also go to a page in the preliminary report, which is page 9 of [LIT0012479].

THE CHAIRMAN: Which is the real page, please?

MS DUNLOP: 194.

A. Which one is it again?
Q. It is paragraph 8.128. Can you see that on the screen?
A. Yes.
Q. If we just scroll down a little bit, we can see this is actually an extract from a set of minutes and it is the minutes of a meeting of the SNBTS co-ordinating group on 24 May 1983. Do you see that?
A. Hm-mm.
Q. "AIDS was discussed."

The minutes read as follows:

"Dr Mitchell reported that he had introduced into the health questionnaire to donors a question inviting those who were worried about AIDS to consult the doctor at the session."

Now, we are interested in trying to find the piece of paper that is the evidence of that. You looked earlier at a leaflet; Mr Mackenzie showed you a leaflet. I think we will just get it back up, if we could, please. It is [PEN0131395].

A. Yes, I think you asked me if that was the one that I was referring to in the minute of the directors' --
Q. If we go down to the bottom of it, you looked at this a few minutes ago but it almost looks like a label or a sticker that has gone on to the bottom of this piece of paper, and it says:

"Have you heard of AIDS (acquired immunodeficiency syndrome)? If you have any doubts about giving a donation, consult the doctor at this session or your own GP or write in confidence to the regional director."

Do you think that this might be what you were referring to at that meeting?

A. It certainly was on the document. The date -- I'm not too sure about this, 16/6/83. I don't know who wrote that. I did check with my then donor manager and asked her if she would look through whatever other documents she had. Unfortunately, she couldn't come up with any other documents. They seem to have been destroyed. So all I can remember is that at this particular time there were lots of other leaflets going about -- some of them I think you have referred to in Dr McClelland's documents and my own -- concerning documents put out by SNBTS, some put out by the National Service for England and Wales, some of which were being constantly reviewed, some of which were left as leaflets for the donor to read and decide if they could understand it and if it applied to them and so on. There were a variety of leaflets being made available at that time. Some of the ones that I think you are referring to could well have been prepared in Scotland as a sort of preliminary Scottish document. We knew that the documents were

being revised fairly regularly. What we were trying to do here was to signal to people.

People who were blood donors at this time, in fact the whole population, knew from television, radio, all sorts of ways that -- they had heard of this killer called AIDS. I mean, some of the documents were copied to me recently showing the multitude of references in the media and in other places to AIDS and suggesting to people who could read the newspapers they should not give blood. What our prime policy was: if you think you are in a risk category, don't even attempt to give blood. That's what we were trying to get across.

Q. Can I just maybe ask you to have a look at another leaflet? This is one is [SNF0013397].

A. Yes.

Q. You see, this is one called "AIDS: some background to the recent publicity". Could we go on to SNF0013398, please? Right.

Now, do you see from the bottom right of this that this is from the Southeast Scotland Blood Transfusion Service and it is also June 1983. Perhaps I could just say to you that that was a leaflet that Dr McClelland was showing to the rest of you at a meeting in June. I just wondered whether you would look at that leaflet and think, "Oh, that's quite a good leaflet," and take

it back to Glasgow and circulate it in Glasgow or were you all concerned to produce your own leaflet?

A. I think there was a certain amount of discussion about all of these leaflets and what was the best way of getting information out to donors. It depended a lot on the type of donor, where they were, what they were doing. Donors are not always the same in each place. For example, at one time it was suggested that you should interview the donors individually. Well, I'm sorry, at a busy session that's just not possible. It is okay saying, "Yes, we can set aside a room." It is okay to say, "Well, the leaflet is there if you want to read it, pick it up and go away." I know that in Glasgow in some places this kind of leaflet would be met with a certain amount of derision from some of the rather hard-working donors who give blood in Glasgow.

Q. So this wouldn't be suitable for Glasgow?

A. It could have been modified in some way. Certainly, when the final documents were prepared nationally, I think it was quite clear -- the donor organisers, remember, were also meeting together at that time, not just the directors; there were lots of people discussing what's the best way to get this information across. So everyone was using whatever means they had to get the information across.

Q. Right.
A. Some of which would be to ask them, "Have you read it?" "No, I'm sorry, I can't read." "Sorry, but we will tell you what it says."
Q. If I suggest to you, Dr Mitchell, that we have found information that makes it look as though it wasn't until 1984 [sic - 1983] that donors were actually asked to say whether they had or hadn't read the leaflets, are you in a position to disagree with that or would you accept that it maybe was a wee bit later that the donors were asked to say if they had read the leaflets?
A. No, no, I recall having meetings with the donor staff. That's the sisters and the doctors in our Glasgow set-up in St Vincent Street. On a Saturday morning it was quite well known for us -- quite common that we would have a meeting in which I would say to the doctors, "What would you like to discuss?" At this particular time, around that time, all the discussion was, "Tell us about AIDS, tell us what you understand about it. Tell us what things we -- " They are doctors, they knew what to be looking for, they didn't need me to spell it out. They knew what they were looking for and therefore to suggest that there was no awarenesses in the West of Scotland about this whole range of communications --

Q. I'm certainly not suggesting that, Dr Mitchell. I'm just trying to find out, as far as we can after this passage of time, what the state of information was, that's all, which is why we were looking at first what seems to have been the Glasgow leaflet and then an Edinburgh leaflet, and I was wondering if you would ever have borrowed text perhaps from an Edinburgh leaflet. That was really all I was getting at.

A. I have copies of the English leaflets, for example. I was attending English meetings as well as Scottish meetings. I was attending the Advisory Committee on the Virological Safety of Blood. I was seeing all the leaflets coming from various parts of England, Scotland, Wales and so on. Of course, I was well aware of that. I asked our organiser, Mrs Eadie(?), "Can you collate any of theses things for me?" I asked her twice. She went back and looked through all the records and she came back and said, "I'm terribly sorry." I checked with her yesterday. She still can't come up with it, except the one -- she has not got the one that you have shown me. I don't know how you got it.

Q. To be perfectly honest with you, Dr Mitchell, nor do I, but --

A. I'm sorry, I don't know how you got it.

Q. -- we do have it. I know it's come to us through the

Blood Transfusion Service.

A. I recognise the document as one of a series of documents. I recognise that one.

Q. You recognise that one?

A. I don't recognise the date particularly. As I said, that's not my handwriting.

Q. The other thing I was interested in was knowing -- and we know this from the preliminary report. It is in the preliminary report that there was a UK-wide leaflet that came out in the autumn of 1983. Between May and that leaflet coming out in the autumn, that Glasgow leaflet, would that have been the state of play in Glasgow?

A. Probably.

Q. Right. Another thing I wanted to ask you about -- and I only have two more things. The first is to ask you to have a look at a document, which is [PEN0100305]. What this is about -- and I'll just take it shortly, if I can, to save you trying to reconstruct it. Do you see there is a date at the top and it is actually January 1984 and Dr Wagstaff's name is mentioned. This is actually a table comparing what sort of a reaction there has been to the UK leaflets towards the end of 1983. Interestingly, if we go to the very bottom, we see Glasgow and it says that the leaflets have been available at donor sessions and through local

special clinics. That would be sexually transmitted disease clinics, presumably, and it says that there has been uptake by donors averaging one or two leaflets per session. A handful of donors have been resigning after volunteering information about homosexuality. Then: 7,000 of 100,000 leaflets issued in three months. So it looks like, after the first three months, you still had 93,000 leaflets left. Do you actually remember this period?

A. I don't remember 100,000 leaflets. I think they would be recovered from the national administrator's office, maybe Morag Corrie. I think that's where they would come from. Certainly, I think I have explained a moment ago that leaflets were put out at sessions and they weren't always taken up. You could put a pile of leaflets and, as I said to you in my other statement, we got complaints from hallkeepers about the amount of litter that was left on the floor.

Q. We were going to look at that actually. It is in this statement.

A. They weren't taken away by donors, they were dropped on the floor by donors. That can either mean two things: One, the donor had read and understood; or, two, the donor was very upset and concerned to see such a reference to what he thought or she thought had been

a group of well meaning people and of which they hoped to be a member. Certainly, to be confronted with this thing which said, "Wait a minute, maybe you are not wanted here." They may have come miles and miles, just for the sake of doing good, to be turned away.

Q. I think, Dr Mitchell, this is actually what you describe. Can we go back to page 2 of [WIT0030033]?

A. The other documents, of course, I had seen, and these were all test areas. Dr Wagstaff had sent them out as test leaflets in different regions. There was no uniformity at that time.

Q. If we look just a little bit further down, we can see that seems to be you referring to the same problem, where you say:

"A study done at one of the Glasgow sessions, where questionnaires were given separately to each donor, resulted in a considerable quantity of leaflets tossed on the floor unread, much to the annoyance of the hallkeeper."

That's really the point you are making, isn't it?

A. That's right.

Q. The last thing I wanted to you look at, please, if you could, is [SNB0143030]. As you can see, this is the minutes of a meeting of the UK Working Party on Transfusion-associated Hepatitis on the

27 September 1983. You were there?

A. Yes.

Q. I particularly wanted you to look at something you are minuted as having said, which is on page 3 of these minutes. So could we go to page 3? Could you look in the second last paragraph? It says -- and I think whoever is writing the minutes is making a wee bit of a joke against fractionators:

"Dr Lane presented the fractionators' view that a variable approach did not provide material of uniform specification ... "

This is actually in connection with the distribution of leaflets:

" ... but Dr Mitchell pointed out the problems associated with any infringements of the integrity of the donor."

Now, in your statement you say you were concerned and anxious to note that healthy, well meaning volunteer donors found to be unsuitable for whatever reason should be treated with understanding and respect:

"It goes without saying that there should be no harm to the donor or patient."

So is what you are really saying here that you didn't want donors to think that the Blood Transfusion Service was casting aspersions on their integrity in

some kind of way. Is that the point?

A. I think that's one of the points, yes.

Q. Well, are there other points to it?

A. I think, Dr Lane being a fractionator, wasn't a regional transfusion director and therefore, you know, people mustn't talk about things they don't fully understand. His job was to make sure what was going into his place -- that was England and Wales -- was of a sufficient quantity and quality. That was fine. Scotland had different ways of doing that and I didn't want to give the impression that the tail was wagging the dog. Cuthbertson was at that meeting, too, you know. You may have seen that, Bruce Cuthbertson was there, quality manager from a Scottish fractionation centre, and I think Brian McClelland was there too. I'm not certain about that but certainly Cuthbertson was there and Dr Lane was presenting and we had representation from our own fractionators. So I don't necessarily think that we were at variance with the kind of quality of standard that we needed. But we had to deal with our own donors as we saw fit and what was good for suburbia might not be good for the Glasgow shipyards.

Q. Thank you very much, Dr Mitchell. I'm not going to ask any more questions.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Sir, there is one question I wanted to ask about the leaflets, not the B1 topic but in relation to C1, and it was in connection with -- the document is [PEN0131395]. Could we have that up on the screen?

I think you mentioned, doctor, the importance of tattooing in the prison population, I suppose in the general population but particularly in the prison population. There's obviously a significance in tattooing just equally as important, you would say, as needles through drug use?

A. No, I didn't say that. No. No. Tattooing was known to transmit Hepatitis B simply because the tattooing was not done professionally. Much of it was done by your best friend, who would tattoo "mum" on your shoulder for you if you wanted. It wasn't a question of going into a tattoo parlour. Similarly going to a dentist, the same idea.

Shortly after that, when this became a problem, clearly government regulations were laid down as to what tattoo artists would have to do. Nevertheless, clandestine tattooing went on. It still goes on. There are still people walking about the street today who wish they had not been tattooed by their best friend.

Q. Surely.
A. So it's not different -- it's very different.
Q. Just looking at this document, there doesn't seem to be any reference to tattooing in it. They are not asked if they have got a tattoo.
A. I think it said something about, "Have you had any inoculations recently?" That's item 4. It says, for example, tetanus and vaccination for smallpox, but most people would say that means, "Have you had anything like a puncture with something?" Most people would understand what vaccination meant in that sense. Vaccination really only applies to smallpox. But injections for tetanus and so on is injection.
Q. Do you think the average Glasgow punter would equate inoculation with a tattoo?
A. I think the staff -- that's my staff -- were taught to look for tattoos, that was one thing, and they immediately said, "This chap has got a tattoo," or, "This lady has got a tattoo." Immediately they were on their guard and then they began to ask more questions, such as, "Where did you get that tattoo? Who did it? How long have you had it?" These were all things that came up at the session if it was obvious that they were tattooed. I mean, if you cared to hide a tattoo, well... But certainly tattoo parlours were licensed,

eventually.

Q. I have no further questions, sir.

THE CHAIRMAN: Piercings hadn't come in at this stage?

A. Sorry?

THE CHAIRMAN: People didn't have piercings all over their bodies?

A. Some people did. Ear piercing is very common, as the ladies will tell you. It was done long before needle stick injury. It was almost a way of life. All our children are given ear piercing at, what, 14, something like that? Sometimes it is done by a friend, sometimes it is done by mum, sometimes it is done with a hot needle, sometimes it is done by the local jeweler.

THE CHAIRMAN: Yes. Thank you.

Mr Anderson?

MR ANDERSON: I have no questions, thank you, sir.

THE CHAIRMAN: Mr Sheldon?

MR SHELDON: I have no questions, thank you, sir.

THE CHAIRMAN: Dr Mitchell, thank you very much.

A. Thank you.

MS DUNLOP: There are no further witnesses today, sir, which is just as well in view of the hour.

THE CHAIRMAN: Until tomorrow.

(4.41 pm)

(The Inquiry adjourned until 9.30 am the following day)

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