Wednesday 23 April 2011

(9.30 am)

(Proceedings delayed)

(10.05 am)

THE CHAIRMAN: Good morning. Yes, Mr Mackenzie?

MR MACKENZIE: Thank you, sir. We continue with topic C1 this morning and the first witness is Professor John Cash.

PROFESSOR JOHN DAVID CASH (sworn)

Questions by MR MACKENZIE

MR MACKENZIE: Good morning, Professor Cash. I would like to look first at your CV, please, which will appear on the screen. I think you may also have a hard copy before you. The number is WIT0030353.

That is your CV, professor. We can see your full name is John David Cash CBE. When and why were you awarded the CBE?

A. Oh, dear, it must have been 1998/1999. Why? The citation was: services to the Blood Transfusion Service of the United Kingdom.

Q. Thank you. If we look at your education and academic history, we can see you went to Edinburgh University. You have graduated with a bachelor of science honours degree in 1958. In 1961 you graduated with a bachelor of medicine and you obtained a PhD in 1966. We can see

you are a fellow of the Royal College of Physicians in Edinburgh and the Royal College of Pathologists. We can also see you were a honorary professor in Edinburgh University from 1987. Is that to date or have you now retired?

A. I have retired.

Q. And we also see you were a visiting professor at Sheffield University in 1994. You then list positions held. We can see you were a member of the Medical Research Council subcommittee on hepatitis virus B, 1970. Then in 1971 you joined the Southeast of Scotland regional Blood Transfusion Service as a consultant and you were in that post until 1974. Then in 1974 you became the director of the Southeast of Scotland Regional Blood Transfusion Service. You held that post until 1979, when you became the medical director of the SNBTS. You held that post until 1988, when in 1989 you became the medical and scientific director of the Scottish National Blood Transfusion Service and you held that post until 1997.

In short, professor, what is the difference between the medical director post you initially held and the medical and scientific director post?

A. In short, the difference is that in 1988, on the advice I gave to the Scottish Office, a general manager was

appointed as the first general manager of the Scottish Transfusion Service and they insisted I had to change my name, the medical and scientific director. But in terms of function, in terms of medicine and science, there was no change.

Q. Thank you. I should perhaps just check, professor, if everyone in the back can hear you clearly. There are nods there. I'm grateful, thank you.

A. I should say the reasons for this, as may or may not emerge in the Inquiry, is there were really quite significant and interesting management problems, straightforward management problems until these were to an extent resolved in 1989.

Q. Thank you, professor. If we can then turn over the page in your CV, please, I should perhaps say, did you retire, professor in 1997?

A. Hm-mm.

Q. And over the page we have a list of memberships of various bodies. Could you, perhaps, professor, start listing them for me, please?

A. Yes. I was a founding member, very founding indeed, of the British Blood Transfusion Society.

Q. In 1981?

A. In 1981. Formerly all blood transfusion matters were incorporated into the British Society for Haematology.

I persuaded some of my colleagues that we needed to go alone for the development of transfusion medicine in the UK. I was a member of the MRC research committee on blood transfusion and that was a very sad story. It was disbanded in 1982 in the middle of doing some very, very important work.

I was a member of the DHSS expert advisory group on AIDS and I regret to say I felt I had a resign because the chairman of that group, who was a CMO in England, advised that Cabinet Office officials were modifying the minutes of this advisory meeting and I felt I couldn't work in that environment.

I was a member of the European regional committee of the International Blood Transfusion Society. I was adviser on blood transfusion for the WHO for quite a long period of time.

Q. Between 1980 and 2004, we can see.

A. Yes. I was a member of the UK standing advisory committee on transfusion-transmitted infection. Between 1985 and 1997. I was a member of the executive committee of the UK Transfusion Service operational guidelines. This is the famous red book. It does not appear in the preliminary report but the red book was an initiative that had a profound effect and it was an initiative that had its birth in Scotland.

I was chairman of one of the subgroups between 1990 and 1995. I was a member of the scientific policy advisory committee of the UK National Institute for Biological Standards and Control. Again, we call that NIBSC for short. NIBSC was to play a major role in enhancing the safety of all aspects of blood transfusion in the UK. It was a great privilege for me to lead those developments in this period of time.

I was a member of the university medical faculty board from 1988 to 1993. I was a founding member of the European Plasma Fractionation Association. This was an association which we felt needed to be developed in Europe because it was an association of those like ourselves, state-run fractionation organisations, and they didn't have a voice in the EU, whereas our commercial counterparts did. So we established that.

I became a full board member of NIBSC in 1995 and remained so until 2004. That again, was extremely exciting work. We were heavily involved in further developments in the transfusion field, in stem cell work and in the development of UK and international standards for PCR, for Hepatitis C, HIV and so on.

I have been external adviser on chairs and readerships for London University from 1990 to 1995. I was president of the Royal College of Physicians for

Edinburgh from 1994 to 1998. I was president of the Blood Transfusion Society from 1997 to 1999.

Q. Thank you, professor.

Could we then move on, please, to your publications. You list that you were the editor of a book, "Progress in Transfusion Medicine", 1985 to 1990. You were also a member of the editorial board of the scientific journal Vox Sanguinis, 1980 to 1986. Over the page, please. This is page 3 of the CV, please. We can see at the top of the page peer reviewed scientific papers, 120. Is that 120 papers in which you were an author or co-author?

A. Yes.

Q. Then we can see you were the author of several chapters in surgical and medical textbooks. Then you go on to list your professional experience and what's called track record, and under "Scientific research" you set out various matters which I won't dwell on today.

You then, under the heading "NHS management", explain that during the period 1979 until 1997:

"I was a director of the SNBTS. This is a complex multicentred organisation. Its annual budget in 1996 was approximately 28 million, a total staff of approximately 1,100, involving interactions between medical, scientific and nursing professionals and

a large multiskilled support staff."

Then you list the non-NHS management. Just beneath that we can see:

"Between 1997 to 1999 I was president of the British Blood Transfusion Society. Chairing a council whose membership is multi-professional was especially challenging, as did persuading the Society to change its management structure and operational activities."

Then over the page, please, professor. We see two final matters on the last page, page 4. We see first international experience, and you explain that your research activities and management role in the SNBTS led to extensive travel outside the UK and the establishment of good friends and colleagues in many countries and much of that overseas activity was directed to scientific communication and teaching.

You also explain you have worked for several governments by way of advising them in blood transfusion development issues, including the UK Government. A study of the National Blood Transfusion Service in England and Wales for the Secretary of State for Health in 1998. Also the Republic of Ireland in 2003. Also in Hong Kong, Malaysia, Canada, India, Bangladesh and Denmark. Also on several academic visits to Australasia you were invited to discussions with senior government

and Red Cross officials. Then finally under "Relevant board memberships" there is reference, again, to the NIBSC. Et cetera.

So I think we can now put your CV to one side. Thank you, professor.

The topic today I would like to ask you some questions about is labelled "C1" and to give it its proper formulation for the benefit of the ladies and gentlemen in the audience, the topic is formulated as follows, namely:

"The acceptance of blood from higher risk donors, in particular (a) prisoners and (b) donors who had a history of jaundice."

Professor, I would like firstly, on the question of collection of blood from prisoners, to look at some statistics in that regard and firstly document, please, [PEN0100026].

Professor, I don't think you have seen this document before; rather it has been provided by the SNBTS as an organisation in response to various queries by the Inquiry and we can see in the first line it is stated:

"The following is the SNBTS corporate response to..."

Various questions on this topic. If we go please to question 2, about half way down the page, we can see the

question was asked:

"From which penal institutions in each region were donations collected."

There is reference to a table attached, which we will come to shortly. Question 3 was asked:

"Were donations from penal institutions put to any particular use or did they simply form part of the general pool of donations."

The answer is that:

"All donations collected from penal institutions were treated in exactly the same way as donations from any other donor session and formed part of the general donor pool."

Is that correct?

A. Yes, absolutely so.

Q. And question 4 was asked:

"Were donations from penal institutions sent to the protein fractionation centres for the manufacture of blood products."

And the answer is:

"Yes, as donations from penal institutions formed part of the general pool, they were treated in the same manner as all other donations and were sent to the PFC for processing."

Again, is that your understanding?

A. It is, indeed, sir.

Q. I'm grateful. Then over the page, please, I think this should be page 0027. It's page 2 of the document. About half way down, professor, the paragraph explaining:

"This table has been expanded to include donations collected in the years 1971 to 1974."

So when we come to look at the tables shortly, we will see that the statistics provided helpfully set out the collections, I think, from 1971 to 1991 and we will come to that shortly, but it is also explained here that:

"No donation numbers are available from the southeast RTC, Edinburgh region, for 1971 to 1974 and the total number of donations collected in the northeast region in Aberdeen in 1971 is not available."

If we go to the next page, please -- it is page 3 of this document; the reference is 0028 -- we can see the heading of this is "Prisons in each Scottish blood transfusion region visited by SNBTS."

The left-hand column lists the BTS region and the right-hand column, the various prisons. We can see in the West of Scotland, I think, there were eight institutions which were visited in the 1970s and 1980s. In the southeast of Scotland and Edinburgh only Saughton prison. In the east of Scotland, Dundee, there are four

institutions. In the northeast and Aberdeen there are two. In the north and Inverness, simply Porterfield Prison and Inverness.

If we could then go up to the next page of the document again, this is page 4 of the document, court book reference 0029. This table provides some context for our Inquiry into the question of collection from prisons. This table 2 is entitled "Donations collected in each Scottish region 1971-1991".

The far left-hand column, the year is stated, from 1971 all you the way through to 1991. We then have the total number of donations for each region, for Edinburgh, Aberdeen, Inverness, Glasgow and Dundee. We then see the column headed "Total Scottish donations".

The next column is the total number of prison donations and then the final column are the percentage of donations which prison donations formed compared to the total donations. So very much by way of example.

If one looks to the year 1975, one can see the total Scottish donations were 248,558. If one looks at Glasgow, one can see that Glasgow collected approximately half of the total Scottish donations. If one then looks at the total prison donations, one can see, of the 248,558 donations, we can see that prison donations formed 5,915. As a percentage, that is

2.38 per cent.

If we go down to 1984, when the practice of collecting from prisons stopped, we can see that the total Scottish donations have gone up to 308,617. Again we can see that Glasgow accounted for approximately half of the total Scottish donations, but in this year the number of prison donations were only 342. As a percentage of the total that is 0.11 per cent.

If one then sticks with the prison donations total percentage column, the far right-hand column, one can see from a high of 2.38 per cent in 1975, there are fluctuating numbers until the final percentage in 1984 is 0.11 per cent. I think if one does the arithmetic between 1975 and 1984, the average percentage is 1.12 per cent in terms of the percentage of donations overall in that period, which were collected from prisons.

I think if one then goes over the page again, please, to page 5 of the document, which is page 0030 in the court book, this table is headed "The donations collected at penal institutions in each Scottish region, 1971-1984". I won't dwell on this table but one can see the number of donations from each of the regions and perhaps unsurprisingly, I think, if we look at the number of prison donations collected in the West, that

quite comfortably, I think, is greater than the number of donations collected from the other regions, which may perhaps at least partly reflect the fact that Glasgow was collecting about half of the total Scottish donations in any event. And for completeness we can see, the far right-hand column, the northern RTC in Inverness, no figures are available at all. A reason is given for that which we will come to shortly.

We can put that document to one side, please, professor, and simply to complete this look at the statistics. If we could next, please, look at document [PEN0100003]. This is a similar document, in that if one looks at the first line again, this is a corporate response which has been provided by the SNBTS. I think again, perhaps, professor, you haven't seen this document before either?

A. No.

Q. If we look at paragraph 1, this explains how the statistics have been compiled. Paragraph 1 stated:

"The total amount of blood collected annually from penal institutions by southeast, west, east and northeast RTCs in Scotland between 1975 and 1984 are shown in table 1. The data are presented as number of donations. The data were collect in total for each year by trawling through donor cards and donor session

records, which were stored under the management of each RTC."

Then:

"The north of Scotland RTC Inverness has no donor card nor donor session records dating from this period as all records were destroyed in a flood in Craig Dunain Hospital."

Then paragraph 2 explains:

"The total amount of blood collected annually by each Regional Transfusion Centre in Scotland between 1975 and 1991 is shown in table 2."

The second bullet point explains:

"The total donation figures were taken from a report provided by SNBTS microbiology reference unit in April 1994."

They explain the provenance of those figures. Over the page, please, at page 2 of this document, which is court book reference 0004, and about a third of the way down the page, professor, a sentence commencing:

"The data indicate the number of screening tests performed by each of the five SNBTS testing laboratories and represent total donation numbers, including failed or part donations and also those that failed on haemoglobin levels. Therefore, the numbers are higher than the number of usable donations."

The next sentence states:

"The total number of screening tests performed has been estimated to be on average between 5 and 6 per cent higher than the number of usable donations."

That's really making the point that one should look at the number of usable donations perhaps rather than the actual total donations collected.

I think if we could then, please, professor, go to page 6, which is court book reference 0008. Essentially what the document now does is for each region it sets out the total donations in each region, the number of donations from prisons and the percentage from prisons for each region. So by way of example, table 3 in the Glasgow West of Scotland region, again the left-hand column provides the year, the next column, the total donations for each year, the next column is the number of prison donations for Glasgow and the West, and the next column is the percentage of prison donation rates.

Sticking with Glasgow and the West, we can see that the percentage of total donations from prisons was a high of 2.83 per cent in 1975 down to a low of 0.23 per cent when the practice finished in 1984. Again, if one does the arithmetic, there is an average percentage of 1.376 over those years in terms of the percentage attributable to prison collection compared to

total numbers, and I think we have seen earlier the Scottish average overall was about 1.12 per cent. So fairly close to the Scottish average.

If one goes over the page, please, at page 7 of the document, this is a similar figure for Edinburgh and the Southeast of Scotland, and again, perhaps looking at the percentage prison donation rate, a high of 1.37 per cent in 1975 down to a low of 0.23 per cent in 1981, the year in which the last collection took place. If one does the arithmetic, the Edinburgh average is 0.67 per cent.

Just to complete this exercise, please, professor, over the page again, page 8, which is court book reference 0010. This is a similar table for Dundee and the East of Scotland. We can see in Dundee in 1975 a high of 3.1 per cent down to a low in 1983 of 1.02. I think the average there, if one does the arithmetic, is 2.22 per cent, which is perhaps a little higher than the Scottish average in terms of the percentage of the total Dundee collection.

Then a similar exercise finally with Aberdeen on the next page, if we can go to that. It is page 9 of the document. We see for Aberdeen, similarly, in 1975 a high of 2.67 per cent in terms of the prison donation rate and then in 1983 the final percentages is 0.51, the Aberdeen average is about 1.19 per cent.

Then finally, professor, to this document, the next page, page 10 of the document. This table shows the date and location of the last prison donor session in each RTC and I think Edinburgh was first to stop. Their last collection was on 22 December 1981 at Saughton. Inverness, the last session was 24 February 1983. Aberdeen was 28 July 1983. Dundee was 2 August 1983 and then Glasgow, finally, 25 March 1984.

Thank you, professor. I think that completes the introduction to put what follows in some context.

Professor, I think you have also provided a statement to the Inquiry on this topic. I would like to go through that with you, please, and ask you various questions. The reference number for this is [WIT0030120]. Is this the statement you provided, professor?

A. It looks very like it, sir, yes.

Q. I think you may have a hard copy of it as well?

A. I do indeed.

Q. Feel free to look at that. Personally I find it easier to look at a hard copy I have to say. So feel free to do that. The first two questions we have dealt with already. They concern statistics. So we can ignore them. Over the page, please, at page 2, at the top of page 2 you say:

"I would advise that placing these annual figures in context with those above should be done with some caution. More appropriate data may be available from SNBTS which would allow a better view of the way prison donations supported the supply of red cells in the early 1980s, at critical but short periods throughout the year."

I think, professor, you are suggesting some caution in looking at the bare statistics in themselves. Can you explain that, please?

A. Yes. Indeed. I think if you found in a region -- and at some time they would all fit into this scope -- that the prison donations were used at certain times in the year, in some instances to plug a gap in terms of the supply from the non-prison population, and so you may find -- like, for instance, there were 342, I see, for Glasgow in its last year -- this might have been a collection that covered half a week. So you see it in terms of an annual. You think it is only 0.22 per cent. It is a very insignificant. In fact, for that week I'm simply saying it might have been more than half their supply and critically important.

I do remember vividly that when we had our heated debate, to which I refer, it was made very clear to me -- and I still remember it very clearly -- that

Dr Mitchell made it very clear that his prison donor sessions, he believed, were extremely important during the period of the Glasgow Fair. Not being a Glasgow man, I wasn't terribly familiar with that but clearly he used to tell us how the whole of the West of Scotland disappeared off to Blackpool and as a consequence of which there were really quite significant problems for them.

So they targeted, he said, their prisons in that way. So all I'm saying is, if you look at it annually it looks rather small. If you take a really short period of time and link up to these when the sessions took place, I'm simply saying you may get a completely different picture in terms of the importance in the concept of blood shortages and so on, that's all.

Q. I understand, and certainly Dr Mitchell gave some evidence to that effect yesterday.

A. Really? I'm very relieved.

THE CHAIRMAN: Just before you leave, I'm interested in that observation, Professor Cash. Does it follow that simply to take the annual average would underestimate the impact in terms of risk of taking blood from prisons since it would have tended to be concentrated in short periods of time, rather than spread over the year?

A. Yes, I think that is possible, sir. I think -- that is

a possibility.

THE CHAIRMAN: It is the other side of the coin.

A. Indeed.

MR MACKENZIE: Yes. So perhaps, professor, if you were in Glasgow during the trade period and needed a transfusion, you perhaps have a higher likelihood of receiving prison blood?

A. Indeed, that's the point, I think, Lord Penrose was making.

Q. Yes, thank you.

Then question 3, professor, we have looked at this. Question 3 asked when the practice of collecting blood from penal institutions stopped in each region in Scotland. There is one inconsistent figure. For Edinburgh the reply here states 7 April 1980, whereas the table we looked at previously said December 1981. Is the table more likely to be correct?

A. Much more -- I need to be careful, sir. I'm just handing information there, from a very distinguished doctor, Anne Welsh. There may be the hiccup. I was just transmitting information that I was given. So I'm really not in the best position but I'm pretty certain that the data we have seen has been carefully looked at and was collected later and is more likely to be accurate, but I couldn't swear that.

Q. I think Dr McClelland also spoke to the September 1981 date as well. We also see for completeness, Belfast, their last collection from a prison was on 26 October 1983 as well. I think that's new information for us. Then question 4, professor, asks:

"Why did the practice stop?"

You explain:

"It may be helpful to acquire information from those regional centre directors who are still alive. But it can be assumed that it had much to do with the comments of the MCA inspectors."

Who are the MCA inspectors?

A. The Medicines Control Agency. We called it the medicines inspectors, the MIs, and they were an integral part of the DHSS down in London. For us they were the key auditing people against the background of the Medicines Act 1968. They came and inspected us.

Q. Can you explain to us a little what the medicines inspectors did and the role their body played at the time?

A. I can tell you what they did; their role I can give you an opinion. I should add that this was the cutting edge of inspections into blood transfusion in the UK. In the period 1975 to 1980 we interacted with the inspectors because it was made absolutely clear from the

Scottish Office that both the fractionation centre at Liberton and the Regional Transfusion Centres would have to fall in line with the Medicines Act in terms of regulatory control. That meant that we needed to get a manufacturing licence for these establishments and thereafter product licences. And the medicines inspectors played the key role in determining whether they were satisfied that the facilities we had, the way we were conducting our processes and so on -- they had to be satisfied before there was issued a manufacturing licence.

My understanding was product licences followed that and these submissions went to the Committee on Safety of Medicines, but the inspectors -- and no doubt they were advising there -- played the major role in the issuing of manufacturing licences and one of the fundamental problems we had, all of us, was that we, in 1975, when we were told we had to go down this track, we, as transfusion folk, knew very little about good manufacturing practice to be honest.

By the same token it was very quickly evident to us that the inspectors knew nothing about blood transfusion. As a consequence of which I invited the senior inspector, a chap called David Haythornthwaite, to spend a week or ten days up in Scotland in which we

looked closely as what we got up to and at the same time he began to teach us about the orange guide about good manufacturing practice in general. When this was all completed, we learned a huge amount and at that point the inspections from which the prison story emerged took place.

So these inspectors were inspecting against standards that at that time had not been delineated. This is for the Regional Transfusion Centres. The ultimate was, as I was saying, they were asking the question: are we going to issue a manufacturing licence to Edinburgh centre, Glasgow and so on.

Q. I think you used the expression "good manufacturing practice". Did that have a particular meaning, say in 1975? Equally in 1982, did that have a particular meaning?

A. I would be unsure about this. I have only recently discovered from my good friend Dr Peter Foster, that the original guide, the government's orange guide, which is for the pharmaceutical, hospitals pharmaceutical industry and so on in terms of good manufacturing practice -- he tells me that in fact the guide was not yet created in 1975. Some time between 1975 and 1980 the orange guide on GMP was actually created.

For Regional Transfusion Centres there was the

additional thing, which came later, and that was the red book, because the inspector was the man that drew our attention to the fact that every transfusion centre he went into had different approaches to delivering their production of X, Y and Z, and it was he that persuaded me that we had to develop a UK approach.

Q. Is it essentially a term of art? Is it to do with their standard operating procedures and so on?

A. Standard operating procedures, also specifications of materials coming in. I'm not a fractionator but the GMP is about documentation; it's about specification. I mean, documentation of the whole process, right through to auditing and batch release. The question of how you in fact specify your products, and if you want to change a bit of a process, there is very strict rules as to who is responsible for that and documentation that it needs to be done.

Q. So good manufacturing practice is about achieving certain objectives, standards and documentation and that has been done, that sort of thing?

A. Yes, indeed. And certainly we took a view that it had a major effect on the safety of the products that were coming through.

THE CHAIRMAN: Professor, you have just indicated that you have had some recent information from Dr Foster.

A. Yes.
THE CHAIRMAN: So you may not be the person to know the full range of published guidance --
A. You are absolutely right.
THE CHAIRMAN: -- at any time.
Mr Mackenzie, I think that somehow or other we have got to try and sort out what books were around because witnesses are going to get into trouble. I have a reference from Dr Mitchell to a red book in 1975 at a time that Dr McClelland tells me there wasn't a red book. So somehow or other, if we can take this out of contention by getting a reasonable picture, it would be to everybody's advantage. I don't know who can do that best. Mr Anderson, you might be the person to procure it for me?
MR ANDERSON: When you say --
THE CHAIRMAN: In other words, I don't expect you to know but someone behind you might find out.
MR ANDERSON: When you say procure it, the information or the book itself?
THE CHAIRMAN: The information, but the book would be far better because we could hold it up and people wouldn't be confused.
MR ANDERSON: We can look into that.
MR MACKENZIE: Between the Inquiry team and Mr Anderson's

team I'm quite certain we can produce an objective list with references to the various books and documents at various stages.

THE CHAIRMAN: Thank you.

A. I should point out, sir, that the red book, and no doubt the orange guide, there are current editions and I'm clear from what you say, sir, you want to know when edition one started, and that's well-known among the people that are in the game. I was responsible for the first issue of the red book. I can't remember what date it was, I am afraid.

MR MACKENZIE: I think, as well, sir, we will come to --

A. But it will be available.

MR MACKENZIE: I will come to some guidance documents with Professor Cash. I think I'll try and avoid the use of colours and stick to titles and dates and I might be able to pin things down as well.

THE CHAIRMAN: I think that might be a great help because undoubtedly the documentary records do confuse expressions from time to time and it is not helpful, certainly not helpful to the witness that is confronted with a quotation that doesn't fit with one's recollection.

MR MACKENZIE: I'm grateful, sir.

Returning to your question 4, please, we were

looking at why the practice had stopped and you provided some helpful background to the medicines inspectors' visits in 1982. Just starting again, you say:

"But it can be assumed that [the practice stop] had much to do with the comments of the MCA inspectors, (though this issue was not raised at the Glasgow, Inverness, Aberdeen or Northern Ireland inspections); the lively/heated discussions of the directors at their meeting on 29 March 1983, when no consensus was achieved; and subsequent regional reflections on ways of sustaining supplies without prison sessions. What is more certain, however, is that these dates do not derive from a national (SNBTS directors') management decision because such decisions required consensus or an instruction from SHHD ..."

That's the Scottish Home and Health Department.

"Neither was forthcoming. What we did do, as did the MCS inspectors, was seek guidance from the DHSS. None came."

I think it would be helpful for us to follow the chain of documentation at that time, ie in 1982 and 1983. I can perhaps ask you various questions which arise from the documents.

I think perhaps the first place to start, please, is document [SGF0010086], which we will shortly see. It is

a report of the medicines inspectors following their visit to Dundee in 1982. We will see that shortly.

The writing is fairly faint but we can see top of the page states:

"Visit to East of Scotland Blood Transfusion Service, Dundee (Nine Wells Hospital)."

The date is 25 March 1982. We can see the inspectors are Mr Ayling and also Mr Haythornthwaite we referred to earlier. In paragraph 10, please, we can see the inspectors state:

"The 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:

"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;

"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."

So essentially, professor, three main reasons given by the inspectors for their concern as to the practice of collecting blood from prisons and borstals. Can you remember, professor, at the time when you first saw this document and you saw these comments, what was your initial response to each of their concerns or the reasons for the concern listed by the inspectors?

A. To be absolutely honest, I can't remember at all. It is so far back. Certainly, when we debated the issue, the heated debate, I happened to be on the side of pulling out of prisons, but I don't think we should put any stock on that, that I remember that, but I don't recall seeing this document.

There were problems in terms of my seeing this document. It has not emerged in the preliminary report but there was a great tension between the Scottish Home and Health Department civil servants and the whole concept of the inspectors, and there were instructions given to us that we should not be dialoguing apart from the particular day when they inspected -- and I wasn't there, I left this to the team -- with the MCA inspectors. It was up to the Scottish Home and Health Department to do that. So there was a problem of a communication difficulty. That said, to be honest,

I'm not entirely -- I have no recollection of seeing this report. I'm sure I did but ...

Q. I'll just continue with the chain of documentation.

A. I do apologise.

Q. No, it may help. The next document, I think, is [SNB0087582]. The next document I think I would like is [SNB0087582].

I think we can see, professor, this is a letter dated 4 June 1982, addressed to yourself and we will come to see from the last page, shortly, that it is from Mr Haythornthwaite of the Medicines Inspectorate. We can see he writes:

"Dear John, inspection reports. I have enclosed copies of the draft reports for your attention. Perhaps I might make a number of observations which may be disconnected but nevertheless apply to many centres."

If we go to the next page, please, which is reference 5783, in paragraph 7(a) it provides:

"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."

So the question of the practice of collecting blood

from prisons and borstals is one of, I think, the issues which may apply to a number of centres. It wasn't simply to do with Dundee, I don't think.

A. No.

Q. We can see some handwriting at paragraph 7, professor, and in particular:

"Is the concern prisoners or prison environment?"

Do you recognise that writing?

A. I don't actually. I apologise. I don't. I can be fairly sure it's not mine.

Q. Certainly, when we heard from Dr McClelland yesterday and he explained why Edinburgh didn't go back to collect in Saughton prison, he explained that both of these concerns were relevant; both the question of collecting from prisoners but also, I think, Dr McClelland's member of staff who organised collections was uncomfortable in putting the staff into the prison environment to collect.

I think the next link in the chain is reference SNB0011983. There is, professor, a letter -- I am afraid we don't have it in the court book system but what I'll do is read out the relevant passages and then perhaps hand it to you to have a quick look at it as well.

It is simply a letter dated 5 July 1982 from

yourself to Mr John Watt, who was the director of PFC.

A. Yes, I think I know that letter.

Q. The letter is headed "Dear John, Medicines Inspectorate report."

You say:

"You will no doubt have received a copy of a letter to me from Mr Haythornthwaite dated 4 June 1982. There are one or two items which emerge from this letter which I believe deserve our collective national attention. These can be summarised as follows."

In item 7 you say:

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

I'll pass this letter to you, professor. I think it is sufficient at this stage just to let the professor have a look at it.

A. I'm familiar with that. (Handed)

Thank you.

Q. It may be we have a different number for this letter. So I'll try again, professor, with this. [SNB0056703]. That way maybe everyone could see it.

Yes, that's the letter. We can all now see. I'm grateful to Mr Di Rollo for that.

So in short, professor, you sent Mr Watt at PFC a copy of Mr Haythornthwaite's letter and asked Mr Watt for his views on the practice of collecting in prisons.

Did you receive any response from Mr Watt, do you recall?

A. I don't. I can't recall now, sir. Knowing John, I'm sure I did get one but I don't recall it.

Q. If you don't know the answer to this question, please, of course, say so, but can you recollect whether Mr Watt was in favour of collecting from prisons, whether he was against it or whether he didn't have a view on it?

A. I can't recollect, sir.

Q. I see. Now, the next document in this chain, professor, is a minute of the directors' meeting on 29 March 1983, and this is reference [SGF0010234].

THE CHAIRMAN: I think you may have responded to the inspectorate in the interval. In November 1982. Would that be possible?

A. Yes, I do recall writing to David Haythornwaite and got into terrible trouble for it, sir -- directly to David Haythornthwaite, but that was the point, as I recall, when we had discussed it and I had said to David, "We couldn't get a consensus but we are going to see if we can work this through and come back to you later," and I suspect that's after the meeting which your colleague

is about to talk about.

THE CHAIRMAN: The letter I have in mind is [SGH0035165], Mr Mackenzie. I have not got full details of it.

MR MACKENZIE: Perhaps we can see if we can bring that letter up, sir. I'm sorry, I missed the number, I apologise.

THE CHAIRMAN: [SGH0035165].

A. Very helpful, sir, yes, thank you.

MR MACKENZIE: Thank you.

A. That's the 29 March 1983 meeting.

MR MACKENZIE: I'm grateful. We can see, professor, the bottom left-hand corner in this document is dated November 1982 and we can see the title of the document is:

"A general response by the Common Services Agency of the Scottish Health Service to the inspection of SNBTS Regional Transfusion Centres by officers of the medicines division."

My recollection from having looked at this documented some time ago, I think, is that there is no reference in this document, in this response, to the question of collection in prisons. Do you have any recollection of that, professor?

A. I think that's right. This is a document I prepared to brief the Blood Transfusion Service committee of the

CSA, and I am reasonably certain, you are quite right, that I made no reference. There were some big, big other issues and I suspect this was a casualty, yes.

Q. What were the big other issues which were perhaps in the forefront of your mind at this time?

A. Well, as an example, as I recall, the inspectors had never seen plasma processing accommodation as bad in all its experience as we saw in Edinburgh. A major issue developed with the Scottish Office that major investment, capital investment, was going to be required to keep us on track with self-sufficiency.

Q. And, professor, did that apply to what was happening at the Edinburgh Regional Transfusion Centre or PFC?

A. No, no, no, the Edinburgh transfusion centre. There were other issues with PFC and that is that in PFC's visitation medicines inspectors had seriously criticised the accommodation. I can't recall the details but Dr Peter Foster does, and Bob Perry: the accommodation, storage things and all sorts of things, again massive development in investing in capital buildings, and this didn't happen. This was in 1982/1983. This didn't happen until 1988/1989/1990. So these were major issues in which great concern developed in the Scottish Office with regard to the activities of the Medicines Inspectorate and the impact it was going to

have on budgets and treasury and so on and so forth. I think, to be honest, there is another document somewhere in the CSA which is all about the buildings and so on and so forth.

Q. Yes, so the buildings, and in particular the Edinburgh Regional Transfusion Centre building, required capital expenditure?

A. Indeed. Historically, it needed a new centre and I was responsible for all this because I was doctor there and was so determined that we got our plasma going we finished up processing plasma in the cellars of a building near the old Royal Infirmary and the inspectors, when we finally arrived, were horrified, and quite rightly.

THE CHAIRMAN: Just as us back to Lauriston.

A. Indeed.

THE CHAIRMAN: But going back to the topic that we are dealing with, one shouldn't draw any inferences from the failure to deal with blood from prisons in this document because its focus was on something quite other than that.

A. I'm saying that that is a possibility.

THE CHAIRMAN: A possibility?

A. Yes, no more than that.

MR MACKENZIE: I'm grateful, sir.

So this document does form part of the chain of this line of documentation but you have explained why the question of collecting blood in prisons doesn't appears in this particular document. But if we could then, please, go to a document where that practice is discussed and this is the document [SGF0010234]. We can see from the heading these are the minutes of a directors' meeting held in SNBTS headquarters unit on 29 March 1983. Professor, at this time how often, approximately, did the directors meet?

A. I think every two to three months. I have forgotten, sir, but it was pretty regular. And we had a facility if there was a hot thing -- we would have extraordinary meetings if necessary to keep the impetus going.

Q. And we can see from those present that you were there, chairing the meeting, and we can see a list of the Scottish transfusion directors. We can see, I think, see Dr Bell and Mr Wastle from the Scottish Home and Health Department. In general, what role did officials from the SHHD play at these meetings?

A. Well, I imagine technically, sir, they were there as observers, but one thing is absolutely sure, that Dr Bell, whom I got to know extremely well, would not hesitate to give me a call before a meeting, because he had the agenda papers to discuss items on the agenda so

that I got a feel as to the department's view of certain topics. This was not frequent but it was an avenue which he used.

Similarly, I could anticipate that the next day, or the next to or three days after the meeting, Bert would phone me, not always, to discuss what he had listened to in the context of their normal practice; they were there as observers. It was, however, evident at this meeting -- I think I put in my witness statement -- that Bert Bell made it pretty clear to us that the Department of Health were a little unhappy that the inspectors had wandered into this donor area. This was the debate we had about prisons. This actually emerged.

There are papers that you have in your big database here in which Dr Boyd Moir in the Department of Health interacts with David Haythornthwaite, and it is an interaction expressing concern that the inspectors are moving into the area of the donor environment. And David Haythornthwaite -- I have a copy of this -- makes it abundantly plain that he feels -- I happen to agree with him -- he felt that it was very important in terms of inspections and manufacturing licence, that they actually looked at the source of where the blood and so on, plasma, is coming from.

Q. So there was a bit of a debate at the time, perhaps?

A. There was a debate.
Q. About the role and locus of the inspectors, whether they should stick to questions of good manufacturing practice or whether they were also entitled to look at issues of donor selection.
A. Yes, I mean, it wouldn't be good manufacturing practice, it would be sticking to the areas of donation testing and plasma processing. But the whole business of the selection of donors and so on and so forth was viewed in some quarters at that time -- it all eventually changed, as it wasn't appropriate. And I think this was a part of the complexity of this particular problem in relation to prison donations.
Q. Albeit, professor, looking at matters this way, did it really matter what the correct locus of the inspectors was, in that if they made certain comments, surely the bottom line was whether these comments or concerns were valid or not? In a way did it matter who was making the comment?
A. I think to some extent that is quite right. I would agree with it. Having said that, I inherited, as all my colleagues there did, a service in which the Department of Health in London in fact dictated the whole business of donor selection as you, I know, are aware. The CMO in London issued this, and you might ask, "What on earth

was he doing that for? What was his involvement?" There is a excellent document from Dr -- ultimately sir William Maycock, dated 1966, in which he describes the organisation of the transfusion service. In many ways he describes the whole question of donor selection and so on as a matter that is national and will be considered by the Department of Health in London.

So there was no question about it that when I became a director and subsequently national director, we tended to say that the Department of Health will tell us what to do there. By 1985, in the height of the AIDS disaster, we, the Scots, decided to break loose and develop our own guidelines, because the department in London wasn't able to move quick enough for us.

You are absolutely right, I think. We discussed the issue and in fact, as you will see emerges, people went home and spoke to their donor organisers and said, "We are going to get out of prisons". We didn't make a policy decision. Those individual doctors decided to do that.

Q. Yes, professor, I will come back at the appropriate stage in your statement to look at specific donor selection guidance documents and to see who drafted them, to look at the respective roles of Government and the Blood Transfusion Service, but sticking, if I may,

with this line of documentation just now and going back to the minutes of this meeting. This is a point of detail but if we look at those who were present, we see two Dr McClellands. There is a Dr D B L McClelland, who I think is a Scottish McClelland at Edinburgh?

A. That's Brian, yes.

Q. There is also a Dr W M McClelland. Was he a Northern Irish director?

A. He was indeed.

Q. We should perhaps bear that distinction in mind if we are looking at future documentation.

Could we then please go to page 0238, which is page 5 of the minutes. In paragraph 7, if we could perhaps blow that up. Paragraph 7 is entitled "Blood collection in prisons and borstals":

"Professor Cash reported that the medicines inspector had commented adversely on the practice of collecting blood in prisons and borstal institutions and he invited doctors to comment on the practices in each region, and to give their views on the medicines inspector's criticism. It was reported by all directors present that sessions were held in penal institutions in all regions, although Dr Brookes and Dr Urbaniak intended to review the situation in their regions. It was not possible for the directors to agree on future

policy but it was agreed that Dr Brookes, as the Scottish representative, should ask the working party on the selection and care of blood donors to consider this issue. In the meantime, D Cash agreed to inform the Medicines Inspectorate of these SNBTS discussions and conclusions."

Do you, professor, have any recollection of that meeting and this discussion?

A. Yes, but I'm not sure. It is going to be very helpful to you. My main recollections were that I was not the boss, that all consultants are equal, that I was merely there to co-ordinate and chair; that individual regional directors had the authority to stick to their view and so on and so forth. That was one of the main things.

I remember it being very heated because my old friend Dr Mitchell was very concerned that if this was precipitously implemented, he would run into problems of blood supply. These were regarded as local matters and we respected his position at that time.

Q. Can you explain that a little more, professor, in that we know at this time you were the medical director of the SNBTS, and on the face of it it may come as a surprise to those not involved to hear you say that in a discussion of this issue you felt you were not the boss. Can you explain that a little more, please?

A. Yes, there are documents, plenty of documents, available in your database in which I write to the CSA and the department and we have letters back from them. In actual fact, trying to get clarification as to my management role in the SNBTS at that time, and what clearly came back -- and I had long discussions with Graham Scott, the deputy chief medical officer -- was that I was the first among equals.

Eventually, I took the view -- this is much later in the 1980s -- that this wasn't, when we were running into really serious difficulties, going to work and we needed a general manager and they changed the management structure; hence the change that I alluded to earlier on.

So I was there chairing a meeting, and if we didn't get consensus and all agreeing there was no way on a particular issue we could go forward. Looking back, the wonderful thing is in the main we nearly always did get consensus, as a result of which we were enormously successful in many other areas.

MR MACKENZIE: I think it is almost time to take a break, but perhaps there is one or two final questions to conclude. This minute, professor, is what you have explained a situation of while there is a National Blood Transfusion Service, the regions have a certain amount

of autonomy?

A. Yes, absolutely. And that was very, very clear and did not change, compared, however, to our colleagues and friends south of the border, because we were coming from single budgeting money into the service, there was huge opportunities for us to collaborate closely together. But, yes, in terms of blood supply at this period of time, we eventually were able to change it. It was very slow. Each region was autonomous. They did their own thing. As the medicines inspectors discovered, each region was doing some things quite different to the next region and so on, in terms of the technology. But, yes, there was huge autonomy.

THE CHAIRMAN: Professor, I'm interested in the fact of autonomy but even more in what the basis of assertion of autonomy might be, and if you can help me to understand that, perhaps after the break, I would be grateful because if it comes down simply to personality and the assertion of independence rather than structural factors, that might interest me.

Anyway, we will have a break now.

(11.30 am)

(Short break)

(11.58 am)

MR MACKENZIE: Professor, before the break we were looking

at the minutes of a meeting of the directors on 29 March 1983 and you mentioned a feeling that you were not the boss during this discussion. In short, presumably, professor, what you mean is that you did not have the power to tell the other regional directors what to do?

A. That's correct.

Q. So in any discussion of this sort, presumably there were essentially three possibilities: either, firstly, the directors agreed on a common position; secondly, the directors did their own thing; or, thirdly, someone from above, who did have the power to tell the directors what to do would have to give an appropriate instruction or a direction.

A. Yes, I think that would be correct, sir.

Q. Who had that power to tell the directors what to do?

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

Q. Did the Common Services Agency play any role in the hierarchy?

A. In my view, no.

Q. I think, professor, I'll continue with the chain of documentation we started earlier. After the meeting on 29 March 1983, I think the next document, if we can go to it, is [SNB0026408].

This is a letter, professor, dated 12 April 1983. You are writing to Mr Haythornthwaite, after the directors' meeting, and you state:

"Dear David, donor sessions at prisons and borstals. This matter was discussed at length by the SNBTS directors at their meeting on 29 March 1983. Opinion was strongly divided and it was not possible at this time to obtain a consensus view."

And Dr Brookes was to raise the matter at the next meeting of the UK working party, which was currently reconsidering the whole question donor selection and care, et cetera.

Do you remember, professor, what was your personal view at this time about the appropriateness of continuing to collect donations in prisons?

A. I am as sure as I can be but not absolutely certain that my view was we should get out of that.

Q. Why?

A. On the grounds that the inspectors had raised, this is an issue, and for all the reasons that they had stated. I have to confess that I'm very uncertain that I was

aware of the work that had gone on in the West of Scotland which was published, but I certainly, in the heated debate, sided -- I don't think it matters -- but I sided with those who wanted to get out.

Q. And when you refer to the work in the West of Scotland, I think that may be a reference, which we will come to --

A. Indeed.

Q. -- to the higher prevalence of Hepatitis B in the prison population in the West?

A. Indeed.

Q. We will come to that.

Sticking with this chain of documentation, professor. I think the next document we can go to is reference [SGH0026764].

Professor, this is a document which has come from the Scottish Home and Health Department. If we go to the very bottom of the page, the bottom left-hand corner, we can see the author is a Mr J G Davies and the memorandum is dated 6 May 1983. At the very top left-hand corner, I think the "PS" may stand for private or permanent secretary -- that may be explained in due course -- of Mr Mackay. I take it, professor, you wouldn't have seen this document at the time?

A. No, not at all.

Q. Today may be the first occasions --

A. It is, indeed.

Q. I'll bear that in mind, professor, when I take you to it. I think it may be helpful just to refer to all of the main documents in the chain in one go for ease of reference later. So that's why I take you to it at this stage, professor. We can see the heading here is "AIDS" and then at the third numbered paragraph "donation policy", it is stated:

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

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

That forms part of this background. We can put that to one side and the next document is [SGH0010575]. We now jump to the Department of Health and Social Security and if we look, a Mr -- or perhaps a Miss J B Brown. I think the reference here is to the DHSS and you can see the date of this memo was 27 July 1983. Again, professor, you will not have seen this document at the time --

A. No.

Q. -- and probably not until now, but I simply refer to it to complete this line and to complete the background. This memo is addressed to a Mr Parker and states:

"Use of blood from prisons. 1. At a recent meeting of medicine and divisions inspection actions group, concern was expressed about the collection and use of blood from borstal institutions and prisons. Blood transfusion centres in Scotland were making use of these sources, particularly the prisons, and some at least of the English blood transfusion centres were also understood to do so.

The group consider this practice to be highly questionable because of the incidence of homosexuals and homosexual activity in prisons and the present unease about the incidence of AIDS among this group of people.

"3, the group asked to be advised of departmental policy on the practice of collecting and using blood from borstals and prisons. I shall be grateful if you will let me have a note about this which I can pass on."

If we then, please, go to the next document, it is reference [SGH0010572]. Again, professor, you won't have seen this at the time. We are now back to the SHHD in Scotland. If we go to the next page, please, we can see at the top the date of this handwritten memo is 11 August 1983. If we go back to the first page,

please, and I'll read the memo. The memo provides:

"Mr Winstanley, DHSS rang. He has received an enquiry from the Medicines Inspectorate re departmental policy on donor sessions in prisons and borstals, given there is now AIDS. He explained that England and Wales have tended to shy off in part because of hepatitis but he wondered what Scottish position was.

"2, Mr Wastle directed me to the discussion at RTD Scotland meeting on 28 March 1983 ..."

Which we have just looked at the minutes off:

"I outlined to Mr Winstanley what was said then and referred to the general position. He was interested in the reference to Dr Brookes approaching the working party on selection and care of blood donors and will try to explore that avenue. He will copy his response to Medicines Inspectorate to us and mention the subject is being put to English RTDs at their next meeting. He made the point that if policy was to be withdrawn, would probably need to consult Home Office in view of the importance placed on the social responsibility aspect of such sessions."

Then put that to one side, I think the next document is then [SNB0026554]. We can see this is a letter dated 23 August 1983 from Dr Brookes, the regional director at Dundee, addressed to yourself, professor, on the

question of the working party on the selection of donors and notes for transfusion and under the heading "Donor sessions at prisons and borstals" Dr Brookes states:

"You asked me to discuss this with my colleagues. In fact no discussion was necessary since, as far as England and Wales are concerned, these sessions have already been stopped. It is now left to the Scottish regions to decide whether they will do the same."

Then the next document is [SGH0010574], which takes us back to the DHSS. We can see the date of this memo is 23 August 1983, written by P A Winstanley, addressed to a Mr J B Brown, whom we saw before, on the collection and use of blood from prisons. I assume again, professor, you wouldn't have seen this memo at the time. I think you shook your head to indicate no?

A. No, I didn't see it.

Q. Paragraph 2:

"It is difficult to advise of any particular departmental policy on the collection of blood from borstals and prisons at the moment. It is for individual regional transfusion directors to determine how and from where donations are sought in the light of the targets they need to achieve and the numbers of donors on their panels.

"3. However, transfusion directors have been aware

of the dangers of relying too heavily on prisons as a sort of donations for some time, ie prior to the advent of AIDS, as a cause of concern because of the risk of hepatitis in prisons (also connected with the higher incidence of homosexuality) which can be spread through blood transfusion. Nevertheless, although most regions, especially those with no shortage of donors, may not need to use prisons, there is at least one which has to view them as a major source of donations in order to meet targets.

"4 AIDS has now, of course, called the wisdom of continuing to view prisons as a source of blood even further into question, and the directors are due to discuss it at their next meeting in September. If the risks are now considered too great to justify continued collection from prisons, some measures will be needed to compensate for the loss of that source of donors, perhaps, for example, a system whereby regions with no need to rely prisons can take extra blood to be transferred to those regions for whom the loss of prisons as source of blood will cause difficulties.

"5. I shall of course advise you of any developments which occur. I gather that this problem has been debated by transfusion directors in Scotland but no particular policy line emerged. 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."

As a slight diversion, professor, in paragraph 4, where there is a reference to the English directors are due to discuss it at their next meeting in September, I have looked into this and I can't find any reference, I have to say, to the English directors having discussed this at their meetings and I provide it simply for the record.

If one looks at [SNB0013412], that is a meeting of English directors meeting on 22 September 1983 and there doesn't appear to be any discussion of collection of blood from prisons. Nor can I find any discussion in any of the minutes after that meeting, either.

Professor, the next document then takes us back to Scotland and a meeting of the Scottish directors on 13 September 1983, and that is reference [SNF0010072]. We can see again, professor, from the first page that you are in the chair. The Scottish directors are there. Dr Bell and Mr Wastle from SHHD are there. We can also see Dr Wagstaff, one of the English directors from Sheffield, was there. Was that a common concern, professor, for the English and Scottish directors to have one representative at each other's meetings

observing?
A. Yes, it was.
Q. So Scottish directors would also attend the English directors' meetings to observe as well?
A. They would do yes, a representative, yes.
Q. If we can go, please, to page 6 of this minute --
A. Perhaps, I might just interject, you make the point about Dr Wagstaff, Dr Harold Gunson, who was the DHSS adviser in blood transfusion, I'm sure as you know, he normally attended and I noticed that he issued his apologies for that particular meeting but Harold and I were pretty close.
Q. Yes --
A. And he was well aware of this issue.
Q. What role did Dr Gunson have at this time in 1983? What was he? What did he do?
A. I would need a little notice of that. Certainly he was DHSS adviser in blood transfusion and I think he was part of the directorate that had been created, but that may have come year or so later.
Q. Would it be fair to say he was one of the leading English transfusion figures --
A. No question.
Q. Then page 6 of this minute, professor. The reference is 0077. We can see in paragraph 8 the heading "The

working party on selection of donors/notes for transfusion". About half way down the page, the paragraphs commences:

"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 had been unable to reach a consensus. The chairman of the working party thought that the practice was diminishing in all regions in England and Wales. Dr Brookes felt strongly that donations should not be collected from prisoners because of the uncertainty about replies to questions concerning health.

"It was reported that the practice had been raised at the medicines inspectors' action group who had refered it to the DHSS administrative division who confirmed that some transfusion centres in England still collected from prisons and borstals and that cessation of this practice would place them in difficulty. The NBTS directors were due to discuss the matter and the DHSS would wish to consult the Home Office who had been anxious previously to encourage donation in prisons.

"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 and Dr Brookes undertook to circularise the English/Welsh transfusion directors and report back to the meeting."

Professor, does that capture the main matters discussed at the meeting or was anything else discussed that you can recollect that we should be aware of?

A. Not that I can recall, sir. It seems to me to cover my memory pretty well.

THE CHAIRMAN: Can I go back to the top of the page with you, professor. There is a reference to the "the working party" there, chaired by Dr Entwistle.

A. Yes.

Q. As far as I can see, Dr Entwistle's name appears without much background. Can you tell me anything about this working party?

A. No. To the best of my recollection, sir, Colin Entwistle at that time was the director of the Oxford Regional Transfusion Centre.

THE CHAIRMAN: And Dr Ewa Brookes had been on this group, perhaps before she came to Dundee.

A. Dr Brookes was representing the Scots on that. In fact it was an English -- an NBTS -- and they invited us to have an observer. So Ewa was there on that job.

THE CHAIRMAN: Mr Mackenzie has mentioned he cannot find any reference in the English directors' meetings but does it appear that at this time, in the summer of 1983 and into the early autumn, there was a working party looking particularly at the selection of donors which covered selection from prisons?

A. Yes, indeed.

THE CHAIRMAN: Thank you.

MR MACKENZIE: Thank you, sir.

Going back to Dr Gunson, professor, I think he was the regional transfusion director in Manchester at this time.

A. Manchester.

Q. I'm grateful.

A. Thank you.

Q. The next document, if we go back to the SHHD. The reference is [SGH0010571]. Again, professor, I take it you won't have seen this memo at the time?

A. No.

Q. Well, we can't see much from it at all other than it is headed "File note". It is undated but it does state:

"Use of blood collected in prisons. The details in Mr Winstanley's minute of 23 August were reported to the meeting of RTDs on 13 September 1983."

I think that must be a reference to the meeting of

the SNBTS directors:

"With the exception of the West of Scotland, RTDs were ceasing collection of blood at prison sessions."

The subject would be kept under review, particularly to hear of developments in England which might be influenced by Home Office views.

Then the next document, professor, goes back to the next meeting of the SNBTS directors. I think the last meeting in 1983. The reference is NNF0010178]. I'm sorry, it might actually be helpful to look at one document prior to that. Could we please have up [SNB0143030].

We have looked at this document before, professor, but we can see these are the minutes of the fourth meeting of the UK working party on transfusion-associated hepatitis on 27 September 1983. If we go over the page, please, we can see the membership at the top of the page and the meeting is chaired by Dr Gunson. I don't think, professor, you were a member but we can see Scottish representation at this meeting, in particular Dr Cuthbertson, Dr Brian McClelland and Dr Mitchell.

If we then go to page 9, which I think is court book reference 3037. Paragraph 7 at the bottom, "Donor sessions in prisons". We can see:

"Members asked if the chairman could provide details of which centres took donations at prisons. They realised the definition of 'prison' ranged from closed to open prisons. The working party felt that problems 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."

Would you have seen these minutes at the time, professor?

A. I don't recall seeing them at all, sir, no.

Q. Does the view of the working party as set out there, 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, accord with your view at the time?

A. That would be my view when we had our contentious meeting, yes.

Q. I see. So that would have reflected your view when the matter was discussed at the SNBTS directors' meetings in 1983?

A. That's correct.

Q. I'm grateful.

If we could then put that document to one side and

turn to the minutes of the meeting of the SNBTS directors on 8 December 1983, which is reference [SNF0010178]. We can see again who was present at that meeting. Again, apologies were notified from Dr Gunson, then at page 0181, please, under the heading "Age working parties on the selection of donors/notes for transfusion":

"Dr Brookes had circulated to her colleagues, Dr Entwistle's final version of the above ..."

In terms of prisons, we can then see her reporting her consultation with the English/Welsh transfusion directors concerning corrections in prisons and borstals:

"Dr Brookes explained that only one of the 12 which she had consulted was attending prisons. It was noted that the only Scottish region to continue holding sessions in prisons was the West."

Can you remember anything more about the discussion of collection of blood in prisons other than what is in this minute, professor?

A. I can't, beyond the recollection that we were waiting to hear from other sources as to whether there was a strong recommendation coming but I can't remember that.

Q. Thank you.

A. Any more than that.

Q. The final document in this chain, professor, can we go to, please, [SNB0048628]?

We can see from the top, professor, these are the draft minutes of a meeting of the infectious hazards of blood products, the NIBSC, 9 February 1984. I think, professor, you were at this meeting and we will come on to that shortly. In the introduction we see that, in introducing the meeting, Dr Smith of the NIBSC welcomed participants and explained that NIBSC was not the licensing authority in the UK but the institute that gave scientific advice to the licensing authority and the Committee on Safety of Medicines:

"The meeting had been called to examine the infectious hazards of blood and blood products, with particular reference to hepatitis and AIDS."

Could we then please go to page 8633. About half way down the page we see a paragraph commencing:

"In discussion, Dr Cash commented that paid donors are perhaps less likely to be truthful about their activities than volunteer donors."

Can you explain that comment, professor?

A. Yes. And one saw this -- I did a major visit to the USA in 1969 and looked at the commercial plasma phoresis centres there and saw at first hand that if you are being paid money for your donation, the question then

arises if somebody asks you a whole series of health check questions, would you be absolutely truthful. And I came to the conclusion that certainly in California, I wasn't convinced that people were being very truthful. So the question of paid donors and safety emerged as a major issue.

Q. In the context of collection from prisons, would it be reasonable to assert or suggest that prison donors are perhaps less likely to be truthful about their activities than non-prison donors?

A. Yes, I took that view, yes. I'm not sure it can be justified, however, but I mean, I took that view. It was a personal view and a view that was in fact fairly widely shared.

Q. During this period in 1983, you took the view that prison donors were perhaps less likely to be truthful about their activities than non-prison donors?

A. Yes.

Q. Is that a view which it would have been reasonable for one to have held in, say, the early 1970s, the mid 1970s, the late 1970s?

A. Yes, I think it is, in a sense, a generic view that if you incarcerate people and they can get an afternoon off out of our their cells or whatever -- there is no payment -- yes, I think it could apply to the early 70s.

Q. It really perhaps just comes down to a judgment or common sense or one's experience or perhaps prejudices in life, perhaps.
A. Sorry, I didn't --
Q. Sorry. It may be there is no hard evidence for such an opinion but it really refers to one's judgment or common sense or perhaps prejudice?
A. It may be all those things, absolutely right. Certainly I was not aware of any data and evidence base that would confirm what I am saying.
THE CHAIRMAN: There is nothing worse than fama as the basis for forming a view, professor. Is this just something that one acquired by osmosis, as it were, sitting around the table and absorbing it from others, or was there discussion of it as an issue?
A. I'm reasonably convinced -- satisfied, sir, that at some point Dr Brookes raised the issue of the truthfulness in terms of responding of prisoners.
THE CHAIRMAN: I think I have seen --
A. Yes, I think it did enter -- this wasn't a private view of mine that was not shared. I think it was a view that was discussed.
THE CHAIRMAN: Before coming to Scotland, Dr Brookes had operated in the London area.
A. That's right.

THE CHAIRMAN: And from other material it is clear that she did attend prison sessions.

A. She had actually been to prison session, that's right, sir.

THE CHAIRMAN: So she had personal information available to her.

A. Yes.

THE CHAIRMAN: I could understand if you were to tell me that you had listened to Dr Brookes and formed a view on that basis but I'm rather concerned that perhaps you are giving the impression that there was a more prejudiced view that prevailed generally. An evidential basis for a view is much better than a prejudice. Can you help?

A. Absolutely. I think in my statement I spent some time visiting Armley Gaol in Leeds and spent some time talking to prisoners, and I did come away thinking that some of these chaps are likely to be less truthful than those who are not in prison if there was some gain to be had, whether it is just free time or whatever. That may be a prejudice and you would hardly say three or four conversations with prisoners represented an evidence base. But that's the way we are, I think.

THE CHAIRMAN: Yes. So those of us who have had many conversations with people in prisons, perhaps shouldn't enter into this debate.

A. Indeed, I appreciate that, sir.
THE CHAIRMAN: Yes.
MR MACKENZIE: Thank you, sir.
Having looked at that chain of documentation, professor, I can perhaps ask two principal questions. You have seen a reference to the Home Office having a view that collection in prisons was a good thing, perhaps from a perspective of seeking to rehabilitate prisoners. Are you aware when the SHHD ever sought to influence or encourage the collection of blood in prisons in Scotland?
A. No, I'm not aware, sir. Encouraged? No, I'm not aware. Nor am I aware that they discouraged either.
Q. Yes. So would it be fair to say that the SHHD were aware of the practice of collecting blood in prisons in Scotland but they were essentially passive or neutral on the issue?
A. Yes. I really can't speak for them and you will be speaking to some of them. I think that is probable. I would add that there is this strong tradition, as I have explained before, that these matters were under very much the governance of DHSS and I suspect, to be fair to my Civil Service colleagues in Scotland, erstwhile colleagues, that they were waiting for a judgment to come up from London on this and they

waited.

Q. So on this topic, professor, just to take this to its conclusion, I think I'm right in saying there is no evidence to suggest the DHSS sought to directly influence the SNBTS in relation to collection of blood from prisons. Is that correct?

A. No, I agree with that.

Q. So any influence the DHSS exerted on the SNBTS would be through the SHHD?

A. That is correct, sir.

Q. Certainly you have no recollection of the SHHD seeking to influence or encourage the collection of blood in prisons in Scotland?

A. Nor do I even have any recollection at all of some of the documents you have shown me that I hadn't seen before, that there was an opinion emanating out of DHSS. Is that it was up to individual directors to determine these practices, depending on -- I think it said their targets for supply. That never came back either. I think that was a communication from London to Edinburgh. I don't recall ever being aware of that.

Q. My second principal question in this area, professor is this: who do you consider was best placed to consider whether it was appropriate to collect blood from prisons in Scotland? Do you consider the SNBTS were best placed

to consider that or do you consider Government was best placed to consider that question?

A. In retrospect, I have no doubt it should have been SNBTS but at that time these matters -- we broke away eventually in Scotland at that time. These matters, the question of donor selection, were very much in the hands of the DHSS and I think we eventually recognised that this wasn't right.

Q. We will come back to look at that point, professor, but, before leaving this, would it be fair to say that medical and scientific matters relating to transfusion were primarily for the SNBTS, whereas wider policy matters may involve government?

A. Yes, but there are, I think, quite a number of issues that policy affected medicine directly.

Q. I understand. It is hard to ring-fence each area; there is a certain amount of overlap and interlinking, I can understand that. Thank you, professor.

If I may now return to your statement, please, which we had before us, [WIT0030120], I think at page 2, a few lines from the bottom, the paragraph commencing:

"My father was a prison chaplain ..."

I think we had reached as far as this. You say:

"On several occasions I did visit HM Armley prison."

Where is that prison?

A. Leeds.
Q. You explain you:
"... judged the health of many paid donors seen by [you] in 1969 in plasma collection centres in Los Angeles was much worse than that of inmates of the Leeds HM prison in 1983. As I recall, the problem of drug addiction in UK prisons in 1983 was not the problem it is now."
Can you remember, professor, what was your knowledge, if any, about drug addiction in UK prisons in 1983?
A. I imagine very little, sir. It is again an impression.
Q. And when you assert in your statement that the problem of drug addiction in UK prisons in 1983 was not the problem it is now, what's the basis for that statement?
A. Nothing more than an intelligent guess. I have no evidence basis. It is not my field.
Q. I see. Just continuing with your statement, you explain:
"Whilst arguably not relevant, it may be worth pointing out that MCA inspectors did not seek to impose a ban on prison donors used by commercial plasma collection agencies in the US which supplied plasma for coagulation factor concentrates destined for the UK. It is my understanding that prison donors were not excluded

in the US until 1990 (I have a reference for this if required)."

I don't think we have that reference. If you were able to supply that in due course, that would be helpful.

A. I'll do my best.

Q. You state there, professor, that:

"Prison donors were not excluded in the US until 1990."

Does that refer to some government instruction that blood should not be collected from prisons or what?

A. Yes, it would be the FDA.

Q. Do you have any knowledge -- and if not, please say so -- about the actual practice in the US in the 1970s, 1980s, in terms of which states were actually collecting from prisons?

A. No, I don't have any knowledge, nor do I have any knowledge -- certainly in 1969, when I was in San Francisco and Los Angeles, I was aware that prisons were being used. That's the only knowledge I have, sir. I'm not aware of -- we are talking about commercial plasma phoresis here -- what the situation was with the American Red Cross in terms of ordinary blood transfusion. But it is possible that the FDA could provide that information.

Q. Thank you, professor. Returning to your statement, please, in paragraph 5 you were asked of:

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

And you say that:

"As far as I can recall, this topic was not discussed by the SNBTS directors until the matter was raised by the medicines inspector in 1982, and furthermore, to the best of my recollection, the news on 29 March 1983 that Edinburgh had abandoned prison donor sessions in 1980 came as a complete surprise to me and all other SNBTS directors."

Professor, this may be a point of detail but when we looked earlier this morning at the minutes for 29 March 1983, there was no reference to Edinburgh having abandoned prison donor sessions in 1980. Is it possible you are mistaken on that or do you have a recollection of being surprised at hearing such news?

A. Yes, I have always been cautious about minutes and whether they cover everything, and indeed in the expert advisory group on AIDS that became a major issue for me personally. I have a recollection -- and in fact this

was part of the chemistry of the SNBTS, that it was not known to me or my colleagues, when it was discussed in 1983 during that heated debate, that Edinburgh had already moved. It may not be 1980. It may be the date is 1981.

Q. You have a recollection of Dr McClelland saying at that meeting that Edinburgh --

A. I have a recollection.

Q. -- no longer collected from prisons. Yes?

A. The chemistry being such that that raised the temperature another notch or so.

Q. I see. Is that perhaps another example of the autonomy of the different regions?

A. It is indeed, sir, yes.

Q. At that time at least?

A. Yes.

Q. Going on to question 6, please, professor, in your statement you were asked whether:

"Ceasing the practice of collecting blood from penal institutions led to any difficulties in maintaining a sufficient supply of blood in Scotland."

And your reply is:

"None that I recall."

But you suggested that each former living director should be consulted, and you explain:

"Certainly, I am aware that on a number of occasions after 1983 surgical procedures were postponed due to blood shortages in the West of Scotland. Whether these shortages had anything to do with the abandoning of prison donor sessions is not known to me but it is worth pointing out that the annual blood collection figures per million of population in the west was significantly below all other regions in Scotland throughout the 1980s. Thus supply difficulties for red cell was a not infrequent anxiety for colleagues in the West, where poverty and deprivation were significant challenges for those responsible for the blood collection programmes. It is almost certain that it was never a problem for Edinburgh or any other SNBTS region."

We have looked, professor, at the beginning of your evidence at how many collections were taken from prisons and we saw the average in Scotland between 1975 and 1981 was about 1.12 per cent, although you explain one would have to be slightly cautious in considering how important that contribution was at particular times of year.

Dr McClelland, professor, gave evidence to the effect that stopping collecting blood from Saughton didn't cause any problems to the blood supply in the east. I think Dr Mitchell's position essentially was

that there were from time to time difficulties in the blood supply but they weren't insurmountable because of the work carried out by him and his colleagues in the west to overcome any difficulties.

Would you agree -- and if you are not aware of this, then please say -- that the general picture appears to be that if a decision had been taken in 1975 that collection in prisons in Scotland should have stopped, that is unlikely to have caused any insurmountable problems in terms of the blood supply in Scotland?

A. Yes, I would agree now in retrospect and I think -- but it would in my experience have required a little less autonomy, a little more cross-regional support, when times got difficult. But if you take the total input of red cells to the whole of Scotland, I don't believe that 1 per cent would have -- we could have easily coped with it.

Q. I'm grateful. I think you have prepared a separate short paper on this, professor, and we will come to look at that at the end of your statement.

A. Yes.

Q. Thank you.

Moving on, please, then to question 7 in your statement, you were 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.

You replied to that on page 4. You answer:

"I cannot recall whether I was aware of this evidence or the work published from the West of Scotland BTS."

You then refer to the Wallace 1972 paper, which is [SGH0029831], and the Barr 1981 paper, which is [PEN0140068]. I think in short both the Wallace 1972 paper and the Barr 1981 paper had similar findings to English evidence, that prison donors had an approximately five times greater prevalence of Hepatitis B antigen than non-prison male donors. You explain that:

"If it was discussed by the SNBTS directors, then I would imagine it would have been raised by Dr John Wallace in the West of Scotland RTD ... "

A. Yes. This is very early.

Q. Yes:

" ... in 1974/1975 and by Dr Mitchell in 1981/1982."

You then explain:

"I must confess I do not recall having ever given the matter on prison donors any consideration until it was raised by the Medicines Inspectorate in 1928/1983."

To pause on the last sentence, professor, we know that in 1974 you were appointed director of the Southeast of Scotland Regional Transfusion Service and then, of course, in 1979 you became medical director of the SNBTS. So is it the position, professor, that really from 1974 through to the 1982 and the arrival of the medicines inspectors you didn't give the matter of collecting blood from prisons really any consideration?

A. I have no recollection, and the only explanation I am bound to give is that we were heavily committed to many other areas related to haemophilia, addressing the problems of plasma and haemophilia. That's the only explanation I can give but I have no recollection of discussions on this topic at all until the medicines inspectors.

Q. Yes, and to try and put this issue in some context, professor, can you recall what were the main issues which were being discussed and considered by the Scottish directors throughout the 1970s and into the early 1980s? Is it possible to summarise that?

A. Yes, very briefly, without any shadow of doubt: the problem of national self-sufficiency in plasma products.

Q. That's a very short summary, professor, thank you.

A. It was a monumental task.

Q. Yes, and we may come back to that in a different topic.

A. Yes, indeed.
Q. Thank you.
THE CHAIRMAN: Just before we leave what was happening, I have got information about the service in England and Wales, having looked at the collection of donations from prisons in 1973, when, it is fair to say, seven were for it and seven were against it and that leading to a report by Dr Maycock to the SNBTS directors on 4 October 1973 informing them of this background. Is that something you would have known about at the time?
A. I don't know. Certainly, I have just been reminded that I was appointed a regional director in 1974, sir. I'm not sure when in 1974 that was. But, no, I would have been a young consultant, a very young consultant, and was not engaged in any of the national discussions at all.
THE CHAIRMAN: Thank you.
MR MACKENZIE: Thank you, sir. We will come back to that shortly, professor, but just sticking at this point in your statement with the paper by Wallace in 1972 and also the Barr paper in 1981, before we actually look at those papers, could I ask you firstly, professor: in the 1970s did you ever attend donor sessions, whether within or outwith prisons.
A. There were lots outwith prisons, the whole of Fife and

the Borders. It was part of the duty for me on a Sunday to go down to these session, yes.

Q. Including sessions in prison?

A. No.

Q. I'm sorry?

A. No.

Q. So at sessions outwith prisons, what steps were taken to try to try to exclude donors who may have injected drugs?

A. I do not recall in terms of specifics. I must confess that my attendance at these sessions in that period was one of director and thanking people for turning up. In other words, I was not involved in the staff that were actually doing the job. So I have no idea, to be absolutely honest.

Q. Do you think it may have been the practice -- and if you can't answer this, just say -- in the 1970s for staff at donor sessions to directly ask a donor, "Have you ever injected drugs?"

A. No, I can say, I don't know but my gut feeling is certainly when we got into the area of AIDS, there was great difficulty for some of our staff asking very straight questions about people's lifestyles.

Q. We really see a step change, I think, in what questions are asked with the arrival of AIDS and we will come to

that topic shortly.

A. That's my memory, yes.

Q. Some of the AIDS questions are really very direct and intrusive.

A. Yes.

Q. As I say, we will come to that.

A. Yes.

Q. Just to finish this small line, professor, could you look, please, to one donor leaflet we do have? It is [PEN0131395]. We can see, professor, from the top, this leaflet is from the Glasgow and West of Scotland Blood Transfusion Service. If we go to the very bottom right-hand page, we can see somebody has written on "16 June 1983". We can see at the bottom left what appears to be a label that has been stuck on the leaflet asking:

"Have you heard of AIDS?"

Can you see that?

A. Yes, thank you.

Q. Which again may help to date the leaflet to about that period. If we then scroll up the page a little, please, we can see a list of questions on the leaflet. There is no reference, professor, to any history of drug use on this leaflet. If you can recall, is the leaflet we see here similar to the type of leaflet and type of

questions we may have seen in a donor leaflet in Edinburgh in the 1970s? Is that something you can answer?

A. I can't. My gut reaction is it may be a little different, the way things were. But I have no clear recollection at all, sir.

Q. Thank you.

Could we then, please, go to the Barr paper, 1981, which is [PEN0140068].

Professor, this is a paper by Mr Barr and others on the question of Hepatitis B virus markers in blood donors in the West of Scotland. Can you recall whether you saw this paper at the time or a draft of it?

A. No. I'm as certain as I can be that I did not see it. I have to say that in 2011, when you think of giant databases for publications, life is significantly easier and I am aware that one of the reasons I introduced in our annual reports the listing of publications coming out of the SNBTS was I became aware that publications would come out from centres, and other centres in Scotland were not aware of them. So we attempted to make that.

I have to say I was not aware of this paper.

Q. Also, just for completeness, could we also have the Wallace 1972 paper up, please, which is [SGH0029831]?

THE CHAIRMAN: Professor, would you look at the very top of the one that we have just got before it disappears. It is published in the medical services laboratory -- medical laboratory services or something. Is that a publication you know of?

A. I do know of it. It is not one that I looked at but in the MLSO, the technology world, it was a very important and prestigious journal.

MR MACKENZIE: I think we can see, professor, Medical Laboratory Sciences.

A. Sciences. These were the medical laboratory scientific officers, the MLSOs as we used to call them. I think it related to their institute, the publication.

THE CHAIRMAN: But it wouldn't necessarily be a publication read by the medical profession generally.

A. No, it wouldn't. That's no excuse, sir, but no, it wouldn't, I have to say that.

THE CHAIRMAN: Thank you, Mr Mackenzie.

MR MACKENZIE: Going back to the 1972 paper, professor, for completeness. That was [SGH0029831]. I think this is Dr Wallace's paper in 1972 published in the British Medical Journal. Is that a publication you would have read at the time?

A. Yes, BMJ. It would be very likely. I was a paid-up member. So I would certainly have got it on my desk.

Q. I think between 1971 and 1974 you were a consultant with the Southeast of Scotland BTS and again I appreciate it is many decades after the event, professor, but do you have any recollection of having seen Dr Wallace's paper at the time?

A. I have no recollection but I don't think after all this time that means terribly very much. I would only add that it's in a professional area that, at that time, I was not involved in at all. So I can well imagine I have seen it, flicked it over and took no great interest.

Q. It is 1 o'clock, sir. I think perhaps we will finish this chapter with another two or thee minutes. I could just stop now?

THE CHAIRMAN: I think if you are going to finish the article, it would help.

MR MACKENZIE: I'm grateful, sir.

Professor, you were appointed director of the Southeast Scotland in 1974 and the medical director in 1979 onwards. At any time between 1974 and 1982 can you recollect, were you aware of the evidence suggesting there was a higher prevalence of Hepatitis B among prisoners in the West of Scotland?

A. No, I regret to say.

Q. Finally, professor, if I can take you back to the 1981

Barr paper, [PEN0140068]. In short, professor, this paper reported a higher prevalence of about five times more of Hepatitis B surface antigen in prison donors compared to non-prison donors, both of which groups tested for the first time. We see in the second paragraph, half way through, the statement:

"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."

If, professor, you had read that at the time in 1981, what would your response have been to those assertions?

A. I'm not at all sure, to be absolutely honest. I think in 1981 I was national director. If I had been that conscious of it, I would have popped it up on to the agenda of the directors to get it knocked about and discussed. That's surmise, sir. I can't be absolutely certain.

THE CHAIRMAN: Professor, if you look at the bottom, there is a note that the paper was presented at the workshop.

A. Yes, and the question, when I saw it, was I there? I must have been there. But I have no recollection, I regret.

MR MACKENZIE: What confidence, professor, do you think one could assert that positive prison donors are not drug addicts in 1981?

A. I mean, now, when challenged, I imagine very little confidence.

Q. And --

A. The difference between males and females outside prison --

Q. Final question, professor, from myself: looking at these assertions now, and I'll repeat them again shortly, what are your views on them? So an assertion that the positive donors are not drug addicts and this high incidence is probably related to social habits and hygiene. Knowing all we know now, what views do you have on these assertions?

A. I think that was an error. I suspect.

Q. And knowing what we know now, what do you think is the most likely explanation for that higher prevalence of Hepatitis B in prison donors?

A. I imagine it would be drugs.

Q. Thank you, sir.

A. And needle sharing. Which would apply to a major area of Edinburgh as well at that time, I imagine.

Q. Thank you. It may be an appropriate moment, sir, to break for lunch?

THE CHAIRMAN: If, of course, those who were suspected of having a drug problem were excluded from the potential donor group by prison authorities, the view might be different, might it?

A. Yes, sir, I think so.

THE CHAIRMAN: This is one of those areas where I can see speculation both ways but, without knowledge of the mechanisms adopted perhaps to avoid the embarrassment of admitting that the prison had a drug problem, one can't really come down on one side or the other, can one?

A. No, I agree, sir.

(1.03 pm)

(The short adjournment)

(2.05 pm)

MR MACKENZIE: Can I please return, professor, to your witness statement and carry on going through that? You were at, I think, page 4. I had come on to question 8. Could we have that up again please? It is [WIT0030120]. Thank you.

Question 8, professor. You were asked whether you were aware of a letter dated 6 January 1975 by Dr Garrot Allan of Stanford to Dr William Maycock of the Blood Products Laboratory warning of the increased risk of hepatitis including non-A non-B hepatitis from the blood of prisoners.

I think the Inquiry has looked at that letter already, so we don't have to go back to that but you answer that as far as you can recall you were not aware of that letter and first discovered its existence when reading Douglas Starr's book in 2007. I think, professor, Dr Garrot Allan had also published a book, perhaps in the early 1970s, on the subject of his research. Were you aware of that book or not?

A. No, not at the time, no.

Q. So the gist of Dr Garrot Allan's studies, I think, were to show the higher prevalence of perhaps post-transfusion hepatitis in paid donors. Is that correct?

A. That's correct, sir.

Q. But you were not aware of that research in the early 1970s?

A. I was not aware of his book. I was certainly aware and wrote myself about the whole issue of the dangers of paid donors.

Q. And this then comes back to your visit to Los Angeles in the late 1960s?

A. Indeed.

Q. I understand.

The next question, professor, question 9, moves off on to a different document and 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 subjects of blood donation and hepatitis. We will come to that letter shortly. You answer that as far as you can recall you were not aware of that communication but the SNBTS may have access to copies of directors' meetings which reveal the contrary.

We shall perhaps look at some documents in this regard, professor. The first document, to put this letter into some context, is document [SNB0012494]. We can see from the top of this letter, professor, that it is a note -- it is made by Dr Brodie Lewis -- from the Aberdeen blood transfusion region. I think this is an example of one of the Scottish directors, having attended one of the English meetings then reporting back. Dr Lewis's notes of the English directors' meeting held in London on 24 March 1974 address this item, the question of donors from tropical areas. In short, professor, it had been noted that donors from tropical areas had a higher incidence of Hepatitis B.

If we can perhaps go on to page 2498, 2498 is an attachment to Dr Lewis's note and is the memorandum by Dr Cleghorn, the director of the North London Blood Transfusion Service. If we go over to the next page,

please, we can see the date of this memorandum is 18 April 1974. If we could go back to the previous page again, please, the memorandum is headed "Memorandum on HBAG carriers":

"There has been some comment recently by the news media concerning our activities in Edgware and the following notes are relevant."

Paragraph 2, there was a question of:

"Towards the end of 1973, following reports by BPL of HBag in three of our five-litre packs, our honorary consultant adviser in virology, Dr Dane, initiated testing by RIA of all such packs before dispatch. Within one week, two were found RIA-positive and in each instance, tests on repeat samples from the contributors identified the culprit as a TA donor.

"3. This led to review of our figures ..."

Essentially it became apparent that there was a higher incidence of Hepatitis B antigen in donors from what was termed "tropical areas". Beneath the figures in paragraph 3 it stated:

"Thus, 25 per cent of carriers detected by IEOP were located in less than 2 per cent of the donor panel."

In paragraph 4 it states:

"The detection efficiency of IEOP is probably not much better than 50 per cent, so that even after

elimination from the panels of all HBag positives to IEOP, an equal number of carriers almost certainly remains and the TA donors must represent comparatively a high risk group."

Then the end of paragraph 5:

"I decided, therefore, to suspend issue of all TA donations until a policy decision could be made."

I think that's the matter which caused interest from the media. Do you, professor, have any recollection of this topic?

A. None at all. Not the documents you have shown, no.

Q. Then over the page, paragraph 7 states:

"It is also proposed to test current and future TA donations by both HA and RIA and to store the serum samples for future reference."

Essentially I think the RIA test was more sensitive than the IEOP test. Then paragraph 8:

"The desirability of taking a more detailed history from coloured donors than has previously been considered socially acceptable is being discussed."

That all forms part of a letter we are going to come to shortly but to go back to page 2494, back to Dr Lewis's note of the meeting in London, the last paragraph states:

"Geoffrey Tovey said that they were still taking

donations at prisons, and he suggested that initially the most sensitive tests for Australia antigen should be used for testing donations from high risk groups."

I take it, professor, from what you have said that you have no recollection of that note from Dr Lewis?

A. No.

Q. Thank you. The next document is number [SGH0030187]. This is Dr Yellowlees's letter of 1 May 1975 to all regional medical officers. We have looked at this before in the Inquiry and it is headed "blood donation and hepatitis" and it commences:

"The department ..."

This is the Department of Health and Social Security:

"... has recently received advice from a group of experts on the use of blood donations from certain categories of donors."

We see that the footnote at the bottom of the page explains the group of experts was a subgroup of the advisory group on testing for Australia antigen. The letter then deals with the question of geographical factors, in particular the question of donors from tropical areas. Then over the page, the second page of the letter deals with the question of prisons and states:

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

I think more sensitive tests is a reference to either the RPHA or the RIA testing.

Just to continue this particular chain, professor, we can see that this letter did make its way to Scotland. If we can look, please, at [SNB0025017] and this is a letter from Dr McIntyre of the SHHD dated 16 May 1975, I think your predecessor, professor. Is that correct?

A. That's correct.

Q. To Major General Jeffrey who was then the national medical director of the SNBTS. And the letter from Dr McIntyre is headed "Blood donations in hepatitis":

"Further to our conversation, I enclose a copy of the circular letter sent out by the chief medical officer, DHSS, to all regional medical officers and

regional transfusion directors in England and Wales."

And the letter concludes:

"We would be interested to have your comments on this matter once you have had an opportunity to discuss it with the Scottish transfusion directors."

I think we can see from the text of that letter that reference is being made to the question of donors from tropical areas, as it was termed, rather than the question of express reference to prisons?

A. Yes.

Q. If we then, please, go to reference [SNB0025016], we can see this is a letter dated 21 May 1975 from General Jeffrey to Mr John Watt at the PFC and Major General Geoffrey states:

"I attach copies of Dr Yellowlees's letter which will be on the agenda for discussion at our next meeting on 11 June 1975."

If we then next go to the minutes after that meeting, the reference being [SNB0024995], we can see these are the minutes of a meeting of the Scottish directors on 11 June 1975. Major General Geoffrey chaired the meeting. I think, professor, you were also present at this meeting along with Dr Wallace and Dr McIntyre among others. I think we can see in the introduction apologies intimated from Dr Cameron and

Dr Maycock. When looking at these minutes, it does seem to be quite a common theme that the English director quite often sent his apologies rather than himself?

A. True.

Q. Yes. For what that is worth.

Then if we can look, please, at page 5 of the minutes, which is court book reference 4999, and paragraph 9 sets out the discussion of Dr Yellowlees's letter. I think we can see that the discussion appeared to have been confined to the question of donors from tropical areas rather than there being any express reference to prisoners. In particular, the minute records that General Jeffrey explained that SHHD would welcome directors' comments on DHSS letter from Dr Yellowlees:

"This stated that in the opinion of a subgroup of the advisory group on testing for Australia antigen, the red cells of donors who are born or had resided in endemic malarious areas should not be used. Dr Wallace explained that his first knowledge of the recommendation as a member of the advisory group was when it was circulated as a proposed appendix to the group's draft report. It has not been incorporated in the final report. Directors agreed to continue with their present practice, which was to ask donors if they had suffered

from malaria at any time not whether they were from endemic malarious areas. It was not a major problem in Scotland. Dr McIntyre noted directors' views for transmission to DHSS."

That, perhaps, professor may be consistent with what you have told us in your statement and today, that you essentially didn't give any consideration to the question of the practice of collection of blood from prisons at the time in, say, the mid to late 1970s?

A. Yes, that's correct, sir.

Q. Thank you, professor. That completes that chain of correspondence.

Could I now, please, revert to your witness statement. I think we had reached question 10 at page 4. Question 10 asks:

"Why the SNBTS continued to collect blood from penal institutions following the Medicines Inspectorate's adverse comment on that practice in March/May 1982."

You answered:

"As far as I recall there were four reasons.

"1. There was bemusement that no mention of this difficulty had been made in the MI reports for Aberdeen, Glasgow and Inverness.

"2. There was a strong view that this could have significant adverse effects on red cell supplies at

certain times of the year, notably in the West."

When you say there was a strong view, professor, who or whom held that view in particular?

A. It is notably the West, my good friend, Dr Mitchell.

Q. Yes. Before we leave that, do you recall at the time, so in 1982 or 1938, which of the individual Scottish directors supported the continued collection from prisons and which of the Scottish directors thought that practice should stop?

A. I don't recall, to be absolutely honest. The only thing I can recall is I tended to be on the side, as I have said before, that we should pull out, but I don't recall. I don't think my old friend, Dr Mitchell, was totally opposed. I think the notion he felt of suddenly stopping when his donor programme had been planned for 12 months ahead and he foresaw major problems with shortages -- we didn't second guess that, we accepted his point of view and it is very interesting that even by 1984 it had dropped from 2,500 down to about 400.

So they were clearly, in 1983, as the others switched off finally, the West team were making strenuous efforts to detach at the same time. So I think you need to go and find as many of the directors as you can to get their views but I don't recall, other than Ruthven Mitchell found himself, he felt, in a very

difficult position.

Q. I see. Returning to this statement, please, professor, the third point you make is that:

"Without SNBTS directors' consensus there was no national management process for considering issues related to the location of blood collection sessions in the regions. Throughout the UK this issue was strictly left to the RTDs and their teams and their priority was maintenance of supply. This management practice and the operational priorities enjoyed SHHD/DOH support."

By management practice and operational priorities, do you essentially mean by "management practice" the question of regional autonomy?

A. Yes, indeed.

Q. And by "operational priorities", you mean the maintenance of supplies?

A. Yes, absolutely right, thank you.

Q. The fourth point you make was that there was uncertainty at the time with regard to the locus of the medicines inspectors regarding donor sessions issues, a view shared by SHHD. We have already discussed that this morning.

Question 11. We have covered. Question 12 we have covered as well, professor. Question 13 asks a question in relation to a July 1984 report by doctors Follett and

Dow on their research project entitled "Non-A non-B hepatitis in the West of Scotland". If we can go over the page, please, to page 6 of your statement. You answer:

"As far as I can recall, the SNBTS directors had first site of Dr Dow's studies in May 1986. Thus the presentation of this work to the directors was not related to prison donor sessions but rather surrogate testing."

We will come on to look at the question of surrogate testing after the summer, as a separate topic.

Question 14:

"The extent to which, if at all, between 1975 and 1984 the SNBTS discussed with officials from the SHHD the practice of collecting blood from prisons and any increased risks of hepatitis."

You answer:

"The SHHD officials were present on all occasions the SNBTS directors discussed this topic. This included the initial verbal briefing immediately after the inspections at the Dundee and Edinburgh centres, every occasion when it was discussed at the SNBTS directors' meetings. SHHD were also aware that we had sought advice/guidance from the DHSS."

We have already covered the interplay between these

organisations.

Before I leave the question of prisons, professor, and turn on to the second question of donors with a history of jaundice, I think I would like to put a number of documents to you, really with a view to asking the question: do these documents suggest that either in the early 1970s or in the later half of the 1970s consideration should have been given to stopping the practice of collecting blood in prisons in Scotland.

So if I may, professor, the first document I would like to take you to is [PEN0020407]. We can see, professor, this is a report of proceedings at the Royal society of Edinburgh in 1972, the topic having been transfusion practice or transfusion medicine.

In particular, if we can, please, go to [PEN0020559]. Professor, this is a copy of a talk you gave at those proceedings. I have to say, when 40 years ago you were down the road At the Royal Society giving this paper, I'm quite sure you never thought that you would be 40 years later having to go over and answer questions on it. But be that as it may, professor, we do have the paper and I would like to put it to you. We can see the paper is headed "Principles of effective and safe transfusion". At that time you were deputy director of the Edinburgh and Southeast Scotland BTS.

At page 0564, at the bottom under the subheading "Laboratories' contribution, Australia antigen testing."

I should perhaps say, of course, that Australia antigen was the initial, original name given for Hepatitis B. So you start a discuss of that. If I could then please fast forward to -- well, slow forward to the next page, please, page 53. It's original reference S53, court reference 0565. At the very bottom of the page, second to last line, it starts:

"Although the recent introduction of total donor screening throughout the length and breadth of Scotland must be regarded as a major step forward, there is still much to be done."

Over the page, please:

"This concerns the quality of the existing facilities and development of more sensitive screening procedures for future use. While it is accepted that the CIEOP technique is basically simple, it is full of pitfalls and liable to give false positive and negative results. Both these events could have serious consequences for the donor and recipient respectively."

Then in the next paragraph I think you make the argument for the institution of a national reference laboratory in Scotland but then a few lines beneath that, so it is seven lines above "Miscellaneous

contributions", we can see:

"In short, the Blood Transfusion Service must be up in front rather than behind for we must not assume that the elimination of all antigen positive units will solve the post-transfusion hepatitis dilemma. Current evidence strongly suggests that the present limitations, which have been calculated to represent a detection rate as low as 25 per cent, cannot be entirely explained on insufficient sensitivity of existing methods, and that other agents are responsible for a significant proportion of the problem."

You make a reference in particular to a paper, 1970, by Gocke, which I think suggested -- or do you recall, professor, what you were getting at in that statement?

A. In that last sentence?

Q. Yes.

A. It sounds pretty prophetic about non-A non-B. I really can't claim any cleverness. One was very conscious, as I was associated with the fractionation side, that Hepatitis B surface antigen was still getting through, despite the testing, and if you in fact then looked at that, you were left, as other people were aware -- there seems to be another area that doesn't relate to hepatitis B.

Q. So two concerns at that time. Firstly, the existing

screening methods weren't sensitive enough to detect all Hepatitis B antigen-positive donors, and secondly, in addition to that, there appeared to be another agent or agents which appeared to transmit post-transfusion hepatitis.

A. Might I just add, there is a third. We had several episodes in which it was quite clear that the test was sensitive enough. The good manufacturing practices, the whole system, had failed, and that raised whole stories about inspection and audit and so on and so forth.

Q. And presumably, professor, in particular, once RIA testing was available for Hepatitis B, then RIA is a sufficiently sensitive test to be able to exclude Hepatitis B as the cause of a case of post-transfusion hepatitis, which would then point to other possible hepatitis agents?

A. I would only add the slight rider -- and there is data in your database, which showed that the RIA produced and available widely in the UK at one point, that was manufactured in the blood products laboratory, was shown by the team in the West of Scotland to be much less sensitive than the commercial kit, RIA kit, supplied by an American company, Abbott. So just using the word "RIA" -- and this takes us into the whole area of NIBCS and producing standards which we eventually did. Just

saying "RIA will totally remove it", is just a little bit simplistic.

Q. Yes, so different RIA kits, made by different manufacturers will have different sensitivities and specificities?

A. Absolutely right.

Q. I understand.

Perhaps the next main chain in this document, if we can just go to a paper I'm sure you will be familiar with, [LIT0010363]. We are starting to trace now the developing knowledge of non-A non-B hepatitis. This is a paper by Prince and others, reported in the Lancet in 1974. The title is "Long incubation post-transfusion hepatitis without serological evidence of exposure to the Hepatitis B virus". Do you recall seeing this paper at the time, professor?

A. I don't. But I don't think -- I don't recall but I wouldn't put much store on that.

Q. But would you agree it is one of the important papers --

A. No question.

Q. -- charting the history of non-A non-B hepatitis?

A. I see Alfred Prince in my 1969 visit to the States, he gave me a small vial of Australia antigen in New York and I brought it back, and that was the first beginnings of testing for Australia antigen, certainly in Scotland.

This was an outstanding group.

Q. From that vial you received from Dr Prince you were then able to initiate the development of Hepatitis B screening in conjunction with --

A. I was, and most importantly for me in that area is that -- and there has been no mention of it in the Inquiry so far -- that one of the colossally impressive things upon me was the death of my close friend, a surgeon in Edinburgh, in relation to the kidney dialysis transplant, viral hepatitis outbreak. And I mention that because it was related to transfusion. A multi-transfusion. The patient had a kidney transplant which was hugely multitransfused.

I mention it because the guys, the virologists who we worked with, with Alfred Prince's stuff, Professor Barry Marmion, they published all this. They said the reason why this attack, this Edinburgh episode is so lethal -- and it took out two surgeons, a nurse, my technician -- bless her, GRO-A -- and about four others. It was a disaster. The reason they said it was so lethal was that they postulated it was a simultaneous double virus infection.

A few years later, when they got the Hepatitis C testing, they showed that this was a Hepatitis B and C and they had reason to believe because of problems in

dialysis units of cleanliness, there might have been E in it.

So the notion that double infections can be particularly dangerous got into my head. If you ask how can you get a double infection? The only way is large pooled blood products.

Q. That's very interesting, professor. The outbreak in the Edinburgh dialysis centre, was that in the late 1960s?

A. My friend died in February 1970. Yes, 1969.

Q. And subsequent testing indicated that outbreak was not solely Hepatitis B but also --

A. That is correct.

Q. -- but also Hepatitis C?

A. That is correct. This is published.

Q. I'm grateful. So going back to the Prince paper in 1974, certainly you were on the lookout really as far back as at least 1972, about the possible existence of other hepatitis post-transfusion viruses, but I think Prince in 1974 was perhaps important in establishing, at least in America, that there was a likelihood of non-A non-B virus or viruses. Is that a fair way to put it or does that put it too highly, that the Prince paper established that the existence of non-A non-B hepatitis viruses was not only a possibility but a likelihood?

A. Hm-mm. Yes, yes.

Q. Is that a fair way of putting it?
A. Absolutely right, sir, yes.
Q. What I'm interested in exploring, professor, is whether, in particular from this point onwards, from 1974 onwards, the possible or likely existence of non-A non-B hepatitis viruses should have pointed away from the collection of blood in prisons in Scotland and whether there should have come a time when that practice should have stopped.

So just to develop this question of knowledge of hepatitis non-A non-B a little, if I could then refer to two further papers, the next is [LIT0013657].

We have looked at this in the Inquiry previously, professor. It is a paper by Hoofnagle and others from America, the Bureau of Biologics in the National Institutes of Health, on the question of transmission of non-A non-B hepatitis published in the Annuals of Internal Medicine in July 1977. On page 3662, which is original page reference 19, on the right-hand column, several observation are set out. Have you seen this paper before, professor?
A. Oh, yes. I don't recall seeing it now, but, yes, sure, in the work-up for the Inquiry?
Q. Yes.
A. Yes, indeed, sir.

Q. I won't go back over the observations because I think we did that yesterday. But I think we can see there various points are made by those at least working in America on this likely agent or agents, non-A non-B hepatitis.

Then to complete this passage, the next document is [LIT0010189]. Again, professor, we have looked at this before. Again, it's a paper from America, from Berman, Harvey Alter and others at the National Institutes of Health on the question of the chronic sequelae of non-A non-B hepatitis, again published in the Annuals of Internal Medicine. I should perhaps ask, professor, in the mid to late 1970s, is this a publication that you would have been aware of, the Annuals of Internal Medicine? Is that a periodical that you would have read?

A. Yes, this is -- and I think I'm right and Professor Oliver can confirm this, but we didn't have the big databases to do the searching but what we did have at this time was a thing called Current Contents, which was a small thing about this size and it simply put together all the journals in the -- the ones I looked at -- the biological sciences, the medical sciences. All the contents pages of every journal that fitted in this thing. My wife will recall that I spent

three to four hours every weekend going through my Current Contents, and on Monday morning arrived with my PA with a list five miles long of papers, and I'm pretty sure it was going at 1979 and I would have certainly picked this up. There is no question about that.

Q. I understand.

A. But we didn't take that journal but we would have had access, no problem.

Q. Thank you. At page 0192 in the left-hand column, last paragraph, the authors state:

"Several interesting features of non-A non-B hepatitis and its relation to chronic liver disease derived from this study."

And five observations are set out. I don't propose to go through them now. Really, the question is this, professor: at some point in the 1970s ought the following to have been thought: firstly, that initially Hepatitis B screening tests were relatively insensitive, in the sense that they did not catch all, or perhaps even most, positive donors but secondly, there did then come a point, perhaps around the mid 70s, when Hepatitis B screening tests were such that they probably did catch most of the positive Hepatitis B donors.

Thirdly, there appeared to be a blood-borne non-A non-B hepatitis agent or agents. Fourthly that there

was an increased prevalence of Hepatitis B among prisoners; and fifthly Hepatitis B is a blood-borne virus. And this is the big leap, or not: so therefore, sixthly, there may also be an increased prevalence of non-A non-B hepatitis among prisoners.

I have set out six propositions, perhaps not very eloquently, but do you essentially agree or do you agree with any or all of these propositions?

A. I'm not sure I can remember all six at the moment but I intended to say, "Yes, I agree with them" as you went along, yes.

Q. Yes. So --

A. Do you want to repeat one to make sure --

Q. I possibly should just go through them, professor. We have the handy transcript to enable that to be done. I think I have probably forgotten myself what I said. We can pause the transcript and I'll just read them back.

Yes, I think the first proposition was: initially Hepatitis B screening tests were relatively insensitive --

A. Yes.

Q. -- in the sense that they did not catch all or perhaps even most positive donors.

A. Yes.

Q. The second proposition was that there did come a point, perhaps around the mid 1970s, when Hepatitis B screening tests were such that they probably did catch most of the positive Hepatitis B donors.
A. I agree.
Q. But thirdly, there appeared to be a blood-borne non-A non-B hepatitis agent or agents.
A. I agree.
Q. Fourthly, that there was a increased prevalence of Hepatitis B among prisoners.
A. Yes.
Q. Fifthly, Hepatitis B is a blood-borne virus.
A. Yes.
Q. So you have agreed with the first five propositions. Does it follow from those five proposition that sixthly, there may also have been an increased prevalence of non-A non-B hepatitis among prisoners?
A. I agree there may have been, yes.
Q. Certainly, should the first five propositions have given pause for thought in the mid to late 70s, as to whether blood should continue to be collected from prisons?
A. Yes. I agree with that, sir.
Q. If one had regard to those five propositions and had paused for thought in the mid to late 1970s to consider whether blood should continue to be collected from

prisons, can you say what the likely conclusion ought to have been?

A. I find that very difficult to answer. Can I postulate what the likely conclusion -- I really don't honestly know to be absolutely -- in 2011. Again, with the power of the retrospectoscope I would say they should have got out of that and the whole of the transfusion world should have moved, including the commercial people, collecting plasma. But that's a very retrospective view and in our country, in the United Kingdom, I have always argued that we did have problems that went on and on, as to who had the duty of care in this area, particularly when one of the departments of health was playing a very lead position.

That doesn't absolve us, certainly from the point of view of viral hepatitis in relation to transfusion. The biggest tragedy for me personally was the disbandment of the MRC research committee because there Harold Gunson, Dr Harold Gunson and our own Brian McClelland were developing a whole major programme on transfusion-transmitted hepatitis, and the whole thing collapsed when it was disbanded. So opportunities were there and we just didn't pick them up.

Q. I think, that committee was disbanded in 1982, I think?

A. That is correct.

Q. We will come to look at that in the topic of surrogate testing, I think, in due course. One final document I should perhaps put to you on this matter for completeness, professor, is an international document. It is reference [DHF0012672].

Professor, this is a 1976 document from the International Society of Blood Transfusion, entitled "Criteria for the selection of blood donors". If we go over the page, please, to 2673, we saw yesterday this was a fairly international body. Do you recall, professor, whether you saw this document at around the time it was published in 1976?

A. I don't. But I suspect I was -- is this an international conference in Paris, is it?

Q. I think it is professor, yes.

A. It looks like it. I very much suspect I was there.

Q. In particular if we can, please, go to page 2683, paragraph 9 "Viral hepatitis". Again we looked at this yesterday. About half way down the recommendation was that:

"Prospective donors should be excluded if it is known that they ..."

Over the page, please, page 2684, number 7:

"... are inmates of a correctional institution."

Again, if one had paused to consider the question of

collection from prisons in the late 1970s in Scotland, if one had looked at this guide, presumably that is something else which would have pointed away from the practice.

A. Yes, I think that's correct, although 1976 was probably six months after the CMO in England said "March on".

Q. Indeed.

A. I suspect -- that did -- I can't recall in detail but I'm pretty sure that must have had an influence on whether this was really seriously picked up.

Q. Yes, although in the CMO's letter in May 1975, there was no discussion of non-A non-B hepatitis in that letter at least.

A. No, but he had the access -- or should I say his experts -- he was surrounded with a vast number of virological experts, were no less expert, in fact a good deal more expert than John Cash in 1971 saying, "I think there might be -- " and the other papers you have referred to.

So the fascinating thing would be to ask the question: what really led Sir Henry Yellowlees to issue that roundelay. And it is fascinating and I certainly don't know. But he had access -- regular access to -- I happen to know the director of NIBSC was a virologist at that time. That was Smith that we have picked up

today. Director of PHLS. These people would have been closely advising. I cannot imagine the CMO in London interfacing with his Scottish counterparts and they in turn would have consulted their senior top -- there were some very top virological experts.

So I think the game was there to be played and a lot of us didn't pick up the ball and run.

Q. I see. Professor, thank you for that.

I think I can now leave the question of prisons.

Can I then, please, return to your statement, to page 6, question 15. We move on in question 15 to the question of accepting as donors those with a history of jaundice or hepatitis. Question 15 refers to the recommendation in the second Maycock report to the effect that blood from donors with a history of jaundice or hepatitis could be accepted if the donor tested negative for Hepatitis B surface antigen. I think in addition, if the jaundice episode was more than 12 months previously. Then in your answer to this question you state, on next page:

"I do not recall this topic being discussed by the SNBTS directors in 1975 but I do recall soon after I was appointed NMD expressing my concern to Dr Ed Harris, deputy chief medical officer London, that the criteria for the selection of blood donors in the UK was left in

the hands of junior DHSS civil servants who had little knowledge of blood transfusion practice nor were they in touch with international experts."

I would like to explore this answer a little, professor. Is there a particular document you have in mind in that answer? You state that your concern was that the criteria for the selection of blood donors in the UK was left in the hands of junior DHSS civil servants. Is there a particular document or manual --

A. I'm sure there will be but nothing springs to mind, but we have already talked about Dr Entwistle's committee that generates views on the selection of donors. Those views are transmitted. They had to be transmitted into DHSS, and DHSS then consulted widely -- it was a very slow process -- and then issued, as I recall, guidelines and the idea was they kept them updated.

Q. If I can go, please, professor --

A. Jack Gillon --

Q. If I can go to, please, to three particular documents by which of example. If we can start, please with document [DHF0012039], this is a 1973 "Notes on transfusion", which, I think we heard from Dr McClelland, provides guidance on the clinical use of blood. It's that end of the transfusion spectrum.

A. I agree.

Q. Over the next page, please, we see at the top the insert page states:

"Notes on transfusion. Issued by the Department of Health and Social Security with the Scottish Home and Health Department and Welsh Office for the National Blood Transfusion Service and the Scottish Blood Transfusion Association."

Simply taking those words at face value, professor, the impression one is left with is that the DHSS essentially publish these notes on behalf of the Blood Transfusion Services, who primarily at least -- or perhaps exclusively are responsible for the content of the notes. Is that an accurate impression or not?

A. No, I don't think it is and I really -- it is such a long time ago but I mean, the issue that arose was a fundamental issue, which I completely understood, that if the DHSS and the Scottish Office and so on, were publishing something they were responsible as publishers for publishing it. And in this area and in another area, which the haemophilia directors will advise you on, the people responsible to ministers for publishing and releasing this stuff understandably consulted very widely, outside the Blood Transfusion Service, wherever they wished to.

Certainly, an impression developed which -- as

I have said, come the AIDS, we decided we had to move -- the impression developed that, as I have said in this statement, is fairly junior -- and I'm not going to name them because they were not that junior. DHSS doctors, because they had to cover their own backs, were suggesting modifications, coming backwards and forwards and backwards and forwards and there were long delays.

So I took the view, and I know my colleague Harold Gunson took the view and he eventually moved with us on the AIDS episode, that the documents that were issued were regarded as DHSS property, and SHHD -- it was a joint -- but DHSS actually did all the work in the context of publishing and consulting.

Q. I understand. Just for completeness, if we could go to the next page in this document as well, please, this states:

"This edition of notes on transfusion, like the four previous editions, has been prepared by the committee of regional transfusion directors of the Department of Health and Social Security and Welsh Office."

What's that a reference to, "the committee of regional transfusion directors of the Department of Health and Social Security and Welsh Office"?

A. I very much regret I have no idea. That's absolutely fascinating. I didn't know the department had its own

little committee of regional transfusion directors, I genuinely didn't. What is for sure is that Colin Entwistle, Dr Entwistle's committee, the idea was that they generated guidelines, these are not notes on transfusion -- I'm thinking of donor selection and so on and so forth -- they generated guidelines and I'm absolutely certain that they would have let the directors have sight of these before they handed them on in to the department. I'm not absolutely certain but I can't imagine they wouldn't do that.

Q. If this is speculation please say so but is it possible that the committee of regional transfusion directors of the DHSS may have comprised some of the regional transfusion directors of the NBTS in England and Wales with perhaps DHSS membership as well?

A. Possible, sir, yes.

Q. Essentially speculation at this stage.

A. I honestly don't know.

Q. Thank you. We can put that document to one side.

Another example of guidance documents is found at [SNB0025348]. Professor, I think this is the 1977 version of the "NBTS memorandum on the selection, medical examination and care of blood donors", and is this the guidance which Dr Entwistle was involved in, I think in the mid 1980s or early to mid 1980s?

A. I would have thought that's right, sir. And I don't know who his predecessor was, I can't remember.
Q. We see there are different versions of this memorandum. We looked at references yesterday and identified at least the references. But this memorandum on the selection, medical examination and care of blood donors, who drafted that and who revised it?
A. My understanding -- I honestly don't know, but I do know who will know if anybody knows, and that's Dr Jack Gillon, and he has produced a superb review paper on this whole area, in my view, and I really -- I feel I may be wasting your time giving an opinion because I don't really know.
Q. I understand, professor. We will come back to that with Dr Gillon.

The last example of a guidance document, please, is [PEN0020249]. We can see this document is dated 1979 and is entitled "Standards for the collection and processing of blood and blood components and the manufacture of associated sterile fluids".

If we can go to page 0251, please. Subparagraph 1 in the introduction states:

"These standards were compiled by the Department of Health and Social Security in consultation with the regional transfusion directors of England, Wales and

Scotland, the directors of the blood products laboratory, Elstree, the protein fractionation centre, Liberton and the Scottish Home and Health Department."

Are you familiar with this document, professor?

A. To be honest, I'm not, but again, I may have just forgotten. If you can keep going, I might sort of catch up.

Q. In short, professor, I was interested in who was responsible for drafting the guidance. Certainly the document states that the standards were compiled by the DHSS, albeit in consultation with the NBTS directors.

A. I mean -- I do realise I have been seeing some correspondence about Diana Wolford in terms of access to her expertise in this Inquiry. But, I mean, the name that springs to mind in DHSS at that time is Dr Alison Smithies, a charming lady. And I have a certain feelings that Alison bore the brunt of this whole area during that period.

Q. Yes. Professor, going back to your answer 15, where you say that the criteria for the selection of blood donors in the UK was left in the hands of junior DHSS civil servants, it is quite a wide statement and I wonder really if one has to look at particular documents and really ask oneself how were they compiled and by whom. And certainly the 1977 guidance on the selection of

blood donors, my impression, rightly or wrongly, was that that was largely compiled and revised by the BTS services in England and in Scotland. Is that fair?

A. I think the typed one we saw -- I'm not sure -- is probably correct. But the published ones came out of the DHSS. And again I think Jack Gillon -- I apologise for not having enough detail in this area but Dr Gillon, I'm sure would be immensely helpful in clarifying that.

Q. And we can check that with Dr Gillon, professor, but I think your point is that anything published by the DHSS, there is likely to have been some DHSS involvement in the content of the document?

A. Yes, they made this very clear. There is a letter on file, for instance, if you take the haemophilia directors, in which they produce guidelines for the management of patients and they submitted this, for reasons that I don't understand, to the department for publication and distribution. And there is a letter on file from a senior medical officer in the DHSS saying they are not prepared to be involved because the clinicians, coming from Newcastle in particular, were looking to develop prophylactic therapy and the Department of Health was not prepared to agree to the whole notion of prophylactic therapy, for funding reasons no doubt, and therefore would not publish the

thing. So there is understandably there is an editorial involvement.

Q. I understand. Thank you.

Question 16 asks:

"The consideration given by the SNBTS between 1975 and 1991 to 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 or hepatitis."

You regret you do not recall specific occasions and advise consultation with Dr Gillon. I think, perhaps, professor, I will explore that a little more with Dr Gillon and Dr Dow.

A. Superb, he has got a superb knowledge.

Q. We all look forward to that, professor. You have set Dr Gillon up for a good performance.

A. No, no, no, it really is -- he has done a lot of research.

Q. And we are grateful to him.

Question 17. Again, procedures. You refer to your previous answer. Question 18 asks about the question of whether there were national policies or whether each SNBTS region had its own practice and policies. You state:

"One of the features in this aspect of blood

transfusion practice throughout the 1980s, 1990s, was the development and maintenance of UK, later SNBTS, guidelines. As far as I'm aware, these guidelines were adopted by each SNBTS RTC. I'm reasonably certain that an independent audit of compliance did not take place during the period I was with the SNBTS."

Paragraph 19 you are asked a question about:

"If donors with a history of jaundice ... had been excluded ... is that likely to have caused ... difficulties in maintaining a sufficient supply of blood ... the extent of which post-transfusion Hepatitis C in Scotland is likely to have reduced."

I think Dr Gillon will speak to that so I think we can pass over that. There is a footnote at page 8 to your statement. If I could take you to that, please. And I think you were asked further questions, one of which was 3, selection of donors. I think you were asked a question in relation to a letter by Dr Brookes to yourself, dated 5 July 1983.

Could we have that on the screen, please? The reference is [SNB0025920].

I think we can see this is a letter dated 5 July 1982 by yourself to Dr Brookes in Dundee saying;

"One of the general points made by the Medicines Inspectorate was that in the SNBTS the

acceptance of a donor was largely a matter of chance. Clearly a gross exaggeration but it has been well-known for many years that the consistency between centres is less than desirable.

"You represent the SNBTS on the UK working party dealing with the selection of donors. I would be most grateful for a note on what is happening in this area and whether you would agree to study the position in Scotland with a view to our having a more consistent policy in the future."

Then in your statement, professor, you give a reply to the query in respect of that letter, basically what you were meaning. On page 8 of your statement you say:

"In 1982/83, the selection of blood donors was the final responsibility of the doctor in a donor session team. In 1977 the DHSS published a memorandum on the selection, medical examination and care of blood donors ..."

Which we looked at shortly before:

"... which no doubt was intended to operate as a guideline for these doctors. The point I was making to Dr Brookes in 1983 was that as sessions doctors we are finally responsible for making these selection decisions and as they were operating from guidelines, it was certain that there would be some differences in

interpretation between different RTCs but also probably between doctors working in the same centres. The question I posed: was there scope for more consistency?"

Again, I think we come back to Dr Gillon's paper which we will look at later.

The final question you are looking at: was there any documentary evidence of blood shortages in the West of Scotland?

You say there:

"I can advise that there are several such documents in the papers you have already received from SNBTS."

You refer to a letter you wrote to Dr Mitchell on this topic dated 15 January 1990. We will come back to that very shortly, professor. But you have no recollection of ever communicating on this topic with any other SNBTS RTC director between 1974 and 1991.

On this question of blood shortages, professor, I think you produced a helpful supplementary paper, which we could also look at. This is reference [PEN0110066]. Professor, could you perhaps read this paper to us?

A. You would like me to read?

Q. Yes.

A. "The provision of sufficient blood and blood components within each region of Scotland throughout this period [that we are thinking of, 1980 to 1997] was the

responsibility of the local regional blood transfusion centre team. As I recall, up until the early 1990s, the concept of regional self-sufficiency was part of the strong independent/regional culture within the SNBTS.

"This culture had existed since the creation of the SNBTS in 1939, and was not modified when the SNBTS became incorporated into the NHS in 1974 or when the first NMD was appointed. Some (including myself) believed that this fierce regional self-sufficiency contributed much to the development of national self-sufficiency in plasma products in Scotland and I must confess I was at some pains not to promote change unless really necessary.

"But change began in the late 1980s, partly as a consequence of the nature of PFC's contributions but perhaps most important of all was the movement of surplus red cells from SNBTS [down to England]. This latter development revealed that there were rare occasions when as one SNBTS region was short of blood others [in Scotland] were shipping their surpluses to England -- wholly unaware of their SNBTS neighbour's needs.

"As I recall, in the late 1980s we established an IT system in which information on RTC blood stocks throughout Scotland was available each day and centres

were encouraged to use those data ..."

I think initially it went on faxes actually:

"... to obtain support from other regions when necessary.

"My recollections of significant blood shortages are that they were rare, that they occurred only in the West and that on file are communications between myself and Drs Mitchell and Crawford [both in the West], on this topic. In addition there are innumerable documents on file which provide an insight into the programme [for] the movement of red cells from Scotland to England. I have always believed that there were never significant blood/blood component shortages in Scotland during this period. The key problems [we had] were fierce local pride and communication glitches. As anticipated, when understood change occurred."

Q. Perhaps the key sentence, professor, is that at the very bottom of the previous page, running into that page:

"I have always believed that there were never significant blood/blood component shortages in Scotland during this period."

I think that is perhaps consistent with Dr Mitchell's evidence that while there were difficulties, they were not insurmountable.

A. Well, I think we have to bear in mind that surgery was

postponed. I don't know what we mean by "serious" but for the patient that's not terribly good news.

Q. If we could, perhaps, professor -- I have almost finished my questioning -- look at three last documents on this question of blood shortages?

Firstly [SNB0037020]. This is a letter dated 30 December 1982 by yourself to Dr Mitchell on the question of blood supplies in cardiac surgery. You say:

"I had cause to be discussing matters with colleagues in SHHD recently and mention was made of a letter you wrote to David Wheatley, which was copied to several colleagues ..."

You say:

"Whilst we must hope that additional funds will be made available in due course, I'm particularly anxious that every possible effort is made to ensure that patients requiring cardiac surgery in the West are managed in the optimal way and that surgery is not delayed because of lack of blood."

You also say:

"I would suggest to you that there may be another option: the provision of red cell concentrates and even whole blood from other SNBTS regional centres."

That's the point you are suggesting, that there should be cooperation and communication between the

centres. So if one region has an excess and another region has a deficit, then that deficit can be made good by the transfer of blood and its components between regions. Is that the point?

A. Yes, absolutely.

Q. I think, to complete this, if we go to document [SNB0036988].

These are the minutes of a meeting of the BTS co-ordinating group, held in the HQ unit on 22 February 1983. We will see those present include yourself, professor, in the chair and also Dr Mitchell. If we then, please, go to page 6990, paragraph 7:

"Blood supplies, cardiac surgery":

"Dr Mitchell had notified Professor David Wheatley that he might be unable to support the latter's cardiac surgery programme because of lack of sufficient funding. Dr Cash had sent to Dr Mitchell a letter, (which had been circulated) drawing attention to the Scottish statistics of expired red cell concentrates. He had suggested to Dr Mitchell that the latter might obtain red cells from other transfusion centres. Dr Mitchell indicated that he preferred to cope from within his own region."

Do you remember this meeting, professor?

A. I don't. But that reported comment of Ruthven fits very

well. It is all about the fierce independence. But I don't recall the meeting as such.

Q. But that reported comment by Dr Mitchell perhaps illustrates two things. Firstly, back to the question of regional autonomy. But secondly, Dr Mitchell told us yesterday that while there were difficulties in the blood supply in Glasgow at particular periods, they weren't insurmountable, which is consistent with him saying he preferred to cope from within his own region?

A. I think the long-term planning is one thing but if you are short for next Monday, these are different issues and problems.

Q. Yes. I think the suggestion I made was that the comment by Dr Mitchell in these minutes, that he preferred to cope from within his own region, was consistent with what he told us yesterday, that there were no insurmountable difficulties in this region.

A. I agree with that, sir.

Q. I have no further question, thank you.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Sir, yes.

Professor Cash, one question I would like to ask you is: do you remember the World in Action broadcast in 1975? Your colleague John Watts appeared in that and

I just wondered whether you recall that programme being broadcast.

A. I don't honestly but if you say "World in Action, I think, "Oh, my God, yeah"; that's about as far as I get. I'm sorry, do you want to remind me what he or I said.

Q. You didn't appear in the programme as far as I recall.

A. That was lucky.

Q. But your colleague John Watt does appear in it. The reason for asking you the question is that there is extensive reference to Garrot Allan's letter which you were asked about in your statement. That is actually referred to in detail, including the proposition that paid donors and prison donors -- I'm paraphrasing -- could be a problem and that there was an agent other than Hepatitis A or B at work. That's just something about that was contemporary -- the letter is dated January 1975 but the programme was broadcast in November, I think, of 1975. And it's really to do with the question of what your awareness of matters was at the time. But you don't recall the World in Action broadcast?

A. I don't recall the details, no, but I do recall -- and it is a fact -- that I think -- we can check it easily -- that in around 1975 I wrote a letter in the BMJ which caused some consternation, in which I advised

people that paid donors are highly dangerous. And we are importing, I said, an increasing amount of virus from the US of A. This was published and I sometimes wondered -- and I have no idea whether the World in Action thing sprang from that.

Q. The context of that is it sounds as though a lot of the effort that goes into self-sufficiency seems to have perhaps lost the emphasis on another problem which may be there, which is the problem within the population here, including the high risk prison donor. Is that a possibility?

A. Of course it must be, but I'm very uncertain that we can explain it on that basis. I don't really know. Certainly in the area of hepatitis, I quite formally delegated that functional sort of area of our work to Brian McClelland, knowing he would be working with Harold Gunson, as I have said, on this MRC committee, and left them to get on with it. Whereas, there is no doubt, my personal time and energy was directed towards self-sufficiency at that time, that's true.

Q. And in 1975 you would have been the Southeast Scotland director at the time?

A. That's correct but if we ever get round to it, what we were doing in Edinburgh at that time is unbelievable in the context of self-sufficiency.

Q. No doubt we will come to that in another context later on.

Another matter I wanted to ask you about was the Medicines Inspectorate report in 1982. I'm not entirely clear that is the first external audit, as it were, or inspection of the service at that time? Had there been an inspection of that kind before that?

A. Yes, I think we need to be careful -- and I think I have got it right -- to divide the service into the regional transfusion centres, who were the people who collected the blood, the red supplies, the local hospitals, (inaudible), and the plasma, the PFC, and then the PFC. And my understanding is PFC was inspected early on in the 1970s. The Department of Health issued this letter to the CSA on July 25th, I think, 1975, saying that the SNBTS had to function as though they were a pharmaceutical company in terms of safety and so on and so forth, and as a consequence of that, PFC, I think, was inspected, because that was the nature of it, soon thereafter. The regional centres were much later, largely because the inspectors didn't know how to, you know, inspect a regional transfusion centre.

Q. So it was the first --

A. It was, in fact, for the regional centres. I make the point that late in the 70s, there was a second, I think,

inspection of PFC. So it was not the first. But the regional centres, yes, absolutely.

Q. In relation to that, as I understand it, the criticisms that were made included the fact that prison medical officers are not involved in assessing the suitability of donors, the increased risk of infection associated with prison populations, the increased risk of transmitting disease through such donations, and the unreliable answers to the pre-donation questionnaire that can occur in such environments. Those were the three matters that were criticised.

Is it right to think that none of those would have occurred for the first time in 1982? All of those three things would have been in existence since the early 1970s -- and obviously before -- but the period that we are concerned with. They weren't new in 1982 is the point I'm making.

A. Yes.

Q. You have told us that you introduced the red book, or the red book was signed off by you initially, the first version of it?

A. No, no, no.

Q. Sorry.

A. The idea of a red book, I have to confess, was mine, after hours with David Haythornthwaite, the medicines

inspector, wrestling with the problem in our own midden in Scotland. There were centres who were making platelet concentrates differently from another centre. And the question arose: was this difference of clinical significance in terms of we were not standardising properly and so on and so forth?

The whole question of donation testing. We have talked about RIA and all of those things. The real thing that cracked all that was the provision by NIBSC -- and this was our idea -- of a standard that was put into every test run that was done every day, and it is still happening today. What we call "go, no go standards".

So the red book was: this should be your specification for a platelet concentrate or a red cell, and these should be the standard operating procedures with ranges, making them and so on, and the provision of standards. That was the red book. And I'm sorry it has been very confusing.

Q. Yes. I must also apologise for confusing matters.

What I'm I am really wanting to ask you is: there must have come a point at which there was a standard introduced whereby prison donors would not be acceptable. We can see from the material that we have been shown today that you stopped going to prisons

but --

A. It was a spontaneous, "Let's get out of here".

Q. But is there something now that was there which says --

A. I do not know. If you asked me to bet, I don't think ever in the red book -- donor selection was not my -- Dr Gillon will for sure tell you, but I don't think it ever actually was elevated into the red book.

Q. Right.

A. Bear in mind, I think, the first red book is 1987/1988 and I suspect by then the whole thing of prisons was passe; it had gone.

Q. It didn't need to be included, it just wouldn't be even thought about?

A. Nobody was doing it by 1988. That's my assumption.

Q. One other thing that you have mentioned, a theme that has come over from your evidence, is that the regionalisation, the regional nature of the organisation meant that you had these autonomous bodies. Clearly what we have seen is that Glasgow perhaps had a particular view, perhaps because it had a particular problem in relation to collection of blood at particular times of the year. The fact that there was regionalisation of that kind, was a function of that an inability to share blood between one region and another? In other words, Edinburgh couldn't help Glasgow out if

Glasgow needed help. Was that because of regionalisation?

A. Yes. If Glasgow had asked, they would have moved blood from all corners. And the problem was, as Dr Mitchell was saying, they wished to crack these problems themselves. So there is no doubt that that in my view -- and some of the letters that have not been up today that I wrote, were saying, "Look guys, come on". And eventually they did come and it worked extremely well.

So, yes, there was a period in which the West of Scotland ran into very temporary blood shortages and I made it very clear to them that, "What you should have done, lads, was --" I heard this on the radio as I was shaving in the morning -- "What you could have done is got some blood from Edinburgh or Aberdeen," and that eventually developed and was very successful.

Q. But you weren't in a position to tell them what to do as the national director.

A. No, no, no. It is a consensus game.

Q. So if any particular regional director wanted to do a particular thing or go a particular direction, that was a matter for that person.

A. Yes. I think we need to be a little careful because on the whole these guys were really fantastically

collaborative and we hunted in a pack most of the time.

Q. But not entirely with this particular issue, it would appear?

A. Absolutely right.

Q. Thank you.

Thank you, sir.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: Just one matter if I may.

Good afternoon, Professor Cash. Can I return to this question my friend Mr Mackenzie put to you after his five propositions. You will no doubt remember the five propositions and the question concerned the appropriateness or otherwise of continuing to take blood from prisoners in the mid to late 1970s. Do you remember that?

A. Hm-mm.

Q. Can I just make sure that I understand your position in relation to that? Do you say that in the mid to late 1970s we knew enough then to know that it was inappropriate to continue to collect blood from prisoners and so the decision to continue to do so was somehow wrong or an error of judgment or, alternatively, do you say that it is with the benefit of hindsight, looking back some 35/40 years, knowing all we now know

about what turned out to be Hepatitis C, that we are able to say, "Well, we could have done things differently"? Which is it? The first or the second?

A. I'm very grateful, and it is the latter. Thank you very much, sir.

Q. I'm obliged to you. No further questions, thank you.

THE CHAIRMAN: Have you taken account of the known unknowns in answering that question and in particular that, as a result of the epidemiological studies in the early to mid 1970s, it might reasonably have been inferred that there was a hepatitis infective agent that would not have been disclosed by Hepatitis A serology or by Hepatitis B screening?

A. Yes, I agree, sir, but I see all these things very much more clearly, having retired, with no responsibility, and with a very large evidence base.

THE CHAIRMAN: I think we all see things more clearly when we have no responsibility, professor, but I wouldn't like you to leave this point without having in mind -- and I'm sure it is going to come back again in dealing with the history of NANBH particularly, but I do have an interest in whether those who had responsibility at the time and couldn't hide from it may have failed fully to take account of the knowledge that there was something that was not known but was contributing significantly to

the pool of infection.

A. I wouldn't deny that. I'm simply saying to my colleague there that it is much clearer and much more positive 20, 30 or 10 years later. That's all. When we get to non-A non-B and so on, if you look at the immense pressure from DHSS from the METAS(?) committee, to turn their backs on all this, the bizarre collapse of the MRC research working party that was in there at it -- you know, as I said, I think we missed some tricks and I very much regret that and it is very much clearer now than even then it was.

THE CHAIRMAN: I hope it will become very clear by the end.

Mr Anderson, I don't know whether you wish to follow that or not. I'm really putting down a marker that it seems to me that there is quite a significant area here to look at in detail.

MR ANDERSON: I understand that, sir. I would only comment that as our American cousins say, hindsight is always 20/20 vision.

THE CHAIRMAN: We will see in due course. Mr Sheldon?

MR SHELDON: I do have a number of questions for Professor Cash. I am conscious that the stenographer may require a break. I'm happy to continue or take a break.

(3.37 pm)

(Short break)

(3.58 pm)

Questions by MR SHELDON

MR SHELDON: Thank you, sir.

Professor, earlier today you were shown some guidance documents from the 1970s. For example, the notes on transfusion by Mr Mackenzie, and I think you expressed some reservations about, for example, the time taken in the preparation of such documents. Do you recall that?

A. Yes, I do.

Q. I think you said yourself that in preparing documentation of that sort, the DHSS would consult pretty widely and certainly beyond the Blood Transfusion Service. Is that correct?

A. Yes.

Q. Would it be fair to say that, in preparing guidance documentation for clinicians, government officials, both at that time and no doubt now to some extent, are heavily reliant on the views of independent clinicians?

A. Yes.

Q. Just thinking about the meeting, the SNBTS directors' meeting of 29 March, would it be fair to say that at least some of the heat generated at that meeting was the result of disagreement among independent clinicians?

A. You mean, the directors?
Q. I do, yes, indeed.
A. Yes, indeed.
Q. The directors being clinicians in their own right?
A. Yes, indeed, absolutely right.
Q. And really the difficulty was that it proved impossible for the directors to reach a common view as to really the balance of risk and advantage --
A. Risk and benefit.
Q. -- in taking donations from prisoners?
A. Indeed.
Q. Now, perhaps some other questions arising from that, but first of all, in view of the sort of difficulties which arose at that meeting, would you agree that it is perhaps unsurprising that civil servants might experience some difficulty in collating responses in relation to guidance documents and reaching an agreed common position for inclusion in guidance documents?
A. Yes, I can imagine the civil servants had all sorts of difficulties, yes.
THE CHAIRMAN: Sorry, I didn't pick that up.
A. I beg your pardon.
THE CHAIRMAN: I have to ask to you speak through the --
A. Yes. I said I could imagine civil servants had all sorts of difficulties in this regard. It is a tough

job.

MR SHELDON: And indeed they might require also to consider issues relating to the public purse and public policy of various sorts.

A. Indeed, absolutely right. I agree, sir.

Q. Moving on then to a slightly different topic, I think you said in evidence that at this time your feeling was that the DHSS dictated the whole business of donor selection from London and to that you added, I think, that Scotland eventually broke away, as I think you put it, in about 1985.

A. Yes.

Q. But that was related to the AIDS issue?

A. It was.

Q. But at least in 1983 -- and we have seen documentation this morning, I think, that London, if I may put it that way, was really saying it was a matter for individual regional transfusion directors.

A. Sorry, which matter?

Q. This was the matter of donor selection.

A. Donor selection?

Q. Do you recall seeing the documentation I'm talking about?

A. No, I said the individual directors was a matter in relation to the prisons but in terms of the care and

selection of donors guidelines, these were produced under the aegis, as I recall -- but Dr Gillon will (inaudible) -- of the DHSS.

Q. All right. So, thinking just for the moment purely about the issue of prison donors, what did you take to be the position about, as it were, guidance from London? Did you regard yourself as being free to take a decision on your own account, or your own accounts, or did you regard that as a matter which was or would be dictated from London?

A. I think initially we asked for guidance from London and we did that through Dr Entwistle's committee for donor selection and we assumed that it would come back quite quickly, if it was going to come back. As far as I recall, nothing came back, as far as we were concerned, from the departments. There clearly were lots of communications going on between the departments but I don't recall that we received -- if you then say, were we in a position to get on and act without waiting for London, the answer is yes, and the evidence of this is actually self-evident, that spontaneously the Scottish directors got out of the park.

Q. Yes, indeed. What is your view about the process, as it were, of breaking away? You said that Scotland eventually did break away in 1985 and created guidelines

of its own. Presumably, if you regarded yourself as free to do so in 1985, you would have been free to do so at an earlier stage.

A. I think that's absolutely right. We just grew up a little.

Q. Returning, if I may, briefly, to the question of the guidance that you sought, after the meeting of 29 March 1983 do we take it that there was a feeling that there was a need for guidance, or at least moderation or adjudication, as between the views of individual directors?

A. Yes, that's right, sir. I think that's minuted.

Q. And this may be an obvious question but why was it thought appropriate to approach Dr Entwistle's committee, or the working party, I think I should call it, rather than, for example, approaching the Scottish Home and Health Department direct for guidance of some sort?

A. Two things. One is, two members of the Scottish Home and Health Department witnessed the whole exercise of the meeting on 29 March.

Q. This was Mr Wastle and Dr Bell. Is that right?

A. Dr Bell, yes. Excellent colleagues. I had anticipated that, as I think I said earlier, there may well be a phone call a few days later calming us all down and

saying he is consulting the department, we should move in that direction. That didn't come and in fact the proper port of call, we felt at the time, was to go to the committee that Dr Entwistle -- this was a committee on behalf of all the transfusion services, that considered the problem of donor selection, and we thought it would be courteous and appropriate that we consulted with them. I think no more than that, to be honest.

Q. Do I take it from that answer that you regarded them as in some sense more expert than the views or the expertise available within SNBTS, or that this was, as it were, simply a process of moderation or adjudication?

A. No, I would have thought we felt -- forgive me, it is many years ago.

Q. I understand.

A. I would have thought we felt that there was a group that had been established, a joint group, by the UK Blood Transfusion Services. We were aware that the Home Office had a card to play in this matter and we felt in the first instance we should go to that committee, and we went, and in due course that committee then asked the DHSS for guidance. As I understand it, the DHSS said, "We will come back to you but we need to consult with the Home Office because they have a role to play in

this."

Q. Yes. I wonder if you would look briefly with me, please, at one document. It is [SGH0010572]. While that's coming up, perhaps I can just ask, was it at that time fairly common, as indeed it may be now, to set up various working parties and advisory committees to advise on particular issues relating to public health matters?

A. Indeed, sir.

Q. So, for example, there would be committees on the selection and care of blood donors and transfusion-associated hepatitis and so on?

A. I'm not sure about transfusion hepatitis. One of our problems was, as I said earlier, that if you take transfusion hepatitis, there were at least three or four committees going on at one time and Dr McClelland was involved with them all, and indeed the DHSS set up its own advisory committee on transfusion-transmitted hepatitis, but then the expert advisory group on AIDS set up another committee that actually was touching on hepatitis. So, yes, there was a plethora of advisory committees on this particular topic.

Q. These were committees, do we understand, which were co-ordinated by the DHSS but independent of it?

A. Gosh, I honestly do not know.

Q. That's perhaps a question for others.
A. If that's a pejorative question, I would say they were not co-ordinated but that's another matter.
Q. All right. If we look at this handwritten memo -- we looked at it briefly earlier today. I wonder if we can look, please, at paragraph 2. I think it is further down the page. This is a note of a discussion with Mr Winstanley of the DHSS and there is really a narration, I think, of the regional directors' meeting of 29 March and the disagreement. It said that:

"[The writer] outlined to Mr Winstanley what was said then and referred to the general position. He was interested in the reference to Dr Brookes approaching the working party on selection and care of blood donors and will try to explore that avenue."

So, just focusing on that passage, does it appear that Mr Winstanley and the DHSS were themselves perhaps looking for advice or guidance from the working party?
A. I honestly do not know, is the answer. I would have thought the main advice they should have been getting is -- the context -- the transfusion people will offer advice, but the main advice, I would have thought, would be coming from the virologists community across the UK.
Q. We saw, again, I think, earlier this morning, that eventually advice was forthcoming from a working party

chaired by Dr Gunson on 27 September that prisoners were a high risk population and should not be used as donors.

The reference, for the record, sir, is [SNB0143030].

Do you recall that advice being reported to the SNBTS directors?

A. No, I don't. Actually I'm lost in terms of documents. My understanding was that we received a message that our counterparts in England directors were going to discuss it, and I have looked at old minutes, as I think Mr Mackenzie has done, and found no evidence that they discussed it at all. So I'm interested in your Dr Gunson comment. I discussed this on more occasions than I care to remember with Harold Gunson and we didn't get very far.

So I'm at a loss with the document you are quoting there. I'm sorry.

Q. Perhaps we can just look briefly at that document then. I'm sorry, it's --

A. Yes.

Q. I think I may have got the order of the documents wrong. It is [SNB0143030] first of all. This is the UK working party on transfusion-associated hepatitis.

A. Yes, that's a DHSS one, yes.

Q. Chair, Dr Gunson. Can we look at page 3037, please? Towards the foot I think there is a section on donor

sessions in prisons and I think the third sentence there:

"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."

A. Yes, avoided. I'm drawing attention to that and I found that pretty disappointing. I discussed this with Harold.

Q. That's interesting. Why do you find the use of the word "avoided" disappointing?

A. For me there is a big difference between abandoning a practice and avoiding it.

Q. Okay.

A. I see a big difference, and I made this clear to Harold and, "Would it be possible to switch, to up that a bit?" Sadly, Harold Gunson is not with us any more and that's been a big bugbear for me. But my understanding at this period was the Home Office were unhappy. I have no record of that but it is just chatting with Harold and so on.

Q. So, so far as the DHSS were concerned, you felt there was an additional factor in the balance, which was not only the balance of risk and advantage in the prison

donor sessions but also the social responsibility aspect. Is that --

A. Yes, I felt that if at one stage the chief medical officer of the DHSS had issued an edict saying prisons are okay providing you use high quality Hepatitis B surface antigen testing, against that background, when we reconsidered the matter in relation to what we are now talking about, he would have come out equally strongly on reflection, 1983, not only the possibility of AIDS but non-A non-B.

I have to say I imagined, when we referred it to this committee, it would quickly come back to us that we needed to get out of there. This is from a government point of view. I recognise that they have to consult very carefully and so on. I understand that.

Q. I appreciate that. Do we take it from your previous answers that whatever the CMO may have said in 1975, you didn't regard that as, as it were, a requirement on you to collect blood from prisons? You weren't bound to collect blood from prisons?

A. No, no, absolutely right, sir. No, you are quite right.

Q. Perhaps if I can just tie this section off, we see Dr Gunson's committee's advice. Can we now go to [SNF0010178], please?

A. As we do, could I mention they are advising Gunson, the

Department of Health.

Q. Understood. This is the minute of the meeting of 8 December. Could we look at page 4 of that document, please? At paragraph (h) there do we see that there's a minute that Dr Brookes had circulated to her colleagues -- that is presumably the directors --

A. Yes.

Q. -- Dr Entwistle's final version of the above. Is that a different thing from the document we have just looked at?

A. Yes, as far as I can recall, sir, yes, and the document we just looked at was the minute of a meeting of this advisory committee on hepatitis that Harold Gunson chaired. This is yet another activity that's going on of Dr Entwistle's.

Q. At all events, we see a little later on in that paragraph that Dr Brookes then explains that only one of English regions is still collecting from prisons. Looking at all this together -- the working party advice, the information that this had become rare in England and the discussions that you had had previously amongst yourselves -- really what it was that influenced you to cease prison sessions altogether in early 1984, as Dr Mitchell then did, I think -- was there any particular factor which persuaded -- I think it is

really Dr Mitchell at this stage -- was there any particular factor that persuaded him to cease?

A. Yes, as I think I said in my statement, we had that meeting in which we all fell out a little. The air was -- we couldn't get consensus but I had the impression, when it was all over, that my colleagues would go back to their regions and quietly do as quickly as they could getting out of the prison set-up.

You could argue that's actually what happened. There was no policy decision. Actually what's happened is that professionals had to go back and talk to the people who were organising their donor session, very complex planning and so on, and they moved inexorably, and the last to come to stream was Ruthven Mitchell, and I think the reason why was because he had a bigger problem than most of them in terms of supply. But the difference between -- all the others packed in in 1983. If you look at Ruthven in 1983, he had fallen from the year before from 2,500 to 400, so clearly the data demonstrates that the Glasgow gang were on track; they were moving. The smaller regions, as always, could move quicker and were nippier than big supply reserves. But he was doing this.

So I think the answer to your question is the splat took place, people went home and began to talk to their

staff, thinking sooner or later we are going to have to get out of here, and they in fact took the appropriate action. It was never a policy decision.

THE CHAIRMAN: Before we leave the particular document, SNF0010181, what Dr Brookes reported back from her work in England was that she had spoken to 12 English/Welsh transfusion directors. Do you have any information about what sort of sample that would be of the total number of directors or areas?

A. Well, as I recall, sir, I think there were 15 English regional centres. I would have to say, I'm sure I have seen a document subsequent to Ewa Brookes's report that in fact there was considerably more than in fact one, and indeed I discussed at great length this particular topic with my good friend Dr Wagstaff from Sheffield, and the situation in England and Wales down on the ground was a little less clear than Ewa genuinely was reporting. But I can't speak with any authority.

THE CHAIRMAN: At the moment I'm just concerned that this is not a complete account of the picture.

A. I actually think that's pretty well right. I have a very good friend who was director of the Bristol centre and he -- it wasn't as clear as we thought it was.

THE CHAIRMAN: Mr Sheldon, do you wish to follow up?

MR SHELDON: Thank you, sir, I have nothing further.
THE CHAIRMAN: Mr Mackenzie, is there anything that you would wish to clarify arising out of the other questions?
A. No, sir.
THE CHAIRMAN: Professor Cash, for the time being, thank you very much.
A. Thank you, sir.
THE CHAIRMAN: Now, Mr Mackenzie?
MR MACKENZIE: Sir, there are three further witnesses on this topic C1, which we should be able to get through tomorrow. Dr Gillon sat all through today but he has also kindly agreed to come back tomorrow at 9.30. We also have Dr Perry of the PFC and Dr Scott, formerly of SHHD, which should then, subject to Dr Dow coming back in due course, allow us to finish the topic of C1, hopefully, tomorrow, sir.
THE CHAIRMAN: Thank you very much. Until tomorrow.
(4.21 pm)
(The Inquiry adjourned until 9.30 am the following day)

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