Thursday, 29 September 2011

(9.30 am)

DR BRIAN MCCLELLAND (continued)

Questions by MS DUNLOP

THE CHAIRMAN: Good morning. I suppose welcome back is appropriate.

A. Thank you, sir.

THE CHAIRMAN: Ms Dunlop?

MS DUNLOP: Yes, sir. Dr McClelland hasn't been with us since June in fact.

THE CHAIRMAN: But his name has never left our lips.

MS DUNLOP: Good morning, Dr McClelland. We are going to talk today about the topic of screening of donated blood for what was to become known as HIV, and you have provided a statement for us on that topic.

The statement is [PEN0171337]. Actually I'm proposing to jump really straight to about question 5 because we asked you some questions before that, to which you responded that you didn't really know, you weren't at meetings or you don't really feel in a position to speculate as to what was meant by certain comments or statements.

So where you do come in is in paragraph 5, which we can see on the screen, and that's in relation to the working group of the advisory committee on the National

Blood Transfusion Service. That is the working group which was formed and met on 27 November 1984. We asked whether this working group had been the first forum in which the introduction of donor screening for HTLV-III was discussed, and you answered by drawing our attention to discussions before 27 November 1984.

The NBTS regional directors had discussed AIDS at a meeting at Colindale on 11 July. We don't need to go to that. There was an AIDS working group established by the CBLA and it met in October 1983, and then you refer to the meeting in London on 28 June 1984, which was attended by Dr Tyrrell, Dr Tedder, Dr Wallington and Dr Contreras, and you had set off but you were unable to get to London. You were certainly one of the invitees.

A. That's right.

Q. It looks to have been really an ad hoc group; would that be right?

A. I think so.

Q. Yes. Could we look, please, at the letter of 3 July, which is Dr Gunson's resume of the meeting, [SNB00065978].

Dr Gunson, in writing this letter, was obviously transmitting information to Dr Alison Smithies and to all those who had been at the meeting and to you, because you hadn't managed to make it in person.

At that point did you know all of the other individuals mentioned?

A. I had certainly met them. I didn't know Dr David Tyrrell particularly well but I had attended one or two meetings which he chaired or was present at.

Q. Yes. In fact at that point, I think Dr Tyrrell had spent quite a lot of time in the common cold research unit. Is that right?

A. Yes, he had and he picked up the sort of AIDS issue, as I recall, for the Medical Research Council, UK MRC, right at the beginning and sort of looked after it for a year or two. I think he was quite close to retirement age by that time.

Q. I just wanted to ask about Dr Contreras because I found it slightly confusing that there are references to the North London Centre and Northwest Thames Regional Transfusion Centre. I think the North London Centre, which is where Dr Contreras was the director, is Edgware. Is that right?

A. That's correct.

Q. And that's different from the Northwest Thames Centre?

A. I'm just trying to rehearse my London geography. I'm just wondering -- I would need to look at a map actually, to be sure.

Q. I have been looking at a map --

A. We always call it "Edgware".
Q. It doesn't matter, it was just that given that in this letter there is a proposal to use serum from the Northwest Thames RTC, I wondered if that actually was Dr Contreras' centre?
A. I think it probably was, the reason being that that was the part of London at the time where it was believed that the donor population, for a variety of reasons, probably would be the one most likely to show early evidence of the virus entering the donor community.
Q. Yes, I see.

We note that there had been discussion on the whole question of testing. I expect you have looked again at this letter recently, have you?
A. Well, I had intended to but actually I haven't for various technical reasons, which I won't bore you with.
Q. Don't worry about it, Dr McClelland, I'm not going to ask you any very detailed questions but on reading it, Dr Gunson is certainly talking about "the test" and "this test", but I think the sense of it is notwithstanding those apparently specific references, he is really just meaning the concept of the test. He is not talking about any specific test. I think that would fit with events as they were unfolding at the time.
A. Dr Gunson would certainly have been well aware by that

time of the developments in the United States and probably also in France, so I imagine he was referring to a test for the virus.

Q. I think the only point I'm trying to make is that certainly by the end of June, it doesn't look as though anyone had a test ready to roll, even in America?

A. Oh, they did not.

Q. Yes. Although we did hear yesterday from Dr Tedder that actually he had a working assay by 4 July, which is quite interesting given that this is the letter sent on the 3rd.

A. I think perhaps it's important to distinguish between a test that would work very well in very expert hands in a research laboratory and something that was sufficiently robust and reliable to do hundreds of thousands of tests day in, day out, in a sort of production environment.

Q. Indeed.

A. And there is a huge difference between those two.

Q. I appreciate that. Simply that it's obviously a useful first step to have something which is working in laboratory conditions.

A. Oh, it was hugely important.

Q. Yes. And we can see that that paragraph mentioning the work of Dr Weiss and Richard Tedder has been underlined

and it is described as "very promising":

"There is some reason to believe that a radioimmunoassay may be available within the foreseeable future."

We have noted various other points in this letter. If we look at the second page, we can see that the intention, once there was a test, was to conduct some early evaluations in selected regional transfusion centres round the country, trying to give,I suppose, a representative picture because of the particular centres chosen, and that's said when stage 3 is discussed. So there was going to be one from London, a northwestern industrial area, and a largely rural community.

And then some mention further down that page of the possibility of the CBLA becoming involved. I suppose with a view to emulating what had occurred with the hepatitis testing?

A. That's exactly --

Q. So that BPL could become involved in manufacture. And then Dr Gunson is concerned at cost, should the United Kingdom have to purchase kits from the United States.

Then just to look at your letter, which goes with this, [SNB0065977]. This is the letter that talks about

the travel problems. You were thwarted by a rail strike but you will be keeping in touch with Richard Tedder. Do you think if you had been at the meeting, you might have proposed a centre in Scotland, to take part in evaluations of a test?

A. I probably would. I think we would have -- we would have, I think, taken the view that -- I would have taken the view that it would be useful for one of the Scottish centres, probably the West of Scotland, which is very experienced in this sort of work, to get in at the ground floor because you learn all the way through these exercises.

Q. Yes, and you tell Dr Cash in your letter that you have gained some information by a somewhat indirect route; that is you have found out from American Red Cross people in Munich that CAMR have the cell line and the virus and are pushing ahead rapidly, and then your prediction is that:

"It is likely to be many months before a test is available and relevant trials come forward to put us under pressure to introduce screening."

What was your general sense at that point, Dr McClelland, about the advent of screening? Was it a sense of relief that a test seemed to be on the horizon or a sense of apprehension because of all the

practical problems, or a mixture?

A. It's very difficult to recall accurately but I think -- I think that I probably recorded in one or two other places the thought that the only -- I mean, before this time, I think, my feeling was that the only way that we could really protect patients from this infection was with a very sensitive screening test, because we were very aware that, although we talked a lot in the Inquiry about all the sort of other approaches to selecting donors and trying to detect through questioning and so on -- we were -- I certainly never felt any confidence that that would be a totally reliable way of avoiding this infection getting into the blood supply.

So I'm sure that, from early on, my view was that an effective test was really going to be the cornerstone of safeguarding the blood supply.

Q. Yes. Certainly from the documents of the time, whether they be internal Department of Health, SHHD or letters, there does seem to be quite a focus on the practical problems that lay ahead. Do you think we are just not getting a sense of the positive response to news that a test was on the way?

A. I think it's certainly true that -- I mean, there was a lot of concern about, if you like, a number of the downsides of testing, possibly -- there was the

practical issues of introducing the test and the fact that that would clearly be requiring additional resources and -- you know, the expectation I think in the transfusion service was that it would be difficult to get adequate resources to do this work.

So that was undoubtedly a sort of management concern. There was also perhaps more substantially -- there was concern -- and I'm sure you will return to this -- about the performance of the tests, the early tests, and the really quite serious implications of tests that gave lots of false positive results, and a little bit later on there was also a concern about the possibility that tests which were insufficiently sensitive, which failed to detect genuine infections, could in a sense lead to a -- you know, a sense of reassurance that would then be damaged by the realisation that some infections had got through.

So those were worries. I think my own feeling, as far as I can recall -- and I think there is only -- there is not very much documentation of this bit but there is, I think, one letter which is referred to in my statement -- that -- I think my own feeling was that we needed to get on with it, and even if we had to struggle with a test that was less than perfect, and even if we had to use it selectively initially, we really needed to

move as quickly as possible.

Q. Right. So for you as a transfusionist, was it a given that screening would be introduced?

A. Oh, absolutely.

Q. Yes. Right.

A. Absolutely.

Q. To go back to the statement, if we could, please, [PEN0171337] at 1340 and moving on to this working group, which met on 27 November, there are a number of documents which relate to that meeting and the first one I would like to look at is [PEN0121942], please.

This is just an agenda. The first meeting to take place, 10.30 am on 27 November 1984 in London. Presumably at premises of the DHSS.

Item 3 is going to be tests for HTLV-III antibody. Can we look at the second page of this, please?

We did look earlier in the week, Dr McClelland, at correspondence in which Dr Bell was writing to the DHSS and asking if the expert membership could be expanded to include you, and we can see that you have been included but you are down as an observer.

In practice, if you can remember being at that particular meeting, were you participating on the same basis as all of those listed as members?

A. I think so. I don't think I paid much attention to the

observer status.

Q. Well, Dr McClelland, there is another meeting around this time, where the DHSS had sent out papers in which Professor Bloom had been inadvertently shown as an observer and an apology was issued to him through the Welsh Office. So I wondered if you ever received an apology through the Scottish Office for having been shown as an observer?

A. I really don't remember.

Q. No.

A. I probably wouldn't have been too exercised by it, to be honest.

Q. The other point which has come up from this list is that Dr Bell was originally to be representing SHHD, and we can see that he is being substituted by Dr Covell?

A. Yes.

Q. Do you know anything about that?

A. The reason for the change?

Q. Yes.

A. No, I don't. I mean, I knew Dr Covell quite well, a little bit after this, but I have no knowledge at all of the reason for Dr Covell attending. It may well be that Dr Bell had other commitments that clashed. I don't know.

Q. Because in fact it was Dr Covell who also went to EAGA,

the expert advisory group which began meeting at the end of January, the SHHD representative on that was also Dr Covell.

A. I think Dr Covell actually, you know, became quite, you know, to some extent the sort of expert in HIV/AIDS issues in the Scottish department. He took a great interest in it and I think it was a relatively small department. I think they possibly tried to concentrate that knowledge in one individual. That's my impression, looking back.

Q. We have certainly been told that he had a background in communicable and sexually transmitted diseases?

A. That's correct, yes.

Q. The next document I would like to look at, please, is [DHF00016027].

This is a paper which was sent out in advance of the meeting, just, I suppose, the background reading for those attending. Would that be right?

Perhaps if we just look at it to familiarise ourselves with what was in it, a bit of background. The topic of donor selection and then if we move on to the next page, please, "Screening for HTLV-III Antibody". Bringing members up-to-date, mentioning the paper in the Lancet in September.

Perhaps slightly puzzling as to what is missing in

the fourth last line of that paragraph. It's unlikely to be a name, you would think from the context. Yes, I did wonder if it was "refusing" or "denying", " ... to authorise the use of the isolate", but I suppose it could be the name of somebody in the United States health authorities.

Anyway, we have an understanding that a negative response had been received on 14 November but in fact neither Professor Weiss nor Professor Tedder is really of the view that that held up development of the Wellcozyme test.

A. No, I think their view would probably be that in one sense we were possibly quite lucky not to have started work on that particular reagent because it was deeply flawed.

Q. Yes, indeed.

A. And the method that had been used by their group to produce the critical -- the antigen for the test was a different approach, which appears to have yielded a rather purer ligand, if you like, for the test, and that had less problems with false results.

Q. Right. Then if we just scroll down, we can see some of the factors for discussion are listed and there is a case for preferential testing, whether there shall be a, I suppose, preferential testing, but in relation to

geographical areas.

If we could look over on to the next page, please, then obviously a need for confirmatory testing. In paragraph 5 the writer is mentioning the need for care in connection with those donors who get a positive result and questions of informed consent as well.

Then there are notes of the meeting. I don't think we actually have the formal minutes of the meeting. I'm not sure why not. But we do have notes prepared both by Dr Abrams and by you. If we look first at Dr Abrams' notes, [DHF0016037].

This particular paper, if we look just at the end of it, please, is one which has been, I think, de-redacted to some extent recently, and my initial hypothesis, based on room 108 at RSQ, that the signatory was Dr Oliver is wrong, it wasn't, it was Dr Abrams. So Dr Abrams was a senior medic in DHSS at this point?

A. Yes, I can't remember what his precise grading was, but, yes.

Q. It's actually dated 27 November, so if we can go back to the beginning, please. He thought the meeting had gone off -- "reasonably", I think that must be -- reasonably well:

"A very full and informed discussion."

And you had been able to complete all the items on

the agenda. We can see that there was a unanimous, strong view that the antibody test must be used for all NBTS donors as soon as possible. A hope that the Tedder/Weiss test could be scaled up very quickly, although Professor Weiss seemed to have introduced a note of caution on that. And then a similar sort of plan to start with an introduction in North London, some monitoring for problems and then an inconclusive discussion on whether kits should be used preferentially in higher risk donor areas; mention of confirmatory testing, some discussion of the question of donors, of leaflets and information to donors. And then if we look at the second page again, please, there is some discussion of heat treatment and a mention of a haemophilia centre directors' meeting to come in December.

I suppose the paragraph numbered 2, which deals with finance, could properly be described as "inconclusive". Dr Abrams is relieved that there has been no pressure to discuss finance but he is recording that there are some very thorny questions.

He thought the meeting went off reasonably well, that's not what you thought. If we look at [PEN0121938], this is your notes and you are summarising firstly new information which was presented, obviously

epidemiological data, donor behaviour, and then on to the next page, please, product safety and then at (d):

"Development of HTLV-III test facility."

You have recorded, obviously, some discussion about possible involvement by BPL and you have said that the departmental enthusiasm for this was muted. And then you have said that you could get no clear picture of when or how a serviceable assay would be provided. Then on to the next page, please.

This, I think, reflects the paper that went out in advance. We can see the unanimous agreement that testing should be introduced.

Discussion of some sort of preferential testing if a limited supply were to be available, the need for reference lab facilities and then some discussion of the handling of donors. And again, you say:

"The potential difficulties of this were inconclusively discussed."

Then on to the final page, we can see donors to be told in advance that there is to be screening, and heat treatment obviously continues to be necessary as well as screening. You have written some notes at the bottom. Are you able just to tell us what they say:

"Local HTLV-III ..."

A. I have no idea what the reference to "Livingstone" is

about. "Follett" is obviously Dr Eddie Follett, whom you will have come across, and I think I must have -- rightly or wrongly, been under the impression that Eddie Follett was himself interested in developing an assay, I think, but I really do not remember the detail about that.

Newcastle. That would be Peter Jones, who was the haemophilia director there. What I had in mind I can't remember. Graham Bird, who was a consultant clinical immunologist in Newcastle had developed a major interest in HIV and actually came to work with us in Edinburgh latterly:

"Laboratory management."

"Clinical ..."

Erm...

Q. "Clinical management."

No? Or not?

A. It probably is "management" actually. Sorry, these are -- I can't really --

THE CHAIRMAN: Is the top line "West of Scotland group"? No?

MS DUNLOP: The photocopying hasn't helped and the scanning, Dr McClelland, don't worry.

A. I am afraid I can't blame the photocopying. These are fairly cryptic scribbles and I honestly can't shed much

light on what was in my mind at the time. I suspect these were scribbles I made, you know, to points that I wished to mention when I was briefing Professor Cash about this.

Q. You have obviously had the Evening News article in your mind as well.

A. Yes.

Q. And that may be an article that we discussed when you were here in June.

A. It might be the famous "Killer Blood" article. I can't remember. No, that wasn't the Evening News. I can't recall which article.

Q. Right. Actually you went on to express your views of the meeting at the next SNBTS directors' meeting. If we look at [SGF0010137]. That's the SNBTS directors' meeting on 11 December. If we can just look to page 3, please. You told your colleagues that you had attended this meeting and you had found the outcome disappointing. In a nutshell, what was the essence of the disappointment?

A. I think -- again I'm -- I don't have a clear recollection but I'm fairly sure that it was a sense -- I took away a sense that there was an awful lot of discussion and perhaps relatively few useful decisions had been taken that would lead to us actually doing

anything. That may have just been my impatience but, you know, that was something of a recurring theme. I think I tended to get very frustrated if we didn't go away with a decision saying this is what we are actually going to do with one or two of the important issues.

Q. Right. I think there is also recorded in the minutes of this meeting a frustration at a possible lack of co-ordination. If we can just scroll down.

I suppose on a more positive note, there was at least the unanimous agreement to test all donors once an antibody test was available and a recognition that some of the problems were very difficult ones. Then Dr Cash was going to be making further representations in pursuit of a more effectively coordinated UK approach. There hadn't been a second meeting arranged, despite the instruction in the preliminary paper that everyone bring his or her diary. And then on to the next page, please.

That comment about no evidence of co-ordination of the many splinter groups which existed.

Right. Can we go back to the statement then, please?

I'm moving on to the turn of the year. We know about Dr Tedder's approach to DHSS for funding and we have also looked at some of the minutes authored by Dr Smithies. Around about this time you yourself were

writing to Mr Madden at Wellcome and we should just have a look at that letter. That's [SNB0059501].

Dr Cash, we can see, was off on sick leave and you were writing. Do you think that was something Dr Cash had asked you to do or were you doing it on your own initiative. It was very hard to remember.

A. I think this was a sort of expression of frustration that we weren't getting on with it. I don't think Dr Cash asked me to do this.

Q. You are really looking for a progress report, I think, in this letter, aren't you?

A. I was looking for a bit more than that, actually. I was really looking for a positive proposal from Wellcome to say, "We have got some development reagents which we are prepared to make available to you to at least initiate some form of selective testing". Whether it was a wise idea or not in retrospect, I don't know.

Wellcome didn't actually respond. I think they were up to their ears in trying to make the test. I can't remember whether I discussed this letter with any of the Wellcome people but I have no recollection and certainly no copies of a written reply from them to this.

Q. You are saying that you are not reassured by the information available.

A. Well, I wasn't, because, as you may have -- you may have

heard from Professor Weiss or Richard Tedder -- I have not seen their evidence -- but there was -- they were relying, I think, on the CAMR, the microbiological research institute at Porton, to produce the critical antigen reagent for this test and it wasn't going particularly well.

Neither Weiss's laboratory or Tedder's laboratory really were set up to do production on the scale required to produce useful quantities of test, and there was another issue which was a concern, that the test that they were developing required significant quantities of very high quality antibody, because it was a competition-type assay and I expect Richard Tedder will have taken you through that rather complicated territory --

Q. He has explained the concept of a competition assay to us and it's only 24 hours ago --

A. So it is fresh and crystal clear.

Q. -- so I think we can all still remember it.

A. So a critical reagent for that was antibody, which at this time, to my recollection, could only really be obtained from human patients with infection. I don't think we had managed to make monoclonal antibodies to HTLV-III at this time. So there were genuine grounds for concern that the -- and you know, on form, on

previous experience, these things always take longer to develop than people hope. So I was concerned that it could be quite some time before we had an assay.

And I think -- you probably will come on to this but I can't -- I cannot recall why I wrote this letter only to Wellcome and did not write to any of the other manufacturers, because, you know, in retrospect it might have been logical to do so. But I think that by this stage there were sort of rather discouraging noises coming from the United States about the performance of the -- well, it was Abbott who were the main manufacturers of an assay based on the Gallo reagents. But I don't remember if that is the reason why I didn't pursue this with the other manufacturers.

Q. Certainly, Dr McClelland, we will go on to look at that and some of the information that emerged about some of the very early Abbott tests, and even some of the later Abbott tests actually as well.

As far as the antibody is concerned, Professor Tedder did explain to us, that they were able -- if I followed him correctly -- to obtain antibody from certain particular patients, I think?

A. Dr Tedder had extremely good contacts with other clinicians in London who were specifically caring for patient groups with a high rate of HIV infection.

Q. I think there were two patients in particular who were very helpful and whose serum was enormously useful in this context.

Dr McClelland, just while we are talking about reagents that might have been available, we have seen in another context the term "the dev kit". Is this when a testing kit is evolving? At some stage it's possible to try out a dev kit, which is a sort of prototype, is it?

A. The term doesn't ring a bell with me but it sounds like a development version of either the kit or the reagents, but it doesn't ring a bell with me at all.

Q. If it was just a development version, that would be a commonplace occurrence, would it, that a development version of a test is made available by the maker for some trial?

A. Possibly to -- you know, to a research laboratory. It would depend very much on the questions that the manufacturer needed to have answered. I mean, I think in general, you know, a serious manufacturer of a test system, designed for, you know, large-scale production use, would actually be quite cautious about releasing an immature version of the test because, you know, these things can get a very bad name very quickly.

Q. Yes.

A. So they would be certainly very selective in any laboratory that they would release that to, but I honestly don't recall that term.

Q. Right. And, yes, you are suggesting limited screening. I think if we go on to the next page, we can see you actually are identifying a possible subgroup of donors and mentioning the urgency of the situation.

I suppose one downside of introducing screening on some limited basis, perhaps designating a particular group of male donors whose blood would be screened, would be the magnet problem, that then you have people who fall within those parameters turning up so that they can have an AIDS test?

A. Certainly. I mean, there are numerous downsides to what I was proposing here and I think, you know, my suggestion (a), that we would be prepared to use an immature test and (b), that we would do selective testing would not have been approved of by most of my colleagues.

There was, as you say, the magnet effect, which we were concerned about. There was the whole -- you know, there is an enormous presentational issue: how do you communicate with the public and with the donors that you are doing a selective -- you are singling out a particular population for testing.

Q. Yes.
A. There was certainly, you know -- to do this in one centre would open up all sorts of potential for criticism of everybody else, you know, why is one place doing it and another place isn't?

So there were lots of downsides, and also using a test that was less than fully mature and evaluated could lead to both, you know, as I said before, inappropriate reassurance, you know, if there proved to be false negatives, and all the problems, which I'm sure you have discussed exhaustively, about giving people misleading positive results. So it was quite a high risk strategy.

Q. Yes, a proposal on which reasonable people could disagree.
A. Yes, I think so.
Q. Yes. Right. Let's move back to the statement and to the end of January. If we go back to [PEN0171337] at 1341, we asked you, no doubt more in hope than expectation, about some of the discussions in London and you have told us that you don't know about such discussions.

On to the next page. You are not sure what was intended in DHSS at this time and what was a DHSS view and what was Dr Smithies' personal view, and you go on

to mention the evaluation, comparative evaluation. I would like to come back to that shortly.

At the moment I really want to talk about EAGA, which is quite a bit further forward, so if we just look briefly at the ensuing pages of the statement, please, question 9, about the draft submission. You say you didn't really know about that. You don't know what Scottish ministers were told. The proposed SHHD/DHSS meeting in Edinburgh; you don't remember being aware of it. This is on to 1344.

Then more questions about the DHSS memoranda. There are obviously a number of different references to the evaluation exercise. It's a little bit difficult to construct a coherent sequence of events because it certainly seems, from what we have looked at, as though early ideas about the London test, if we can call it that, centred around using it in the centres chosen in England, and then there seems to have been a sort of parallel train of thought about evaluating the American commercial kits, and then at some point the whole exercise is rolled into one. That seems like a reasonable summary of events, but quite what happened when and who suggested what is sometimes a little bit difficult to work out.

We did actually ask you, in question 11, about what

appeared to be slightly contrasting Department of Health documents. I think in particular the one we see dated 21 January, at 9143 -- I don't want to go to it because they are quoted in the question -- and the other one, 7101.

We thought that the responses at 9105 and 9143 were at odds and you went on to say that you didn't understand the question. We can see that if we turn over the page. I think that the point we were trying to make was that within the same government department, DHSS at the same time were circulating two ideas concerning the Middlesex Hospital, for shorthand, and its test, if you call it that, or a test developed there, would be a participant in a form of competition; and then the second idea: that it would, in some way, be the judge of the competition.

So I think that was the point that we were seeking to make: that these ideas are difficult to reconcile, at least if you pay attention to notions of conflict of interest. But we have looked at a number of other memos which show that subsequently the evaluation was decoupled and given to Dr Mortimer at the PHLS rather than to the Middlesex, which I think looked at retrospectively, and also obviously at the time, appears more appropriate. So I think that was the only point we

were trying to make.

A. Yes, I didn't really see an inconsistency. It seemed to me that there was a discussion going on about where the evaluation should take place, and one of the options for that evaluation, which was obviously considered and later rejected, was the Middlesex lab, for the reasons you have mentioned. The other was: what should be evaluated?

So I didn't really -- I didn't see the conflict here. I think the idea of the Middlesex lab doing the evaluation was probably floated quite early on and was really quite quickly rejected, apart from which they wouldn't have been able to do it. They didn't have the capacity to do an evaluation on the scale that should have been done.

Q. I think Professor Tedder's position, as he thinks about it now, is that he is relieved that they weren't asked to because of the pressure.

A. I think they would probably have had major problems. They weren't actually -- I would say that laboratory had huge experience and skill but not particularly in the field of the sort of evaluation that was required here. It's quite a specialised area.

Q. Right.

A. And I don't think they had the capacity to do it.

Q. I see. Can we move to the next page, please?

We have actually had some discussion also about the thinking on the part of Wellcome but I don't feel it's particularly useful to ask you to speculate about what they meant in a particular letter they sent. That quote that we can see on page 1347, about the American tests using a different technique, I think we now understand that the American tests were all solid phase assays, whereas the Wellcome test, the test developed by Tedder and Weiss, was a competition format test and, as I indicated, we have had a tutorial on the difference between those two ideas.

You go on to answer a question we posed about EAGA and I would like to look at the set of minutes of the first meeting. That's [SNB0010002], just to get a sense of the meeting. It's quite useful to look at this.

We can see quite a long list of members, both yourself and Dr Cash and then Dr Covell there from SHHD. Actually, if we scroll down to the bottom of the page, we can see that the two of you have been added in. Dr Abrams advised that the names of Dr Cash and Dr McClelland, not spelt correctly, should be included in the list of expert members.

Then page 2, we see some introductory remarks from the CMO, public health implications, I think mainly

concerning whether or not AIDS should be a notifiable disease and if we could jump, please, on to page 4, we can see a heading "The availability of the AIDS Screening Test". And Professor Weiss is presenting a report. Paragraph 20:

"General support for the introduction of a blood donor screening test as soon as practicable."

Then a point with which we are now familiar, the preference for the use of the RIA in the NBTS is made by Dr Gunson but Professor Zuckerman is obviously emphasising the need to think about ELISAs.

Then 22, discussion of what is in effect alternative testing facilities and then we see 23, a subgroup was set up comprising Dr Gunson, Dr Mortimer, Dr Pinching, Dr Rodin, Dr Tedder and yourself to consider various aspects of screening tests, and Dr Smithies is going to chair that.

Dr Covell also prepared a note of the meeting and that's [SGH0027296]. It's quite a full recital. Also present were the two of you and you have obviously -- I'm not sure if that's both of you -- made quite a lot of contribution to the meeting. But he says:

"The agenda was much too long for a morning meeting and many of the items were highly controversial. Some discussion had to be unnecessarily curtailed."

Do you remember your early impressions of EAGA?

A. It had a -- I think my main impression was that it had a huge span of responsibility, because it was looking at the whole of the AIDS problem, and I think Dr Cash and I both felt on occasions that the things that were really important to us in relation to transfusion perhaps didn't always get an adequate exploration.

It was -- you know, I think it -- overall it was quite a good group, it produced a lot of very sensible guidance, and in fact still does. It still functions and, as these advisory bodies go, I think it has actually had quite a good record.

Q. Right. I think if we just move through on to the next page, a discussion of notifiable diseases, surveillance and then, perhaps more importantly, on to the next page, [SGH00027296] at page 4, if we could just complete looking at that. Yes, there we are. The availability of the AIDS screening test.

It's always the case, Dr McClelland, that when there is more than one note of a meeting, you get different things from different versions.

A. Of course.

Q. I think particularly when one of the documents is the set of minutes and others are the notes made by individuals. So that comment at the end of the first

paragraph:

"It may turn out that overseas tests may be produced quicker and could be more reliable."

I should have asked Professor Weiss about this. I don't know whether he would remember whether he said it or not. Somebody seems to have said that. It looks as though it is being attributed too him.

Professor Zuckerman is talking about the progress in the United States. Some of the same material, obviously. The mention of the RIA test. Then Dr Abrams is recorded as having said that the department would be evaluating all the tests, and then mention of the subgroup.

THE CHAIRMAN: Just going back to the first paragraph, the last sentence, do you think that's a comment that Professor Weiss would have made at that time? Or is this more of the character of an editorial comment?

A. I think it's quite possible that Robin Weiss may have said that because his primary interest was not to become a developer or manufacturer of diagnostic tests. I think -- I may be misrepresenting him but my impression all those years ago was that -- he is a research scientist of a very high order. I don't think he was -- I think -- he was possibly quite nervous about getting lumbered with excessive involvement in

what he would have seen as essentially a routine diagnostic development. I may be misrepresenting him but I wouldn't be at all surprised if he was trying to take the heat off himself a little bit with that remark.

MS DUNLOP: I suppose a fair-minded person, aiming to be objective might easily record this.

A. Absolutely. He would have been aware that the amount of resource that had gone into developing these tests in the United States was many orders of magnitude more than we got in the UK.

Q. Yes, and of course this is in the end why there is to be an evaluation exercise?

A. Yes.

Q. To try to find out, as far as possible, the accuracy of the different kits. So whether this is just Dr Covell's observation or something said and by whom, I don't know that we will ever find out.

Moving on from that, can we go back then to the statement, please? [PEN0171337] at 1349.

I just wanted to ask a little bit more about the different subgroups or smaller groups, particularly those who were addressing screening and the evaluation. Can we look first at [DHF00019250], please? This just looks like an internal meeting within DHSS on 13 February and we can see section 2:

"Proposed evaluation of commercial kits."

It's agreed that a screening evaluation is necessary to inform the NHS about which products are worthy of consideration. Dr Mortimer by this point has expressed a willingness to undertake an evaluation on behalf of the DHSS and he is going to be submitting a draft protocol. That's in 2.3. A panel of sera is being put together by Dr Tedder and Dr Mortimer. And then perhaps not unreasonably, Dr Mortimer is looking for some more resources as well.

If we just look on to the second page. It's actually not very clear who is going to be on this group. This is Dr Mortimer, two consultant virologists, Dr Pritchard, and an observer from Scotland and Northern Ireland.

You were on the working party of the regional directors, you were on the EAGA subgroup --

A. Yes.

Q. -- were you on this group?

A. No.

Q. I didn't think so.

A. No, I wasn't.

Q. Right. That was 13 February. Can we look at [SNB0010170]? This is 15 February and this is the screening test subgroup.

So if there is an ad hoc expert group which is being put together by the DHSS -- and we have just seen that on 13 February -- what then is the role of the screening test subgroup of EAGA?

A. I think they had two completely different tasks. The first group that you referred, my understanding was it was specifically put together to design and possibly oversee the technical evaluation, that was all about comparing the actual performance of the different tests in the laboratory environment.

This group -- I'm sure there was a wee remit somewhere, but my recollection was that it was really trying to look at the broader group of issues for the transfusion service that had to be addressed in preparing to introduce large-scale screening testing of blood donors.

Q. Yes, actually --

A. This group did not look at the technical issues of the test. Obviously, it was interested in knowing about the level of false positives and false negatives but primarily, from the point of view of how that would require the tests to be managed in the working environment.

Q. Yes. In the meeting at the end of January, the subgroup is designated as being to consider the various aspects

of screening tests for AIDS, and then we see the subgroup terms of reference set out here at the first meeting:

"To advise the expert advisory group on the introduction of a test for antibody to AIDS-related virus."

Then there is a reference to the DHSS group. That's the ad hoc panel of experts, with DHSS officers and they are going to be agreeing a protocol, and as you say, that's a much more limited and technical remit.

A. Yes.

Q. Right. And then can we just look at the following page, please? You had done a paper for this meeting, describing USA kits and their results:

"The kits had not tested the same serum samples."

That has been mentioned earlier this week, Dr McClelland, and I think we understand that the reason for that was that the exercise in the United States had been used as a way of finding out information about prevalence, and of course if you use a collection of different sets of samples, you are going to get more information on that topic. But I suspect you would say the price for doing that is that the comparison between the different test kits is not as good as if they were all assessing the same samples?

A. Well, absolutely.
Q. Yes. And you didn't want to follow that track in the United Kingdom because you are saying it was essential to do repeat assessments on the same samples. You are obviously being given a bit of work to do. We can see that particularly in paragraph 10, you and Dr Gunson.

Then regional transfusion directors had been unanimous in wanting a common date for the introduction of a test into NBTS. Including also SNBTS? Was that the thinking at the time?
A. This is a recurring theme, that all these notes and discussions south of the border always refer to NBTS. I used to be very unpopular on EAGA for saying "and SNBTS", but it never made any difference. It implies the UK Blood Transfusion Services.
Q. And then familiar issues recurring. Then the next meeting is on 1 March. We will just look at that too. That's [SNB0010172]. You were there and again you have been doing some further thinking to contribute to this group. You and Dr Gunson have prepared a paper outlining a proposal for the evaluation of test kits in a field trial using 10,000 specimens. I think we understand, Dr McClelland that, the plan at this stage was to have a phase 1 assessment.
A. Correct.

Q. Yes, which was looking at a much smaller number of samples and I suppose a laboratory-based assessment rather than this description of a field assessment, so that phase 1 was being coordinated by Dr Mortimer and then phase 2 would be carried out by the Blood Transfusion Services. Is that right?

A. Yes, and that was a fairly conventional sequence of events because, as I said before, the questions that would arise -- the issues that arise in a sort of rather expertly staffed research laboratory might be quite different from those that occurred when you put it into sort of mass production.

Q. Yes. I want to scroll through this and go up on page 3, thank you.

We see that and then the next page. So some discussion of technicalities and then also wider considerations about how to deal with donors and people needing counselling, and then a mention of the letter to the Lancet, which is obviously very recent.

If we just complete paragraph 9:

"It was agreed that the letter, whilst in danger of being misinterpreted in that it might be regarded as recommending open access screening, did point to the concern felt about the early reports of the unreliability of commercial tests produced in the USA

and the need for their full evaluation before they were introduced into regional transfusion centres."

Practically everybody, Dr McClelland, has referred to the need for local evaluation of a test kit, and I think we understand it's quite a basic common sense point that information obtained from a group of American donors may not be directly capable of being extrapolated to a group of British donors?

A. Absolutely.

Q. Yes. Right. Can we go back to the statement, please? [PEN0171337] at 1349.

I should say, of course, that that subgroup continues to meet and, as part of its function, reports back to the main group --

A. Yes.

Q. -- on its discussions, and from time to time prepares formal written reports to go back to the main body.

Right. Still in January 1985. In paragraph 18 we referred to a letter from Dr Cash dated 24 January 1985. We have looked at that several times. We asked you firstly about this secret meeting and you say you have no knowledge of it. That's on the next page. Then we asked about various personnel and again you are not suggesting anyone particular who we should be approaching. You say possibly Dr Barbara.

But then a slightly different topic, also coming from the letter of 24 January 1985, that of a possible SNBTS evaluation of test kits. If we could just look at the narrative in this section, we quoted a passage from the letter. Could we look on to the next page, please?

We know that in a letter dated 25 January, Dr Cash was writing to Dr Ruthven Mitchell, asking him to proceed with an evaluation of commercial kits and then there is a decision at the SNBTS coordinating group on 19 February not to pursue that idea at the moment. You tell us you don't have much recollection of this particular episode.

Dr McClelland, you have told us before that you are very suspicious of being helped to remember?

A. Hm-mm.

Q. And I'm bearing that in mind, but can I ask you to look at what Dr Cash has said, please? Could we go to the transcript for Tuesday? I think it's page 83. I'll just let you have a look at this. You see, supposedly a question beginning "right"? Could we just let you read that little passage. (Pause)

We are actually quoting a extract from Professor Cash's statement.

A. That's line 16, is it?

Q. Yes.

A. Sorry, just for clarification, is that a quote from his recent statement or a contemporaneous quote?
Q. That is a quote from his recent statement. So that's a 2011 quote.
A. Right, thank you. (Pause)
THE CHAIRMAN: Can we go down a bit?
MS DUNLOP: Yes. I think there might be a "he" missing in line 9.

So Professor Cash is saying that the only necessary funding for his proposed evaluation exercise was overtime payments and that there was mention of that perhaps not being forthcoming, I think is the sense of this.

So, Dr McClelland, I'm trying not to help you to remember but having read that, do you remember this episode?
A. I honestly don't remember it at all. I have no recollection of this whatsoever.
Q. Right.
A. I mean, Professor Cash made one reference to having discussed this with Dr Mitchell and myself.
Q. Yes. That's why I'm asking you.
A. Yes, I realise that. I do not remember that. And I don't certainly remember being involved in any discussions with the department of -- the Scottish Home

and Health Department but then that's not surprising because Professor Cash frequently had discussions with SHHD officers that I was not involved in obviously.

Q. Right.

A. I do not recall the -- and I'm slightly surprised about this, but I don't recall any of the SNBTS discussions about the evaluation. You know, asked from cold, I would simply respond -- you know, my best crack at a recollection, if I can put it that way, would be that we accepted that this evaluation would be funded by the DHSS for the UK Transfusion Services and would be carried out by the PHLS, which I have to say seemed to me to be a perfectly reasonable position for the first part of the evaluation.

Clearly, the second, larger, as it were, in-service evaluation had to involve the transfusion services because that was the operating environment in which the test would have to be proven, and I think I would have expected that the West of Scotland BTS, Dr Mitchell's centre, would be sensibly considered a part of that programme because they had a very good track record in the evaluation of hepatitis tests over quite a number of years. They were good at it.

That's -- I have no recollection of this particular little spat that's referred to.

Q. Well, we still have an opportunity to ask Dr Mitchell about it and we will be doing that tomorrow, but thank you, Dr McClelland.

Can we go back to your statement then, please, [PEN0171337] at 1357. We set out some further narrative. This time we are talking about a different body. That is the working party of the regional transfusion directors, and you were a member of that as well. We know that there was a report produced in the summer of 1985 from that group. What was interesting about that report was that a first version of it suggested that screening couldn't be introduced until the evaluation exercise in toto was complete and that was changed by a corrigendum because of the pressure of time. So we were interested in any memories you had of that.

Certainly we say that the first stage, the phase 1, was completed by the end of July 1985 but the phase 2, which we saw a moment ago you had earlier envisaged as perhaps involving as many as 10,000 donors, was not completed before the screening was introduced in October 1985 but you tell us -- and this is on the next page -- that you do not actually remember discussions that might have led to this change of plan. And you have actually looked for documents as well, that

pertain to the issue.

You make two points, certainly the first of which is easy to follow, that time was really getting very short and, as you say, a point had been reached that screening just had to be introduced. But the second point is that second generation tests were already on the horizon. So I suppose it then becomes a question of how much effort one puts into evaluating first generation tests when the next edition are going to arrive shortly?

A. This is a problem that has recurred subsequently with Hepatitis C as well.

Q. It certainly occurs in the Hepatitis C story, yes.

A. And it is genuinely very difficult because when an important agent is identified, there is enormous pressure on all concerned to get on with it, including the development of tests, and inevitably there is a high risk that the first iteration of that development will not be -- well, the improvement will occur with the sequential development process and that's true of all of these tests.

So that -- I guess -- would have been quite a difficult decision but it could have been a huge waste of effort and possibly actually quite misleading to do 100,000 or 10,000 samples, rather, with the test which one knew already was about to be superseded by something

which was supposed to be better. That, I have to say, is speculation, I don't remember that argument being deployed.

Q. Yes. I think just so that we know it exists, can we look at the report of phase 1, [SNB0048847]? This is a long document and quite technical. Well, a lot of it is in fact tables of the performance of different kits. But we can see from the cover the listing of the kits which were examined, the personnel involved, then perhaps if we just look quickly, to give ourselves a flavour of it, I think it's about the first 12 or 13 pages which are narrative. Contents.

Actually, sorry, can we just look at the contents again. I don't want to take up time but there is quite a lengthy section and we can see it there, section 4, in which comments from manufacturers and evaluators are set out. So for those who want to read this at home, perhaps unsurprisingly those whose kits hadn't done so well in the evaluation had more points to make about the evaluation and then the points that had come from the manufacturers were responded to by the evaluators. So that's what's in that section, then various appendices. And actually at the back you also find the summary of findings, which is a document we have looked at before. But just perhaps if we could move on and have a brief

look at the text.

The introduction. This is the phase 1 report. We can see that the protocol was drafted by an ad hoc expert working group. Disappointingly, this report doesn't include the names of the members of that group. That's the document which remains redacted, which we looked at earlier.

Just if we can look at a little bit more of the text, the method is set out. Actually very technical, this paper. So I think we would recognise --

THE CHAIRMAN: I think there is a new expression there, isn't it: the fifth commercial assay was of the competitive type that the specimen, an anti HTLV-III et cetera was "conjugated" with an enzyme. I don't think that Professor Tedder introduced us to that notion, but I could be wrong.

MS DUNLOP: It's obviously a flexible notion, Latin verbs and specimens and antibodies. Anyway, conjugation. Obviously, we can understand that there is the solid phase group, and the fifth commercial assay is obviously the Wellcome one, the Wellcozyme. And there is another two, the Compria assay and the Gacria assay and it becomes steadily more technical.

Perhaps if we could look at another couple of pages to get the impression. I think Professor Cash was

taking issue with the numbers involved. We can see the numbers there: 220 successive blood donor sera, 83 from patients in high risk groups and 57 from individuals with conditions likely to give rise to false positive reactions, and so on.

We also actually have a draft report relating to phase 2, such as it was, but I'm not sure that we have been able to find the final version of that and we know, as we have just been saying, that that part of it wasn't complete before 14 October anyway.

Sir, this is a really a natural break because I'm going on to look at the detail of the introduction of screening in Scotland.

THE CHAIRMAN: Let's take advantage of it.

MS DUNLOP: I think it might be a good moment to stop.

Thank you.

(11.05 am)

(Short break)

(11.29 am)

MS DUNLOP: Thank you, sir.

Dr McClelland, just before we leave the topic of the phase 1/phase 2 evaluations, I think you did want to make a point about not just the numerical difference, you know, the difference between looking at, whatever it is, 300 and something samples in phase 1 and maybe

10,000 samples in phase 2, that there was a sort of qualitative difference in the two phases as well. Is that right?

A. Yes, it was really just a comment from a re-reading of that rather complex report that you referred us to earlier, actually, the number of -- as it turned out, the findings of that report appeared to me, looking back, to have been the basis on which two particular tests were selected, and looking at the actual -- the nature of that evaluation and particularly the number of blood donor samples that were included, actually a very, very small number on which to draw a conclusion about false positivity, particularly.

So I think it was just to make the point that the original concept of the evaluation, which would have move on to a 10,000 evaluation, that was correct. That would have given a much more robust estimate of the false positive rate. It still wouldn't have told us anything about false negatives but it would have told us about false positives, and I suspect, looking at again that report, there may actually have been two slightly conflicting objectives implied in the evaluation.

One was to look at the suitability of these tests for use in a hospital diagnostic context, and this may have been slightly confounded with the evaluation for

the use in the blood donor context.

Q. Yes.

A. I have to say that's a re-read of a document after many years and I don't know whether it's relevant or not. I think actually, experience proved that the decision to choose, certainly the Wellcome test, probably actually was the right one but the basis for it may have been less robust than perhaps I had recalled.

Q. Right. So essentially, as I think we were saying during the break, the differences between people evaluating a test for use in a diagnostic situation, where a patient is ill and there is a need to find out what's wrong with them, versus a very large chunk of the population, most of whom you assume are healthy and the test is needed to pick out the very few who are not suitable as blood donors, these are different exercises?

A. They are profoundly different and the second is subject to all the problems of any large-scale population screening programme, that you risk finding positive results which actually don't have any significance and you then risk doing things to the unfortunate individual based on those results, which may not be to their advantage.

Q. Thank you.

With those remarks in mind, let's look at the detail

of the introduction of screening in Scotland. Can we go back to the statement, [PEN0171337] at 1353, and actually you talk about a small in-house assessment of the two kits.

So we know that the kits which had been listed as at the end of July 1985 were the Wellcozyme one and, I think it's Vironostika, the Organon one.

Can we look firstly at [PEN0121950], which you mention, because it refers to this in-house assessment. This is a pretty detailed count down, Dr McClelland, and I suppose it represents an appreciation on the part of those, at least in your area, of the many practical steps that had to be accomplished before screening could be introduced, and I suppose you are preparing exactly the sort of document that you might have wanted to see at the end of the working party meeting in November 1984, something with a column headed "Action" and some people's initials. Let's have a look at that.

There is going to be a mini evaluation, looking at the Organon and Wellcome kits and so on, and I think, just to get a flavour of it, if we could look at the pages of it because we don't need to know the detail but just to see the volume of work that was anticipated, it's a six-page document dealing with such matters as space and staffing, equipment, and then on to further

arrangements: confidentiality of results, reporting procedures, national surveillance, pre-donation information to donors, a chart for the management of results and then finally on the last page, a next meeting is arranged. So that was 19 August and 30 September the group is going to meet again.

Can we go back to the statement. You mention the fact that testing began actually slightly before the agreed date of 14 October and the point of that, you explain at the bottom of that page, was that all blood in stock could be said to have been tested by October 14th, and you say:

"This latter target was achieved across SNBTS."

Can we just look at that reference, [SNB0058091]? This is actually Dr Cash reporting to Dr McIntyre. I think for these purposes the important part is (a). Is that right?

"All stocks of products held at RTCs were tested prior to 14 October 1985."

So it wasn't that on 14 October everyone arrived at work and said, "Today we start testing"?

A. No.

Q. No.

A. In fact, although it's not specified in Professor Cash's letter and I cannot find the relevant documentation,

1 although I know I have it somewhere, I'm pretty certain
2 we actually also tested -- we exchanged all stock held
3 in the hospital blood banks so that by the time of the
4 actual go date, 14 October, everything held, all the
5 stock held throughout the NHS in Scotland, was tested
6 and negative.
7 Q. Right.
8 A. Although I see John Cash did not actually specify it in
9 his letter, that is my recollection and I'm sure we have
10 documentation, if I could just find it again.
11 Q. I have the same problem.
12 If we could go back to the statement, please, at
13 1354, you say that you had prepared a paper entitled
14 "Introduction of Testing". If we can just look at that,
15 [SNB00059600]. This is a paper that you sent to
16 Dr Gunson and you copied it to Dr Cash and Dr Gillon.
17 As you say, you are just putting down on paper some
18 issues that have occurred to you, and they are the sort
19 of issues that we have heard others mention this week
20 already.
21 A. This, I'm sure, really was summarising points that had
22 come up in the various meetings of the subcommittee that
23 you referred to before the break.
24 Q. Yes. Yes, you personally were having a number of
25 different opportunities to discuss these issues in the

first part of 1985.

A. I think it does bring out the -- again, the point that actually, when you get down to the nuts and bolts of this, there is an awful lot of detail that has to be attended to and that can cause surprisingly big problems if it goes wrong.

Q. Yes. Let's just look to the end of this document, if I could, please.

THE CHAIRMAN: Can we just note its date?

MS DUNLOP: Yes, 15 May. In fact the day after the announcement of the results of the evaluation. You tell us this is in the statement but we will just go straight to the letter you mentioned, which is [SGH0026977]. The day following the announcement of the results, Dr Cash put pen to paper as well. I had thought that this was just a letter to Dr Whitrow in Inverness.

A. No.

Q. But you suggest in your statement that it was to all the directors?

A. I'm sure this was his marching order for all the directors.

Q. Right. It's a very detailed letter and it even says at the end, "Go back and read paragraph" so and so, "because these are the most important ones".

A. It's just very good briefing.

Q. Yes. So again, if we could perhaps just move through it and see the sorts of matters that are addressed. In the latter weeks of September your centre should be slowly introducing selected donor screening. You need to have made up your mind by the beginning of September about the kit you want to buy. Buy four months' worth of kits. Then quite interestingly, I suppose, in letter (d), that Dr Cash had had in mind that both the kits would be being used in Scotland. His plan was for Inverness, Aberdeen, Dundee and Edinburgh to use one of the kits and Glasgow to use the other and that, I suppose, would have given ready-made comparative data, but that's not what happened.

A. There was another very solid reason for making that recommendation, which was that having contracts with two separate suppliers meant if one of them had major problems, we were in a much better position to continue the testing programme. If we held even a week's or two weeks' stock of both types of kits, we could swap over to the other manufacturer and that was a principle that I personally believed quite strongly in. In the event it didn't happen but ...

Q. Yes. Then kit and equipment performance monitoring. Donor counselling. An action flowchart. You are going to be providing the final solution but I suppose,

consistent with the autonomy of regional directors, the document you are providing would be recommendations and then letters to donors and reference centres, you and Dr Cash were working on that.

Then onto the next page, please.

A. If I may just return to item 7 there, in fact -- on this issue there was no argument about the autonomy -- despite what John says in his letter, we all worked, as far as we possibly could, to the same flowchart and it went through -- because it was quite complicated, it went through a number of iterations over the years and those were introduced concurrently, I think, in all the centres.

Q. We can actually see that in England, Newcastle broke ranks and introduced screening ahead of other centres but there was never any problem with that in Scotland.

A. For HIV?

Q. Yes.

A. For HIV also?

Q. Yes, I think that happened.

A. I wasn't aware of that.

Q. HIV as well as with hepatitis.

A. Right.

Q. I'm sure we have a reference for that but I don't want to take up time.

Then just at the end of the letter there is that comment about going back and re-reading the most immediately important items.

Can we go back to the statement, please?

Another issue is addressed or returned to, which is the alternative testing facilities question. And you talk about Dr Brettle. You referred us to a grant proposal, which was submitted to SHHD by Dr Brettle, Gillon and yourself:

"For a study to evaluate a confidential self-referral clinic for AIDS testing."

We can look at that, [PEN0121956].

Dr McClelland, in the second line there is either a typo or the Board's AIDS group called itself "Lothian". I thought perhaps the second sentence should read that the proposal had been discussed by the CAMO of Lothian Health Board's AIDS group.

A. I think the health board, the Lothian Health Board -- well, it did have an AIDS working party or group or whatever. I can't now remember what its correct title was and I may have --

Q. There is maybe an "and" missing?

A. Actually there is an "and" missing. There is an "and" missing. That's what it is.

Q. So funding is sought for a six-month period to assess

the need for the service, and that's a sort of turn up and be tested facility?

A. Absolutely.

Q. So something you don't need to access through your GP or through a GUM clinic?

A. Correct.

Q. Yes.

A. Our concern was that a lot of individuals would be extremely reluctant to go to the GP. I mean, we had good reason for that concern, and equally other people, you know, might also be reluctant to go to what would then have been called the "VD clinic". It didn't have a fantastically good image amongst some people.

Q. Yes.

A. So we wanted to have this completely neutral. And we wanted to be able to actually publicise it, and I think in the grant proposal we did give some indication of how we wanted to disseminate information as widely as possible that this facility was available. The double purpose being first of all to draw people away from blood donor sessions to this facility, which could actually give them a much better service and that second one was an investigative reason, which was actually to try and understand -- to begin to get some data to understand the epidemiology of this infection in

Lothian.

Q. You, of course, say that you can only answer really for Edinburgh, Edinburgh and Southeast Scotland, and that's the context in which you are telling us about this.

The picture is completed for us by a letter from Dr Brettle. Can we look at [PEN0170682]. These alternative turn up and be tested facilities were provided at the City Hospital. Dr Brettle said that the clinic began operating, he thinks, in October 1985.

A. Dr Brettle has, as you, I'm sure, know, extremely extensive and detailed records and many publications about the work of that clinic. So I'm sure he could nail the precise date. My clear recollection was it was one of our absolute objectives that this should be operating and open for business before we started our donor testing.

Q. Yes. Just staying with that train of thought, Dr McClelland, there is some ex post facto evidence to show that the concerns were well founded and I wanted to look at two documents in that connection. The first is [PEN0121968]. This is a letter, of which you were a signatory and also Dr Brettle, and it is quite interesting. Sorry, we need to look at the date, if we can go to the top, thank you. 10 May 1986 in the Lancet.

Just looking at, I suppose, would you say the epidemiology of the attendances at the City Hospital clinic? At least according to the information that patients themselves provided, the largest number seemed to have been intravenous drug abusers. If we see in the second paragraph, 202 patients had attended by the end of March. The first 100 records reveal that 91 were self-referred. So obviously there was a need for somewhere where people could just go on their own initiative. IV drug abusers accounted for 46 patients, of whom 65 per cent had antibodies to HTLV-III.

If we look slightly further down, we can see in relation to sexuality, first of all -- well, 21 of those tested were sexual contacts of IV drug abusers and then 13 of those tested were homosexual or bisexual and only one of these was positive for HTLV-III antibody. The remaining 20 patients had a variety of reasons for attending the clinic:

"The importance of attempting to deflect high risk individuals from the transfusion service is emphasised by the finding that 14 of 96 clinic patients confirmed that they would have used the transfusion service for testing if no other facility had been available. Three of these were positive for HTLV-III antibody."

Then I think perhaps a companion document --

THE CHAIRMAN: Sorry, Ms Dunlop, that last sentence may be quite significant too, that five out of the seven people who were confirmed on routine screening were past or current intravenous drug users. So you had both sides of the coin represented.

MS DUNLOP: Yes. So there obviously was a decision from the very opening of this clinic to monitor the sorts of people who were arriving.

A. But that was part of the --

Q. Part of the grant application?

A. -- part of the proposal, yes.

Q. Yes. Then the other letter I wanted to look at is [SNB0132889]. It's a little further on. 31 July 1987.

Dr Cash is writing to Dr Macdonald, and it's simply the second paragraph. It is interesting to note that the overall HIV positive rate was 1 in 57,000 but that for new blood donors it was 1 in 28,000. I suppose one can draw the inference from this that the magnet problem, to use a shorthand, might still have been occurring?

A. Yes, sorry, what is the date of that?

Q. That's 1987.

A. Yes, I mean, the other factor, of course, is that -- and this applies to all comparisons of regularly attending -- repeat attending donors and new donors, is

that the donors who have attended before will have had all the positives screened out, and this is a contributory factor to the --

Q. Yes.

A. So I think it would be difficult to tell to what extent this was magnet effect and pre-screening.

Q. I see, right. Can we go back to the detail of what was happening in Scotland, please? So go back to the statement at 1355.

You did provide some thoughts about responsibility for arranging alternative testing but I think dealing with English material. Can we look, please, at [PEN0170567]? That's a letter from Dr Scott. We have looked at that already. That's 8 July 1985. It does seem to be quite clear, doesn't it, that he is saying health boards should consider what facilities should be made available for testing persons other than bona fide blood donors.

So it does look as though the same problem of a possible lack of clarity didn't happen in Scotland.

A. No, I actually hadn't seen this letter when I wrote my statement, but I couldn't lay hands -- I think it was quite clear in Scotland actually.

Q. Yes. To go back to the statement then, please. Can we go on to the next page, 1356?

We asked about short-term contracts, possibly entering into short-term contracts earlier in 1985, and you say you don't know if any suppliers would have been able to supply. It is not particularly easy at this remove to establish the supply position. You say you do not know what enquiries were made apart from your letter to Wellcome, and that's the letter from January that we have looked at already.

A. Hm-mm. I must apologise, there appears to be an extraneous and irrelevant paragraph following that. I have no idea how that got in there.

Q. Right. The support in [DHF0018019]. I wasn't completely sure what point you were making there.

A. Neither am I, I apologise.

Q. It's a letter dated 1 October 1985 and I wondered if the point you were making -- I shouldn't be suggesting to you what your point might be, but I wondered if you were just saying that, as late as 1 October, there was still a bit of hedging about what the date would be and that might reflect some supply problem or something.

THE CHAIRMAN: I suppose an alternative is that if there was a determination to roll out the programme right across the country, this might be an indication of when they were first able to do that.

A. I think that is probably the correct explanation, sir.

MS DUNLOP: Right. Thank you.

Then the reference centre point. We asked about when the centres were established and when they were able to start carrying out confirmatory testing, and you provided quite a lot of detail, Dr McClelland, about that. During August 1985 SNBTS made arrangements with virology departments in Glasgow and Edinburgh to undertake confirmatory testing. I don't think it's necessary for us to look at all these references but can we look at the first of them, please, [SNB0010344]?

This is Alison Smithies again, writing to Dr Cash on 3 July 1985. This is on the topic of standardisation of reference centres' results for anti HTLV-III tests, and a Professor Alan Glynn, director of the Central Public Health Laboratories, has agreed with the suggestion that the two Scottish reference centres should be included in the distribution of standard sera.

So what exactly is going on then? Just to make sure that everybody is testing against the same benchmark, is it?

A. Well, a reference laboratory needs to have a good supply of established sort of positive and negative controls and particularly the positives, covering the range of different types of positives which occur, because this is a quite heterogeneous population of antibodies in

these different infections, and this was simply a sensible arrangement being set up, so that there could be a common set of reference reagents available to all the reference labs.

Q. Then she records at the end gratitude for the enormous effort that I think Dr Gunson and yourself are putting into the discussions and the practical aspects of introducing a screening test.

It must have taken a lot of your time in 1985, Dr McClelland?

A. Yes, it was a busy time.

Q. Can we go back to the statement, please, at 1357? The ensuing references, just to go through them but not to them, [PEN0121969] is Dr Cash writing to Dr McIntyre:

"There is a problem in Edinburgh."

I think it's Professor Collee at Edinburgh had some difficulty but there are discussions, and by 6 August 1985 -- that is the second reference, [SNB0093415] -- the Edinburgh problem has been solved and there is a suggestion of a meeting on the topic of reference centres.

[PEN0121972] is you arranging that meeting and that's to happen on 27 August 1985. Morag Timbury from Glasgow, Professor Collee from Edinburgh, and yourself, obviously, Dr McIntyre, Dr Peutherer and Dr Follett.

The next 2, 1972 and 1973 are just respectively Morag Timbury and Dr Peutherer saying they are coming. [PEN0121974] is the minutes and perhaps we can look at that.

It's interesting that the very first item in the minutes is that:

"Dr McIntyre emphasised that no additional monies are going to area health boards for their testing work."

I suppose that's setting out the ground rules at the start, is it? As far as the process for confirmatory testing is concerned, there does appear to have been a decision -- this is looking at (d) -- to go it "alone", in inverted commas. So your little group is firming up on reference testing?

A. There is a little bit of background to this because there were -- and I don't know whether Professor Tedder may have mentioned this in his evidence, but there were quite strongly held opinions among some of the virologists as to whether the so-called Western Blot, which I won't bore you with the details of was --

Q. I think we did get a bit of that impression, yes.

A. We had actually done some work early on in that with Dr Peutherer -- this was in Professor Collee's department. So he was actually quite supportive but I'm not quite sure what the other problem with

Professor Collee was, I can't remember. But Dr Peutherer, who was the senior -- the reader in virology and a then young doctor called Peter Simmonds. Peter Simmonds basically developed the Western Blot assay and did a lot of very nice work on it very early on. So we actually had it and knew pretty much what it did. So we were quite clear that that was a preferred route for confirmatory testing, and it has proved to be quite good.

Q. Is it a solid phase assay or a competitive assay or something different?

A. It's a sort of a solid phase assay. Basically, you take the virus and sort of break it up into bits and then spread it out on a piece of paper and then you allow the patient's serum to react with that and what it gives you is a sort of spatial picture. With the enzyme assay, it's either yellow or it's not yellow. With the Western Blot -- and there are numerous variants of this type of test -- you actually see the different parts of the virus spread out in a series of blobs on a piece of paper and then, when the antibodies from the patient react with that, you can identify the pattern of reactivity. This really needs a picture to explain this.

But it's not a perfect test but under a skilled and

experienced hand and with proper controls, it gives a lot of additional information, which can usually allow a fairly confident decision to be made between a false positive -- as I said to you at the break, the sticky protein problem -- and a specific pattern of reactivity.

Q. Right.

A. It's still used after all these years. So it can't be that bad.

Q. I think it's only a one page-minute. Perhaps we should just check that --

THE CHAIRMAN: Ms Dunlop, I have a recollection that a Professor Collee was involved in some way in the problem of getting proper classification of a laboratory for testing all these things. Is that the problem or not?

A. That's probably correct actually. That does ring a bell.

MS DUNLOP: Yes, I think it's narrated in the correspondence. I didn't pay a lot of attention to it once I discovered it was solved.

THE CHAIRMAN: Which is fair enough. It's just because Dr McClelland had left it in the air as something he couldn't identify.

A. Thank you.

MS DUNLOP: Thank you.

Oh, yes, I'm sorry, there is a second page. Here we

are. And actually there is an intra-Scottish carve-up. So if we look at (a), Dr Peutherer is going to handle Southeast Scotland, so that's you, Edinburgh and Southeast Scotland, and East, that's Dundee, and the Northeast, so Aberdeen. And then Dr Follett is going to deal with Glasgow and Inverness. Is that right?

A. Yes.

Q. Yes. Can we go back to the statement, please? We are now at 1357. We just wanted to fill in information about which test was chosen for the West, and we know too that it was the Wellcome test.

Can we go on to the next page, please? I think we have actually covered this, about the whole radioimmunoassay point. Then this comment about revenue sparing being as important as saving. Do you actually understand the difference between revenue sparing and saving?

A. It was lost to me, I have to confess.

Q. Right. Then you say that you weren't aware of a preference for RIA within SNBTS. There was a preference in NBTS to use an HTLV-III antibody [test] that was very similar in operation to the BPL RIA for Hepatitis B. You explain and others have made the same point, that there was a substantial reason in terms of minimising the use of ionising radiation in the

laboratories to move to a form of assay that did not involve the use of radioactive isotopes. And I don't think we need to ask about that, Dr McClelland, because we have gone into that.

Then on to the next page, please, so on to 1360. I don't need to ask you, I think, about the letter in the Lancet because we have looked at that. Actually that particular reference is a draft of the letter which appeared in the Lancet in March and we have the reference for the March publication. Then Professor Bloom writing. We have looked at his letter to the DHSS and his letter to the BMJ and indeed we looked at some letters that Dr Cash sent to him immediately afterwards, I think it would be fair to say, protesting at the decision to lob the issue into the public arena.

Then paragraph 36. We are asking a little more about false positive results and you say that you had contacts with virologists working on HTLV-III tests including Professor Weiss and his team and Dr Richard Tedder, and members of SNBTS staff had attended meetings at which these matters were discussed. You are sure that both sensitivity and specificity of tests would have been discussed during these contacts.

Then you took us to John Crewdson's book for some

information about the extent of the problems of false positivity and I think we should look at that too. So can we look, please, at [PEN0170568] and go firstly to our page 22. We have dipped in and out of this book already, Dr McClelland, and it's interesting to see there that, as we know, Margaret Heckler's six-month deadline, the October 1984 deadline for the test, came and went and:

"... Abbott and the other licensees were still field-testing their ELISAs in cities where significant numbers of potential blood donors were presumed to be infected."

Just reading from the end of that first paragraph after the break:

"The computer printouts Abbott was sending the FDA showed that at least 60 per cent of blood samples scoring positive contained no AIDS virus antibodies at all."

There is a footnote reference there which actually is found on page 567 of the book. So if we go to page 31 in our text, it's (e):

"Abbott Laboratories' product licence application dated December 19th 1984. 7,758 blood samples from 'normal healthy donors'. 42 tested positive. Of these, 17 were true positives and 25 false positives."

Perhaps it becomes a bit more difficult now that we are more aware of the different meaning of the notion of "false positive", you know, whether the test has been repeated to eliminate some of the false positives and so on. But nonetheless, that's one of the references in the Crewdson book about some perceived problems with the Abbott test.

If we go back to the main text, to our page 23. There was obviously still quite a lot of political pressure in the United States. We can see mid-February arriving with no AIDS test in sight. Actually perhaps above that we should also note a comment, which we recognise as having been made in the United Kingdom as well, that only a small number of those with positive test results would go on to develop the disease itself. I think that sort of wishful thinking was really quite prevalent around this time.

Then we can see that in America the Red Cross was already negotiating a draft contract with Abbott, whom the FDA had pushed to the front of the line. But not everybody was enthusiastic about the Abbott test.

Then we can see that:

"On a Saturday afternoon in early March 1985, Margaret Heckler announced that the FDA at last had approved a blood antibody test for HTLV-III. Jack

Schuler, the Abbott executive, recalled being summoned to meet with Heckler early that morning and then watching from her anteroom sofa as the delegation from Electronucleonics, one of the other licensees, filed out of the secretary's office. Schuler's first thought was that both Abbott and Electronucleonics were being approved at the same time, which would have cost Abbott a substantial share of Red Cross business. Once the Electronucleonics team departed Heckler reassured Schuler that the FDA had decided to approve Abbott first. She had merely been explaining to Electronucleonics that the approvals were being issued in alphabetical order."

Then a little bit more financial information. If we read on to the next page, we see that:

"The first blood bank in the world to get the AIDS test was the Red Cross blood centre on Ohio Street in downtown Chicago. Accompanying each of the 2,000 test kits delivered that Saturday afternoon was a warning that false positive test results can be expected with a test kit of this nature."

Then:

"Abbott only had 60,000 ELISA kits on hand, not nearly enough to fill the nationwide demand. The AIDS test would be rationed among 14 cities."

Then if we go back to page 31 in our text, this time to (h), there is a breakdown of those figures and we can see how the tests were rationed. Philadelphia, Boston, Los Angeles, Detroit, Cleveland, Washington and Atlanta.

Then to go back, if we can, please, to 24 in our extracts. Looking at the middle of the paragraph in the middle of the screen, we can see:

"It wasn't until mid-April of 1985, after nearly 3 million AIDS tests had been distributed, that Margaret Heckler was able to report that the domestic backlog had been filled. As a result, she told researchers attending an international AIDS conference at the CDC:

'Our manufacturers will now be able to turn their attention to your needs, meeting the foreign demand for the test, which has been significant. That is a contribution to the international community we are very proud to make'."

Could we go next to page 33 in our extract, please? This is another of your references, Dr McClelland. It's page 219 in the book and it talks about the first four months of testing. So we can see there was still --

A. This actually illustrates very nicely your point about what one means by "positive".

Q. Yes.

A. Our practice for many years has been to try and make a clear distinction between what we would call an initial screen positive, which is something that turns yellow when you do the test, as it were, and confirmed positive, which is when you have done everything that you can to dissect out the false from the true. And as this paragraph illustrates, there are huge differences in the numbers.

Q. As is obvious, when you think about it for even just a moment or two, Dr McClelland, it is going to depend on what's the numerator and what's the denominator.

A. Of course.

Q. Professor Tedder was talking to us about the important detail being how many of your repeat reactives turn out to be confirmed positives.

A. Yes.

Q. Would you agree with that?

A. Oh, yes.

Q. Yes. It's not always clear because there are such widely varying rates described around this time, you know, people talking about false positive rates in single figures or very high, and I think everybody is perhaps using different language or different measurements.

A. Yes, it is, I think, a classic example of something that actually requires some form of -- or for me anyway, some

form of graphical preparation, because you can draw it as a sort of flowchart which shows the various -- starting with your number of screen positives up here, (indicates), which may be very big, and then winnowing out all the various different forms of false positives, to come down with a hard and confirmable number. That's really the clearest way to see what these figures mean.

Q. Yes.

THE CHAIRMAN: The paragraph beginning "The change" does illustrate it, doesn't it?

A. Yes.

MS DUNLOP: Yes.

THE CHAIRMAN: It relates the ultimate rate to the initial screening number only.

A. Yes.

THE CHAIRMAN: If one had related it to the total number tested, there would have been a completely different picture.

A. Absolutely. Because the other factor that's hugely important in interpreting this is the actual true prevalence of infection in the community, because if it's 1 in 10 million, then almost any positive result will in fact be a false positive.

MS DUNLOP: Yes.

THE CHAIRMAN: Just as a matter of probability, the chances

of striking the one --

A. Are immense, yes, exactly.

THE CHAIRMAN: Exactly. If you happen to get two, you would know you were in trouble.

MS DUNLOP: We could see the practical problems that were caused in the United States, looking at the Springfield Red Cross.

A. I mean, the practical problems in fact went way beyond what's referred to here because we, as I think any potential patient would have expected us to do, established a rule that, even if -- you know, once an initial positive screen test was detected, we had to take steps to ensure that that donor -- were that donor to reattend anywhere, their donation would not be transfused. And obviously, if you have a very large number of people in your donor panel who are giving these false positive results, you very quickly create an enormous backlog reservoir of people who have got a positive result who you cannot accept a donation from, or rather you cannot transfuse the donation or put it into your blood bank. But you cannot inform them of their test results until you are satisfied that it is a genuine positive, and we actually ended up having to setup quite elaborate additions to computer system to deliver those requirements. A major undertaking.

Q. Hm-mm. Let's read on to the next page, if we could, please.

This is about trying to persuade Abbott that there is a problem to be addressed. They formed an HTLV-III task force and the Red Cross in November 1985 arranged a competition, and indeed the book goes on to elaborate on the intellectual property problems and about the French application languishing in a cardboard file, I think, somewhere within the FDA system.

Can we move forward then, please, also to page 38 in our extract? This is page 228, another of your references, Dr McClelland. Picking up what we notice, that the Pasteur test had been found to be more accurate than the Gallo test, the Gallo version:

"In the blood centre of southeast Louisiana ... two thirds of the donors testing positive with the Gallo/Abbott ELISA weren't infected ... North Colorado ... Hayes, Kansas, where there was no AIDS ... the town doctor complains to the FDA that unless something were done about the false positives, there soon wouldn't be anyone left who was eligible to donate blood."

Then some instances of the effects of false positive tests. Then we see, if we go a little bit further down, that:

"The FDA official in charge of monitoring the

performance of the AIDS test was Tom Zuck."

Whom Professor Cash has mentioned, I think.

I think we should just read for ourselves that little passage from the foot of 228 on to 229. (Pause)

We can see the interactions between Abbott and the FDA, trying to solve the problem. If we go a little bit further down, just finish with that reference to the FDA wanting Abbott to fix its test.

Sorry, can we go back up to the top of the page, please? This is our page 39.

Then, Dr McClelland, you gave us some additional references from the Crewdson book. I think indeed dealing with false negativity as well. Can we look now at [PEN0171057] at page 10? Going to much later in the book. I should say, I'm not actually going to all your references about the problems with test kits because you have set them out for us and they are contained within this set of pages, but this one, 447, talks about problems in France and you have marked particular passages. You have marked these passages about Abbott in France.

That reference to comment by Jean-Pierre Allain that the specificity of the Abbott test during the first six months to a year was not very good. Can we go next then to page 11 in this extract, please, which is the next

page?

This is the reference to false negatives and you have marked that for us at the top of 448. Some interesting information about the cross-approvals, if you like, the approval of the Abbott test in France and the approval of the Pasteur test in the United States.

Actually we should note that there is a reference there to Abbott not having enough blood tests to supply the American market, much less France, and we will look at that reference, (c), in a moment.

Then can we go back one, to page 11, then on to 12. We will see the note, (c), about supplies:

"Abbott had planned to supply France and other European countries from a factory in Delkenheim Germany, which it intended to come on-line in May [1985]. Because of delays, Delkenheim didn't begin producing test kits until the fall of that year, which meant that any Abbott tests reaching France would have been flown from Abbott's Chicago headquarters, which was unable to make enough tests for the US market."

So I'm grateful to you, Dr McClelland, for drawing our attention, specifically to the book because it contains a lot of information, particularly from the United States.

If we go back to your statement, [PEN0171337] at

1661, there is this trio of problems, really, problems of false positivity, false negativity and supply, and you have mentioned all of these in that passage in your statement.

I think you are reminding us, Dr McClelland, that we cannot have any discussion about what could have been achieved in a vacuum. We have to take into account what was available, and certainly you can't evaluate kits you do not have and you can't introduce screening if you don't have a large number of kits.

Then just to conclude your statement, we asked you about rates of false positives and I think bearing in mind that the definition of what exactly one is measuring is important in a discussion of false positivity. You make some points that you have said a moment ago and also that others have said, about the dependence on the prevalence of infection in the population tested and the rates of true and false positive detection.

Then the reference on the next page, [SNB0048847], is the report of phase 1 that we looked at a little while ago. You say it was small numbers of samples, but it does show that:

"Among the tests evaluated, the Abbott test appeared much more likely to give positive or equivocal results

with patient samples that the evaluators judged likely to give problems with false positivity."

I think actually, if we were to delve back into that long document, we would see that Abbott protested at the heat treatment of the serum and they said that was one of the reasons why their test kit hadn't performed very well.

A. They did indeed, and I think that was a fair point. But the point about the patient sera was independent of heat treatment.

Q. Indeed.

A. It was very reactive with the sera, whether they were heat-treated or not heat-treated.

Q. Yes. Then we asked you about obtaining information from abroad and you say that you don't recall, I think, anything specific, but you say:

"It's likely that personnel from UK transfusion services would have been aware of issues through links with other European blood services."

The next question we asked was about the possibility of introducing testing without any public announcement. I suppose that would have been difficult, because you wanted to tell donors in general that this testing was occurring. It wasn't something that you wanted to do in secret.

A. Well, I mean, I think it's fairly clear that any attempt to introduce this testing in secret would have been a complete disaster. We would have been in the dock long before now if we had tried to do that.

Q. Yes.

A. And my -- this was discussed -- all these issues of what information should be given to donors attending about testing, was discussed very fully and the conclusion, thank goodness, was always the same, that we had to be completely upfront and open about it, and I'm extremely glad that that's what we did.

Q. Yes. You say that donors must know in advance that they would be tested. This is on to the next page, 1363:

"Donors should not be informed of a positive test result unless it was beyond reasonable doubt that the result was a true positive rather than a false positive."

THE CHAIRMAN: Ms Dunlop, can I have some estimate of where you're thinking of going because I will have to make alternative arrangements with the university.

MS DUNLOP: We are actually at the end, sir. This is the penultimate page of the statement. I'm hoping to be finished within the next five minutes or so. If that's in order.

THE CHAIRMAN: Well, it's inevitable, whether it's in order

or not.

MS DUNLOP: I think, Dr McClelland, as far as the second part of the question is concerned, where we postulated the deferring of the giving of positive test results until the results had been confirmed, that is in fact what happened.

A. Yes.

Q. Then in the final question, we asked you about the 8 January 1985 letter, and we have already covered that.

Could we go on to the final page?

I think we had some discussion earlier about the possibility of defining a subset, males, say, between the age of 18 and 30, and you said there were a number of downsides to that and you accepted reasonable people might differ on whether that was a sensible strategy.

Then, finally, we asked about using tests as an interim measure and you say that you think it's most likely that consideration would have been given to using any test that was believed to be available and would perform reasonably well.

Thank you very much, Dr McClelland.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: I did have one matter I wanted to ask about, sir, in relation to false positives.

What it was, Dr McClelland, was that the issue of false positives is obviously important in the decision-making at the time, throughout 1985, but it does appear that SNBTS introduced a system in order to deal with that problem.

A. Hm-mm.

Q. It's referred to in various documents. Just taking the matter shortly, it does appear that SNBTS managed that; in other words, there was, obviously, always going to be a danger of a false positive but there was a system in place for dealing with that problem.

A. Yes.

Q. So as to reduce unnecessarily frightening a donor into thinking that they had an infection which they didn't have. I just wondered, having got that system, robust system, in place, whether the danger of false positives was not a bit overblown; in other words, the problem about the false positives could be dealt with by having a robust system in place. Do you follow me?

A. I follow you exactly. I think there are two points. One is there is the sort of time sequence of this because the system for dealing with false positives was evolved during and after actually the last few months around the introduction of testing. So we didn't have that solution already in the can, as it were, when we

started to consider the use of testing.

The second point is that the way we managed false positives worked reasonably well. With both HIV and Hepatitis C it still caused a lot of problems because, as I explained earlier on, depending on how quickly one could establish a true test result, ie get a confirmatory test, and how quickly one could then re-establish contact with the donor and so on, you build up a large backlog of people who are in this limbo position where they have a test result in the system but you cannot accept them, and you run the risk -- and this happened quite considerably -- of regular donors attending on several occasions and donating blood which could not be transfused.

That has two consequences. One, it provides a very substantial complication in the orderly flow of the whole testing process. It requires quite complicated IT and quarantine procedures to deal with it, all of which increase the potential for something going wrong. The second consequence is that actually you are forced into a situation where you are accepting blood donations from an individual under false pretences because you know you are not going to transfuse them, and that really raises quite a lot of ethical issues.

So I believe that we were probably quite correct to

be alarmed about the implications of a high rate of false positives. It was difficult enough to manage with the systems that we put in place, even when the rate was really very low.

I could take a lot longer answering that question but I'm aware that there are time constraints.

THE CHAIRMAN: We have got to get your answer, Dr McClelland, whatever the implications are. So if there is anything you want to add, you had better do that.

A. I think that probably gives you the flavour.

MR DI ROLLO: I'm grateful for that. I have no further questions, sir.

MR ANDERSON: And I have no questions, sir.

THE CHAIRMAN: Mr Johnston?

MR JOHNSTON: I have just one short point, if I may, sir.

Questions by MR JOHNSTON

MR JOHNSTON: Dr McClelland, you mention in your statement a minute of a meeting on 27 August 1985, at which Dr McIntyre, as the very first point, emphasised that no additional monies would be available to area health boards for their testing. I would just like you to look at one document to complete the picture. Perhaps you could tell us if you have seen it. It's [SGH0027029]. You will see there it is a memo from a Mr Henderson --

we see his name at the bottom -- dated 2 September 1985, and it's addressed to Dr Forrester and copied to a number of other persons. I should give you the heading first:

"New developments in health care reference testing for AIDS in Glasgow."

And we see:

"On the basis of the information provided and in light of earlier discussion, I agree that the sum of 11,000 or so should be made available to Greater Glasgow Health Board for back-up tests."

And so on. I just wonder if you were aware of that when you wrote your statement?

A. I didn't draw any particular significance from that first line. I think that was actually the department's own note and I merely enclosed it as a reference because it was the only document I have got describing that meeting. I certainly would wish to correct any impression, if I gave it, that I thought the department had delayed or inhibited the confirmatory testing for financial reasons. That certainly was not my implication and that would appear to confirm it.

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

THE CHAIRMAN: Ms Dunlop?

MS DUNLOP: No, I have no further questions, thank you, sir.

THE CHAIRMAN: Dr McClelland, thank you very much.

Dr McClelland will be coming back in the next --

MS DUNLOP: Yes, I fear so, possibly just once more, though.

THE CHAIRMAN: Let's wait and see, Dr McClelland, whether it's once or more than once.

Thank you.

(12.50 pm)

(The Inquiry adjourned until 9.30 am the following day)

I N D E X