

Friday, 30 September 2011

(9.30 am)

DR RUTHVEN MITCHELL (continued)

Questions by MS DUNLOP

THE CHAIRMAN: Good morning.

MS DUNLOP: Good morning.

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Good morning, sir. We have Dr Mitchell with us again this morning.

Good morning, Dr Mitchell.

A. Good morning.

Q. We wanted to ask you some questions about the introduction of screening of donated blood for what later became known as the HIV virus.

So could I ask firstly that we have your statement on this topic in front of us? That's [\[PEN0171002\]](#).

Could we look at the first page? We can see in bold an extract from our snapshots and landmarks document and then a question, which is in bold and in italics. We are actually already rather familiar with the correspondence in Scotland in January 1985 and then the coordinating group meeting on 19 February. The question we posed was:

"What particular steps had the SNBTS taken with regard to the introduction of HTLV-III screening in

1 Scotland as at 24 January 1985?"

2 You say in your answer that:

3 "Major steps were being taken by the SNBTS well  
4 before January 1985."

5 I just wondered what the major steps were.

6 A. Yes, well, we had lots of contact with many other people  
7 throughout the world who were interested in this  
8 problem. We were aware that through the MMWR reports  
9 there was this new disease, mainly in America but some  
10 other places, and we began to get information that there  
11 might well be a transfusion-transmitted element to it.

12 That was the reason we began to consider the  
13 possibility of doing individual testing of donations for  
14 this virus, provided we could get sufficient materials  
15 in which to do it. So far as I know there was no test  
16 available in Europe at that time and the Americans were  
17 only just beginning to start their various test systems,  
18 mainly Abbott Laboratories and one or two others. There  
19 were many American commercial companies who obviously  
20 saw tremendous commercial advantage in introducing such  
21 a test.

22 So they were very keen to liaise with Dr Gallo in  
23 order to obtain samples of his materials, to develop  
24 various types of detection system. So certainly we were  
25 well aware of that but how we could fit into it was

1 another problem because we really didn't have access to  
2 any of the materials at that time.

3 Q. Right.

4 A. We were aware that Dr Tedder of course, having tried  
5 also unsuccessfully to get samples in order to evaluate  
6 them in the UK, had been unable to do this with Gallo,  
7 and he and Robin Weiss, of course, had prepared a eluate  
8 themselves from a known patient in London. And so that  
9 was the position, as I understood it, just  
10 before January 1985.

11 Q. Right. Do you remember a point when Dr Crawford went to  
12 visit Dr Tedder?

13 A. No, I don't actually, no, no, I'm sorry. It's not  
14 unusual. Certainly there were lots of contacts  
15 throughout that time.

16 Q. Yes. Don't worry at all. It's a very long time ago.

17 A. Many of us were attending meetings in various places,  
18 including North London and elsewhere, with Dr Contreras  
19 and John Barbara and many other people who were  
20 involved.

21 Q. Perhaps you could just have a look at a letter which  
22 Dr Crawford sent to you on 20 December 1984. It's  
23 [\[SNB0048803\]](#). This is, as you can see, Dr Crawford  
24 writing to report on a visit to Dr Tedder on  
25 18 December.

1 A. Yes.

2 Q. If you don't really remember the event, then I suppose  
3 you won't remember what had triggered it or why or how  
4 Dr Crawford came to be making the visit?

5 A. Well, I understand why Bob would go because clearly he  
6 would go with my blessing. Bob was very interested in  
7 the whole question of AIDS and its transmission and so  
8 on. He had a special interest in that and it was only  
9 right and proper that he had been involved with  
10 counselling of donors and that kind of thing.

11 It's quite natural that Bob would wish to do that.  
12 He was also, of course, interested in the science of the  
13 subject and this was just an example of trying to  
14 determine how close we were to obtaining a suitable  
15 test. I think the early work of Gallo was -- he was, of  
16 course, a Glasgow alumni. He had spent some time with  
17 the virology department at Glasgow University, which in  
18 those days, I think there were only about eight people  
19 in the whole world who knew much about retrovirus.

20 So I believe -- I think I remember that Gallo came  
21 to Glasgow to give a talk on his interesting information  
22 and one of the professors in Glasgow, I remember, coming  
23 through Glasgow Airport and saying that -- at the time  
24 of customs declaration -- he had many millions of virus  
25 in his top pocket. Whether he was stopped or not,

1 I don't know. But that was really part of the beginning  
2 of this, how this all came about, and it was not unusual  
3 that Bob should go down to Richard Tedder and try and  
4 find out just what was going on.

5 I think other people were doing the same thing but  
6 naturally Richard was a bit reluctant to say too much  
7 about it having had difficulties with Dr Gallo and the  
8 question of rights of access. It is difficult to share  
9 information in that kind of climate.

10 Q. Certainly, Dr Mitchell, we have heard tales of people  
11 bringing virus in a flask from Paris and leaving it at  
12 Waterloo Station and I have also seen a reference to  
13 somebody flying across the Atlantic with virus packed in  
14 dry ice. So I can imagine that people travelled around  
15 at this point with their samples of virus, but you have  
16 a memory of Dr Gallo being in Glasgow?

17 A. I tried to think back to these days and I have a feeling  
18 that he did come to Glasgow, and the professor that went  
19 to get some of the material and bring it back, he was  
20 interested in possibly producing a vaccine to the virus  
21 at that time. We actually invited him to speak at one  
22 of our first Scotblood meetings, which is the annual  
23 meeting of the Scottish National Blood Transfusion  
24 Service in those days, of which I was the originator of  
25 the scientific meetings. And it's interesting just

1 looking back over many, many years that that's the sort  
2 of position we were in at that time.

3 We knew about this, we knew it was going on, we knew  
4 that people were interested, mainly in the States,  
5 because they had a bigger -- a huge problem, as far as  
6 the literature would indicate, so perhaps -- I don't  
7 know if that answers your question?

8 Q. Actually I think we are slightly off the track but it's  
9 interesting, so if you don't mind, I'll pursue it  
10 a little bit. Which professor in Glasgow are you  
11 talking it?

12 A. Jennett, Professor Jennett.

13 Q. Brian Jennett?

14 A. Yes. He is unfortunately not still with us.

15 THE CHAIRMAN: Just get it into the notes what his  
16 discipline was.

17 MS DUNLOP: Actually he was a neurosurgeon.

18 A. It was his brother. I think he was the veterinary  
19 professor in Glasgow. Brian was the chap who did the  
20 head injury studies, yes.

21 Q. So he was at the vet school in Glasgow?

22 A. That's right, yes, as I remember it.

23 THE CHAIRMAN: How much did you have to do with the vet  
24 school? I'm interested in their knowledge of  
25 retroviruses.

1 A. Not a lot.

2 THE CHAIRMAN: Not a lot?

3 A. Not a lot because as I say, in Scotblood it was in its  
4 early days at that time. We had only started just  
5 briefly before that, and we knew that Professor Jennett  
6 [sic - Jarrett] had an interest in other oncogenic  
7 viruses, and he had written about this, mainly in  
8 cattle.

9 So in just general terms for the interest of the  
10 audience and people in blood transfusion, it was  
11 interesting just to talk about viruses and the activity  
12 in general terms. We had other people who spoke. We  
13 had one lady who spoke about cervical cancer and the  
14 papillomavirus and so on. It was a scientific meeting  
15 but also a meeting of colleagues --

16 Q. Yes.

17 A. -- from various disciplines.

18 Q. I understand. Thank you.

19 So in that light you weren't at all surprised to be  
20 reminded that Dr Crawford had made a visit to see  
21 Dr Tedder to find out exactly what was happening at the  
22 Middlesex Hospital?

23 A. Yes, yes.

24 Q. And just to look at the letter, Dr Crawford is setting  
25 out some information about the two different tests,

1 first of all Dr Tedder's test, and he is saying that in  
2 the Tedder test, if we just call it that for the moment:

3 "Unknown serum and labelled antibody compete."

4 A. Yes.

5 Q. Actually it does look as though it's still  
6 a radioimmunoassay he is describing at this point.

7 A. That's right.

8 Q. I think that must be right with the reference to counts  
9 per minute?

10 A. That's right.

11 Q. Then the American test, which we understand is not the  
12 same kind of format, solid, phase, purified antigen,  
13 unknown specimen, presumably, and then an enzyme  
14 labelled anti-immunoglobulin. It can be made sensitive  
15 or specific but not both.

16 A. Yes, there are all different ways of doing it.

17 Q. Yes, and then a reference in the section headed "Source  
18 of Antigen" to the growing of the Gallo isolate in the  
19 cell line, H9?

20 A. Yes.

21 Q. We understand that in due course that actually led to  
22 some problems with false positives?

23 A. Yes.

24 Q. Yes. I don't need you to you explain that to us because  
25 we have had some explanations of it but you were aware



1 of that, were you?

2 A. Yes, I think the American literature was absolutely  
3 clear on that. All the technical information from the  
4 various companies in the States who had been looking at  
5 it, always were reporting large amounts of false  
6 positive information. And what was more worrying was  
7 the false negatives.

8 Q. Yes. I think we understand that for a transfusion  
9 service, both cause problems; both false positives and  
10 false negatives, obviously.

11 A. Oh yes.

12 Q. Then we can see Dr Crawford reciting the names of the  
13 five firms -- four firms actually -- who are working to  
14 develop tests and that Dr Tedder had asked American  
15 companies for antigen with which he could work and that  
16 he wasn't able to do that, and he explained to us that  
17 he thought that was really to do with the legal  
18 position.

19 A. Yes.

20 Q. Then mention of industrial culture facilities. That's  
21 CAMR Porton?

22 A. Yes. Certainly I knew this bit of information, yes.

23 Q. This material is all quite familiar information?

24 A. Oh, yes.

25 Q. Then the reference on the second page in that second

1 paragraph to the possibility that given cells and virus  
2 and support from Middlesex, Scotland might go it alone.

3 A. Yes, that's right.

4 Q. What do you think he was meaning by "go it alone", do  
5 what alone?

6 A. I think we could have helped considerably with the  
7 development of a test.

8 Q. Right.

9 A. I think that's the important aspect of this. There is  
10 no use having a test that would work in a test tube --

11 Q. Yes.

12 A. -- with half a dozen specimens. We have got 100,000  
13 specimens to do.

14 Q. Yes. Then Dr Crawford, maybe with that in mind, has  
15 turned his attention to talking about safety for those  
16 working with the virus.

17 A. Hm-mm. That's right, that's very important.

18 Q. Yes. Then on the final page we can see that he has also  
19 addressed what I think was a live topic around this  
20 time, which is trying to ascertain from laboratory  
21 testing if the heat treatment that PFC were carrying out  
22 was being effective.

23 A. Yes. That's correct.

24 Q. Right.

25 THE CHAIRMAN: Dr Mitchell, what would have been the basis

1 for confidence at that time that Scotland might go it  
2 alone? Was there some relevant experience or a body of  
3 skill or whatever, that would instruct that view?

4 A. Well, we certainly had a lot of experience from mass  
5 screening in terms of the Hepatitis B virus. We had  
6 done a lot of work on that. We had a lot of knowledge  
7 and experience of doing those kind of work-ups for these  
8 tests, and so if conjugate had been available, then I'm  
9 pretty sure that the West of Scotland would have played  
10 a very considerable part in developing a suitable test.

11 It was important to have a test which would be  
12 reliable and would answer the question of: did it have  
13 specificity and sensitivity? You wouldn't buy a car  
14 from someone without doing a test drive. That's my  
15 answer really.

16 MS DUNLOP: Yes, indeed.

17 A. We would have been most interested in doing it. Again,  
18 for many reasons but mainly because we had a staff who  
19 were particularly good at doing these kind of  
20 evaluations.

21 As you probably saw from the hepatitis studies,  
22 Glasgow was very instrumental in making sure that many  
23 of these tests that were being used were in fact up to  
24 speed and up to standard. That was the case in the  
25 States. I mean, many of the tests developed there were

1 miles out. I mean, 1986, I think it was, that I read,  
2 they were still talking about 90 odd per cent false  
3 positives.

4 THE CHAIRMAN: That's a sidetrack.

5 A. I'm sorry, that doesn't answer your question.

6 THE CHAIRMAN: I wonder if I could ask my second question  
7 and let you decide where you are going to go.

8 I probably should have known but wasn't aware until  
9 now that Gallo was one of the Glasgow mafia.

10 A. I don't think that's true.

11 THE CHAIRMAN: Do you know when he graduated?

12 A. No, I think he was doing a PhD at the time.

13 THE CHAIRMAN: You don't know who his contemporaries might  
14 have been?

15 A. I think the professor in virology was Scharpey Schaffer.

16 THE CHAIRMAN: Not someone who figures in --

17 A. No, Scharpey Schaffer is dead now. That's how  
18 I remember it, but it's a long, long time ago.

19 MS DUNLOP: Just before we leave Dr Gallo, are we talking  
20 about Gallo actually being a student in Glasgow?

21 A. No, I think he was doing part of his PhD. I wasn't  
22 involved with that department. So I really couldn't  
23 answer that question.

24 Q. Right.

25 A. As far as I know -- it was said at the time that one of

1 the reasons he came back to say hello to Glasgow was  
2 because he was coming back to thank his mentor, ie the  
3 professor of virology. That was what was said at the  
4 time.

5 Q. I see.

6 A. Because as I said to you, I think at the time there were  
7 only about eight people in the world who knew anything  
8 about retroviruses.

9 Q. And one of them was in Glasgow?

10 A. Well, one of them was a professor of virology in  
11 Glasgow, yes.

12 Q. Yes. Right.

13 THE CHAIRMAN: Was he in the vet school --

14 A. No, no, no. He was in the university department of  
15 virology, which is a separate organisation.

16 THE CHAIRMAN: I'm just conscious, you see, that I have  
17 heard already that information tended to be exchanged  
18 rather readily between people who had historic contacts  
19 with each other.

20 A. That's right.

21 THE CHAIRMAN: And I was wondering whether there was any  
22 significance in Gallo's association here.

23 A. I don't think -- as I say, I was only an observer at  
24 that time. I wasn't involved.

25 MS DUNLOP: Do you remember Dr Forbes --

1 A. Charles Forbes?

2 Q. Yes. Having contacts in America as well?

3 A. Not personally. I didn't know of that. I had a feeling  
4 that perhaps he did have information from again,  
5 haemophilia colleagues in the States. That would not be  
6 at all unusual because reports had been received in his  
7 speciality as well. And of course he had worked over in  
8 the States.

9 Q. Yes.

10 A. So he was aware of people who were there, and no doubt  
11 kept in touch with them.

12 Q. Just going back, if we could, to the idea of what might  
13 have been possible in Scotland in early 1985, can we go  
14 back to the statement, please? We are still on the  
15 first page, [\[PEN0171002\]](#)? You say that you were aware  
16 of the refusal of Dr Gallo to agree that the DHSS would  
17 have access to his isolate and then you have told us  
18 that in fact there was a British isolate anyway. So  
19 that gap was plugged by the research work, I think,  
20 mainly of Professor Weiss, whose forte this was?

21 A. But it didn't go simultaneously. The Weiss isolate was  
22 really in desperation not being able to get the American  
23 one.

24 Q. But perhaps focusing a little more closely on what was  
25 happening in the West of Scotland, we do have some

1 information about the idea that there could be  
2 evaluation of commercial kits in the West of Scotland,  
3 and can we just look at a pair of letters on that topic?  
4 The first is [\[SNB0059715\]](#). This is a letter from you to  
5 Dr Cash.

6 A. Hm-mm, yes.

7 Q. And you are thinking that you and he have had a process  
8 of thought transfer?

9 A. Hm-mm.

10 Q. And you have already had a visit from Abbott  
11 Laboratories.

12 A. Yes.

13 Q. This is as at 21 January 1985. You had had a visit from  
14 somebody at Abbott. Did you have contacts within  
15 Abbott?

16 A. Only with the representatives who came from time to  
17 time.

18 Q. Yes.

19 A. Because we were using Abbott technology for the  
20 Hepatitis B virus.

21 Q. Right. I think Abbott had a base in England, didn't  
22 they?

23 A. They probably did, yes. I'm not sure where their base  
24 was.

25 Q. Right. So they had come and asked if you might be

1 interested in a --

2 A. I think I had asked them.

3 Q. Oh, you had asked them?

4 A. I had asked them if they had access to any suitable  
5 materials that we might test.

6 Q. Do you actually remember this? As you sit here today,  
7 do you have a mental picture of any of these contacts  
8 with Abbott or any discussion about evaluating their  
9 kit?

10 A. Well, all I can tell you is that Abbott did come, not  
11 infrequently, but fairly frequently to the laboratory to  
12 see how things were going with the other testing, and if  
13 they were developing another test, then clearly they  
14 might have come and said, "Would you be interested in  
15 this test?" I would have said, "Yes, of course."

16 I think that's probably how it arose. It was  
17 probably them coming and saying they have a test.  
18 I knew very well that they had a test in America but  
19 whether it was available in the UK or not, I don't know.

20 Q. Right. You seem in this letter to be raising some  
21 practical issues in connection with this proposed  
22 evaluation.

23 A. Hm-mm.

24 Q. You are actually trying to speak to Dr Cash on the phone  
25 and you were hoping to speak to him at a meeting,



1 I think, last week, but hadn't managed. You go on to  
2 refer him to a copy of the MMWR. In particular you are  
3 referring to the content of that publication on the  
4 topic of screening?

5 A. Hm-mm.

6 Q. Abbott have asked you to write a letter to satisfy the  
7 FDA requirement. I am afraid we haven't been able to  
8 find the enclosed draft, and you are making some  
9 enquiries of Dr Cash in connection with ethical matters.  
10 If we just look at the second page of the letter, we can  
11 see that.

12 A. Yes. Do you want me to comment on that?

13 Q. By all means.

14 A. I would imagine that the reason that Abbott would be  
15 interested in a method of making sure that no  
16 information was released to competitors, for example,  
17 would be a prerequisite of their coming into the market,  
18 as far as we were concerned.

19 I think that was -- and I think the other problem,  
20 if I could recall at that time, would be the whole  
21 question of blinding the samples. Quite clearly it  
22 would be a bit unusual to test samples without looking  
23 at the consequences of the result.

24 Q. Right.

25 A. You might find yourself holding a very delicate and

1 important piece of information from a person who could  
2 be named and identified.

3 Q. Yes.

4 A. With a test which was really, as far as we were  
5 concerned, in its infancy. So that's the reason that  
6 one would look at blinding samples.

7 Q. Yes.

8 A. It was a question of trying to find out what was the  
9 frequency of positivity, how well did it perform in the  
10 field, as against what would you do with the answers if  
11 you got them.

12 Q. Yes. Just to be 100 per cent clear, by "blinding" you  
13 mean anonymising samples?

14 A. Anonymising them, yes.

15 We had a system in the service in Glasgow that  
16 Bob Crawford, whom you mentioned -- we had  
17 an arrangement that Bob was the only man in the  
18 department that knew anything about any particular  
19 positive individual, and these were all very  
20 confidentially marked and kept by Bob. No one got  
21 access to it. I didn't have access to it. No one else  
22 had access to it. It was a 100 per cent lock-up of  
23 information. That's how it came about initially; but so  
24 far as Abbott were concerned, I think their interest  
25 would really be in blinding and secondly in the

1 commercial secrecy.

2 Q. Right. The other letter, which goes with this one, is

3 [\[SNB0059713\]](#).

4 A. Can I go back to the ethics committee, because that

5 was --

6 Q. I'm sorry?

7 A. I'm just noticing there, it was Ronnie Girdwood, who of

8 course was in fact the chairman of the Scottish National

9 Blood Transfusion Association, which was set up to look

10 after the interests of donors. That's what it really

11 was all about. And he did a very good job in that sense

12 and he had this ethics committee, rightly so, which

13 said, if you are going to be doing work with donor

14 samples, you have got to clear it with us, and that was

15 the reason that I was referring it to the ethics

16 committee. What did they think about how we should

17 handle the specimens.

18 Q. I understand.

19 THE CHAIRMAN: This is an association ethics committee, not

20 a hospital ethics committee?

21 A. No, no. When the SNBTS was set up -- that is the

22 service was set up at the time of the founding of the

23 National Health Service, the old SNBTA, which was an

24 association, a kind of voluntary organisation, which ran

25 blood transfusion, it was disbanded or stood down. But

1 in Edinburgh the SNBTA continued because it had this  
2 link with donors, and Professor Girdwood, when he was  
3 a member of the working parties and coordinating group  
4 of the National Blood Transfusion Service, he still kept  
5 his chairmanship of the SNBTA, which of course, was  
6 a very valuable thing because it was the way in which  
7 the Blood Transfusion Service could still get into what  
8 the donors thought about this, what did they feel about  
9 having the samples tested, anonymously or otherwise.

10 Q. Yes. So the role of the SNBTA was to stand up for  
11 donors, as it were?

12 A. That's right.

13 Q. And to promote the interests of donors.

14 A. Yes, that's exactly what they did. They had  
15 a considerable interest in donor care and management.

16 THE CHAIRMAN: I think the general interest, I do  
17 understand, is the particular indication you have given  
18 that included in that was an ethics committee because  
19 that might imply a structure for application,  
20 consideration, assessment, adjudication and so on. Is  
21 that what one should understand?

22 A. Yes, yes. I can't remember all the people who were on  
23 the ethics committee but I think it's true to say that  
24 they were not active blood transfusion directors or  
25 active individuals in blood transfusion.

1 I remember one was an eminent haematologist in  
2 Glasgow, Dr Robert Cumming, who was a haematologist at  
3 Stobhill Hospital in Glasgow. I remember he was  
4 a member of it but there were others and Girdwood was  
5 the chairman. But I think it was interesting that they  
6 did not disband it. It was originally ran from an  
7 Edinburgh legal office, in Edinburgh, it was Neil Milne  
8 who was Writer to the Signet in Edinburgh, who was the  
9 first, if you like, secretary general of the SNBTA,  
10 being legally -- he being a lawyer, had an great  
11 interest in making sure that the service ran very  
12 smoothly, so far as donors were concerned.

13 MS DUNLOP: I think lawyers are good at that.

14 A. I would imagine so. That's their job.

15 Q. I think we are happy to accept the compliment,  
16 Dr Mitchell.

17 THE CHAIRMAN: Only if we accept the responsibility that  
18 goes with it, Dr Mitchell.

19 A. Sometimes I become the director, you see, that's not  
20 uncommon.

21 MS DUNLOP: But when you say it was run from an Edinburgh  
22 legal office, that's the whole SNBTA, not the ethics --

23 A. Yes, the early SNBTA, the association, was an  
24 association of the five regional transfusion centres,  
25 right, and they met as an association of directors.

1 Q. Do you want just to go back to the previous letter so  
2 that we can see in its context the reference to  
3 Professor Girdwood, if we could, please. That's  
4 [\[SNB0059715\]](#).

5 A. I saw it at the bottom of the letter. It is approved by  
6 the ethics review board.

7 Q. He is on the next page.

8 A. Yes, just when I saw that, I remembered Ronnie Girdwood  
9 being the committee chairman.

10 Q. Yes.

11 A. But it was an ethics committee of the SNBTA, but SNBTS  
12 clearly recognised that as a very important standing  
13 group.

14 Q. Right.

15 A. That would give us advice.

16 Q. So when somebody within SNBTS was contemplating some  
17 form of research, involving work on donor samples, would  
18 they have felt it proper to consult Professor Girdwood's  
19 committee?

20 A. Yes, I think it would be very valuable to do that.

21 Q. Right. Can we go back to the other letter, please.

22 We can see that there have been discussions  
23 involving, obviously, yourself, Dr Brookes from Dundee.  
24 Now, Bill, is he --

25 A. Bill Wagstaff?

1 Q. You think it might have been Bill Wagstaff?  
2 A. Bill from Inverness.  
3 Q. Bill Whitrow?  
4 A. Yes.  
5 Q. And then Brian would be Brian McClelland at  
6 Trinity Park House.  
7 A. That's right.  
8 Q. Dr Cash is going on to say that the blood transfusion in  
9 the West should undertake initially evaluation studies  
10 of commercial kits.  
11 Dr Cash doesn't restrict this to Abbott. So were  
12 there kits from other manufacturers in mind?  
13 A. Well, there were people -- other manufacturers, yes.  
14 Q. Right.  
15 A. I think John had more contact with individuals than  
16 I did.  
17 Q. I see. Then in paragraph 2 he sets out a proposal to  
18 use retrospective studies to donor samples currently in  
19 store, and then we can see the point you make about  
20 anonymising the samples.  
21 A. Hm-mm. I think that's fairly clear, what John says in  
22 his letter.  
23 Q. Yes. If we look on to the next page, we can see the  
24 third paragraph: sufficient volume to enable certain  
25 particular steps.

1 A. I think that's no problem. That's exactly how it would  
2 be done. I think it's important to look at point number  
3 4. It's very important to keep residual aliquots of  
4 what I would call all the interesting samples. That's  
5 where the ideas of these Tricky Dicky stuff comes in.  
6 You are always looking for the unusual. You are looking  
7 for the needle in the haystack, because that's the one  
8 that will come back and jab you.

9 So we have to keep samples of these things and they  
10 were often exchanged between individual labs. You will  
11 know that many of the Glasgow samples from donations  
12 eventually found their way into national quality control  
13 standards.

14 Q. Right. And then the question of ethics is dealt with in  
15 paragraph 4 and actually Dr Cash is anticipating that  
16 Professor Girdwood may give ethical approval himself,  
17 without calling a meeting of his committee.

18 A. Yes. I think that's true, and it's true to say that  
19 John's penultimate paragraph, or ultimate penultimate  
20 one, saying that we certainly didn't want to be  
21 pressurised by any particular company. They obviously  
22 had a very considerable financial interest in having  
23 a test which would be rapidly introduced.

24 Q. Yes.

25 A. At considerable cost.



1 Q. Yes.

2 A. But that was never the name of the game. Never.

3 Q. Because?

4 A. Because we wouldn't want to put ourselves into all the  
5 difficulties of sorting out all the problems that we  
6 knew would arise, that had arisen in other testing  
7 systems that we had investigated in the past. We  
8 wouldn't go ahead with a test which was not fit for its  
9 purpose.

10 Q. I see. So if great speed had been used, quality might  
11 have suffered. Is that the point you make?

12 A. I'm sorry.

13 Q. If great speed was used, quality would suffer. Is that  
14 the point you are making?

15 A. Oh, yes.

16 Q. Right.

17 A. I think hasten slowly would be the answer.

18 Q. Right. Dr Mitchell, I'm wondering, have you had a look  
19 at the transcripts of some of the evidence this week?

20 A. Very briefly. I think they are still coming in.  
21 I think yesterday I saw a fax or an email, yesterday and  
22 I think the day before. Things have been coming in at  
23 that speed. Tedder's I hadn't seen until yesterday  
24 afternoon.

25 Q. I see. I just wanted to ask you what happened to this

1 initiative? I think before you answer, we would be  
2 primarily interested in your own personal recollection.  
3 So anything you can remember, unprompted by whatever you  
4 may have read recently.

5 A. I think the difficulty would have been to pursue this  
6 idea would be -- firstly, the availability of samples,  
7 availability of commercial tests. I think there would  
8 be a difficulty in any manufacturer at that level, at  
9 this time, supplying sufficient tests for us to have  
10 a look at and -- I think they were busy as it were, in  
11 their own backyard, trying to develop the tests.

12 I think what Abbott might have been saying was, "In the  
13 event that we were willing to do this, we would ask you  
14 to do the following things", or insist on the following  
15 things.

16 I always said to all companies that ever approached  
17 us about any test, "We will look at your test, we will  
18 analyse it, quite unknown to you, we will look at the  
19 results, we will publish the results, fear or favour."  
20 We believe in telling what exactly we find. We will not  
21 be stampeded into making allowances for this, making  
22 allowances for that. We had to be sure that the test  
23 was fit for purpose. That was for mass screening, day  
24 in, day out. Same test today, same test tomorrow, the  
25 same expected results, the same expected performance.

1 Q. What sort of --

2 A. I think the reason that we couldn't pursue this was just  
3 because the materials were not available, weren't  
4 readily available.

5 Q. Is that how you remember it?

6 A. Yes. I think John has made that point very clear. Even  
7 with Bob going down to London, Tedder wouldn't be  
8 prepared to let Glasgow or anywhere else, outside the  
9 little group in London, have access to his material.

10 Q. What sort of number of kits would you have needed for it  
11 to be a meaningful exercise?

12 A. That's a difficult question because clearly you don't  
13 know. If you are getting false positives of 90 per cent  
14 and they give you 1,000 kits, then it's not much use.  
15 A lot depends on what you expect. You do a preliminary  
16 study first and then you start scaling it up. There  
17 would come a time when you were scaling it up to maybe  
18 being able to do a week or a day's complete turn with no  
19 problems. Then you might say the time has now come to  
20 think of a bigger introduction.

21 Q. Right. When you say "90 per cent false positives",  
22 I think we can understand that what that must mean is  
23 that nine of every ten samples which have reached  
24 a certain point turn out, on confirmatory testing, not  
25 to be positive, is that right?

1 A. No, no -- well, yes, when you do the confirmatory test,  
2 yes.

3 Q. What I'm wondering is, what is, as it were, the  
4 denominator? Nine out of every ten samples that ...  
5 Is it initial screening or is it repeat reactive?

6 A. That would be the initial screening.

7 Q. Right.

8 A. But many of them would just repeat again and again and  
9 again.

10 Q. So if you repeat the initial screening, you must get rid  
11 of some of them?

12 A. You might get rid of some of them.

13 Remember, these samples that were giving false  
14 positives, they were folk walking about who were  
15 perfectly normal healthy people. You had no reason to  
16 believe that they were suffering from some related  
17 condition like HIV. They weren't suffering from slim  
18 disease or any other lymphoma or any other problem that  
19 you were aware of. These were healthy people. That's  
20 what the donor's information says: the donor shall be  
21 healthy.

22 Q. You didn't actually give me a figure and I don't want to  
23 press you if you don't want to give me one, but I think  
24 just a ballpark would be interesting for us. When this  
25 exercise is being discussed, would you have wanted to

1 get your hands on 100 kits or 500 kits or a thousand or  
2 5,000? What sort of number of kits would you have  
3 wanted?

4 A. It's difficult to answer that. Certainly five kits  
5 would be useless, ten would be useless. 1,000 might be  
6 doable.

7 Q. Right.

8 A. I don't think you would get a manufacturer to give you  
9 a large number of kits. Because you might find  
10 something that he didn't like.

11 Q. Okay. But if you had been able to get something of the  
12 order of 1,000 kits, the exercise would have been worth  
13 doing. Is that what you are saying?

14 A. I think we would have been prepared to have a go at it,  
15 to look at it, but whether it would have revealed  
16 anything in particular that would promise to go on and  
17 accept large numbers, that would be a different thing.  
18 Much would depend on the results of the first run, the  
19 first analysis.

20 Q. You have covered in your answer to my question the whole  
21 topic of availability of kits. We understand that. You  
22 can't do any sort of experiment with kits if you haven't  
23 got the kit, but was there any other reason why this  
24 initiative didn't bear fruit? Did something else bring  
25 it to a halt?

1 A. I think -- as far as I understood it at the time, around  
2 about that time anyway, there was that group in London  
3 that were doing evaluations or starting to do  
4 evaluations of the Tedder kit or the development of that  
5 kit, and I think that -- what's his name? -- the  
6 virology department had looked at the various kits that  
7 were available.

8 Q. Philip Mortimer?

9 A. Philip Mortimer. He had been able to get information  
10 from -- small numbers of kits from various -- I don't  
11 know how he did it but he got some. Clearly Gallo  
12 wasn't prepared to do that but he got them from the  
13 various manufacturers and they did an analysis, but  
14 their testing didn't do much except -- I think the  
15 number was 360 samples they examined.

16 Q. Right.

17 A. Was it five or six individual kits?

18 Q. Yes.

19 A. And on the basis of that they had advised the Department  
20 of Health, or others, that two kits came out as being  
21 the most likely kits that might be useful to examine.

22 Q. Yes, Dr Mitchell --

23 A. One of those was not Abbott.

24 Q. I don't want to interrupt you and you are absolutely  
25 right about that but you are taking us a bit further

1 forward, because that exercise was completed by the end  
2 of July.

3 I am just interested in whether in January in 1985,  
4 something choked off this plan to do an assessment in  
5 the West of Scotland?

6 A. I think it stood on that basis that, "If you have a kit,  
7 please come, offer it to us and we will have a look at  
8 it for you". You see, the one thing that -- why Glasgow  
9 is chosen to do many of these tests or evaluations was  
10 because of two things: we had a very excellent technical  
11 staff. Secondly, we had an almost inexhaustible supply  
12 of test samples, being the largest region.

13 Q. I see.

14 A. And that's one of the reasons -- there would be no point  
15 putting this into Dundee or Aberdeen or perhaps  
16 Inverness. They just didn't have the throughput. So it  
17 was natural that Glasgow should be asked to do that.

18 Q. I'm going to prompt you a little bit. Can you have  
19 a look at the transcript for Tuesday, please? It's  
20 going to come up on the screen at page 83. Can you see  
21 that question that starts about line 7, where it says:

22 "We have established, I hope, the position  
23 in January, what the concerns were, and that you were  
24 initiating some evaluations in Scotland, principally or  
25 perhaps exclusively in the West. But then you ..."

1           And the "you" is Professor Cash because this is me  
2           questioning Professor Cash:

3           "... you say that you were invited to discuss the  
4           situation with Dr McIntyre and that he made it clear  
5           that SHHD was strongly opposed to the prospect of SNBTS  
6           undertaking its own kit evaluation."

7           There is then a quote from Professor Cash's current  
8           statement, so a statement he has recently written.

9    A.    "SHHD have given assurance to the department that they  
10       were content ..."

11        Yes, that's true, I think that's right, yes.

12   Q.    The next bit. Professor Cash has said in his 2011  
13       statement:

14        "As I recall, I thereafter consulted with  
15       Dr Mitchell and Dr McClelland and we agreed that in view  
16       of the hostile reaction of SHHD, this SNBTS initiative  
17       should be stood down."

18   A.    Yes.

19   Q.    Do you have a recollection of that?

20   A.    Yes.

21   Q.    You do?

22   A.    Oh, yes.

23   Q.    All right. Can you tell us about it then, please?

24   A.    As I say, this was the whole argument that went on  
25       about -- the Gallo stuff was not available in the UK.



1           Someone in London had developed a similar system.

2   Q.   Yes.

3   A.   I think there was a general feeling that it might be  
4       a good idea to promote the British system, the British  
5       test, and it might be available more readily than  
6       something which was considered to be confidential and  
7       patented and so on elsewhere.  And I think that was the  
8       reason that the department set up -- that is the  
9       Department of Health -- did set up an evaluation group,  
10      to look at the Tedder isolates and Tedder materials.

11           Clearly, if such an evaluation was going on and the  
12      SHHD had agreed that they would go along with it, then  
13      we were dependent on them for funding and all sorts of  
14      things, and if they said, "No, we don't want you to do  
15      that," there is nothing else we could do.

16  Q.   Right.  Everything you say makes sense, Dr Mitchell, but  
17      I just want to press you on whether you have an actual  
18      memory of an occasion when Dr Cash is confiding to you  
19      that he has had a difficult meeting with Dr McIntyre.  
20      Do you remember that or do you not?

21  A.   I often think about why did we not start the testing and  
22      clearly we would not have abandoned it except if  
23      John Cash, being national director, had agreed it with  
24      us.  I think that's all I can tell you.  When you say to  
25      me do I remember a meeting on 5 December, or whatever it

1 was, I don't remember --

2 Q. I know, that's really hopeless actually. We can all  
3 think back to the 1980s, it's very difficult.

4 A. I can remember it being said, "Look, we are not going to  
5 do this test, we are not going to do the evaluations  
6 because we understand there may well be a British test  
7 on the horizon, albeit a little bit behind the field".

8 Q. I see. Thank you.

9 A. It may take a little longer to get a British test up and  
10 running but if and when it came, we would be delighted  
11 to look at it.

12 Q. Right. Thank you, Dr Mitchell.

13 Can we go back to Dr Mitchell's statement then,  
14 please, [PEN0171002].

15 Over the page. Some of this we have covered  
16 already. If we just look at the questions, we can see  
17 what's being asked.

18 A. Yes. I think in my answer there -- I think that's again  
19 just what I have said.

20 Q. Yes.

21 A. That clearly the confirmatory testing was being set up  
22 by Dr Follett and Dr Peutherer in Edinburgh, and to us  
23 that was a very important development.

24 Q. Yes.

25 A. Because, if we had a test that we were using, we would

1       have no way of doing any confirmatory work in my  
2       laboratory.

3   Q.   You are referring in your answer, Dr Mitchell, to some  
4       difficulty in obtaining test materials from England.

5   A.   Yes.

6   Q.   You remember this, do you?

7   A.   Yes, hm-mm.   Yes, that's right.

8   Q.   And this was -- are you remembering the --

9   A.   This is because technical staff do talk to one another  
10       on a regular basis.  We had many other things to be  
11       going on with.  So they do tend to keep in touch, and  
12       when you hear someone else is doing something, you say  
13       "That's interesting, could we do that, please?"  And we  
14       tried to get materials from the evaluation team in the  
15       south but unsuccessfully, again, because, as I think  
16       I have said there, DOH had funded the thing and why  
17       would they give us free materials when they had funded  
18       it, albeit that we were not part of the evaluation team.

19  Q.   Yes.

20  A.   We would only be given limited access to samples and  
21       test systems.  It was really a question of, "Could we  
22       have a flying start on this?  Could we have a quick look  
23       at it, please?"  The answer was, "No, wait until the  
24       evaluation is complete and then we will tell you what  
25       the results are".

1 Q. As the director of a regional transfusion service and  
2 a big one, the biggest one in Scotland, what was your  
3 mood when you knew there were going to be HTLV-III tests  
4 on the market, that they were coming? What was your  
5 personal feeling about that? Were you relieved or were  
6 you apprehensive because of the problems, or was it  
7 a mixture? What were your sentiments?

8 A. You mean the test on the horizon was the English test?

9 Q. Just any test. When you realised in 1984 that there was  
10 going to be testing.

11 A. Just general disappointment that we weren't looking at  
12 things that other people were looking at. I think that  
13 was the general feeling, a feeling of disappointment,  
14 not so much relief. We certainly would be relieved in  
15 the sense that we didn't have to do all that extra work.  
16 Remember, we weren't in any way funded to do this.

17 Q. Yes.

18 A. We were doing it because we were interested.

19 Q. Yes.

20 A. You may think interest is not all that relevant but it  
21 is. If you are actually working in a field, it's very  
22 important to keep up-to-date with what's going on.

23 Q. I appreciate that, Dr Mitchell.

24 A. So that's why we were talking to the English all the  
25 time.

1 Q. I think I'm just trying to capture the mood of the  
2 transfusion service when you learned that the AIDS risk  
3 would, one hoped, be alleviated by the arrival of  
4 testing.

5 A. Yes, I think you have got to consider that the American  
6 set-up was quite different from what it is in the UK:  
7 different population of donors, different availability  
8 of kits, different manufacturers, some manufacturers who  
9 couldn't meet the deadlines. If you read the American  
10 literature, you will see that some couldn't even -- even  
11 Abbott, for example, couldn't supply all of America,  
12 although they were -- I think, I believe they were  
13 licensed -- not licensed but given an undertaking to  
14 take this on as a contract. But even they were unable  
15 to supply the whole of the market. And even then, the  
16 number of positives expected in the UK would be much  
17 less than you would expect in America.

18 Q. Right.

19 A. So we were disappointed not to be involved in the  
20 evaluation in the United Kingdom.

21 THE CHAIRMAN: You are still concentrating at this stage on  
22 the initial evaluation exercise?

23 A. Yes; yes.

24 THE CHAIRMAN: And that's what you have been talking about?

25 A. Yes. I think --

1 MS DUNLOP: Did you regard it as a given that screening  
2 would be introduced?

3 A. Yes, I'm pretty sure it would be, yes, when a suitable  
4 test was available, yes.

5 Q. How did you feel about that?

6 A. Excellent, great idea, no problem. We would be very  
7 pleased at such an event.

8 Q. Right.

9 A. Yes.

10 Q. So what we are, I think, appreciating from your account,  
11 Dr Mitchell, is a sense of frustration that you weren't  
12 more directly involved.

13 A. Yes.

14 Q. That you weren't evaluating kits yourselves and --

15 A. Yes.

16 Q. And you couldn't get your hands on any sort of supply?

17 A. There were many other things going on at the time, but  
18 we would like to have been a bit busier.

19 THE CHAIRMAN: Quite apart from that, this surely must have  
20 been one of the big challenges facing your profession at  
21 that stage.

22 A. I think that's right. I think Robin Weiss wrote a paper  
23 in 1996, I think it was, I read it, saying that it was  
24 the major thing in blood transfusion; the most important  
25 event was that one, because here we were looking at

1 a lethal disease in those days.

2 MS DUNLOP: Yes.

3 A. "Lethal" meaning pretty quick.

4 THE CHAIRMAN: And you weren't getting in on the act.

5 A. We weren't seeking to give people bad news.

6 THE CHAIRMAN: No, no.

7 A. But at the same time we would have liked to have

8 introduced the test as soon as possible in the Blood

9 Transfusion Service in Scotland.

10 THE CHAIRMAN: There is a pride. When I refer to the

11 "Glasgow mafia", it's not a pejorative expression.

12 I reckon to be part of it. But --

13 A. We have a certain pride --

14 THE CHAIRMAN: You had a pride.

15 A. -- in our job, and anything in blood transfusion that

16 was going on, even if on the purely physical side,

17 I wanted to be involved. I wasn't a bystander. It

18 would be very easy for us to just have said, "Oh, just

19 leave it alone, don't bother with it. You know, it will

20 unfold in its normal way and one day we will all waken

21 up and there will be a test system and we will have

22 a turnkey system, all we do is turn the key and it will

23 work." That wasn't the way we looked at it.

24 MS DUNLOP: Yes. And this sense of positive anticipation

25 that the testing was going to be introduced, that must

1 have been something that you realised when the virus was  
2 isolated or when the news broke that the virus, the  
3 cause of AIDS, had been found. That must have been your  
4 response, that a test would come and that donated blood  
5 would be capable of being tested.

6 A. The feeling then was, "Thank God --

7 Q. Yes.

8 A. -- we have a handle on this thing."

9 Q. Just looking again at your statement and trying to get  
10 as much information as we can about the availability of  
11 kits, you have been asking Dr Dow -- we have been asking  
12 Dr Dow as well -- as somebody who might have information  
13 about that, but I think really the only picture we are  
14 able to build up is that around July 1985 SNBTS was able  
15 to do mini evaluations of the two selected kits. That  
16 must have been July/August, so the Organon kit and the  
17 Wellcome kit, which had made it through the phase 1 of  
18 the evaluation. There were supplies of those kits to  
19 permit the different areas in Scotland to do their own  
20 mini evaluation.

21 Of course, then, based on the results of their mini  
22 evaluations, they would make the choice between the two.  
23 So obviously in the summer there were kits available.  
24 Do you remember that mini evaluation process?

25 A. I have a good idea I remember it, yes.



1 Q. Right.

2 A. I think a number of labs were asked to do a mini  
3 evaluation, a look at it, when it became clear from the  
4 PHLS group what tests were going to be recommended.  
5 I think was at Organon, and the Wellcome one.

6 Q. Yes.

7 A. And at that time I think a number of people were saying,  
8 "Look, hallelujah, let's get on, we have got something,  
9 let's look at it." But remember what I said to you  
10 earlier, that the Mortimer study looked at 360-odd  
11 samples, which were selected. Some of them were pretty  
12 obviously going to be positive, they were known cases of  
13 the disease, whereas when you had to scale that up to  
14 the point of technical know-how -- Mortimer's group was  
15 a group of very eminent virologists, who didn't run  
16 a blood transfusion centre, didn't run anything to do  
17 with blood transfusion.

18 What they said was good, their evaluation was very  
19 thorough, and I don't think we could have done it at  
20 that level of virology, molecular virology. But at the  
21 same time 300-odd samples did not really add up to mass  
22 screening.

23 Q. Yes.

24 A. And we had to evaluate -- they were telling us what to  
25 do but we knew how to do it, if you know what I mean.

1 Q. Yes.

2 A. But, in the knowing how to do it, there was  
3 a considerable amount of work still needed to be done.  
4 We had to do all sorts of things about sample  
5 identification, computerisation, all sorts of things.  
6 My centre was the first one in the world to have  
7 a computer on line to the test the system.

8 Q. Right. We do know, Dr Mitchell, that, as originally  
9 envisaged, the evaluation exercise was supposed to have  
10 two phases: the Mortimer phase, if we can call it that,  
11 and then the second phase, where, according to our  
12 paper, to which Dr McClelland contributed, there would  
13 have been 10,000 samples looked at.

14 A. That's right, yes.

15 Q. As far as we can tell, however, because of pressure of  
16 time, the whole of that exercise was not carried out  
17 before October 1985, when screening was introduced.

18 A. Yes.

19 Q. But that sort of phase 2 exercise is what you are  
20 describing, I think --

21 A. No, the mini evaluation started -- (inaudible) start  
22 with the phase 2.

23 Q. But it's on a very much smaller scale?

24 A. A much smaller scale because they weren't available, the  
25 test materials were not available.

1 Q. And so what we can take, I think, from what you are  
2 telling us and what's in your statement is that kits  
3 were available in the summer of 1985 for the West of  
4 Scotland to do its mini evaluation and choose between  
5 the two, but before that you think that you had also  
6 made an unsuccessful attempt to get some test kits from  
7 Wellcome earlier in the year?

8 A. No, I don't think --

9 Q. Well --

10 A. -- that's right.

11 Q. -- it's this sentence:

12 "Professor Cash had asked Harold Gunson to release  
13 some of the English test materials from Wellcome."

14 A. But that wasn't successful.

15 Q. That wasn't successful?

16 A. No, no.

17 Q. Right.

18 A. But I think -- did Brian McClelland not write to  
19 Wellcome?

20 Q. He did, yes.

21 A. Asking for a small amount of material and was not really  
22 terribly successful with that?

23 Q. Yes.

24 A. When you said the middle of July, I'm sorry, I can't  
25 remember the exact date when it was we received a number

1 of kits from Wellcome. Whether Wellcome are in  
2 a position to scale up and go 100 per cent overnight,  
3 I doubt that very much. I think, if I remember rightly,  
4 the early samples that we got were good, they were fine,  
5 and we could detect known positives and known negatives  
6 and so on with the small amount we got, but when that  
7 was scaled up, then we ran into all sorts of  
8 difficulties.

9 Q. Yes, Dr Dow has indeed given us some further detail on  
10 that.

11 A. Yes, that's an example of where what looks good suddenly  
12 goes bad in your hand when you scale it up. You see,  
13 a virology department has all the time in the world --  
14 I don't mean that literally, but lots of time to look at  
15 a thing: Two hours, two days, four days, next week ...  
16 That's fine.

17 Q. Right.

18 A. Blood transfusion has to get this stuff on the shelves  
19 this afternoon.

20 Q. Yes. I think you are telling us exactly that at the  
21 bottom of page 2, talking about the difficulties --

22 A. When you start scaling it up and you discover that you  
23 have got to repeat your tests over and over and over  
24 again on the same day to get any sense out of it -- that  
25 is that the manufacturer's own controls are working okay

1 as against the samples, to be sure the results are  
2 genuine -- then you begin to see, "My goodness gracious,  
3 this isn't really fit for purpose at the moment."

4 Q. Can we move on to the next page of the statement,  
5 please, and look at your passage under the heading  
6 "Introduction of HTLV-III screening in Scotland?" Now,  
7 we know from a number of sources -- and you are  
8 obviously particularly well placed to tell us -- that  
9 the West also went for the Wellcome test.

10 A. That's right.

11 Q. And we asked some questions about short-term contracts.

12 A. Yes.

13 Q. And you have answered that. You think it would have  
14 been unwise to introduce an interim, unvalidated test  
15 whilst validation was being carried out?

16 A. I think I have just explained that to you.

17 Q. Yes. And you say no decision had been made to override  
18 any evaluation, and you also say:

19 "Funding for such a venture would not have been  
20 agreed for any one region, so as to avoid premature  
21 regional variation within donor and patient anxiety."

22 Were you in favour of a uniform date for the  
23 introduction of screening for the whole of the UK?

24 A. Yes.

25 Q. Right.

1 A. I think if you consider Scotland as part of the UK.

2 Q. I think it was -- and is.

3 A. You could have people coming from Carlisle up to  
4 Dumfries.

5 Q. Yes.

6 A. That was known. Donors in Carlisle give in Dumfries.

7 Q. I take your point. But one area did go it alone.  
8 I don't know if you remember that. There was an area in  
9 England that started testing.

10 A. That was Hepatitis C.

11 Q. Oh, well, let's look at [\[DHF0019468\]](#). Do you see this?

12 A. Newcastle.

13 Q. This is 19 March 1985, and this is the DHSS writing to  
14 the PHLS and talking about the need to put resources  
15 aside in 1985 to 1986 to fund the introduction of  
16 screening tests, but the regional general manager of the  
17 northern region had replied to say that:  
18 "Antibody screening is already being undertaken by  
19 the PHLS in Newcastle."  
20 And that money had been allocated by the region to  
21 a consultant at PHLS to develop tests for the Blood  
22 Transfusion Service.

23 A. That's PHLS. That's not the blood transfusion  
24 department.

25 Q. Right.

1 A. That's not the regional centre. Dr Sherlock was not  
2 doing screening of donors.

3 Q. He wasn't screening donors?

4 A. No, no.

5 Q. Right.

6 A. This might well have been somebody trying to do what  
7 Eddie Follett was doing. They are trying to set up  
8 a regional reference lab. I think that's what -- sorry,  
9 I haven't seen that letter.

10 Q. No, indeed.

11 A. But that's what it would reveal to me. The general  
12 manager was trying -- as John Cash and David McIntosh  
13 and others have done -- to get reference centres in  
14 various regions. This was to stop -- if the tests came  
15 in, why should Newcastle send all its material, its  
16 doubtful specimens, down to London. They might get the  
17 answer back next week, whereas when we had somebody like  
18 Eddie Follett on the doorstep. And no doubt Peutherer,  
19 you were able to get an answer pretty quickly. Each  
20 region would have its own reference centre.

21 Q. It was just this reference to antibody screening already  
22 being undertaken by the PHLS in Newcastle.

23 A. Sorry, again, I'm only reading the letter as you give it  
24 to me. The PHLS in Newcastle may well have been  
25 offering an service to --

1 Q. To clinicians?

2 A. -- the clinicians for the urinary medical clinics or the  
3 haemophilia centres down there, I really don't know, but  
4 I think that would be what they were doing. They might  
5 well have been offering a clinical service, which was --  
6 remember what Scotland had said: in order to avoid  
7 donors, or bogus donors, as I call them, attending to  
8 get a free test, it was very important that the area  
9 health boards should set up a reference laboratory which  
10 could handle the clinical samples.

11 Q. Yes. We can see the sort of reasoning that the DHSS are  
12 employing.

13 A. Yes.

14 Q. If we look down in the letter, they say:

15 "In the first place the introduction by one region  
16 of a test to screen blood donations could severely  
17 embarrass other blood transfusion centres."

18 A. That's right.

19 Q. And then:

20 "Secondly, we are concerned at the possible  
21 emergence of different standards of positive results  
22 ..."

23 A. Yes.

24 Q. And then:

25 "Lastly and most importantly, as was made apparent



1 at the recent meeting at PHLS, the Gallo isolate was  
2 being used to provide the antigen for the test in  
3 Newcastle. You should know that the department, some  
4 nine months ago, wrote to the United States government  
5 asking for their permission to use the isolate sent by  
6 ..."

7 I suppose that will be Gallo to Professor Weiss:

8 "... in order to provide antigen for development of  
9 tests in the NHS. Permission was not given and in the  
10 knowledge of this the department cannot but look askance  
11 at the entrepreneurial exercises that are being carried  
12 out by ..."

13 A. I'm sorry, I have no knowledge of that. I didn't see  
14 that letter at all.

15 Q. It was just an opportunity, Dr Mitchell, to refer to the  
16 fact --

17 A. I'm very, very surprised at that actually.

18 Q. There seems to have been, at least to some extent,  
19 a slight breaking of ranks?

20 A. I hope it wasn't within the blood transfusion ranks.

21 Q. I take your point.

22 A. It was quite clear that we were all to sing from the  
23 same hymn sheet.

24 Q. And you agreed with that?

25 A. Absolutely.

1 Q. Can we just scroll right down to the bottom? Thank you.

2 Yes, there we are.

3 A. Sorry, I hadn't seen that before at all until now.

4 Q. Can we go back to the statement, please, and just move  
5 over on to the next page, so we are talking about  
6 [\[PEN0171002\]](#), now at 1005. In this section we were  
7 focusing on the letter which was sent to the Lancet. It  
8 actually appeared in the Lancet in March 1985 and it  
9 registered the concern of transfusion directors at the  
10 likely incidence of false positives with the commercial  
11 kits then coming on stream.

12 But, of course, we know too that by the end of May  
13 Professor Bloom was becoming very anxious about the lack  
14 of screening and we know about his letter to the BMJ, to  
15 which Dr Rizza and Dr Forbes were also signatories.

16 A. Yes.

17 Q. And we asked about your sources of information  
18 underpinning the belief that there was a high rate of  
19 false positive results with the commercial kits. We  
20 asked what SNBTS had done to try to obtain information  
21 from other blood transfusion services abroad and we  
22 asked about various measures that might have been taken  
23 to lessen the effect on donors or transfusion recipients  
24 and you drew our attention to the letter from  
25 Dr McClelland to Mr Madden. We have already looked at

1 that this week.

2 I think you actually went on to say that you  
3 wouldn't have been in favour of introducing tests by the  
4 back door. I suppose there would be two different  
5 possibilities. I think maybe what the question was  
6 getting at -- and I didn't put this well yesterday, but  
7 the question was really getting at introducing donor  
8 testing perhaps with information to donors when they  
9 were in the centre but without public announcements, so  
10 you wouldn't have this problem of people turning up to  
11 get a test. The information would have been, I suppose,  
12 discreet and within the transfusion centre but wouldn't  
13 have been in the newspapers or in the public arena, no?

14 A. Maybe that's what wishful thinking would reveal but in  
15 the real world I think you would find that that sort of  
16 information would get out pretty quickly.

17 Q. Yes, I take your point.

18 A. Remember the number of people who were actually handling  
19 all this material. The same thing happened with  
20 hepatitis, if you remember. All the information --  
21 stuff was being leaked to the press like mad and one  
22 couldn't determine how it was leaked but at the same  
23 time that kind of information, as I think I did say,  
24 that getting out into the public domain would have been  
25 devastating on the public. They would have lost all

1       credibility, blood transfusion would have lost it, and  
2       people would have lost all interest in becoming blood  
3       donors. They would say to themselves, "Well, if that's  
4       what you think of me, don't bother calling me. Don't  
5       bother telling me anything more. I don't want to know  
6       if you are going to do that." You test one lot and not  
7       another lot and the guy in Carlisle says, "Maybe if  
8       I had been working in Dumfries, I would have had  
9       a test," and the chap -- you can't have people crossing  
10      boundaries and going around to find out if they are  
11      positive or negative. There was an element of that --

12   Q.   Yes.

13   A.   -- early on.

14   Q.   We know that from a very early stage the need for  
15      alternative testing facilities was identified, so people  
16      whose only purpose was to get an AIDS test were not  
17      wanted as potential donors. We have some information  
18      about the alternative testing facilities in Edinburgh  
19      and I just wondered what the alternative testing  
20      facilities were in the West.

21   A.   As far as I know, the area health board in Glasgow did  
22      set up access testing through the regional virus lab.  
23      That was through Eddie Follett and that group. I think  
24      they were well up and running about the time that we  
25      were talking about Eddie Follett setting up the

1 screening test and the confirmatory testing. I think  
2 they were a little bit running in parallel with blood  
3 transfusion.

4 Q. Do you remember as at autumn 1985 what avenues would  
5 have been open to a member of the public in Glasgow who  
6 just wanted an AIDS test. Where would they have gone?  
7 Where could they have gone?

8 A. I think some people did approach us.

9 Q. Right.

10 A. And we would have had to say to them, "I'm sorry, we are  
11 not offering it to general public; what we are doing is  
12 trying to get a test for donors. Please go and see your  
13 own doctor." Their own GP might well have said,  
14 "I don't know if I can have a test done but I'll find  
15 out if the regional virus lab are doing it." I think  
16 that's --

17 Q. So was there anything in the West of Scotland where  
18 people could just walk in off the street and say to  
19 somebody, "I would like to be tested for AIDS," and that  
20 would happen?

21 A. No, not that I am aware of that. No, I don't think so.

22 Q. So a self-referral facility? You don't think so?

23 A. No, I think they would either have to go through their  
24 GP or go through one of the clinics.

25 Q. Right.

1 A. You know, the drug abuse clinics or the other clinics or  
2 genitourinary infection.

3 Q. Right. And then I think the other point that you are  
4 making, Dr Mitchell, in your response, if we look at the  
5 final page, 1006, relates to information from other  
6 countries.

7 A. Hm-mm.

8 Q. Is it your position that it wouldn't have been safe to  
9 introduce tests straight away in the UK on the strength  
10 of evaluations that might have been carried out in other  
11 countries. Is that what you are saying?

12 A. Yes.

13 Q. Right. So you couldn't just say, "This test has been  
14 tried out in America, we can introduce it immediately in  
15 the West of Scotland"?

16 A. No.

17 Q. Why would you not say that?

18 A. You know from the American literature the number of  
19 false positives that they were finding.

20 Q. Right.

21 A. A tremendous number of false positives. As I say, even  
22 as I read, I think it was in that Crewdson or that paper  
23 that was sent to us. I think, if I remember rightly,  
24 there was one saying in 1986 they were still trying to  
25 improve the test so as to detect false negatives.

1 Q. Yes.

2 A. And I think in the States it was perhaps easy to say to  
3 someone, "Well, you are a donor, we pay you for this but  
4 just don't bother coming back. We don't quite know  
5 what's wrong with you." You know? But I think the  
6 position in the UK would be, "We have got to get  
7 something done about this." Your donor has now become  
8 a patient and you then have a duty to say, "Well, I'm  
9 going to get you the best information I can get for  
10 you."

11 Q. Well --

12 A. And that's where our beloved Dr Crawford took over.

13 Q. I understand that, Dr Mitchell, but I suppose I'm really  
14 just wondering whether, if there had been a very good  
15 commercial test from another country -- let's say the  
16 United States -- a test that had very positive research  
17 underpinning it and the field evaluations had all been  
18 carried out in some part of the United States, that  
19 would have been good enough to justify its introduction  
20 without evaluation in the UK, or would some sort of  
21 evaluation still have been needed?

22 A. We would certainly want to have a look at it first, to  
23 see if it was compatible with our testing systems.  
24 I mean, there may have been bits like, gearing up your  
25 lab, having to buy extra equipment, extra staff, as

1 I said, computing, all the -- all the paraphernalia of  
2 doing it on a large-scale.

3 Q. But is information about how a test performs on American  
4 donors a reliable guide to how it will perform on  
5 British donors?

6 A. No, they had a different population, you see.

7 Q. Right.

8 A. Many of their donors, as I understand it, were recruited  
9 from penitentiaries and places like that, where clearly  
10 there was a large degree of drug addiction and other  
11 hazardous occupations or things. So I don't think we  
12 would necessarily have just immediately willy nilly have  
13 accepted the American tests.

14 I think even the American, if you read, they had  
15 difficulty deciding among themselves what would be the  
16 most superior test. As far as I read, there were  
17 perhaps five or six individual tests all being used  
18 throughout the States. None of which were compared with  
19 one another. Nobody was exchanging samples to say,  
20 "Look at this tricky one. Can you detect that? Or can  
21 you detect it?" There was no correspondence between  
22 individual centres.

23 Q. Yes.

24 A. You know, what's positive with me has to be positive in  
25 Edinburgh --



1 Q. Yes, I think we can --

2 A. -- and London.

3 Q. We can understand that a proper comparison is really

4 dependent on different test kits looking at the same

5 samples. I think we can understand that, Dr Mitchell.

6 A. I think one of the difficulties was that many of these

7 people in their confirmatory testing were testing the

8 confirmatory test against the original virus, the

9 isolate, whereas in actual fact they should have been

10 using two separate tests, at least two separate ones.

11 It's like comparing cheese and chalk.

12 Q. Yes.

13 A. That was the difference.

14 Q. Right. Excuse me a moment, Dr Mitchell.

15 Thank you very much.

16 THE CHAIRMAN: Should we have a break or ...? I'll just

17 find out whether there are questions.

18 Do you have any questions?

19 MR DI ROLLO: Not for me.

20 MR ANDERSON: Nor I, sir.

21 MR JOHNSTON: Nor me. Thank you, sir.

22 THE CHAIRMAN: I don't think we need a break for

23 Dr Mitchell's purpose.

24 What's your general position?

25 MS DUNLOP: I have no further witnesses for today, sir, but

1 I do have a number of other statements, as perhaps is  
2 common towards the conclusion of any one topic. There  
3 are a number of other statements and I would like to  
4 tender them.

5 THE CHAIRMAN: Then we should have a break and come back.

6 MS DUNLOP: I think a break would be sensible, yes.

7 THE CHAIRMAN: Thank you very much, Dr Mitchell.

8 (11.03 am)

9 (Short break)

10 (11.30 am)

11 THE CHAIRMAN: Yes?

12 Tendering of other witness statements by MS DUNLOP

13 MS DUNLOP: Yes, sir. I simply wanted to mention some of  
14 the statements from witnesses who have not attended to  
15 give evidence in person, and the first such statement is  
16 from Dr McIntyre, [\[PEN0170552\]](#).

17 If we look at that ourselves, Dr McIntyre is  
18 entirely naturally not able to remember very much and  
19 has difficulty in answering most of the questions, and  
20 we also have to bear in mind this is an omnibus schedule  
21 of questions and much of it relates to happenings within  
22 the DHSS, which one would perhaps not ever have expected  
23 him to know a great deal about.

24 If we just perhaps look at the second page, one  
25 point which does come across is his strong support for

1 the idea of an evaluation of test kits before they are  
2 introduced. We can see that particularly in  
3 paragraph 8.

4 THE CHAIRMAN: Is this generally or with reference to the  
5 particular examples?

6 MS DUNLOP: He does say "generally". He says:

7 "It is normal practice to evaluate a new test."

8 THE CHAIRMAN: That can't be a surprise really, can it?

9 MS DUNLOP: No, it's common sense but I think it's as well  
10 for us to educate ourselves on these points.

11 THE CHAIRMAN: It is better to have evidence to rely on than  
12 common sense, which is a variable element in any  
13 assessment of a position.

14 MS DUNLOP: In paragraph 9 he makes reference to a briefing  
15 minute to the Scottish health minister. That's the  
16 Mr Macpherson minute, that one. [SGH0027226] Mr Macpherson's  
17 minute of 21 March 1985.

18 Then on to the next page. He also goes back to the  
19 topic of evaluation, this time more specifically in  
20 relation to the HIV test kits and that's looking at 11.

21 Then on to the next page. He perhaps encapsulates  
22 the difficulty for people being asked these sort of  
23 questions when he says:

24 "This all feels logical but is no more than my  
25 attempt to elucidate the thinking of DHSS colleagues

1 after a lapse of 25 years, and my comments should be  
2 read in light of this caveat."

3 Perhaps a caveat that should apply to most people  
4 asked and would, I suspect, apply to us as well if asked  
5 about events in the 1980s.

6 THE CHAIRMAN: Yes.

7 MS DUNLOP: Then going on to the next page as well, he talks  
8 about personnel. He talks about Dr Bell in particular  
9 in paragraph 23, and Dr Bell's various minutes.  
10 Dr Alison Smithies and then Dr Ed Harris and  
11 Dr Mike Abrams, and then Dr Diana Walford initially  
12 before handing over to Dr Smithies.

13 Then his initial response to the idea of the SNBTS  
14 evaluations is set out in paragraph 26. He did actually  
15 say:

16 "I cannot recall being involved in any discussions  
17 between SHHD and SNBTS regarding this matter. It was  
18 also agreed at this meeting ..."

19 That's the coordinating group:

20 "... that no transfusion centre in Scotland would  
21 commence routine HTLV-III antibody testing  
22 unilaterally."

23 To try to be a little bit more specific, we did put  
24 Professor Cash's version of events to Dr McIntyre. We  
25 asked the Scottish Government to do so and we have an

1 email response, which is [\[PEN0171836\]](#). I think perhaps  
2 I should just let everyone read it. (Pause)

3 THE CHAIRMAN: Yes. The last paragraph, which of course we  
4 have seen before, actually misses the point. I don't  
5 think Dr Cash's complaint is as to the tone of the  
6 intervention but as to its effect. When I read this  
7 first, I didn't really think that worrying about the  
8 hostile character of it and so on mattered, nor is it  
9 necessary to say that they treated colleagues in  
10 a professional manner. You can treat people in  
11 a professional manner and still fail to give them the  
12 comfort they are looking for, I suppose.

13 MS DUNLOP: I suppose the question is perhaps whether it was  
14 an offering of advice or opinion or an instruction.

15 THE CHAIRMAN: Yes.

16 MS DUNLOP: I'm not sure we are going to get to the bottom  
17 of that.

18 THE CHAIRMAN: No. Well, the one thing that seems to be  
19 reasonably clear -- and I will be interested in other  
20 people's comments -- is that however it came about,  
21 there was an acceptance as between the two major centres  
22 in Scotland, who might have been involved, that the  
23 process that was taking place in England was the right  
24 way to go about it, properly funded, and that it  
25 shouldn't be replicated here.

1 MS DUNLOP: Yes. I think there does come across an anxiety  
2 immediately after the New Year in 1985 about whether  
3 anything very much was happening.

4 THE CHAIRMAN: Yes. That's bound to be if people aren't as  
5 involved, as clearly Dr Mitchell would have liked them  
6 to be, even on an informal basis.

7 MS DUNLOP: Yes. When you look at material from the DHSS,  
8 it is plain that steps were being taken to put together  
9 a panel of experts to oversee the evaluation, to draft  
10 protocols and so on.

11 THE CHAIRMAN: Yes.

12 MS DUNLOP: The next individual who has provided a statement  
13 is Dr Macdonald, Dr Iain Macdonald. And his statement  
14 is [\[PEN0170559\]](#).

15 He was the other deputy chief medical officer but he  
16 points out that Dr Graham Scott, as deputy chief medical  
17 officer, had responsibility for blood transfusion  
18 matters.

19 I have to say, without intending any criticism,  
20 a number of his answers do begin with "I do not know",  
21 and given those circumstances and the lapse of time,  
22 that would seem to be understandable.

23 THE CHAIRMAN: Certainly when the alternative is "I imagine  
24 ..."

25 MS DUNLOP: Well ...

1           If we look at the second page, we can see, however,  
2           a reference to DHSS as a Whitehall department taking the  
3           lead. This is an expression that does crop up from time  
4           to time. He makes a general point about DHSS:

5           "... having significantly larger numbers of both  
6           administrative and medical staff who could give their  
7           attention to health matters than SHHD. Individual  
8           members of staff in DHSS could handle in greater depth  
9           a smaller number of issues than their opposite numbers  
10          in SHHD".

11 THE CHAIRMAN: I can see that in fact. I'm not sure it  
12          answers what might be a question in the long-term, which  
13          is whether DHSS had a role that subordinated thinking in  
14          SHHD, or whether SHHD had a continuing responsibility to  
15          assess issues for itself; no doubt with the assistance  
16          that was derived from SHHD work.

17          I'm not sure that I know where this should end up.

18 MS DUNLOP: Well, we certainly have another big topic to  
19          look at, which is analogous in relation to the  
20          introduction of Hepatitis C screening.

21          On the topic of evaluation, he goes on to say in 8  
22          that:

23          "The government would have been criticised had there  
24          not been an assessment of the available tests."

25 THE CHAIRMAN: That's clearly correct, isn't it?

1 MS DUNLOP: Well, it would certainly seem to be supported by  
2 the evidence, and I don't think actually anyone suggests  
3 the contrary.

4 THE CHAIRMAN: There has been no suggestion otherwise?

5 MS DUNLOP: No.

6 THE CHAIRMAN: I don't think that is really challenged in  
7 any way by Dr Mitchell, whose department was the one  
8 that would have been doing something different.

9 MS DUNLOP: Then if we go on through the next pages, perhaps  
10 particularly 24 is worth noticing, he says --

11 THE CHAIRMAN: Paragraph 24?

12 MS DUNLOP: Yes.

13 THE CHAIRMAN: That's skipping a lot that I have not read.

14 MS DUNLOP: There is a lot of "I don't knows".

15 THE CHAIRMAN: Okay.

16 MS DUNLOP: It's actually only one page. If we go to the  
17 next page, 562.

18 THE CHAIRMAN: Right, it's quite compressed through that.

19 MS DUNLOP: Yes. 24, he does say he has some sympathy for  
20 SNBTS in wishing to do things on their own account  
21 without waiting for NBTS.

22 THE CHAIRMAN: But he really doesn't remember or know  
23 anything about the background.

24 MS DUNLOP: No, I think that's really right, sir.

25 He does make general comment in 27 about this idea



1 of one service introducing testing in advance of the  
2 other. Then he also remembers the need for alternative  
3 testing facilities. That's covered in 29. He makes the  
4 practical point, that perhaps no one else has said in  
5 terms, that the sheer numbers of people who might have  
6 turned up would have caused a logistical problem.

7 THE CHAIRMAN: I think I might have been more concerned with  
8 the possibility that with an inefficient test system,  
9 there would be false negatives that would expose  
10 patients to greater risk.

11 MS DUNLOP: Well, indeed, and that would certainly dwarf any  
12 point about running out of kits.

13 Then there is really nothing on the last page.

14 We then have a statement from Alexander Murray --  
15 Sandy Murray, I think he was -- which is [\[PEN0121899\]](#).  
16 He was a branch head. He says in (iii):

17 "My job title in SHHD was head of branch 3 of  
18 division IVD."

19 I'm not sure if that's 4D or IVD? Four, thank you.

20 It's 4D. He explains a bit about the set-up.

21 THE CHAIRMAN: I will just read that paragraph more  
22 carefully, if I may? (Pause)

23 How should one understand the relationship, if any,  
24 between A and B?:

25 "... to carry out the administrative and executive

1 functions in relation to the CSA as such."

2 And:

3 "... a number of divisions of the CSA, including the  
4 SNBTS."

5 Should one understand a hierarchical structure with  
6 the SNBTS functions being subsumed under the CSA, or is  
7 the care of the SNBTS separate from care of the  
8 Common Services Agency so that there is a direct  
9 relationship between branch 3 and the SNBTS, or what?

10 MS DUNLOP: Well, I understand it to have been pyramidal,  
11 sir. I'm not sure about the hierarchy but certainly the  
12 Common Services Agency appears to have had resourcing  
13 and staffing of its own and then underneath it would be  
14 the divisions of the Common Services Agency, and he  
15 instances the SNBTS, the Scottish Ambulance Service and  
16 the Scottish Antibody Production Unit, and as I think we  
17 have said before, the Central Legal Office too.

18 And branch 3 has had duties in relation to both  
19 levels. So the level higher up the pyramid, which  
20 oversaw all of these divisions, and --

21 THE CHAIRMAN: Would the exercise of a function relating to  
22 SNBTS have been channeled through the CSA or would it  
23 have impact directly on the SNBTS? I don't think he  
24 tells us that.

25 MS DUNLOP: No, but I think we can see from the documents

1       that sometimes Mr Murray is considering directly such  
2       matters as funding of the introduction of screening,  
3       without there having been some kind of intermediary from  
4       the Common Services Agency getting the message from  
5       SNBTS and transmitting it to SHHD. So there seems to  
6       have been some issues where there was direct liaison.

7   THE CHAIRMAN: But the question is what the inferences might  
8       be that one could draw from that, as to whether there  
9       was a properly structured hierarchy or something much  
10      more casual, which I think I may have to look at in due  
11      course.

12  MS DUNLOP: Well, I suppose, sir, it really depends on the  
13      issue, doesn't it? It's impossible to prescribe in  
14      advance how any structure will respond to any issue  
15      which might arise, and there seems to have been a degree  
16      of flexibility, which no doubt was advantageous in some  
17      circumstances.

18  THE CHAIRMAN: Well, may have been advantageous in some  
19      circumstances.

20  PROFESSOR JAMES: You could perhaps put that the other way  
21      round and say there was a degree of vagueness which  
22      could have been disadvantageous in certain  
23      circumstances.

24  MS DUNLOP: If it's necessary for the Inquiry to express  
25      value judgments on these management structures in the

1 early 1980s, I'm sure we can ask some further questions  
2 about them, but it's no doubt difficult for people to  
3 give an overall impression at this juncture.

4 Mr Murray points out on the second page that he has  
5 no medical or scientific qualifications and he says he  
6 is unable to answer many of the questions put to him.  
7 And there are again a number of questions to which his  
8 response has to be that he doesn't know.

9 Then on to the next page, please. He mentions the  
10 ministerial involvement in decision-making, which we  
11 have seen in the minutes and indeed telexes  
12 from February and March 1985.

13 On to the next page. He sets out circumstances in  
14 which an issue would be brought to ministers' attention.  
15 Then he talks about submissions going first to a junior  
16 minister and then to the Secretary of State.

17 Then not really much else on the final page, 1903.

18 Immediately above Mr Murray was Mr Davies and we  
19 have a statement from him, [\[PEN0171007\]](#).

20 THE CHAIRMAN: You say, all right, he moved across from  
21 science then to become a principal administrator?

22 MS DUNLOP: Yes.

23 THE CHAIRMAN: A principal of the general division, right.

24 MS DUNLOP: So he is head of IVD, and then IVD had a number  
25 of branches and Mr Murray was head of one of the

1           branches.

2   THE CHAIRMAN:  It is interesting that Mr Davies came into  
3           the service as a scientist.

4   MS DUNLOP:  Yes.  With a background in computing, in fact.

5   THE CHAIRMAN:  Computing, oh, all right.  I see that.  Well,  
6           it doesn't necessarily mean that was his background.  He  
7           became involved in computerisation, but I think --

8   MS DUNLOP:  It's just that sentence:  
9            "I had a background in computing ..."

10           That makes me think that must have been his  
11           background.

12   THE CHAIRMAN:  Yes.

13   MS DUNLOP:  But I suppose quite early in the process, so the  
14           division which he headed between 1983 and 1985 had  
15           overall responsibility for SNBTS-related matters, and  
16           then Mr Macpherson headed another division, which had  
17           responsibility for inter alia, misuse of drugs and  
18           communicable disease.  So I suppose we have had some  
19           examples of the crossover.

20   THE CHAIRMAN:  In Civil Service terms, Mr Davies had a very  
21           interesting career path, didn't he?

22   MS DUNLOP:  Yes.  I think some members of our team --  
23           certainly one member of our team is able to remember  
24           Mr Davies.  
25           We can see in paragraph 5 he is mentioning

1 discussion of donor screening, but again I think really  
2 reconstructing events rather than speaking of any direct  
3 recollection. And predictably perhaps quite a lot of  
4 "don't knows" or "I am unable to answer this question."

5 Go on to 3, please.

6 THE CHAIRMAN: Paragraph 22 indicates that even though he  
7 wasn't directly involved in the scientific side of this,  
8 the message has got through to him that everywhere was  
9 extremely reluctant to use tests that ran the risk of  
10 giving high numbers of false positives.

11 MS DUNLOP: Indeed, yes.

12 THE CHAIRMAN: And an equal concern about false negatives --  
13 well, not equal. It's different. He doesn't remember  
14 that as much.

15 MS DUNLOP: Hm-mm.

16 THE CHAIRMAN: We should remember that the tabloid press at  
17 the time were hysterical. Does this period stand out  
18 particularly for that?

19 MS DUNLOP: Then on the next page, he doesn't really again  
20 remember anything of substance, although from the  
21 paragraph at the bottom of the page he, and indeed his  
22 wife, remember this as an anxious period.

23 THE CHAIRMAN: Yes.

24 MS DUNLOP: Then on to the final page, if we could, please.  
25 It's just a small section.

1           So that's Mr Davies.

2           The next document is [\[PEN0170504\]](#). That relates to  
3           Dr Alison Smithies. We did see if we could get  
4           a statement from Dr Smithies and this is the response.

5   THE CHAIRMAN: It rather misses the point, does it -- or two  
6           points? It's not really for Dr Smithies to decide  
7           whether she should be helpful or not and the comment  
8           that a person can make on a contemporary document may be  
9           of great assistance even though that person doesn't  
10          fully appreciate the total context in which the answer  
11          is to be considered. There you are.

12   MS DUNLOP: We also, sir, mindful of the suggestion made by  
13          Professor Cash and indeed Dr Mitchell too, that Dr Dow  
14          might have useful information, contacted Dr Dow and he  
15          provided at the same time a statement very swiftly.  
16          [\[PEN0171680\]](#).

17          This is the one that we looked at earlier, and we at  
18          least can see the different colours, but I don't know  
19          that anybody who is reading it later will be able to or  
20          not? They will? Yes, if they look at the PDF version,  
21          they will be able to see the black, blue and red.

22          At the bottom of the page Dr Dow is setting out his  
23          recollection of events in January 1985 and beyond. I'm  
24          not completely sure about the meaning of that sentence,  
25          that he knows that there was an Abbott system being used

1 in Ruchill. I'm not entirely sure why this is.

2 THE CHAIRMAN: That was the question I raised, prompted by

3 Professor James, about what was happening in Ruchill.

4 MS DUNLOP: Maybe it's worth looking. Leave Dr Dow's

5 statement open. It's worth looking at the mention of

6 Ruchill to which I alluded when I replied, sir, which is

7 in [\[DHF0019169\]](#).

8 So on February 11th, 1985, Abbott -- and can we just

9 look at their letterhead, please. They are actually

10 writing from Delkenheim. That's the factory we saw

11 mentioned as supposedly coming on-stream in 1985 to

12 supply Europe. They are writing to talk about the

13 Abbott HTLV-III EIA diagnostic test kit.

14 They say that they have already contacted three

15 British evaluators. If we look over the page, there we

16 have it.

17 THE CHAIRMAN: There is Ruchill.

18 MS DUNLOP: Yes.

19 THE CHAIRMAN: Yes, the question is: what was the population

20 that Ruchill was dealing with at that stage? I think

21 the suggestion is that it may have been people who had

22 problems of HIV/AIDS infection, not related to

23 haemophilia.

24 MS DUNLOP: I suppose one can speculate that in practice

25 there are likely to have been problems with any kind of



1       planned evaluation at Ruchill of a similar sort,  
2       particularly if it was in March and April 1985, that the  
3       availability of the kits seems to have been so limited  
4       that in spite of what may have been intended by Abbott,  
5       any evaluation exercise on anything approaching  
6       a large-scale may have had to have been postponed or may  
7       not have proceeded. But I take your point, sir, that  
8       there is another aspect to this, which is simply that  
9       the kits could have been being used for diagnostic  
10      purposes in Ruchill at this time.

11   PROFESSOR JAMES: I would think that would be extremely  
12      likely.

13   MS DUNLOP: Yes.

14            So can we go back to Dr Dow's statement then,  
15      please? He refers to the West of Scotland mini  
16      evaluation and that's at the bottom of the page. Can we  
17      just go up a little bit. He says:

18            "Around July 1985, SNBTS were in the position to  
19      perform a mini evaluation of these two proposed  
20      commercial anti HTLV-III tests."

21            Then he says on the next page:

22            "... there were insufficient supplies of any (other  
23      than the Abbott test) commercial HTLV-III test kit in  
24      early 1985 for a significant evaluation for blood donor  
25      screening purposes."

1 THE CHAIRMAN: Interesting expression:  
2 "I realised that a national evaluation had been  
3 performed."  
4 There is nothing to indicate that he knew in advance  
5 of the arrangements being proposed or put into effect.  
6 MS DUNLOP: No.  
7 THE CHAIRMAN: Of course, he has already said that he wasn't  
8 involved in procurement, which I imagine was general and  
9 not just specific to the example he gave.  
10 MS DUNLOP: But he was at Ruchill because he said at the  
11 start that he was on a part-time secondment to Ruchill  
12 in 1985. I don't think he actually says what month he  
13 began at Ruchill.  
14 Then at the point when we framed our questions, we  
15 were more interested in the deference between RIA and  
16 ELISA than in the difference between a competitive  
17 format and another type of format, and I think that we  
18 have been on a bit of a learning curve on that topic.  
19 So we did ask quite lot of questions about RIA versus  
20 ELISA and he gives some interesting information about  
21 the supply issue. He says that:  
22 "Today, kits sometimes have expiry dates over a year  
23 in advance but that wasn't the position in the 1980s."  
24 Then the point made by almost everybody that the use  
25 of isotopes for radioimmunoassay tests were also under

1 strict control, with laboratory staff having to wear  
2 monitoring badges:

3 "So it was necessary for transfusion services to  
4 accept the use of ELISA techniques that resulted in  
5 completely new equipment being used."

6 Another practical consideration which one should  
7 bear in mind in assessing the timing of all of this  
8 process. He has given us a photograph of the equipment  
9 necessary for performing the anti HTLV-III ELISA test  
10 made by Wellcome.

11 Further down then, please, we asked about the  
12 working party -- that is the regional transfusion  
13 directors' working party -- amending its report, and  
14 about various practical arrangements that had to be  
15 made. He says on the next page that he is unaware of  
16 a second stage to the evaluation but, of course, we have  
17 seen the draft report of the second stage. Then he goes  
18 back to the mini evaluation.

19 Again, a now familiar point about the initial  
20 problems with plate validation failures and the test kit  
21 being less sensitive than the developmental batch tested  
22 in July. Of course, Wellcome, in one sense, had been  
23 almost too successful because, despite there being two  
24 tests approved, Wellcome seemed to have attracted custom  
25 from almost the entire United Kingdom blood transfusion

1 services.

2 THE CHAIRMAN: Possibly the three factors identified by  
3 Dr Dow were generally appreciated.

4 MS DUNLOP: Yes.

5 PROFESSOR JAMES: They were probably also supplying the  
6 routine public health labs throughout the UK, when it  
7 became clear that that was a better test at the same  
8 time.

9 MS DUNLOP: Yes.

10 THE CHAIRMAN: It certainly must have put them under  
11 tremendous stress to have to gear up to cover  
12 everything.

13 MS DUNLOP: Yes. Then there is another --

14 THE CHAIRMAN: The plates would come from somewhere else,  
15 I take it, or would they be Wellcome too?

16 MS DUNLOP: I don't know about the plates, I am afraid, sir.  
17 Perhaps one could speculate that in that he says that  
18 equipment was delivered; it may have been that Wellcome  
19 subcontracted some aspects of that and delivered  
20 a package, but we don't actually know.

21 THE CHAIRMAN: It would be Wellcome who would treat the  
22 plates in the first instance, so that they would come --

23 MS DUNLOP: I expect so, yes.

24 THE CHAIRMAN: -- with their antigen and so on --

25 PROFESSOR JAMES: I think that's where the failures will

1       have lain. It's the displacement. We know what sort of  
2       assay it is. So it will be the fact that these plates,  
3       with multiple little sort of dips in them, as it were,  
4       you know, just weren't properly coated to a really high  
5       standard when they began to really, really mass produce  
6       them. That would be my guess as to why some plates as  
7       a whole, worked and others, you know, just didn't.

8       THE CHAIRMAN: So plate validation is much more likely to  
9       deal with the plate ready for a test.

10      PROFESSOR JAMES: Exactly, yes, yes.

11      THE CHAIRMAN: Yes.

12      MS DUNLOP: Then he actually gives us some more interesting  
13       information slightly further down about the  
14       practicalities of storage. He says:

15                "Three months' supply would have filled several  
16       shelves of our laboratory refrigerators."

17      THE CHAIRMAN: Yes.

18      MS DUNLOP: Perhaps on to the next page as well, please.

19                This is talking about confirmatory testing. Then  
20       this table, which we have seen before. Statistics for  
21       the first 176,149 donations tested. Actually it looks,  
22       looks, as though the positive predictive value is only  
23       about 20 per cent. But then he goes on to say that  
24       Abbott was tried and proved even less specific.

25      THE CHAIRMAN: Yes. All the information about Abbott that

1           has been adduced tends to suggest that there were great  
2           difficulties with their test.

3   MS DUNLOP:  Yes.  And of course, Dr McClelland made the  
4           point that the Abbott explanation for the less  
5           successful performance of their kit in the evaluation  
6           doesn't work once you get into the field and you are --

7   THE CHAIRMAN:  That's right.  It certainly doesn't work for  
8           the American experience.

9   MS DUNLOP:  No.

10   THE CHAIRMAN:  But it does suggest that, had the Abbott rep  
11           succeeded, when the fly was cast, over Dr Mitchell  
12           in January 1985, in attracting sufficient attention,  
13           things could have been bad in Glasgow if a supply had  
14           become available in April/May.

15   MS DUNLOP:  It's perhaps fair to point out, though, sir,  
16           that there is almost no information available about the  
17           Electronucleonics test, which was approved very close to  
18           the time when the Abbott test was approved in the  
19           United States.

20   THE CHAIRMAN:  No.  They are the people who complained very  
21           bitterly about discrimination, in effect, in America?

22   MS DUNLOP:  Electronucleonics?

23   THE CHAIRMAN:  Yes.

24   MS DUNLOP:  I'm not sure that I can remember that.

25   PROFESSOR JAMES:  Are they the ones that were seen by the

1 chief executive of Abbott coming out of the door --

2 MS DUNLOP: Yes, and assumed them to have won, yes. But

3 then I think sent away with the explanation that the

4 approvals were granted in alphabetical order.

5 THE CHAIRMAN: Which I have to say is not a terribly

6 persuasive explanation.

7 MS DUNLOP: Then on to the further page. It gets rather

8 more technical. I suppose Sheffield, having chosen the

9 Organon test, was useful.

10 If we go a little bit further down in Dr Dow's

11 response, we can see that there was what seems to have

12 been some kind of standardisation exercise required of

13 regional centres.

14 THE CHAIRMAN: Can we go up just a little, please, to see

15 the sentence introducing that?

16 MS DUNLOP: Yes.

17 THE CHAIRMAN: All right. Do you understand what the panel

18 2, panel 3, panel 4 and panel 5 differentiation is? We

19 have got a low positive one, a high positive one and

20 then panels 2, 3, 4 and 5.

21 MS DUNLOP: No, I don't know what the difference between

22 these panels would be, sir.

23 THE CHAIRMAN: And the other thing we don't know, as far as

24 this is concerned, is what the result of retesting of

25 the Ruchill weak positive was. But does it come? Yes.

1 MS DUNLOP: I should say, sir, that the view I have taken is  
2 that both this information and the information which  
3 Dr Dow has given on the following page, about practical  
4 problems in the conduct of testing, has not been further  
5 investigated because this topic is really meant to  
6 relate to the introduction of testing and not to go  
7 further into what happened once testing had been  
8 introduced.

9 THE CHAIRMAN: Yes, indeed. And in any event, if it gives  
10 us a general conclusion, it is probably much more  
11 valuable than the analysis of the technical detail.

12 MS DUNLOP: Yes.

13 THE CHAIRMAN: And he does say here that the testing staff  
14 of all UK RTCs got confidence that their testing  
15 procedures would identify known positives day-to-day.

16 Yes, but I appreciate what you say, that you aren't  
17 really focused at this stage on the effectiveness of it.

18 MS DUNLOP: No. Then if we go on to the last page, we can  
19 see that Dr Dow has provided a number of references. He  
20 says [these papers show the]:

21 "Problems associated with the introductory use of  
22 the Wellcome HTLV-III kit with regard to sensitivity and  
23 address the problems of false positive tests  
24 (specificity)."

25 So these references are there.



1 THE CHAIRMAN: But that again --

2 MS DUNLOP: Yes, we are going perhaps rather further than we  
3 need to. So that is Dr Dow's contribution.

4 Could we go next, please, to [\[PEN0171000\]](#)? This is  
5 Dr Mortimer's response. Well, it's the letter to  
6 Dr Mortimer and then we have his response. So perhaps  
7 if we just take a moment to look at the letter to  
8 Dr Mortimer. (Pause)

9 THE CHAIRMAN: Can we go on down the page, please? I think  
10 you can go on to the second page.

11 MS DUNLOP: Yes, we are still on the topic of ELISA versus  
12 RIA.

13 THE CHAIRMAN: Yes.

14 MS DUNLOP: Then he replied, [\[PEN0171761\]](#), giving very  
15 similar information about the change to ELISA from RIA.

16 THE CHAIRMAN: Another new expression "sandwich ELISA".

17 MS DUNLOP: Yes, I am afraid I can't explain that.

18 Then he talks about the other precautions which were  
19 taken, if we go a little bit further down. Then perhaps  
20 we could turn over. He suggests another enquiry we  
21 could make, but we obviously have tried to look at the  
22 whole question of statistics and we do have information  
23 which we looked at in March.

24 Then next, if we could look at [\[PEN0131396\]](#), please.  
25 This is from Professor Leikola and the only purpose in

1 looking at this in this particular topic is just to  
2 note -- I think it's paragraph 7 -- that he gives  
3 information about when screening began in Finland. Yes,  
4 there we are:

5 "Testing of blood donors ..."

6 Well, in the Helsinki area, he says,  
7 was September 1985. I'm not sure whether that would  
8 cover the whole of Finland but obviously very similar to  
9 the timing in Scotland and England. And that's the only  
10 thing in the statement I wanted to look at in this  
11 context.

12 Just finally, sir, in relation to our enquiries, we  
13 do have an email -- well, a short statement, in fact,  
14 which has been sent to us from Dr Perry, about the  
15 letter -- I think it's [\[SNB0074920\]](#) -- that mentions an  
16 evaluation of French testing kits at the end, which  
17 seemed interesting and we did follow it up. It's not in  
18 court book yet but perhaps I can just distribute hard  
19 copies of it. Thank you.

20 We have a very short response from Dr Perry and yet  
21 again, I think we have caused some meticulous research  
22 of old files and no one has been able to find anything.

23 (Handed.) [\[PEN0190860\]](#)

24 THE CHAIRMAN: Yes.

25 MS DUNLOP: So if I can just simply tender that as an answer

1 to what was an interesting question earlier in the week.

2 Those are really all the documents which, together  
3 with the oral evidence we have had this week, represent  
4 our investigation of this topic.

5 THE CHAIRMAN: Thank you very much.

6 Mr Di Rollo, do you have any comment or question or  
7 other contribution at this stage on the topic?

8 MR DI ROLLO: I don't think so. Thank you, sir.

9 THE CHAIRMAN: Mr Anderson?

10 MR ANDERSON: I have no question, comment or contribution.

11 THE CHAIRMAN: Yes. Mr Johnston?

12 MR JOHNSTON: Neither have I, sir.

13 THE CHAIRMAN: Yes, thank you all very much. So ...

14 MS DUNLOP: We are not sitting next week and then we return  
15 a week on Tuesday to hear from Professor Howard Thomas.

16 THE CHAIRMAN: Right.

17 (12.28 pm)

18 (The Inquiry adjourned until Tuesday 11 October 2011 at 9.30

19 am)

20 I N D E X

21 DR RUTHVEN MITCHELL (continued) .....1

22 Questions by MS DUNLOP .....1

23 Tendering of other witness .....58  
24 statements by MS DUNLOP

25

