Thursday, 24 November 2011

(9.30 am)

DR BRIAN MCCLELLAND (continued)

Questions by MS DUNLOP (continued)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you, sir.

Dr McClelland, we were looking yesterday at your statement and we should go back to it. Can we have it up on the screen, please? It's [PEN0172491]. I think we were looking at the next page. Probably we should complete that page that's on the screen, just by noting that we did ask you about the composition of the two different committees and you said you thought there was no -- probably no documented process:

"Individuals would have generally been invited to join the ACTTD by Dr Gunson. They would, in the main, have been people known to him and believed to have knowledge relevant to the remit and probably also NBTS personnel with responsibility for microbiological testing of donors."

Then on to the next page, you don't know how the DHSS would have selected membership of the ACVSB, but you assumed that, again, people approached would have been those known to the department to have relevant expertise.

One of the things that is noticeable about the two bodies is that the TTDs committee has almost parity in terms of members from Scotland and members from England --

A. Yes.

Q. -- whereas VSB maybe has two members from Scotland and an observer from SHHD and so on. But I suspect that the latter format was conventional with government-organised bodies. Would that be right?

A. Yes, it certainly was entirely consistent with the remit of the ACVSB which was, explicitly, to cover all the territories, as they refer to them. So it had to have either observers or participants from the other territorial health departments.

Q. Yes. I suppose then -- what is different about the TTDs committee, that enables it to have almost parity in terms of the numbers of members from Scotland and the number from England?

A. I think that was typical of a number of sort of working groups and things that were set up over many years by the transfusion services, where, while there were always political borders, the people charged with putting together a group to deal with the problem tended to look at where they could find the best input rather than look at it on a geographical basis or a political basis. Who

knows about that and can make a useful contribution to getting a good product from the working group or committee.

Q. Right.

A. Sorry, just to add, there was a period when there were -- there was a disproportionate sort of amount of kind of research and development work in various fields in Scotland. There was proportionately a lot -- in relation to the population and the size of the country, there was a lot more going on in Scotland than there was in the National Blood Transfusion Service over some of this period.

Q. Right. Now, you weren't a member of either committee?

A. No.

Q. But you were there at the time. You will have been aware of developments and of the issue being debated in both fora. You have also looked back at the period in connection with the preparation of this statement. You were a member of EAGA, which was obviously a different kind of body because it was disease-specific; it was the Expert Advisory Group on AIDS.

We did ask you to reflect on whether, given those factors, you thought there were any useful or interesting comparisons to be made between this process and the way in which EAGA operated, perhaps particularly

in the whole area of screening because EAGA took an interest in the introduction of screening of donated blood for HIV. Do you think there is anything that can be drawn from a comparison between the two processes?

A. I think there are some quite striking differences. It's important, I think, to preface anything by saying that EAGA was a very, very different animal. It was a much bigger group. It was a much more multi-speciality, multi-interest group. It was operated at quite a high level. It was chaired by the chief medical officer and it was -- the broad issue that it was looking at, which was AIDS and everything to do with AIDS, was seen as a very large public health priority matter. Post-transfusion hepatitis wasn't; it was a niche problem, if you like -- I'm sure in the view of the sort of senior policy people in the Department of Health, transfusion and transfusion related infection would have been seen as a fairly small issue across the total horizon of things they had to worry about. I think that was probably entirely appropriate.

Q. Thank you. Just to change the subject slightly and to look more specifically at some of the meetings. We posed a question in our paragraph 5 about the two May meetings, the TTD's meeting was on 19 May 1989 and the VSB met on 22 May 1989. We were really trying to focus,

in this question, on some of what was said at the latter meeting and you were wondering if that was indeed the meeting at the minutes of which you should be looking. So we have confirmed that to you and I wonder if we could have the minutes then, please? That's [SNB0019416].

That's the VSB meeting, we can see, of 22 May 1989. Can we go into it, please, to the discussion about non-A non-B Hepatitis, if we go on to the next page. Here we are, "Overview of hepatitis". "Hepatitis B" and then on to the following page, please. There we are. It's really that section there, 16 to 21. We asked about the source of the figure of 50 per cent that we see in paragraph 17. This is May 1989 and what's being said is that:

"The Chiron test was estimated to pick up approximately 50 per cent only."

And there was a need for caution. Then the other point we asked was: what further data from Chiron appears to be being anticipated? I think you have had another look at these minutes within the past few days, Dr McClelland; is that right?

A. Yes, I have.

Q. Are you able to add to your written answer on this particular meeting? Perhaps you should start with the

50 per cent sensitivity figure?

A. I think that's the sort of critical point really. I thought about this quite a bit. Obviously, I wasn't at the meeting, as you will have already been told, the members of this were for some reason sworn to secrecy, which, in itself, is quite interesting. But I have no idea whatsoever where that figure came from.

It's interesting that it's minuted in an exceptionally anonymous fashion. It doesn't even attribute it to one member. It says, "Members agreed that ..." Some member of the committee must have reported that figure to it because the secretariat will not have invented it. But the only more or less contemporaneous data that I could think of that might have been being quoted was the original paper, the second of the two papers published in Science. But, in fact, the numbers in that, if I recall, suggest a nearer to 70 or 80 per cent detection, admittedly in a very small number of samples. I'm not aware of any data that, even with the mark 1 test, Chiron -- the antibody test that was as bad as 50 per cent detection.

Q. Let's have a look at the article that you are referring to. Can we keep those minutes open, please, but look at [PEN0172764]? This is the publication from April 1989, so would have been contemporaneous, in broad terms, with

this meeting and I think this is the one you are referring to?

A. Yes. That's ...

Q. Yes.

A. It's quite a difficult issue to be confident about, you know. It would have been and, in a sense, it still is difficult to be confident about any estimate of the sensitivity of the assay at a time when it was completely new, when there was no reliable, as it were, independently certified set of known positives.

Q. Indeed.

A. So what the authors here were having to do was to work from the standpoint of: think non-A non-B Hepatitis, see what proportion of those come up positive in the test. What they, very sensibly, did in this abstract is to differentiate between those with chronic disease, where -- which would have been judged, I think, more likely to have been associated with some chronic viral infection, and in that group they estimate 80 per cent.

I think those samples -- yes, Italy and Japan turned out to be quite high prevalence HCV countries, whereas, as the Inquiry has already heard from numerous sources, non-A non-B Hepatitis was a rag bag of multiple causes and you would not expect anything like 100 per cent of patients with that sort of rag bag diagnosis to be

positive with this test.

So it could be that it's this 58 per cent of patients that has been sort of truncated to about 50 per cent in this minute, but if that's the case, it's a very -- it's either not a very intelligent or it's a rather manipulative interpretation of the data.

Q. In fact, the sentence before the sentence referring to Italy and Japan is interesting too, is it not, that they looked at ten blood transfusions that resulted in chronic NANBH and found at least one positive blood donor in nine of the cases and all ten recipients seroconverted during their illnesses?

A. You are absolutely right. I should have added that -- the other criterion which, even before we had Hepatitis C, we used to take very seriously and we used to use for excluding donors was: has blood from this donor been involved in a previous case of non-A -- so transmission of something to the recipient was a very important criterion. You are absolutely correct, this was again a suggestion that meant nine out of ten donors and ten out of ten recipients were positive -- who actually got hepatitis and were positive for the test.

So I remember when I read this first, I thought that looks like the business, that looks pretty good. In fact, for a newly developed and completely novel

approach, it looked spectacularly successful, you know, amazingly successful.

Q. Of course, this is Chiron's own RIA, as it were. This is not the Ortho test. So we have to bear in mind that caveat.

A. The general caveat that I would apply to that would be that any new technique, in the hands of the laboratory who has developed it and who will know all its little sort of ins and out and technical foibles, will almost always produce better results, initially. The translation of a new, as it were, laboratory-derived technique into something that will work reliably in the hands of hundreds of different technologists and labs over the world is a big step. That's development. So the fact that the first production assays may not have worked as well as this is not surprising at all.

Q. Right. So I suppose, just going back to the minutes, if we could, please, there are a number of unknowns and we certainly can't know them now, but looking at these minutes from May 1989, one could, at least, say that there was information around that suggested a better sensitivity than 50 per cent in relation to the Chiron test?

A. I can only sort of repeat that my response to that would be based on the reading of that paper. To me this looks

like an exceptionally negative read of that information.

Q. Right.

A. I would have expected this to be presented saying, you know, while some caution may be needed, this is clearly a major forward step in the detection of a very important condition.

Q. Right. The other aspect we asked about, namely the desire to see further information from Chiron, perhaps particularly the end of that paragraph 17:

"Once the sequence was published it would be possible to test without recourse to Chiron."

Then 21:

"The use of Chiron or surrogate testing would be influenced by Chiron data once released."

What do you think is in the minds of people making those comments?

A. Well, first of all, the last sentence of paragraph 17. It's a bit cryptic, but to me that implies that somebody says, oh, well, once we have got the sequence we can do it ourselves. Chiron is a little smarter than that because they patented it very effectively. But that's how I would read that. I cannot remember the membership of this committee but it probably included people like Richard Tedder, who is absolutely intuitive, ingrained reaction to be to say we can do better than that, but

they needed the sequence because they didn't have it because Chiron were the only people who had sort of reverse engineered the RIA.

Q. Could we just go back to the first page of these minutes, please, before we leave them? There we are. We can see who was present. And indeed there is Dr Tedder. Can we go back to Dr McClelland's statement, please?

A. Just if it's appropriate, I don't think -- I think I got myself slightly sidetracked in responding to your question about EAGA and the ACTTD, the other two committees. You asked me were there lessons to be learned about how they functioned and I think I answered a rather different question. Just very briefly, I think I would say the thing that characterised EAGA was that it was -- it was actually -- and I think remains, from fairly recent experience of it -- a very well chaired and disciplined committee that behaved in a -- it coped with a very large number, a very diverse range of topics many of which were highly contentious. My recollection is it coped with them generally in a fairly systematic and transparent sort of way and tended to produce results, in terms of practice recommendations and so on that were well accepted in the professional community.

The other important difference, which probably

reflects -- is probably reflected in the way the committee actually functioned was that it was very multidisciplinary and therefore a problem would be looked at rigorously from probably more different angles than would have been the case in these transfusion virology committees, which actually tended to be quite a sort of, comparatively speaking, a narrow specialist view of things.

I think those are -- in answer to the question that you asked, those are probably the two points that I should make.

Q. Right. Certainly EAGA in the period we have looked at before from time to time had subgroups as well.

A. Yes.

Q. So, I suppose members who maybe had a particular speciality, particular focus, could go off in groups of four or five and discuss a specific issue. Is that the way it functioned?

A. I was certainly a member of one of the subgroups, there were two related to testing and the evaluation of tests, which the Inquiry has already heard about. I think perhaps the important thing -- I mean, lots of committees spawn subgroups, but I think when the subgroups came back with -- while they were preparing their recommendations and when they came back for

consideration by the main committee, they would get a -- they would be scrutinised and -- from a much wider range of view points.

Q. So not so secretive?

A. It was certainly less secretive.

Q. Right.

A. I don't remember ever being instructed or nudged to -- that there was a confidentiality element to the proceedings of EAGA. That may be a misrecollection.

Q. I won't take up time. We can look back at some of the minutes and probably they may say "In confidence", or something like that. But your recollection of the atmosphere is that it wasn't obsessively confidential?

A. Most definitely not. Perhaps just to -- one specific example would help. One of the regularly attending and very contributive members was -- I think he was a medical doctor who was a senior member of the board of what was then the Terrence Higgins Foundation, which was, then, the gay men's organisation, set up to deal with the broad range of issues of AIDS. I think his name was Dr Nicholas Partridge, we can check it in the minutes but I'm absolutely certain that he reported the committee's proceedings regularly to his -- you know, his board of the Terrence Higgins Trust.

I think the committee almost certainly would have

identified certain issues as being confidential at the point of discussion, simply because some of them were highly contentious and sort of premature -- a premature release of a conclusion that might turn out not to be the final conclusion on a particular issue could have caused an awful lot of extra hassle and trouble and press releases and everything for people. But I think that it was a more -- it was a very pragmatic approach to confidentiality and selective. I apologise for returning to the issue, but I thought that was important.

Q. No, I certainly wanted you to complete your answer. So I'm sorry if I cut you short. It wasn't deliberate.

Can we move back to the statement, please? We were on page 2493. We then moved on to ask you about the first Scottish evaluation of the new tests. That's paragraph 6. Can we move on to the next page, please? We asked about the two evaluations that began in 1989. There is an English one and a Scottish one and we asked if they were similar and you said you thought that the Scottish one reported in [SNB0061596] was broadly similar in design to that first reported in [SNB0019545], and certainly they do appear to have had a common objective, which is looking at prevalence in donors. But we have looked at the Scottish report and

we see there were another eight objectives as well, so it was quite an ambitious study. It was looking at all sorts of different questions.

We asked what the particular function was of the studies. You said you had little or no involvement in the design or conduct of the SNBTS study, but it would have been consistent to perform initial assessments such as these and to follow them, if possible, with a larger scale assessment on which could be based a decision about the suitability of a test for routine testing of large numbers of donor samples.

In fact, the number of donors looked at in the Scottish assessment was 2,745. So, in the scale on which you work, doctor, that's not a particularly large exercise. Is that right?

A. I think for a test -- you only know the answer to is that -- to the adequacy of the size of a study like this once you see some of the data, because it depends very much on the frequency of the events that you are looking at. So 2,400 would have detected -- you know, if we look at the 1991 prevalence figures, it would have detected 2 to 3 or probably 0 to 6 positives in the donors. So actually it was quite small.

Q. Right.

A. In terms of its statistical power, it was very small but

actually at the time it was quite a big study and it was quite difficult to get hold of the test kits, as I recall. If we had to pay for them, we probably had to pay a lot for them.

But this was a period when everybody and his wife was wanting to evaluate these kits because it was a really new thing and it was important.

Q. Yes. We had been a little bit confused about that exercise and then the reference to samples of special interest. This is question 7 and you explained -- and I think we can now see this from other contemporaneous documents actually -- that the samples of special interest were looked at within the context of this study as well.

A. Yes.

Q. These -- I mean, in broad terms, these were thought to be samples from people who had NANBH, possible related donors and so on. Is that right?

A. Yes, absolutely. Every laboratory interested in this sort of test will have a freezer full of samples, accumulated over years, which they will draw on to look at the performance of any new procedure. It will include, as you suggest -- in this case would have included samples from patients thought to have post-transfusion hepatitis that was negative for all the

other tests.

It might also -- I can't remember if it was the case here or not but might also include samples of a type known from experience to be -- give particular problems with false positive results in certain types of tests. So, for example, patients with some types of immunological disorders have proteins in their blood which can interfere with or produce false positive results, much more frequently than do blood samples from healthy individuals.

Q. I see.

A. So a wise lab will shove in samples of that type as well into any initial assessment.

Q. Then can we move on through the succeeding questions. We asked quite a specific question about the VSB meeting on 3 July. You said you have no personal knowledge on which to base a reply to these questions and you repeat a view that you say you have already expressed: that the scale of non-A non-B post-transfusion hepatitis in the UK was still being underestimated at that time. I think you are really referring to the statement and now the evidence that you have provided on our C2 topic. Is that right?

A. Yes.

Q. More questions about matters that don't directly involve

you, Dr McClelland. You say that you think that, in early August 1989, there may still have been some uncertainty about the introduction of the HCV test for blood donations in the UK.

The next comment you make is that you can't speak for Dr Cash, but you are fairly certain that in August 1989 you -- and that is the SNBTS directors, I guess -- would have expected to start HCV testing earlier; in other words, less than two years.

A. My recollection of around about that period is that, as I have already said actually, once we saw the second Science paper, I think the view -- certainly my view and the view of the people with more expertise, technical expertise in testing for these things -- was that this was going to be, if not the answer, a large component of the answer to our problem with non-A non-B Hepatitis. So I think we really expected to go full steam ahead to implement.

Q. If someone had told you it would take slightly more than two years, you would have been surprised?

A. I probably would have.

Q. Yes. Right. Can we move on to the next page, please, the questions there for Dr Mitchell and then a question that we are going to put -- on the next page -- to Mr Tucker. You have given us an answer, insofar as you

can about relationships, working relationships between SHHD and DHSS. You mention a recollection of a letter in relation to surrogate testing, in which Dr McIntyre had made it explicit that SNBTS would toe the UK departmental line.

You were under the impression that the UK health departments expected the HCV test to be introduced at the same time across the UK and it was generally accepted among the Scottish directors. You think you would have mainly gained that impression from Dr Cash.

You say you don't remember questioning the basis of this assumption, although you were quite clear that you had a professional responsibility to push hard for early implementation of measures that you believed were important for patient safety. I think that perhaps bites a little later in the story. We will come to that at the appropriate time.

Can we look at the next page, please? This is starting to look at the matter of confirmatory testing and I think perhaps we will come back to that because you do mention it again later. I suspect we are not entirely clear about the terminology in this area, but I'll come back to that shortly. Perhaps we can just note what you say at this point about increasing confidence in a given antibody screening test by

comparing the results with those obtained with a different screening test performed on the same sample.

A. The short answer to your question is, yes, that is correct.

Q. Yes. Then the use of a second screening test is certainly better than not using any form of confirmatory testing. There is then mention of the Rome symposium. Dr Mitchell attended that and I'm going to ask him about it. Then on to the following page. You give us some information about the reaction in Scotland to Mr Justice Burton's decision in A v The National Blood Authority.

A. I apologise, that's really totally irrelevant to the question that you asked me.

Q. It is interesting, though, Dr McClelland.

A. Yes.

Q. We note that you were at a consultation with counsel and that it was discussed.

Then question 16. Just to have a quick look at these minutes, this is the SNBTS directors meeting on 29 September 1989. We were slightly confused about what exercise was being discussed here. Could we look, please, at [SNB00024517]? This is a directors meeting, 29 September 1989. You, in fact, sent your apologies. Can we look at page 2, please? Just noting this en

passant, Dr McClelland, the whole question of the extent to which deliberations at the VSB committee could be revealed to others was on the agenda. We can see there is a work in progress on that point, and I'm going to come back to this with Professor Cash because he has taken up this point of the confidentiality in his response to us as well. So we can see that it was certainly an issue that was occupying people, whether Dr Perry and Dr Mitchell could disclose to the directors, SNBTS directors, what had been discussed at the meeting, discussed or decided.

Can we go to page 3, please? I think what puzzled us, Dr McClelland -- and it's probably neither possible to get to the bottom of it, nor important, but this reference that we see in paragraph (e) and then (ii):

"Scotland had not been invited to participate in the UK evaluation group, but the SHHD had asked that they should, so west and southeast obtained kits for evaluation."

Now, you have said in your answer, Dr McClelland that the study, which we looked at with Dr Dow and with which we are now glancingly familiar, did include some samples from Edinburgh and they were some of the special interest samples, in fact. But this seems to be something different; this seems to be, well, you,

southeast, evaluating kits. But you don't have any memory of what this is about?

A. No, I don't. I should perhaps, just by way of explanation for my particular lack of memory about these things -- I should -- by this point in my sort of evolution, I was actually focused very much on another area. I had actually moved, you know, away, as it were, from the laboratory testing aspect, which had interested me a lot when HIV came along. I was very much involved in that and I have a much better recollection of what happened.

I had actually, with encouragement from Professor Cash, a little bit before 1989, started to focus on the patient end of the transfusion cycle and really started to explore what we could do, in terms of improving the quality and safety and security of the prescribing and administration of blood. I was spending most of my time working on that area, which has not, I think, really been much considered by the committee. But, if you like, the focus that we have had up until now is all on the safety of the product. What I was trying to look at from about the late 1980s on was the safety of the patient, which is actually a very different focus.

I do recall feeling that it was -- there was plenty

of fire power being directed at the Hepatitis C issue, so I probably didn't pay as much attention at these long, interminable meetings, to the Hepatitis C work as I would have done in previous years, when it was related to HIV. So I am afraid my recollections are even worse on this topic.

Q. 22 years ago, Dr McClelland. I don't think anyone can fault you, even without the explanation you have just given.

Can we go back to the statement, please? I don't think we need to ask you to supplement your answer 16. On to the next page. We do return to the question of confirmatory testing and you do remember that there were differences of opinion among the testing experts about the value of this test; that is the first RIBA.

A. I can amplify that a little. My recollection is quite specific and I think it's probably something that the Inquiry may already have heard about. There was a general acceptance, among most of the virologists, that tests of the general type of the immuno-blot tests -- which we can come back to -- of which the RIBA was one and the Western Blot was one -- I think most people in the field felt that those were a useful addition and provided valuable extra information to interpret the result of a positive ELISA test.

There was one group, led by Professor -- then Dr Richard Tedder, who was passionately opposed to these tests and felt they were a waste of time and didn't provide any new information and that's specifically what I was referring to.

Q. Right. Dr McClelland, we have noticed a debate between something properly called a supplementary test and something properly called a confirmatory test. From other material it does appear that the term "confirmatory test" is used quite loosely at times. Is this sort of debate just a debate for purists, or is there a point there that we should understand about the difference between the two kinds of tests?

A. I think it's important for the Inquiry to be clear about what these terms may have meant when they were written. I can only quote from my own personal dictionary.

Q. We are happy with that.

A. I haven't looked up and I suspect, from past experience, that looking up other definitions would be highly uninformative because one will find that there are numerous definitions invented by various people. But, to me, a confirmatory test is a very simple concept. If you test a blood sample and you get a result -- if you test a blood sample with test A, which typically would be a screening test designed to provide rapid results on

very large numbers of samples in some sort of automated system and let us say you get a positive result in that, you must ask the question: is this a real positive result or could it be a false positive?

You do another test. That is a confirmatory test. It doesn't actually matter what kind of test it is, provided you have established -- you have evidence to show that it will give you a degree of disambiguation of the primary result, the screening test result and whether you call it a supplementary test or a confirmatory test, to me is irrelevant. But I think "supplementary" is a much less useful word than "confirmatory". Confirmatory specifically says: I want to confirm, it said positive in the first result; is it positive or is it negative?

Q. Doing exactly the same test again wouldn't count as a confirmatory test, though, would it? We understand about the concept of the best of three. So you would want to repeat the test to see if you got the same finding and if you didn't, you would have to do a third test to see: well, which one looks to be the initial result?

A. I think there is a fundamental difference between repeating the same test and performing a test which you have evidence has a different profile of performance.

I can expand on that if you want.

The reason for repeating the test. There are basically two reasons why it might be relevant to repeat the same test once, twice or three times. Repeat testing is particularly relevant for tests where the answer is a continuous variable, as opposed to a yes or a no, because every result in a test that may give an answer between 1 and 15, shall we say: whatever number it gives will have a statistical range about it. By repeating the test you will narrow that statistical range, so you will be more confident in the number that comes out.

If the test is a yes or no test: it's either yellow or it's not yellow, then repeating the test really doesn't address that issue. It doesn't make it -- it doesn't change the degree of yellowness. The only exception to that is if a result is marginal, you know, if it's just slightly yellow and you read -- you put the test in your reader and it's just a little bit above zero.

In that case some people may say it may be appropriate to repeat it two or three times and see if it helps you. So you are then, by doing that, you are viewing what is actually a yes/no test, a sort of binary result, you are then beginning to view it as

a continuous output test. I think most statistical people -- most methodologists would say that's actually not a good thing to do.

Q. Right.

A. So there is another reason for repeating the test. If I can illustrate that: I'm one of these people who can take five numbers and add them up on a calculator and get five different answers. So when I do that, I tend to say: if I can get the same answer three times, that's probably the right one.

If you are not confident in the reliability of each step in your process methodology, you have -- say you have a manual testing process, where every step is dependent on a person doing the right thing, then the possibility of errors may be relatively high. So repeating a test may be a way of detecting a result that is wrong because of a mistake, as opposed to uncertain because of the properties of the test system.

Q. Yes.

A. I don't know if that helps anything or not.

THE CHAIRMAN: Ms Dunlop, I have got a problem that is fast disappearing. Page 28, line 8, there was a word that I didn't quite pick up. I think it must be disambiguation.

MS DUNLOP: Making something less ambiguous. Thank you.

THE CHAIRMAN: Where did that word come from, Dr McClelland?
A. It came from an eminent forensic phonetician.
MS DUNLOP: I think some of the material about confirmatory testing that we have seen shows perhaps the virologists saying quite early on that the RIBA wasn't really adding value because it was really, in effect, doing the same test again. So it was the same test really as the ELISA, just in a different way, but you wouldn't agree that the RIBA failed to represent added value?
A. I don't agree, I don't agree with that.
Q. Right.
A. I think this type of test provides additional information. Do you wish me to expand on that?
Q. If you could, yes.
A. It will take a moment. If we go back for a moment to the construction of the screening test, the screening test will, in essence, be constructed by taking -- let me just walk you quickly through the process because it's important to do this to understand the second part of what I'm going to say.

You are trying to test for a virus, so you need -- you are trying to test for antibody in a blood sample that reacts with the virus, so you need to construct a test that will do that. The general approach to this is to grow culture, sufficient quantities of the virus,

in some sort of system. Frequently this involves animal cell lines or occasionally human cell lines or occasionally bacteria. But, at this time, the only way of getting sufficient quantities of the virus to use on a manufacturing scale to make large numbers of tests was to grow it in some sort of fermentation, some sort of brewery process, if you like.

That would give you a crude material which -- within which there will be proteins which are specific for the virus. But those might only be a tiny proportion of the total mix of proteins that are there. So, in building the tests, you would try to purify the virus protein to a reasonable extent, but that can be very difficult to do.

So, when you go to the next stage of making the test, you will actually be taking a mixture of proteins, some of which are from the virus, some of which will actually be derived from the cells, be they animal, human or bacterial cells that were used in the manufacturing -- culturing process, and some of them may actually be animal proteins that were used in the culture medium, typically calf serum is used in culture media and calf serum is not that different from human serum, it has the same broad types of proteins in it.

So when you have made your test by taking this viral

extract, this contaminated viral extract and sticking it on to a plastic surface of some kind, washing off as much of the extraneous material as you can. You then take your patient's blood sample, plasma sample, and you put a little bit of it on this plastic surface. The concept of the test is that if there is an antibody which is a molecule that specifically binds to the virus protein, then that antibody molecule, an immunoglobulin molecule, will stick to the plastic surface via the virus-specific molecule.

Then you can use a whole range of techniques to actually detect the presence of that antibody and we don't need to bother about those.

From what I have already said, I think it should be apparent that, because the material that's adhering to the plastic surface is complex, it's not pure virus protein. Secondly, because the human -- the serum or plasma sample is complex, antibody is just one of a myriad of proteins in human plasma -- there is a real possibility that something else will stick, as well as the antibody that you want.

You hope to avoid this by a whole series of steps in the development of the test but it happens. The result of that, in terms of what you can actually detect, either by the human eye or with an optical device that

looks for the colour change, you will have something that goes from clear to yellow. All that actually tells you is that something has stuck to the plastic surface, but it doesn't really tell you what.

These other techniques, RIBA or Western Blot -- there is a whole family of these techniques which are generally similar -- are still -- they are subject to some of the same difficulties but there is a fundamental difference. Instead of just taking the virus, the preparation of virus protein, which -- mixed with other things, and sticking it directly on to a plastic surface, what you do is put it on to something a bit like blotting paper and spread it out.

I'm sure many people here will have seen something about the process of chromatography; it's just a way of taking a mixture of chemicals proteins, carbohydrates, whatever and using a physical force of some kind to spread them out so that you get the big ones at this end and the small ones at this end; you get the positively charged ones at this end and the negatively charged ones at this end. In practice, what happens if you design the system right, these things form a series of relatively discrete blobs on your blotting paper.

Those can be stained with dyes to show a -- not to the naked eye, but that only tells you that they are

blobs of a particular size, shape and position, it doesn't tell you what they are. But if you then do a second step, which is exactly analogous to the second step of the ELISA test -- that is, you take some human plasma or serum and apply it to this blotting paper, on which you have spread out the different proteins -- you can again see -- you can use a system then to detect where something in the human blood sample has stuck to one or more of the blobs on the blotting paper.

You will still have reactions that are -- if there are reactions there, which are due to an antibody reacting to a viral protein, ie what you want to detect. You will see those clearly in this system because you will know from appropriate controls where the different viral proteins sit in this string of blobs.

But what you will also see is if there are other reactions there, for example there is something in the human -- in the serum, the patient's sample that reacts with calf albumin, you will see that as well but it will be in a different position. So if the antibody reaction -- the antibody to the virus is there on your blotting paper, the reaction between something in the human -- in the patient's sample and the contaminated calf protein might be here.

So what you introduce essentially is a spatial

element. You are not just dependent on yellow or not yellow, you are looking at evidence of binding to a particular thing which has a recognisable position and shape and density on this chromatographic image of the mixture. I'm not sure whether that's at all clear?

Q. It is, thank you. What I understand from your explanation is that the key feature of the use of the blotting technique is that you are able to rule out what were some false positives because you can see that the reaction is occurring in a different place; therefore, it's not what you are looking for.

A. It should allow you to see three possible situations -- I'm trying to avoid using the word "scenario". One is there is antibody to one or more elements that you know are part of the virus. So that's a genuine positive. Secondly, you could see there is a reaction between something in the patient's sample and something in your blotting paper that is not to do with the virus. That's a genuine false positive. The third situation, which is not uncommon, is that you see both; so that you can say there is antibody to the virus, one or more of the virus proteins, as well as something else.

Q. Yes.

A. I should just say that what none of these tests can do, and it's sort of by definition: none of them can tell

you more about a sample that comes up negative on the screening tests because that one will not be subject to further testing.

Q. Well, indeed. But the added value represented by the blotting aspect is that it improves the specification of your overall testing process?

A. Specificity.

Q. Specificity, I'm sorry. Excuse me a moment. (Pause)

A. That, I should perhaps say, has subsequently been largely validated by comparing the results with those from tests to detect the virus RNA, which can be, if properly performed, virtually completely specific.

Q. Now, can we move on through the statement, please. We have covered, I think, the whole concept of confirmatory testing and the use of blotting tests. Moving on to the next page, we have already answered with other witnesses what a dev kit is.

Paragraph 21 talks about the status of the Ortho test kit in the United States of America and you say your understanding is that Ortho required an export licence to be permitted by the US authorities to market the kit in other countries. Indeed, we have already looked at a letter that confirms that the export permit had been issued. That's 27 November 1989. We won't go to it but, for the record, it's [SNB0061560] and it

explains that Ortho will now be able to make the kit available for diagnostic purposes rather than simply for research purposes, which is a discussion that we had in part yesterday.

There is then a succession of questions which I think are not really for you, quite a long succession. If we look on to page 11. Then on to 12: we are getting, by the time we reach page 12, to the issue of the start date. We have said, in our paragraph 31, that we have not found it easy to determine why, given a decision being reached by VSB at the end of November 1990, it took until September 1991 for testing to be up and running. We have prepared an expanded version of this section of the preliminary report.

Can we look firstly in this regard at a letter, [SNB0052555]. Here it is.

So, if that meeting was 21 November 1990, here is Dr Cash writing on 27 November 1990 to all of you, the directors. Dr Mitchell has reported back to him and Dr Cash says:

"We are a wee bit nearer to D-day."

Looking to plan for the actual introduction. The choices to be that of the individual centres; whether to use the Ortho or Abbott kit. He is asking what would be

the earliest date you could start routine screening.

He sets out a very clear list of information required and draws attention to the prospect of buzzing with Dr Mitchell. I suppose that means picking his brains, if he has more information about the different kits.

On to the next page, please. He has even given a deadline, he wants the information by Christmas Eve.

Can we look then, insofar as your area is concerned, at [SNB0047202]. Dr Gillon replied on your behalf and he said that:

As far as your part of Scotland was concerned, the earliest date at which routine testing could be commenced would be 25 February 1991.

So that's that process. Can we go now, please, to [PEN0172165]? This is our fuller version of this part of the preliminary report and there are some events in it which we can note as we try to understand where the time went between November 1990 and September 1991.

We see that exchange referred to on the first page. Can we go to the next page, please? I should say, sir, I'm not going to go to the supporting documentation because it's really -- all the key features are quoted in the text and this is, I think, quite a condensed account of the period but including, I hope, all the

relevant material.

THE CHAIRMAN: I think it will be important to make sure that we have all the references noted. That's the only thing I would ask.

MS DUNLOP: Indeed. I'll do that.

THE CHAIRMAN: I have not checked that. I have just noted that they are not all in footnotes.

MS DUNLOP: I think they are there. If we look on the next page, there is a passage in italics relating to 7 January 1991. Sorry this is the second page of this document. Mine is printed out slightly differently. Fine, we can cope.

Can we go back then to the previous page. We will do it by paragraph numbers. Yes, it's that reference to 7 January 1991, a meeting of the NBTS/SNBTS liaison committee. We can see who is on that and Dr Gunson conveying his concern that the Department of Health has still not decided on a start date:

"It now seemed probable that May/June 1991 would be the earliest possible. 2. Dr Gunson advised that he believed the major problem for DOH was mechanisms for finding the money for NBTS RTCs and for England/Wales confirmation testing ... 3. Dr Cash requested a more definitive operational description for 'start date' ..."

That's [SNB0117258].

The next paragraph I would like to look at is 9.251, please. 22 January 1991. Dr Gunson sent a memorandum to the regional transfusion directors of England and Wales, advising that the Department of Health had agreed that routine testing could be put into operation. He is asking to be advised of the earliest date directors considered they could commence testing. That's [SGF0012029]. That would seem to be the equivalent of the letter that Dr Cash had sent in November 1990.

Then we see in the next paragraph, Professor Cash replied to that very quickly. He was copied the letter as well. He mentioned the Gulf War: just for the record, the Iraqi invasion of Kuwait began at the beginning of August 1990 and aerial bombardment began on 17 January 1991, at least according to my references on the Internet. So plainly that was part of the background at that time.

That response from Professor Cash, which we can see for ourselves, the material parts are quoted -- is [SGH0027887]. He is mentioning:

"A firm commitment to starting on the same day as our NBTS colleagues."

He would suggest, if pressed, a May/June date should be considered.

PROFESSOR JAMES: Could I just add -- perhaps you are going

to ask Dr McClelland about this -- but for a very brief instance it was thought possible that there would be very large numbers of casualties brought over from a war in Iraq. I can remember it very clearly, our hospital made plans in Newcastle, for example, it was the same throughout the UK -- that there could be some very seriously injured people brought back from Iraq in big numbers. So they would have to be distributed throughout major intensive care units and so on in the specialist units in the UK.

I imagine that there was -- this probably only lasted for two or three weeks. There was planning for this and that might very well have included, you know, issues around blood transfusion and so on. In the event, of course, none of this happened and that passed off very quickly.

MS DUNLOP: Yes, I think we did understand that the reference to the Gulf conflict was an expectation that this could provide a separate and independent strain on blood resources.

A. There were two elements to it and I completely endorse what -- my recollection is the same as what Professor James has said. The other factor which caused quite a substantial problems for the Blood Transfusion Services across the whole country is very similar to

what happened in the United States after 9/11, that the services were overwhelmed with donors. That actually is a huge problem. I don't want to expand on it, but we had that problem in spades for a period. I think, at the date that Professor Cash wrote this letter, actually it was quite a reasonable suggestion. I think probably in retrospect the period of maximum perturbation was a good deal shorter than he anticipated, mainly for the reason that you have already mentioned, sir. But it was -- we were quite pressured.

Q. Can we move on to -- in fact it's still on the same page -- that reply from Dr Gunson, 28 January, which is [SNB0044574]. Dr Gunson advised Professor Cash:

"It was never my interpretation that anti-HCV testing should take place with any great urgency."

Which may, in retrospect, have been an unfortunate choice of words, at least in the context of the current examination. But one would have to ask him and we can't, whether all he was meaning was: it has not got to happen this week.

A. I'm quite certain that Dr Gunson was entirely clear about the importance of getting this started. I have no doubts about that.

Q. Yes. Then can we move down to 252, please, and on to the next page? Another letter which seems to bear on

this. 4 February 1991. We can see it on the screen, Dr Follett wrote to Dr Gunson on the subject of the HCV trial, that Abbott had only supplied four kits and:

"They are not allowed to provide further kits until April 14 as Ortho have taken out an injunction preventing sale in the UK."

That can't have helped. That is [SNB0116960].

Then Dr Hilary Pickles on 5 February 1991 in a memo, in which the recipient's name has been redacted, so we are not able to say to whom, but in a memo observing that Dr Gunson had been in touch with the directors in England about the starting dates and there were all sorts of problems. He was trying on her 1 July 1991:

"Would this be too late? My initial reaction was this would be okay. Attempting to go earlier would mean some stragglers would be left behind, a slight delay increased the chance of the finance being sorted out and with the diversion of RTC resources to Gulf-related activities a short time date might not be feasible."

Then moving on, please, to 13 February, which I think is going to be on the next page. A note within the SHHD from Mrs Falconer, a civil servant sending a note to Mr Hogg, another civil servant saying that she had spoken to Elaine Webb -- this is at the Department of Health, regarding a date for the start of testing:

"She advised that officially no date has been given. There was to be a VSB meeting on the 25 February and the date will be discussed then. Unofficially it's hoped to commence 1 July. Elaine did say this date is confidential and the Department of Health did not want SNBTS or anyone outwith the office informed."

That's [SGH0027886].

Dr McClelland, why would SNBTS not be told that the date to be aimed at was 1 July, when plainly it had to involve them?

A. I have absolutely no idea.

Q. Right. Then 15 February, Dr Gunson wrote to the directors in England and Wales, advising that routine screening would commence on 1 July 1991. That's [PEN0160189]. Perhaps we could just have a quick look at that letter, please, because that's quite a significant letter.

THE CHAIRMAN: This appears to be letting some deadly secret out of the bag.

A. I can only, just thinking about it now, only assume that they thought we would probably write another inflammatory letter to The Lancet.

MS DUNLOP: So there we are. A circular letter going round all the directors. A copy of the minute of the meeting with a lot of other material and then on to the next

page, please. There we are. A report on the comparison of the kits and that report was the first generation kits. Work is now proceeding really on the second generation kits. It's a bit like painting the Forth Bridge, this evaluation process, as soon as you finish evaluating one set of kits, another set of kits is launched, but there we are. In paragraph 10:

"An agreed date of commencement for anti-HCV screening of 1 July 1991 has emerged."

So that's that one. Then back to the narrative, please, [PEN0172165]. We can see further correspondence. After that Professor Cash replying. The next item I want to highlight is 26 February 1991, please. Secret's certainly out by now because Mr Bayne and Mr Panton of SHHD meet Mr McIntosh of SNBTS [SGH0027880] and Mr McIntosh is able to say that testing would commence on 1 July.

Then 21 March, please. On to the next page. The procurement directorate sending a letter to Dr Gunson in respect of the phase 2 evaluation of the HCV screening tests. That's [SNB0063953]. The department has agreed that there should be a second round comparative evaluation of Hepatitis C kits at the Newcastle, North London and Glasgow transfusion centres and the work was to start in February and be completed by the end

of April.

Then any repeat positives previously not identified to be sent to the reference lab. Then mention of expenditure. Then, on, please, to 27 March. On the next page, Professor Cash is writing to Mr McIntosh and advising that NBTS are struggling, on a number of accounts, to meet the 1 July deadline:

"Professor Cash believed the fundamental problem to be one of financial resources. At a recent meeting of the Advisory Committee on Transfusion-transmitted Diseases it was agreed that Dr Gunson would advise DOH that the 1 July start date should be delayed until such time as an evaluation of the new screening tests had been completed."

It's worth observing too that a copy of the letter was sent to SHHD and a handwritten note was added by Mr Panton, we think:

"This is worrying, please speak to DOH. We can't go to the minister until we know the start date."

[SGF0012026].

Then 9.262, 3 April 1991, Dr Gunson wrote advising that it would not be possible -- advising his fellow directors in England it would not be possible to introduce screening by 1 July. This is because of the failure to begin the evaluation of the second generation

kits. So transfusion centres should aim to commence routine screening for anti-HCV by 1 September 1991.

The reference for that is [SNB0044883]. Then looking at the next passage -- well, the passage in italics beginning at the very bottom there. On 5 April Professor Cash thanked Dr Gunson for his letter of 3 April and stated:

"My colleagues would wish you to know that this most recent development leading to a start date on 1 September 1991 has the SNBTS directors fullest support."

[SNB0063958]. That's all the letter says, actually.

Then 11 April 1991, a draft letter which was to be going to all health authorities in England and Wales. [SGH0027869]. By this time the form of words being used is that:

"The introduction of routine testing is unlikely to be before 1 September 1991. You will be informed as soon as a date has been agreed."

And funding. Could we look at this point at [SNB0101108]? Yes, sorry, I'm slightly ahead of myself. Can we keep that open, but just minimise it for the moment. I was wondering if that was the reference for 15 April 1991. I think we are missing that but we will supply the reference for 15 April 1991, which is

Mrs Falconer again sending a note to Mr Hogg. Saying that:

"There is a proposed date for introduction, unlikely to be before 1 September, should they now put forward their submission." [SGH0027864]

Then moving on to 30 April 1991 and that is the document I wanted to look at. Can we have a look at that, please, [SNB0101108]. This is the SNBTS/NBTS liaison committee. If we look on to the next page, please. By this time, 30 April, it is being suggested a commencement date would be appropriate, but Dr Gunson is reporting that Newcastle regional transfusion centre, the general manager there being Dr Hugh Lloyd, had commenced testing within the past week:

"No confirmatory testing is being undertaken and no information was available on donor counselling."

The health departments have been or are being told. Dr Gunson had been hoping to establish multi-centre evaluation of second generation kits, with Newcastle as a participating centre. So in fact it does look, from all the correspondence around this time, as though that breakaway was wrapped up in the evaluation process?

A. Yes, that's certainly my recollection.

Q. Yes. Then, if we go back to the narrative, please. Sir, I want to look a little bit more at the Newcastle

breakaway, if I can put it like that.

THE CHAIRMAN: Certainly and the relationship with Glasgow I think would be helpful to follow. So we will have a break at this time.

MS DUNLOP: Yes.

(11.06 am)

(Short break)

(11.32 am)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you, sir. Dr McClelland, just before the break, we had reached the end of April 1991 and that entry that we can see towards the bottom of the screen, telling us that Newcastle had unilaterally commenced HCV screening. Can we look then at [SNB0045129]?

This is Dr Lloyd's letter dated 2 May 1991, which he sent to all directors of transfusion services. It's specifically copied to Dr Gunson and Professor Cash.

We can see that he refers to there having been a date of 1 July set, but fairly recently it has been changed with a provisional date set for September:

"In view of the fact that we were already set up for testing, I have decided to keep to the July date. By 1 July all units of blood for transfusion in the northern region will be negative for Hepatitis C antibody."

I think some confusion which was in my mind about dates is clarified by this -- the reference by Dr Gunson to the screening having started at the end of April, appears to have been so that, by 1 July, Dr Lloyd could say that all units would be negative. So there was a lead-in time and he appears to have begun before 1 July. Does that make sense?

A. Not entirely.

Q. Right.

A. The lead-in time that one would need and that we, I think, used as a minimum was -- it relates to the shelf life of the product basically.

Q. This would be quite long?

A. 35 days is the shelf life of a unit of red cells and that's the critical -- that's essentially the cell product. Frozen products fall into a different category because they are easier to manage. But if you start testing on 1 July, then you would be able to have a fresh inventory -- you would be able to look at the freshest and -- the freshest products in stock at that time. Am I explaining this correctly? Let me not make it too complicated. You need about a month to ensure that the inventory is all tested and you need to be able to go through the business of replacing all the stock in all your hospital blood banks, which has not been

tested, with tested blood.

Q. Well, we may not --

A. I think -- I don't understand the gap between April and July.

Q. No. It's slightly confusing, but I think the more important point is that he did begin early.

A. He began early.

Q. Yes. This letter provoked some replies and we have a number of them. Can we look firstly, please, at [SNB0064010]. Dr Mitchell wrote to Dr Lloyd and here is his letter of 7 May. He had already heard of the decision and I think we can see for ourselves what he is saying. He is recording that:

"The West of Scotland is engaged in assessing the differences, if any, between the Abbott first generation test and the Abbott second generation test."

He is looking forward to discussion of the results. We also have copies of letters to Dr Lloyd from Dr Harrison in London, Dr Contreras in London, Dr Ala in Birmingham -- these are all transfusion directors of the time, I think.

Can we also look at Dr Cash's letter, please, which is [SNB0118726], also dated 7 May? Dr Cash is saying to Dr Lloyd:

"I cannot but conclude that this unilateral action

is both disgraceful and mischievous."

Just reading short:

"It seems to be dog eat dog time, Hugh and I would suggest it is also time when you should remove the heading "National Blood Transfusion Service" from your headed notepaper and time for you, and any of your staff who serve UK BTS and or NBTS committees and working parties to be excluded."

Then on to the next page, please:

"If you want to be on your own, so be it, you will find it an operational and professional lonely spot and one which you should discuss carefully with your RHA legal advisers. I beg of you to reconsider the matter. Collective responsibility and security has much to commend it and, if you can spare the time to study the HIV haemophilia litigation papers, you should confirm this conclusion. Kindest regards."

There is some further correspondence, Dr McClelland and it's plain that they met at an event in July. We will be looking at that with Professor Cash but, what seems to be the last letter in this particular short chain is [SNB0117806], which I would like to look at as well. This is, again, Dr Cash writing to Dr Lloyd, now 19 July 1991. Dr Lloyd having written a conciliatory letter of 4 July.

Dr Cash making a number of points to do with the team approach. He is expressing his sustained concern at "...the continued Balkanised mentality of BTS in England."

He finds statements such as, "Accepting the lowest common denominator" to be deeply disconcerting. That's because Dr Lloyd had made the point about, "Going at the speed of the slowest", if one can put that shortly:

"In our team we pick up the weakest and carry them until such time as they have grown strong."

Then on to the following page, please:

"It is a fact of life that, if a member of a team starts scoring goals for the opposition, he is excluded from further participation. I did not propose, in my letter of 7 May 1991, that steps should be taken to exclude you and members of your staff from national committees et cetera; I simply stated an inevitable happening if, as it appeared, your centre wished to reject the authority of such committees."

Then Dr Lloyd is to be in Edinburgh. He is to be there on 14 August and he would be welcome to come for lunch and Dr Cash is hoping that Dr Lloyd will take that opportunity of apologising to the SNBTS directors:

"In 30 seconds flat, the sorry episode will be over."

We can see that if he does that, he would become an active member of the team. Then the final paragraph on the last page is just, I think, wishing good luck, is it? Can we just check the final page? Yes:

"Good luck and best wishes ... Kindest regards."

THE CHAIRMAN: This is another letter to his very good friend, is it?

MS DUNLOP: We were interested, Dr McClelland: did this lunch with accompanying apology happen?

A. I have absolutely no recollection of it and I'm pretty sure I would have remembered it. I think it would have been an event.

Q. I don't think you had seen that letter until this morning?

A. I have never seen that letter before this morning.

Q. Yes. I don't want to leave the extended narrative hanging. Can we go back to it, please, [PEN0172165]? We are now, obviously, into May, 9.269 we were at. Going on, we can see the reference to the Newcastle episode. If we go on to the next page -- I should say, sir, that that list of letters at the end of the first full paragraph, we can see on the screen, is the letters to which I referred from the others. We don't need to look at them. They are in similar sorts of terms, although perhaps not really quite the same.

THE CHAIRMAN: They won't be quite so colourful, I take it.
MS DUNLOP: No. Then, as a narrative of what happened in May, various other pieces of administration and then, I think we are going to come on to look at events in June with Dr McClelland. Then, obviously July and August are really finalising the arrangements for the introduction of screening in September. By that point really things are on target and that is achieved.

So to go back to your statement, please, Dr McClelland -- that is [PEN0172491] -- paragraph 35. We mentioned Newcastle and we asked about the position in Scotland and you said that:

"There certainly was consideration of an earlier start."

Your recollection is that at the board meeting on June 11 and June 12 1991, there was a discussion about the timing of starting HCV testing. Why was it two day board meeting? Was that just the volume of business that had to be transacted?

A. I don't think it was so much the volume of business as the volume of talk. There were frequently two-day board meetings.

Q. Right. You wrote to Dr Cash. Can we see that, please, [SNB0027902]. You are writing to Professor Cash on the subject of Hepatitis C testing. It's actually dated

11 June 1991, which is the first day of the two day meeting. Yes. You want the item to be discussed. You say at the end of the first paragraph:

"The fact that some centres are carrying out testing, albeit on a large pilot study basis, leaves us in a very exposed position.

"I would like to be reassured that we are taking the correct position, both professionally and medical legally, to stay in line with the positions of the majority of English regional health authorities; I think this is ... what we are now doing rather than abiding by a Department of Health policy because it seems to me that de facto, may no longer be a Department of Health policy in this area."

Some of this must have been prompted by the development in Newcastle, was it?

A. I'm sure it was, yes.

Q. Yes. We know that the item was discussed and we have looked already at the minutes, which simply record the decision, not the discussion. Was it quite a heated discussion?

A. Well, I actually -- I did not have a recollection of the discussion but -- so I can't tell you whether it was heated or not. If there had been a real sort of barny, I probably would have remembered. But I have no

recollection actually of that meeting. I have only got my notes of which you are aware.

Q. Yes. Can we -- if we look at the end of your statement, we can see that you have provided us with a copy of your handwritten notes and we did ask if you could type them up for us, which you have done. Sir, these are not in court book but there are hard copies of them. I don't seem to have one. So if I can just equip myself -- (Handed). Thank you, I have the notes.

Perhaps if you could just briefly run through them, Dr McClelland, because they are obviously summary, so it's maybe easier for you to talk us through it than for us to try and guess.

A. I'm not sure that I would even dignify it with the name of "summary" they are notes: what I tried to do, typing them up, was to lay them out approximately as they were laid out in the actual original notebook because I think -- I have not tried to create order out of chaos, if you know what I mean.

I can endeavour to interpret each of these sort of entries, if that's -- would be that helpful?

Q. Let's be a little bit more focused. I suppose we should note, first of all, that you have recorded that Glasgow has started. That's a reference to Glasgow's participation in --

A. The multi-centre.
Q. -- the evaluation of second generation kits. Is that right?
A. I must have been aware they had started some time ago.
Q. Yes. Did that put particular pressure on you, as representing the other half of the central belt?
A. I was very concerned that half the population was, in effect, getting tested blood and the other half wasn't. It didn't seem a particularly good idea.
Q. Right. We can see, about half way down the first typewritten page, if everyone has the one with the little Venn diagram on it, "Start date September 1st stands." Then you have --
THE CHAIRMAN: Has there been a certain amount of imaginative reconstruction Dr McClelland, of the material in manuscript?
A. No.
THE CHAIRMAN: I can't see, for example, how fast can we institute and so on.
MS DUNLOP: That's on the next page, sir. I think we are looking at them in a different order.
THE CHAIRMAN: That doesn't help. Could we get up the ...
A. Just for the future, I did provide a copy of the -- a photocopy -- a scan on which I had marked the sections which I transcribed.

THE CHAIRMAN: I don't have that.
MS DUNLOP: I think I'm probably the only one who has that.
THE CHAIRMAN: That's fine, so long as we are not looking at the same page, I don't need to be misled.
MS DUNLOP: Yes. You transcribed the sections that related to this issue?
A. Yes, there was a substantial amount of stuff which was completely not related to this and I have left that out.
Q. Yes. You have, I take it, tried to type them out in the order in which they were probably made?
A. Yes, well, in the order in which they appear in the book.
Q. In the book, yes. Right. So this -- I think we may need to get something that looks a bit more like it on the screen. If we go on -- we have, "SNBTS board." We have a page headed that in handwriting. Then we can see this 3.1.2 is at the bottom. I think it would just take up an awful lot of time, Dr McClelland. For the moment, sir, I think we should just trust Dr McClelland, that he has typed up --
THE CHAIRMAN: Absolutely. I wouldn't have raised it except that there was a complete mismatch between --
MS DUNLOP: A disconnect, yes. I appreciate that.
A. If I have been creative, it's entirely accidental. I was trying to create a typed facsimile of my

scribbles, which is not easy.

Q. This flowchart at the bottom -- not a flowchart perhaps, just some thinking on your part, thinking in boxes "medico-legal issues."

A. "Product liability."

Q. "Long-term relations."

A. "Long-term relations."

Q. Yes, then you are saying:

"Allow us, if pushed, to say the programme has started."

I suppose that's a reference to what is happening in Newcastle and Glasgow:

"Avoid hassle with clinicians, which may lead to more publicity... September 1st announcement."

Then on to the next page:

"How fast can we institute report back starting date possible."

Is that you reporting back that perhaps you could do it in Edinburgh and Southeast Scotland, do you think?

A. No, I think that's probably simply a note of part of the discussion, probably Professor Cash saying: we need to know how quickly we can start, report back on what is the possible starting date. Specifically can we hit -- something I couldn't read -- September 1.

Q. Then that's obviously Professor Cash saying, "The UK

pack is still a pack."

A. The capitalisation was in my original note and the underlining was in my original notes, for what it's worth.

Q. I think that's the same point, isn't it, you are either a team or a pack?

A. Yes.

Q. Then how that might be used to advantage.

A. The next section, if I might just explain, is -- the top part is self-explanatory because that was --

Q. That's your timeline?

A. The timeline from whatever date this was, from mid -- when was it? What was the date of this?

Q. The date --

A. June 1991 -- it was the timeline from then until starting. The bit below was, I think, probably my own notes of how I proposed -- first thoughts about how I proposed to handle it in my own centre, which was actually to start as early as we could and test everything as soon as we could. But I have -- you can see that I have made a note saying:

"Don't put any of the results into the database until the formal start date."

So basically I think, and I think I have some other documents which support this, what we were trying to do

was "evaluation", but it was in effect operational testing. So we were just trying to mirror what was happening. So actually I could be confident that we weren't putting out any antibody-positive blood from the earliest possible date that we could get going.

Q. Then the final typewritten page, please. Well, saying please, we don't have it on the screen. So if we can manually look at the final typewritten page, which is headed up "HCV intro/timing."

A. The first part is just about plasma, which I think is probably not relevant to this decision. But we were -- that was just recording the agreements about when the testing of plasma for fractionation would start and the fact that there was a formal decision that plasma would continue -- non-Hepatitis C tested plasma would continue to be shipped until date X, which I think was what happened everywhere.

Q. Right: then we note perhaps also on the last page the three bullets:

"Data to Harold by 15 July. Reported conclusions to department by August 1st. Ministerial decision by time for September 1 start."

A. Yes.

Q. Can we just look at the final page of Dr McClelland's statement, please? Professor Cash sent a letter to

Dr Gunson referring to a near disaster in Scotland. You think that that was a reference to the discussion -- that is the discussion about earlier testing and the fact that there had been a proposal to start testing before the September start date.

You are right, Dr McClelland -- and we will ask Professor Cash a bit more about that. If you had started earlier, suppose the decision had been at the board meeting in June that testing really should start as quickly as possible; how long would it have taken? How quickly could you have got kits?

A. I really can't answer that now. I think by June -- we probably actually started as quickly -- I'm speaking for my own centre. We probably started as quickly as we could. I cannot remember how -- I think we were probably into routine testing and, again, I have some documents for this which -- I have forgotten the precise dates, but I do have records of instructions given to my lab staff of dates of testing, I think either towards the end of July or early August. So I think in fact we probably went as fast as we were able to go from that time onwards.

Q. Right. If you look finally at Mr McIntosh's letter, [SNB0054822]. This is a letter from 30 August 1991, which you have had the chance to read again, I think,

Dr McClelland. We asked whether you, as one of those providing a statement, agreed with Mr McIntosh's views. You said:

"I agree that there were failings in the process leading to the introduction of HCV screening."

I just wondered, with or without reference to Mr McIntosh's letter, can you elaborate a little on what you think the failings were?

A. I think the most -- I think the failings essentially were the results of whatever went wrong, let me put it that way, that there were a number of occasions, certainly one very specific occasion, when I believe it probably would have been possible for the whole of the UK to start testing. Or for an earlier -- I mean, there were various test dates, but for an earlier initiation of testing. Something happened, and it appears to have been -- have happened, at least been manifest, at the ACVSB, that said we have to wait until we have these better kits.

That's one specific example. There is plenty of evidence of stalled decision-making before that. It's slightly less clear to me whether, if decision-making -- and again it's largely around the ACVSB and the ACTTD, I think. I mean, originally an earlier state -- earlier start dates had been mooted and had even, I think, been

proposed or agreed and each one seemed to disappear and slip, for reasons which really are not particularly clear. The only point at which there is an explicit reason seems to be, oh -- the point at which it was agreed by someone that testing should not start until we had the second generation kits, or until the second generation kits had been evaluated.

I think, if one leaves aside the -- for the moment, the nature of the decision-making process and the nature of the organisations involved and just asks a simple question: was it possible to start testing earlier, in terms of the availability of the relevant equipment and machinery and test systems? The answer is clearly, yes, because a number of countries in Europe did. So to me the question is: what is the nature of the -- what are the elements that mean that the Netherlands and Finland, for example, relatively small countries, could start very quickly, whereas the UK, for some reason, couldn't? I say the UK -- I'm not saying Scotland. I think the question of whether Scotland could have started -- could have or should have started before England is a different question.

But something about the nature and the functioning of the institutions concerned in the UK was profoundly different and led it to actually being one of the last

countries to institute Hepatitis C testing. The historical evidence -- it's all fully reviewed by Krever and so on, showed that lots of other countries, not necessarily better resourced than we were, were able to start sooner -- well, let us say they did start sooner.

Q. Do you think that the -- let's call it the understanding in the summer of 1989, which seems to have been near unanimous amongst all three really of the politicians who were involved, civil servants, government departments who were involved and the transfusion services, that there would be a common UK start date. Do you think that understanding was a mistake?

A. I think there are different ways of looking at that. If you look at it from the point of view of an individual patient, you know, someone who is going to have a transfusion, then I think that understanding was a mistake because some patients, who subsequently -- there are a number of patients who clearly must have been exposed, or were exposed to Hepatitis C infection, who would not have been if we had started testing earlier. That's self-evident.

So from that viewpoint I think, if the understanding that we had to have a common start date actually was the cause of a patient becoming infected, then that was a bad thing. I'm not saying it's a mistake; I'm saying

it was a bad thing, especially from the perspective of that individual and their family.

But I'm not saying that it was completely -- that the concept of having a common start date is wrong; I think there are many cogent reasons why that is actually -- there is considerable value in that. There are considerable downsides from having a fragmented introduction of testing in a fairly small and compact country like the UK, that you can easily -- I'm sure you have heard about them at earlier sessions.

There are many potential disadvantages. It's the sort of postcode prescribing problem, which carries -- there is an issue of inequity, there is an issue of, you know, potentially generating very bad publicity and adverse reputation and litigation and you know, the whole thing.

So it's not -- it's not an unmitigated bad to have attempted to provide a common start date.

Q. Right. So to aim for it may not have been the problem, but maybe the issue is: if it doesn't look as though that is producing an expeditious process, at what point is it legitimate for an area to depart from the agreement and just get on with it, if it can? Is that really the question?

A. My personal view was that I had, as I think I have said

elsewhere -- as a medical person with responsibility for providing products to be used for treating patients, I had to decide what was the most important priority and I think my most important priority was the safety of the patients, the recipients of the product. However -- I have lost myself. Can you repeat the question, please?

Q. I was wondering if the question is where a team has embarked together and is aiming for a common start date but things don't seem to be moving along very well, maybe the question is: at what point should an individual depart from that and, to use a phrase we see in these critical letters to Dr Lloyd, "Go it alone"?

A. I think simply committing a UDI in this situation probably wasn't a very clever thing to do. The results of it were not very good for Dr Lloyd. What I think we should have been much more open to recognising -- and I say "we" in a very broad church. I think we should have been much more open to recognising that there were problems in certain parts of the country and looked for a way of managing a phased introduction.

Not by UDI, but by saying, okay, there are very good practical reasons which we are not trying to keep secret, why this will start somewhere before it starts somewhere else. That could have been presented by

analogy with practically everything else in healthcare, which is different wherever you go in the country. I mean, variations in the way and the quality and the amount of care provided is just an inescapable feature of a large National Health Service.

So I think that perhaps it wouldn't have been -- not to present it as a UDI, but to start testing as soon as possible where it was possible and to present that as a plus, rather than a disaster was an approach that perhaps should have received more consideration.

Q. It's also noteworthy that it isn't really until November 1990 that anyone starts articulating a start date. Even then, it isn't in the minutes of the VSB.

A. I can only sort of return to the -- because I find this very -- you know, looking back now, I find this very hard to understand. I have to come back to what we discussed on a number of occasions before, which is what could be the explanation for that lack of urgency, because that's what it is.

I think it has to go back to this perception that non-A non-B Hepatitis was an American problem. I can't come up with a better explanation. Because it's not that we are dealing with people who were negligent or unconcerned with patient welfare, or motivated to try

and do a very good job. Yet the lack of decisions, in retrospect, are extremely hard to understand.

Q. Excuse me a moment. (Pause).

In retrospect -- I'm not expecting a precise answer, but, in retrospect, how long a period do you think could have been achieved or how long a period -- these are two different questions, I'm sorry. But how long a period would have been satisfactory?

A. How long a period for what, sorry?

Q. Well, let's take the spring of 1990 because there is a useful concrete piece of information there about the kits being available for order. Ortho had kits, first generation kits, available for order in March 1990 and the first generation RIBA was coming through in May 1990.

So you can't start screening without kits. If we thought about that, are you able to give a period perhaps in a number of months or something from that point, when it would have been reasonable for screening to be introduced, or do you not want to go down that route?

A. I could only make two comments on that. One is that I think one has to look at when other countries, not hugely -- on the surface not hugely different from the UK, managed to start screening. That's a matter of

record, although the record may not be quite as clear as it looks in the Krever report, I have to say.

The second, which is documented, was that the question was asked, either at the very end or beginning of 1991, not long after the period you mentioned and Dr Gillon gave a date which I think we have seen earlier this morning which said we could start in, I think -- was it February?

Q. 25 February 1991.

A. Dr Gillon was responsible for this work in the Edinburgh centre at that time, because I had delegated this to him. Obviously he can be questioned about this, but I'm confident that Jack Gillon would not have given that date unless he was confident that he could have delivered it.

Q. Right. Thank you very much, Dr McClelland.

THE CHAIRMAN: Dr McClelland, in the West of Scotland an evaluation process clearly began that became somewhat expensive, so far as testing was concerned. Indeed, you have indicated that you were rather apprehensive that the whole of the West of Scotland were benefiting from it. Do you know when that started?

A. That started very soon after the Newcastle --

THE CHAIRMAN: After Dr Lloyd --

A. My recollection is it started in April. The second part

of your question: I was not apprehensive, I knew that what was happening in Glasgow, Newcastle and one other English centre which I can't remember, probably North London, that every donation was being tested. The reason I'm confident of that was because the Newcastle full testing started and I thought it had started in April. I'm confused about the dates there too, the decision seems to have been made very quickly, as Ms Dunlop said, to wrap that in a multi-centre evaluation, but the evaluation was in fact full testing.

THE CHAIRMAN: There may be all sorts of reasons for the selection of language, but the reality was that full testing --

A. The reality is that full testing was being done.

THE CHAIRMAN: The implications, in practical terms for you, must have borne in on you fairly early on --

A. They did.

THE CHAIRMAN: -- after that. Is the position that you did, to some extent, initiate the process?

A. We didn't initiate the process in April, but the documentation -- my recollection and the documentation that I have is that we -- about June we moved from -- some date in June around about the middle of June, we moved, as quickly as possible, to start testing everything but not declaring it as -- we actually quite

deliberately called it "equipment evaluation" or something.

THE CHAIRMAN: This is why I want to follow it just a little, because it's the bottom section of the first page of your typed-up document. Really, to tease out just exactly what you were deciding to do at that stage. Your aim is there: to test everything?

A. Yes.

THE CHAIRMAN: But in effect to create a little bit of a smokescreen as to what you were doing?

A. Yes.

THE CHAIRMAN: You were going to avoid publicity, avoid conflict with others but effectively screen all blood --

A. Yes.

THE CHAIRMAN: -- and only come out with reports of that after the official start date of 1 September?

A. Yes, from a safety point of view, the only important issue was that, if a donation of blood was found to be positive, we made sure that it didn't get transfused. All the rest was just paperwork at that stage.

THE CHAIRMAN: As from what point do you think you succeeded in realising this particular ambition?

A. I have tried very hard to find the original laboratory records of that and I actually remain convinced that they can be accessed somehow, but I have not yet

succeeded. I think it was, at the latest, some time in August, but may have been earlier than that. I think, for reasons that you have already alluded to, I may have been economical with documenting this.

THE CHAIRMAN: I think that would have been consistent with the general plan.

PROFESSOR JAMES: Could I ask, in Mr Dawson's words, a couple of quick questions?

Can you just be a little bit more clear? It seems to me that, as a matter of fact, what was being done in the West of Scotland and what was being done in Newcastle was really the same thing, but it was just being presented in a different way.

In the West of Scotland, they had access to continuing to evaluate the kits and they said they were evaluating the kits but, de facto, they were screening the blood, all the blood, and just, as you have said, removing it from circulation without doing anything else.

Probably Dr Lloyd when started doing something similar because he was involved in an evaluation of kits, but he decided to be more kind of explicit about when he was going, sort for the full monty. Would that be your understanding of what was going on?

A. I think that Dr Lloyd probably started testing in

a slightly clandestine way some time in April, possibly not at that stage testing every donation.

PROFESSOR JAMES: He probably was involved in a slightly different way, but as were a centre in London, as were the West of Scotland, in the evaluation of phase 2 kits at that juncture.

A. I think we have actually seen a minute this morning that, I think, makes pretty clear that the evaluations in Glasgow and North London were intended to essentially wrap up what was going on in Newcastle, which then became called an evaluation.

PROFESSOR JAMES: Okay.

A. So there were three evaluations going on, but it was essentially a cosmetic exercise to sort of relieve the stress.

PROFESSOR JAMES: So my second question is: where do you think -- when we were previously discussing the question of surrogate testing, the concept which appeared to be uppermost in many people's minds, regardless of the sort of strength of value, if you like, of surrogate testing, was the concept of minimising risk for recipients. Of course it has always been uppermost in your mind throughout. Where do you think it went in those various committees during 1989 and 1990, that concept of minimising risk?

A. I think this perhaps touches back to the question that Ms Dunlop asked me this morning, which is, you know -- was asking why the advisory group on AIDS worked differently to the two transfusion committees. I think it probably has to do with both the composition and the chairmanship of those committees, that the focus was very virological, very transfusion process-orientated and there wasn't a loud enough voice, or there weren't a sufficient number of loud voices saying: what about the patients?

There was one side -- I'm just reminded this morning, who was on the ACVSB -- there is Dr Tuddenham, who was a clinician, but a very, very scientific clinician and may not have been a vociferous patient advocate, I really do not know Ted at all. But the other person who definitely was -- to my recollection, spoke out very strongly in favour of the importance of patient safety, was Dr Philip Mortimer, who was a public health orientated virologist.

PROFESSOR JAMES: But he might have been a slightly lone voice?

A. I think he was. On many occasions -- Philip Mortimer and I frequently found ourselves fighting in the same corner of various committees.

PROFESSOR JAMES: Thank you. Finally, it has been suggested

that one of the -- I'm not quite sure where but I believe I'm correct that one of the disincentives put forward for starting testing with the phase 1, kits -- which is effectively what Ms Dunlop was suggesting might have happened, for example, after the FDA approved the US kits in mid 1990, towards the end of 1990 -- was that if you started in a RTC, using a phase 1 kit, it would be difficult, when better kits came along six or eight months later and better confirmatory tests, whatever they may be, to change from one system to another.

Do you think that holds water at all, that idea; or do you think that just wasn't really a consideration or if it was, it was incorrect?

A. Well, if it was a consideration, it was completely incorrect because, I mean, that was our routine job, you know, every year we would expect to see an improved, sometimes a radically improved, procedure. The question would be to introduce it as quickly as possible and there were obviously sort of downstream issues to be resolved, like you might have a whole pile of people who you tested as positive and retested them with more discriminating reagents and discovered that they were negative and then you had decisions about what to do, how to deal with that. Could you release back into the donor panel an individual who actually was on record as

having a positive HCV test, even though you now knew it was a false positive?

So there were issues, but it was entirely normal practice to take on board an improved test.

PROFESSOR JAMES: Thank you. Thank you very much, sir.

Questions by MR DI ROLLO

MR DI ROLLO: Thank you, sir. Dr McClelland, can I ask you just one or two things: do you think that the Scottish National Blood Transfusion Service pressed as hard as it could in order to get HCV screening introduced during this period?

A. That's you know, the sort of life, the universe and everything question really.

Could we have done anything different to make it happen faster? I actually think that the SNBTS alone probably couldn't. What it may have been able to do was to work harder on particularly influencing, through Scottish Home and Health Department, civil servants and medical officers -- as it were, through influencing them, influencing the minister to make a decision that on this issue Scotland needed to get on with it and go it alone.

I think -- whether -- if -- when we campaigned harder to persuade the relevant individuals in the Scottish Government to support us in an early

implementation, I don't know whether we would have succeeded or not, but I think that's the only way we could have done it, because we couldn't have done a Newcastle because we didn't -- we didn't have the money. The money was approved, in principle, by the relevant bits of the then Scottish Government but -- the Scottish Home and Health Department -- but SNBTS could not have done a UDI. We would have broken, you know -- it was not possible to do it without approval for the finance.

Q. Was there a lack of appreciation on the part of Scottish National Blood Transfusion Service of the danger posed by Hepatitis C?

A. I think I have already made my views on that pretty clear actually, sir, that I feel there was a -- there was, not just in Scotland but in the sort of relevant professional communities across the UK -- there was to some degree a failure to internalise the scale of the issue. I said repeatedly that I think that is the only explanation I can find for a sort of apparent lack of urgency.

Q. Can you just tell us -- you mentioned, in the course of your evidence this morning, that you started concentrating more on -- you drew a distinction between patient safety and product safety and that was something

that was interesting you during this period of time.

A. Yes.

Q. Can you just -- I didn't really understand the distinction and its importance. What is the distinction between concentrating on patient safety, as opposed to product safety?

A. It's very simple. You can have -- and it's nothing specific to blood, it applies to all treatments really and certainly to drugs. If you have a therapeutic product which in all cases, one hopes, has the potential for offering benefit to patients, but in all cases carries a degree of risk -- which may be large and recognised, small and recognised or may be unrecognised for various reasons -- the patient safety depends, specifically in respect of blood transfusion, but it applies to any treatment -- is hugely dependent on a proper assessment, for the individual patient, of the balance between the benefit that can reasonably be expected from getting the product, the treatment, and the risk. That's what's strictly called effectiveness, clinical effectiveness of a treatment -- is the net sum -- the sum of benefit minus risk.

Transfusion is a form of treatment that evolved and became established way before the era in which a new product had to be -- its effectiveness and safety had to

be demonstrated by randomised controlled clinical trials and all the stuff that licence applications now require. I realised, you know, during the 1980s, partly from -- well, partly just from watching what was going on and partly from a specific large multi-centre European project that I was involved in, that there was an enormous variation in the way that blood transfusion treatment was being used for very similar patients. Not only in different countries, but even in different hospitals within the same country and even by different clinicians within the same hospital within the same country.

That is always evidence of profound uncertainty in the clinicians about when exactly the product should be used. The reason for that uncertainty is -- was at that time and to some extent still is a profound lack of reliable, sound evidence that says transfusion will benefit this patient and will not benefit this patient.

So my simple thesis -- and I can tell you in a moment what actually triggered me into action about this -- was that our focus had been, and had to continue to be, very -- we had a very tight focus on the safety of product, but that alone was not enough. If we were interested in the welfare of the patient, we also had to focus on doing whatever we could to ensure that these

products, which we knew would always carry a risk, would only be given to patients in situations where there was a real probability that the benefit would outweigh the risk.

So that was one strand of the work. The other strand of the work was related but different, which was that in the early 1980s I did a small study based on some experiences we had had in Edinburgh, when patients had, owing to errors, mistakes, in the hospital processes, been transfused with blood that was actually intended for somebody else. It happens with drugs, it happens all over the place, a good field for medical legal litigation.

When a colleague and I investigated three separate incidents in which patients had received the wrong blood, we discovered that each of these was -- there were multiple steps in the process from the blood being requested, the sample being taken, the blood being matched in the blood bank and going back to the patient and being transfused. We found that, in two of these three episodes, there was -- in something like five of those steps, there had been an error or an omission.

So we started to get interested in the process of actually getting the right blood into the right patients, quite independently of whether it was

prescribed appropriately or not. I did a very small simple survey across the UK and discovered that this was a huge problem. Everybody in the UK who was running a blood bank was really worried about this.

So we began then a series -- a whole pile of work, which is still going on. It was partly to look at the process and try and make the process intrinsically safer, and secondly to collect really good data to increase people's awareness that this really was an area where patients could be harmed. Thirdly to try and develop teaching and education and training programmes in the hope of having it done better.

So there are those two elements of patient safety. Product safety remains absolutely fundamental, but without attention to these other aspects, patient safety cannot -- you can kill a patient with very safe blood.

Q. Thank you. The other matter I wanted to ask you about was Professor Cash's correspondence with Newcastle. We have seen reference to two letters, [SNB0118726] and [SNB0117806]. The first letter is the initial letter which was sent and we can see that, in forthright terms, Dr Cash is extremely clearly upset at the decision of Newcastle. It's obvious from the correspondence that is the case.

What I wanted to ask you about is: obviously SNBTS

had in the past been prepared to go it alone from time to time, for example with the American test kits in the HTLV-III stage. There was a willingness on the part of the SNBTS to act unilaterally, as distinct from down south, and also in relation to surrogate testing. I think all the directors of the Scottish National Blood Transfusion Service -- they made a recommendation to the government, the SHHD, that surrogate testing should be introduced. So that would tend to suggest there was a willingness there to go it alone, if I can put it like that.

Clearly Dr Cash's theme in these two letters is that it's absolutely -- it's an absolute no-no to go it alone in relation to this screening test issue. Why is there such a difference? Why is it that it was okay to be unilateral in certain things, but not in relation to this matter?

A. I think that's a question that actually really has to be addressed to Professor Cash. I think that he had clearly -- and it's evident in the second letter that I saw for the first time today -- and I knew this anyway, that he had a very strong belief that there were -- that, you know, the co-ordination, the sort of commonality of action within the services was very important. The origins of that belief you would have to

explore with him and I have already said that I can perfectly understand and respect that there are very important justifications for that view.

Was it different? I think you are asking me: why was it different for Hepatitis C? I'm not really sure that I can answer that. Well, was it really different for Hepatitis C? I think we would need to scrutinise that quite carefully. In the case of HIV, without backtracking on lots of old ground, I think it was a bit different. I think there was a huge sense of urgency about HIV. It was, as I've said earlier this morning, seen as a national emergency.

Q. Let's just look at surrogate testing because that's to do with hepatitis and not HIV. If we look at surrogate testing, in relation to your recommendation, which you were a signatory of, you were someone who was party to that proposal to the SHHD that surrogate testing should be introduced in Scotland. That's right, isn't it?

A. I was an agitator about surrogate testing, first of all about doing a trial and then about saying it's too late to do a trial, we need to get on and do it.

Q. Presumably -- am I wrong in thinking -- the impression I have is that you would have gone along with the idea of Scotland going it alone in relation to that, if that had been a possibility, or if that was something -- if

SHHD had said: right, you are on, we will do that; you would have been fine with that?

A. I think as I said this morning, while fully respecting the importance of the transfusion service presenting a common, you know, co-ordinated and rational approach to implementing a test. Faced with the choice of that or fulfilling that requirement or trying to provide, you know, better treatment for a larger number of patients, early, as a clinician I would have no choice in saying, one has to put the patients first.

Q. So --

A. At a sort of philosophical level, it's quite straightforward.

Q. Fine. So the question then is what's the difference between surrogate testing in that situation and screening. And Professor Cash's, obviously quite strong, reaction to Newcastle?

A. I really do not think that I can answer that on behalf of Professor Cash.

Q. All right. You don't have any insight into that at all for your own part then?

A. I think the only comment I could make is that -- and it actually might be helpful. Over this period we were moving from -- let me find the right words.

When I started in transfusion at the end of the

1970s, as we have discussed many times before, the transfusion services were essentially, although called a national transfusion service, were independent entities. The concept of quality control, quality management and the concerns about, you know, liability and so on were of a completely different order; they were tiny. Our preoccupations were not with those sort of -- if you like, regulatory sort of issues. You have heard all of this. Over the years, the whole series of changes has taken place, which has increased the regulation, increased the focus on quality assurance, you know, increased the focus on product liability and so on.

By the 1980s -- I mean, as a regional -- the early 1980s, certainly, as a regional transfusion director actually I could pretty much decide that I was going to change the kind of blood bags I used or -- I had a lot of freedom and it wasn't a big deal. In fact, I was expected to do that. If you look at some of the early correspondence, even from the department, certainly in London, you will see, oh, that's the responsibility -- the individual transfusion directors must decide as medics what they want to do about that.

I think, coming back to your question, what may have changed and may have quite heavily influenced

Professor Cash's thinking about this, was a rapidly increasing awareness of the risks, the real risks of fragmentation and inconsistencies in all sorts of aspects of the way that we did things across the UK.

Q. Risks from where, though?

A. The risks of being exposed to a whole -- you know -- let me just take one example: medical legal risks, the risks of litigation result from it emerging that a patient in city A was getting a test for this particular virus and city B wasn't.

Q. So a united front means that it's easier to deal with a threat of litigation and product liability?

A. There are quite a lot of reasons here and I don't want to go on about this. Equity is another issue. There is the question of what are the rights and wrongs of offering testing, you know, offering blood that's tested to people in one part of the country and not in the other. I'm just trying to do what little I can to answer your question and I think the general -- the only general point I'm trying to make is that, if you like, the kind of awareness of the regulatory and related issues increased enormously over this period and if there is -- if I'm to try and identify a factor that perhaps may have made Professor Cash and others more concerned, that may be it, or part of it.

Q. Thank you. Thank you, sir.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: I'm obliged, sir. Dr McClelland, you will remember Dr Gillon's letter of 19 December 1990, in response to Dr Cash's enquiry as to when was it thought the soonest date would be; do you remember that?

A. Yes.

Q. Dr Gillon's reply was 25 February 1991, do you remember?

A. Yes.

Q. Would I be right in thinking that that date was arrived at from purely transfusion considerations, as it were; in other words, we would have the kits, we would have the counselling in place, we would have our side of it ready --

A. Yes.

Q. -- would be that right?

A. That was undoubtedly how he would have approached it.

Q. Would that date -- would the achievability of that date be dependent on other factors, for example ministerial approval?

A. Absolutely.

Q. So, in real terms, the achievability was dependent upon forces over which SNBTS had no control?

A. Most certainly, and I'm sure that when Dr Gillon

answered that -- responded -- wrote that letter, he would have taken it as read that this was subject to the approval of the necessary finance.

Q. The finance would be a matter for the Scottish Home and Health Department?

A. Yes.

Q. Thank you very much.

THE CHAIRMAN: Mr Johnston?

Questions by MR JOHNSTON

MR JOHNSTON: Just one point, I wonder, Dr McClelland, if you actually know when the finance for this testing regime was in place in Scotland, or not?

A. I can't honestly tell you the precise date but my understanding -- my recollection is of the fact that -- it depends what you mean by in place. I think that -- my recollection is that the relevant department in the Scottish Home and Health Department had agreed that an allocation would be available some time quite early in 1991, but that was obviously not the same as that funding being available to one or more of the regional transfusion centres to start testing. Because a further process would have had to have been gone through to say: you can have it, you can start spending it now.

Q. So as far as you understand it, the funding had been set aside?

A. That's my understanding.
Q. Thank you very much I have no more questions.
MS DUNLOP: I have no other questions, sir. I should just say that before Dr McClelland goes, we have checked and the EAGA minutes were shown as, "Not for publication." That's the answer to that question.
A. After you asked me about this, I did have a further recollection because I do remember preparing my own summary of the meeting and discussing with David McIntosh the rights and wrongs of making that available -- I made it available to him, as our general manager then and I know he had some concerns about whether it was okay to make that available to the SNBTS directors. I think in fact we did, but what I said this morning was not quite correct.
MS DUNLOP: Anyway, that's the answer to the status of the minutes of EAGA. Thank you very much, Dr McClelland.
THE CHAIRMAN: We could have a wonderful discussion as to whether sharing information among RTDs was publication but it's better leaving it all alone, I think. Thank you very much, Dr McClelland:
MS DUNLOP: The next witness, sir, is Mr Tucker.

MR GEORGE TUCKER (sworn)

Questions by MS DUNLOP

MS DUNLOP: Good afternoon, Mr Tucker.

A. Good afternoon.
Q. You have provided a statement for us and we will go through your evidence by having the statement in front of us. It is going to appear on the screen in front of you. It's [PEN0172060]. You have explained that your full name is George Webster Tucker and you are a retired civil servant. You give us, in the second paragraph, a little biography. We can see that you joined the Civil Service in September 1959 as a clerical officer with the Crofters' Commission. You had a number of different posts and in 1989, when you were promoted to assistant secretary, you joined SHHD, where you took over from Duncan Macniven. So I think that was a promotion for him as well. Is that right?
A. No, he was moving sideways.
Q. He was moving sideways, I'm sorry. That was your first position in health, apart from your stint as private secretary to Hector Munro and Robert Hughes. Is that right?
A. No, I was in the NHS audit in Inverness.
Q. Right. I was imagining that to be more about finance or scrutiny, rather than working directly in health-related issues. Am I wrong about that?
A. We had to examine and visit hospitals and examine records and information in hospitals. So we knew what

was happening at the coalface.

Q. Right. In the next paragraph you have explained to us that, as assistant secretary, initially you had four branches reporting to you. The first was concerned with NHS property, which you have explained as selling off the NHS estate. I think, remembering the climate of the time, I hope occasionally you bought some as well. You didn't sell it all off?

A. Not in my branch.

Q. Oh, right. So someone else did the purchasing, did they?

A. I think so, yes.

Q. Right. The third branch was the branch concerned with the Common Services Agency and that was headed by Mr Rab Panton and that dealt with blood, ambulances and supplies.

Can we move to the next page, please? You took voluntary early retirement in 1995. You then go on to explain that Mr Panton was the administrator who had the most detailed knowledge of the issues in which the Inquiry is interested.

As assistant secretary it was your job to quality control check briefings and to channel advice to ministers. The detailed content of the advice would generally be provided by Mr Panton and he could call on

the medical experts. Unfortunately, Mr Panton is now deceased.

You reported initially to Hamish Hamill, undersecretary, and then in time he was replaced by Don Cruickshank who, I think, had a background in industry. Is that right?

A. Yes.

Q. And is there again as Sir Don Cruickshank now.

A. Did you say he is not in the health service.

Q. No, he is back in industry, as I understand it, I think, now Sir Don.

Then you say that before attempting to answer your questions, it might be useful to set out the channels of funding. Basically, if we move up from SNBTS, what I understand you to be telling us is that SNBTS were funded by the Common Services Agency, the Common Services Agency were funded from SHHD, SHHD was funded through the Scottish Office and the Scottish Office was funded by the Treasury, if we can put it like that. Then, if we were drawing that in a linear fashion, when we come to SHHD, we would draw, I suppose, at right angles the finance department because they are watching over the activities of SHHD. I think that's what you are telling us.

A. Yes.

Q. You say:

"The Scottish Office finance department would look over the shoulders of SHHD finance."

So in fact SHHD had its own finance department as well?

A. That's correct.

Q. Right. You then move to answer some specific questions. We asked about the two different groups. You answer that on the next page, if we could move to that, please. The distinction you are drawing is that ACVSB was an official group and involved civil servants who represented the health departments and outside experts; ACTTD was more of an operational group:

"I believe it was set up by the transfusion people, with no official involvement."

Let's have a brief look at the circumstances in which these groups were set up. Could we look, please, at [SGH0031257]? This is a letter, dated 25 October 1988, to Duncan Macniven, so in fact to your predecessor as assistant secretary. Given that this is in 1988, he would be in the job into which you moved in 1989. Is that right?

A. That's correct, yes.

Q. This is from Malcolm Harris in the Department of Health. He is sending a draft submission to ministers on the

Advisory Committee on the Virological Safety of Blood:

"The proposals have already been discussed on the medical net ... "

I don't think that's the Internet, I think it's a bit early for that: the grapevine perhaps:

" ... and I understand all departments are content."

And asking for confirmation that SHHD is content with the proposals, in particular that the committee operates on a UK basis, that the committee reports to the CMOs of all four health departments, that the terms of reference are acceptable and that the membership and observers' arrangements are acceptable, and looking for an early response.

Can we go to [SGH0031252]? Mr Macniven replied on 11 November 1988. He wrote back to Elaine Webb at the Department of Health. Originally it seems to have said, "Advisory Committee on the Urological Safety of Blood," but someone has changed that to "virological".
Mr Macniven is confirming he agrees with the proposals and is content that the committee should operate on an UK basis and report to the CMOs of all four health departments, the terms of reference and membership arrangements are acceptable. He proposes two minor amendments, wanting reference to SNBTS as well as to NBTS and to amend the description of Dr Perry. He is

wanting to see the final submission in due course.

Mr Tucker, I'm not showing the draft submission because it's very, very similar to the final submission which we have.

Can we look, please, next at [SGH0031242]. Just so we can work out what's happening here, even though this is 13 January 1989, I suspect this is still before you have arrived in SHHD. Is that right?

A. That's correct, yes.

Q. So a letter from Roger Freeman. Can we just look at the medical heading, please. From the Parliamentary Undersecretary of State for Health. Roger Freeman to Michael Forsyth, who was then minister for health in Scotland, and he says:

"I attach a paper supporting the formation of a new advisory committee to provide advice to the chief medical officers on the virological safety of blood and on which our officials have consulted."

Have a look at this submission that was enclosed with that. It's [SGH0031235]. We have actually seen this before. I think this has been prepared by Dr Moore; we can see Dr Moore's name at the top. So Dr Moore in the Department of Health is at least being shown as the author of this. We are roughly familiar with the format of this paper: a bit of background,

interested parties. On to the next page, please.

The need for a new advisory body, the structure of the new advisory body, early tasks, which we know includes looking at non-A non-B Hepatitis. Then on to the following page, please. Suggested membership at appendix 2. Observers from the territorials.

You would recognise yourselves in that description, would you, in SHHD, the "territorials"?

A. Yes.

Q. And decisions sought:

"Ministers are asked to agree that the new body should be established with the remit at appendix 1."

Mr Tucker, was this a reasonably common format, that, firstly, officials would communicate on a proposal or a plan and then, once they had achieved agreement, ministers in Scotland and England would correspond?

A. Yes, generally. Can I just say this is the first time I have seen these papers. I have never actually seen these papers before. But I don't see why I would because the committee was up and running by the time I took over. But that was the regular way of doing it: the officials would consult and put the name forward and then it would go up to the minister and the minister would put his agreement and he would notify the Department of Health minister.

Q. Mr Tucker, I'm certainly not going to ask you for comment on these papers; it's just to elaborate a little more fully than I think we were able to do when we sent the schedule of questions what the paper trail was that led to the formation of ACVSB.

Just to complete that -- I think we can complete that before lunch -- if we look at [SGH0031233], we know that all of this is happening in January 1989. We can see Mr Macniven, on 6 February 1989, is sending the paperwork to Mr Forsyth. That "PS/Mr Forsyth", that would be "Private Secretary", would it?

A. That's correct.

Q. Going to the private secretary to Mr Forsyth and a number of others and recommending that the minister should agree the proposals in Mr Roger Freeman's letter. A little bit of explanation of what it is that Mr Freeman is proposing, saying there is no suitable existing body to give advice on the range of issues involved in decisions on virological safety, a proposal of a new advisory body, and then Mr Macniven comments:

"We were consulted about the proposals in terms of reference at an earlier stage. We entirely agree that they are sound. I therefore recommend that the minister should write to Mr Freeman supporting the initiative. Draft attached."

That would be the draft letter for Mr Freeman, presumably?

A. No, that's Mr Forsyth writing to Mr Freeman.

Q. Yes. Yes, I'm sorry, that's what I was meaning, the draft of the letter that's to go from Mr Forsyth to Mr Freeman.

I think we can see the final letter if we look at [SGH0031232]. Dated 8 February 1989. To Roger Freeman. That must be Mr Forsyth's handwriting -- Mr Forsyth as he then was.

Mr Forsyth has turned this around very quickly because the submission was dated 6 February and he has dated the letter and send it out on the 8th. So that looks to me to be about as quickly as possible.

A. Yes, indeed.

MS DUNLOP: Sir, that would be a good moment to stop. In view of the fact that we still have another witness coming today, I would, if possible, appreciate a prompt start after lunch. I know that we have to have a decent break but perhaps if we could aim to start at ten or five to two. I don't know if that's acceptable.

THE CHAIRMAN: Let's aim to start at quarter to and see if we can make ten to.

MS DUNLOP: Thank you.

(1.03 pm)

(The short adjournment)

(1.48 pm)

MS DUNLOP: Good afternoon, Mr Tucker. May we return to your statement, which is [PEN0172060]. We had looked at a little bit more of the background to the establishment of the advisory committee on the virological safety of blood. Can we go to the third page, please?

We asked some questions which are really more to do with others. We asked about Professor Cash and the contact with Ortho and then we asked about what sort of time period was being envisaged, in the summer of 1989, for the introduction of screening.

Then, going on to the following page. We see question 13, or more correctly, paragraph 13, which finishes with a question. The introduction to this is a memo that you sent to the then Mr Forsyth. Could we look first at the article which was in The Guardian, which triggered this memo. That is [SGH0028010].

It was 24 August 1989. Perhaps if we take a moment just to have a look at it ourselves. (Pause).

I think that reference to the meeting in October, that's obviously around about the time when there was expected to be a meeting of ACVSB. We can see that Harold Thompson has provided some comment for The Guardian and then some concern for the wellbeing of

donors, particularly when given information about tests.
THE CHAIRMAN: Professor James says that it's Professor Howard Thomas.
MS DUNLOP: Oh, it's Howard Thomas? Quite a significant mistyping. I thought he was somebody else we hadn't heard of, but that's a much more obvious explanation.
You sent a memo, Mr Tucker, which we can also see. It's [SGH0028008].
Perhaps I should just ask you, Mr Tucker, how something like this would come about. Would you do this on your own initiative or do you think: this is a sensitive matter and I should provide some input?
A. The article would appear -- probably the medics, Dr McIntyre or whatever, would have brought it to our attention and would have said, "We need to alert the minister to this."
Does that cover --
Q. Yes, I'm just interested in how the system worked really.
THE CHAIRMAN: I suppose you had a press office that had a cuttings service that passed material like this in and then someone would scrutinise it and see whether there were issues --
A. Yes, it would come into the branch with the cutting.
MS DUNLOP: You have obviously had some input from others to

give you some of the detail that's contained in this, for instance the information about Ortho, the information about other countries.

A. Yes, that would have been supplied via Mr Panton, via the medical advisers --

Q. Right.

A. -- and probably some of that would have come from the Department of Health.

Q. Right. Then there is a reference to the meeting between Ortho and the director of the NBTS in England and Wales, Dr Gunson. Dr Mitchell was also present. It was made clear that they were not representing the UK health departments. Then, just to read on through the memo, if we could, please. There is no CMO meeting planned for October but there was the ACVSB meeting on 17 October, although we know that that was subsequently postponed until 6 November.

Then mention of cost. Then finally, "Line to take".

We were interested in the final paragraph, Mr Tucker:

"This is a UK issue and the Department of Health will be taking the lead but SHHD and SNBTS will be represented in any meeting and the minister will be consulted before any decisions are taken."

So we saw that. We also noticed -- and this is

going quite a bit further on, but to find a similar reference to the common UK position, we can look at [SNB0024627]. This is the directors, the directors meeting, of 13 February 1990. There is other material, exchanges of correspondence between Professor Cash and Dr Gunson, but this is one example of the policy position as it was seen by the directors of the Blood Transfusion Service.

If we look on the next page, please, "Virus safety of blood". Just in passing, we can see something else that we are going to come back to, another issue we are interested in, but not asking you about. There is this message coming through that:

"It would be in order for Dr Perry and Dr Mitchell to report the discussions and findings of the committee to fellow directors but not copy the minutes."

Then the Advisory Committee on Transfusion-transmitted Diseases is discussed. Can we go on to the next page, please? Look towards the bottom. Dr Watt is awaiting a formal recommendation on the SHHD. He is awaiting a formal recommendation from the DOH advisory committee on the safety of blood before offering advice to ministers.

So I think we were interested, Mr Tucker, in trying to probe a little bit how the decision on the

introduction of screening in Scotland was being taken and you have given us your answer to that, if we can go back to the statement and look at answer 13, please. You have said:

"It was intended that the position to be reached would be a UK one. It was not unusual for the Department of Health to take the lead in respect of national issues and because SHHD was a smaller (both in terms of numbers and resources) department there was a general desire to make whatever use we could of DHSS resources."

So not reinventing the wheel perhaps.

A. Yes.

Q. "There was a real desire not to duplicate effort."

Then you say:

"It was also important that DHSS as the bigger department was able to exert more pressure on the treasury. It certainly made sense to be in partnership with DHSS, and in any event both SHHD and DHSS obtained the same advice from ACVSB."

Then we requested whether Scotland would simply follow England and you have said, "yes and no". So I think your answer to this is allowing for the possibility that circumstances could have been different on a particular issue in Scotland, necessitating

a different approach. That would be one situation in which the approaches might diverge.

You have also instanced the possibility of receiving contradictory Scottish expert advice and you have given an example of perhaps the ACVSB not being unanimous. I suppose in reality, however, it would be difficult to know if an ACVSB recommendation was unanimous or a majority? Would that not be a practical problem?

A. No, I mean, if one of the members of the ACVSB had registered his dissent, it would be in the minutes.

Q. So you would be imagining something as formal as that when you are talking here about the ACVSB not being unanimous; it would be evident that someone dissented from the decision of that body?

A. Right.

Q. You say:

"We would certainly have looked at the issue further in the light of the information that other countries were testing. We would not necessarily have followed ACVSB's recommendations."

You say Mr Forsyth, the minister at the time, was unhappy about -- I am sorry you say:

"If he was unhappy, he would call us civil servants".

There is no evidence of his having done that on this

issue and you would assume he was happy for DHSS to be allowed to take the lead.

What about a situation in which nothing seems to be happening? Can you think how that might have been dealt with? I think you are talking about a situation where there is active advice to particular effect coming, or possibly split advice. What if there is no advice?

A. The committee was an expert committee. They were there to give advice. I can't understand them saying, "We can't give you any advice". They would have been asked, "What do you think about this problem or situation?" And they would have come up with something.

If they had come up and said we are divided on this, there is a view in the medical section that disagrees with that view in the other medical section, then that would have had to have been reported. I can't say we would just be left in limbo when they had been specifically asked and were looking at the matter.

Q. I'm really just wondering about a situation in which the whole process seemed to be taking a very long time. Would SHHD make active enquiries as to what was happening and when a decision was anticipated, or what the forward planning was?

A. Our medics were on the committee.

Q. Dr McIntyre certainly was there as an observer.

I suppose you were getting the reports back from Dr McIntyre?

A. He would be reporting back and if he thought there was some concern, I would have thought he would have said to us, "This is not going to be answered ever", which seems strange to me.

Q. So, as far as you remember the matter, and as far as you have been able to refresh your memory by looking at the paperwork, the situation was that this decision had been entrusted, or at least the assessment of the factual position had been entrusted to ACVSB --

A. Yes.

Q. -- and the department was content to leave that to take its course?

A. Until we got the experts' advice, yes.

Q. Yes. Can you just expand for us, a little bit please, that reference to the desire not to embarrass each other. So ministers -- you say:

"Ministers were part of the same government and there would be a desire that they shouldn't embarrass each other."

Can you explain a little bit what you mean by that?

A. Well, if one minister -- if one department's minister took a different course on a policy matter, then there would be concern that courts might look at it saying:

here's one part of the UK doing something different, why are you not doing it? They would want to present a united government on a issue like this.

Q. Right. Then there are a couple of questions which, I think, are perhaps more appropriately addressed to others.

Can we move on to the next page, please? Question 22, we were asking about a document which was transmitted in February 1990 by Dr Cash to Dr McIntyre and then by Dr McIntyre on to the Department of Health. We asked about a handwritten note on the copy that was within SHHD and you said you didn't remember the incident and you would suggest that your former colleague, Mr Angus would be the most appropriate person to answer the question.

This is a document on which is written that this press release from America has, "Stirred up a hornet's nest". We will just have a look at what Mr Angus has said. Can we have a look at [PEN0172084], please. Can we go to paragraph 8? Mr Angus in paragraph 8 he tells us:

"The hand written note at the foot of Professor Cash's letter was written by me. Pam Reenay was a higher executive officer in the Department of Health's policy branch for the National Blood

Transfusion Service.

"Although I can't remember the specific circumstances around my note, I think that it would be reflecting the unexpectedness of the American announcement and the expectation of calls for the immediate introduction of similar testing in the UK. The reference to having stirred up a hornet's nest reflects that unanticipated nature of the announcement, rather than any anger felt by anyone."

So you were right, Mr Tucker, Mr Angus had something to say on this particular note, given that he wrote it.

Can we go back to Mr Tucker's statement then, please, and we are at page 2065. The question -- we should perhaps give a little bit more information before I ask you.

Actually the precursor to this is a memo from Dr Young, which was suggesting some concern about progress on the issue of Hepatitis C screening. This actually -- I think it would make more sense if we were to look at this document. So if you will allow me a moment, I'll just pull it up. (Pause).

It's [SGH0027939]. Can we just take the date of this? I think it's -- is it at the bottom? Yes, it's from Dr Young, 23 May 1990. Who was Dr Young at this point?

A. I believe he was -- well, he certainly was the deputy chief medical officer. I'm not sure if he was the deputy chief at that time. But I suspect, from what he is saying, that he was. I don't know if his predecessor had gone but he certainly was the deputy chief medical officer.

Q. Right. He is reporting back from a meeting of the Common Services Agency management committee on 23 May.

A. He was a member of that committee.

Q. Right:

"Members had asked for a position paper, in layman's terms, on Hepatitis C testing for the June meeting. They were concerned at the legal liability aspects and wished to take a firm grip on how this issue was handled (using BSE as a model they would wish to avoid)."

Dr Young had said:

"The central advice was not yet, but when confirmatory tests and tests with better sensitivity became available, this situation could quickly alter. I also mentioned the problem of false positives and counselling donors."

Dr Young is wanting to be briefed and discuss what kind of paper should go, who would draft it and would it be necessary to involve Professor Cash. This is Dr Young to Dr McIntyre, and you. Then Mr Panton has

written that you are on annual leave for the next two weeks and he is wanting to have a word with Dr McIntyre to discuss the paper. That's 31 May. Then if we go up to the top, this does look like your writing, doesn't it, 24 May? Is that you?

A. Yes, that's me.

Q. Yes. So you had asked Mr Panton to liaise with Dr McIntyre. Then Mr Panton, a week later, is saying to Dr McIntyre that you are on holiday. Then whose note is that on the top left? Is that Mr Hogg?

A. That's Mr Hogg.

Q. Yes. To Mr Angus and Mr Bayne:

"Please arrange to bring forward."

Mr Panton has got a note to Mr Hogg bringing things forward on 8 June. So that's the background to your answer. If we go back to the statement you say:

"Dr McIntyre responded to this memo on 6 June."

Can we look at that, please? That's [SGF0012034]. It's quite a long response, a long memo from Dr McIntyre back to Dr Young. Things are moving very fast, he says. That's linking in with a letter that we looked at yesterday -- in fact we looked at the version of it that was sent to Dr Perry, who was also a member of ACVSB, saying that the next meeting of the committee was being brought forward from 24 July to 2 July.

Dr McIntyre's view:

"I'm in little doubt that, for a variety of reasons, many of them non-scientific it will be decided that there is no alternative but to recommend the introduction of the test."

Then giving a little bit more medical information and pointing out that there is a danger of litigation saying,"The whole issue is something of a minefield."

Then on to the following page, just to see the end of what Dr McIntyre is saying. He is basically saying: let's wait until after the meeting on 2 July, pointing out that Dr Mitchell also attends the meetings of ACVSB. Then Mr Panton has a handwritten note on this. If we go back to the previous page, we can see it, please.

So Mr Panton, I think, is picking up the funding thread and saying to Mr Hogg: well, you are already in touch with Finance 5. That's the financial part of the department, is it?

A. That's the SHHD finance division responsible for the health.

Q. Mr Panton is saying:

"It looks as though the study is not going to be undertaken but ..."

You are already in touch with them about financing the study:

"So continue to press for funds. Bring forward to 3 July after the ACVSB decision. I have alerted ..."

Mr McIntosh, I think that is. Can we go a little bit down, please:

"... will speak to Mr ..."

I'm not sure who that is:

"... about the first dip into the contingency fund."

We asked you a little bit about that. If we go back to the statement, please, to paragraph 25. You have explained that:

"10 per cent of each division's budget would be held in reserve. This is known as the contingency fund."

Then we asked you for some more information about funding. We wondered if there had been an attempt to introduce screening before the financial year 1991 to 1992, but the cost of that could only have been met from the reserve, the contingency, is that correct? You said you didn't think that was right.

So I think what you are saying here, Mr Tucker, is that, if screening had been introduced at a point where there was no money in the reserve, other ways would have been found to discover the money. Is that right?

A. That's correct. Can I just clarify one point? The previous one was talking about a pilot study --

Q. Yes.

A. -- not the routine screening of all donations. Are we clear on that?

Q. Yes, I think so, that the pilot study was being funded from the contingency fund. I think what we were wondering was -- and this is just surmise on our part -- whether -- if there had been a sudden instruction to commence the screening of all blood donors, it would have been necessary to use the contingency fund and you are saying: no, that's not how it would have worked. Am I right about that?

A. If there had been a suitable test which would have enabled the routine testing at that point. In other words, it would have cost £1.2 million --

Q. Yes.

A. -- then that money would have had to be found, if not within the contingency or the CSA, the health budget, it would go up the scale.

Q. Yes. You have given some examples of ways in which money might have been released from other areas.

So I suppose the first port of call would have been the Common Services Agency budget, I think you are saying. Then, if not there, then you would look at other Home and Health Department divisions and, if not there, the Scottish Office generally. So I think what you are communicating is that there was room for

manoeuvre?

A. Yes.

Q. Is that right?

A. Yes.

Q. Yes. You conclude by saying:

"The question is theoretical because we were not in a position to move forward with the test before that financial year."

In our questioning we then moved to the ACVSB meeting on 21 November 1990 and we tried to follow what happened after that. You have given your own understanding, if we go on to the next page, please. I think some of this you have presumably reconstructed from the material that we have been able to send you. Is that true?

A. That's correct, yes.

Q. Yes. Paragraph 9.10 of the preliminary report is, itself, a summary of what seemed to have been factors that were involved. But plainly we have to ask those who were more directly involved in the decision making than you were; is that correct?

A. That's correct.

Q. Right. Then there is the question of what happened as far as communication to the minister is concerned, after the decision on 21 November 1990. Can we look first,

please, at Dr McIntyre's note of that meeting. That's [SGH0028501]. Dr McIntyre begins his meeting note by rehearsing the conclusions from the previous meeting, which the chairman himself had repeated at the start of the November meeting. Can we go down to number 8, a submission would be put to ministers. So, from November 1990, it had been identified that that was to happen and then mention of the studies that were underway.

Interestingly, a reference to that possible reduction of 30 per cent, which, if we follow the minutes through, I think was subsequently corrected to 70 per cent, at least insofar as figures from France and Germany were concerned. If we go on to the next page, There is the meeting note carrying on:

"The following decisions were made ..."

Just look down through to the end of that, please. Counselling:

"It was agreed that a submission should be made to ministers along these lines and the chairman and his administrative colleague, Mr Canavan, agreed to send a copy of draft submission to Scotland, Wales and Northern Ireland."

That seems to have been reasonably commonplace as well, Mr Tucker: if there was a field in which all the

departments were active, the Department of Health seems, quite frequently, to have sent its draft submission to you. Is that right?

A. To our department, yes.

Q. What was the point of sending it?

A. The point to send it was to show what the Department of Health were proposing to put to the ministers.

Q. Yes. Would you have needed that guidance? You wouldn't have been able to write something yourselves?

A. We could have written but we would need to take advice on what they were doing as well.

Q. Right.

A. Since they were servicing the advisory committee, they would have all the information.

Q. Right. Can we just look on to the last page, please? This is about specialist laboratories. Dr McIntyre saying that:

"Dr Follett may be able to carry out further tests, but this of course would involve some financial arrangement with Greater Glasgow Health Board and an assurance that the money allocated for the task was used for same."

So this would be about accounting, I take it, that if money was given for a specific purpose, there has to be some measure in place to ensure that it's not spent

on something different. That seems to be what that's referring to.

Can we look at the next document from around this time, please, which is [SGH0027890]. This is actually into January 1991 and this is from you. It's dealing with two different topics and it's obviously the first one that we are interested in, which is testing for Hepatitis C. You had had information from Mr Canavan that the Department of Health ministers had given their approval to the submission on Hepatitis C testing:

"He does not know what date for the introduction will be chosen, since some laboratories will require new equipment. He is to convene a meeting with RTCs (regional transfusion centres) to ascertain what would be practical. He agrees that there should be a common starting date for the whole of the UK, but there appears to be some concern from English public health laboratories about testing."

The next paragraph is interesting, Mr Tucker, in the context of our examination. Why did you think it might be a good idea to set a specific target date?

A. Well, because we wouldn't have gone to our minister without telling him when the testing was going to start. We wouldn't have said to him, "As soon as practicable", because he would have said, "What does that mean?"

Q. Right.
A. So, 1 April was the date we knew that we had funding place, because the PES survey for the year had been agreed by ministers and the funds were then available.
Q. You are using the PES?
A. Public expenditure survey.
Q. Right, thank you. Sorry, please carry on.
A. That would be in place. But I put that as a suggestion to Mr Canavan and he was going to consider it. But, at that time, I was not aware that the advisory committee were still evaluating the second generation of the tests and hadn't come down firmly in -- were waiting for the results of the evaluation.
Q. Right. But, Mr Tucker, you had long experience of running things and you were suggesting that it might be a good idea to set a specific date. Was any part of that drawn from your experience of running things, introducing new systems and so on?
A. Yes.
Q. Did you think it was better to aim for a specific date?
A. Yes, I agree.
Q. Why is that?
A. Then we could all move forward at the same time.
Q. Right. I think you explain your thinking a little bit in the memo, don't you. You say that:

"Delaying for the slowest could mean a long wait."

So, one of the drawbacks about not saying everyone has to start something on the same day is that then, by definition, you are waiting for the last person to be ready. So is that likely to have been your thinking? It's quite a simple common sense idea.

A. That probably was my thinking 20 years ago.

Q. I don't expect you have changed your mind about that. It's a fairly straightforward notion, isn't it; that, if you set a time or a starting point, then everyone has to work to try and be ready?

A. That's what happened with 1 September.

Q. Yes. I suppose perhaps what I'm wondering is, if the date had been clearly set as 1 April, some parts of the country at least might have achieved that.

A. That's true, but surely it would be better for the people who were actually involved in the transfusion service to tell us exactly when they would be ready.

Q. So you do not think that it was really for government; either yourselves or the Department of Health, to set a date?

A. Well, it would be pointless to set a date which could not be achieved by the people closest to the action, unless they indicated privately or publicly that they could put the system in operation, that the tests were

satisfactory and that they had the staff and equipment to do so.

Q. Yes. I'm not suggesting that you would set it by plucking a date from thin air, I'm wondering perhaps if a date could have been set, after consultation with those who would actually have to carry out the work?

A. I think that's what happened. He was going to consult with the RTCs.

Q. Right. Can we look then at the next document in the sequence, which is [SGH0027880]? This seems to be the contributions of a number of different people. I think it maybe has started out being Mrs Falconer's memo. Is that right? That is her writing we see, with SF and then 19/3, yes?

A. That's correct, yes.

Q. She was in SHHD --

A. She was in Mr Panton's branch, yes.

Q. Mr Panton's branch, yes:

"Now we have date of commencement of testing, 1 July 1991, what about submissions?"

She is asking. So I suppose people in the department are aware that, at some point, there is going to be a submission going to the minister and they are trying to time it appropriately. Is that correct?

A. That's correct, yes.

Q. You have told us that a submission wouldn't have gone before a definite date had been set?

A. Until we were sure that we had a test that was recommended by the committee and a date -- a firm date was -- for the UK was being set, yes.

Q. Right. So there wasn't any sense of going to the minister for approval in principle?

A. Well, I thought the approval in principle had really been given when the minister signed off for the public expenditure survey, not specifically but in the fact that he did not object to that money being allocated to that purpose.

Q. Right.

A. We had also agreed that this would be a UK basis -- that's down through lots of the documents I have been able to read since. So, in my mind, the minister would not have taken a different course.

Q. Let's just look at Mr Panton's writing, if we could scroll a little bit further down. Mr Panton is saying:

"Draft submission based on English one -- shorter version".

I'm not sure if that's an instruction or a description of what has been already been achieved.

A. I think that's an instruction.

Q. Right:

"Other ministers have agreed."

Can we look next, please, at [SGH0027828]? Here we have the submission, I think. Can we look at the end of it, please? This is your signature and it's 24 July 1991. So I suppose there will have been a number of drafts before you sent the final version.

A. The draft would have come up from Mr Panton, having shown that to the medical people, and would have come for me for a final check and sending forward, yes.

Q. The minutes informing the minister of:

"A decision, by the other UK health departments, to approve routine testing of blood donations for the antibody to the Hepatitis C virus from 1 September 1991."

So that has obviously been a further change of date:

"And recommends that similar testing in Scotland should be introduced from that date."

There is then some arguments for and some arguments against. A bit of background. This is mainly medical and scientific. Then the Scottish position. Recommendation:

"As Department of Health ministers have already agreed to the screening for Hepatitis C, there would be criticism if Scotland were not seen to be taking similar action."

In paragraph 9:

"No specific publicity is being given by Department of Health ministers to the introduction of the tests in England and Wales. This is probably in view of the current sensitivity surrounding blood transfusions and HIV and the need to avoid giving an opportunity for further criticism that testing should have been introduced earlier.

"It is considered that an announcement may prompt questions about blood safety and that it would give rise to another pressure group seeking compensation for contracting Hepatitis C. If, however, the minister considers that the balance of advantage lies in assuring the public that all possible steps are being taken ... we shall prepare a press release to this effect for the minister's approval."

So that recommendation went to the minister and we can see the response, if we look at [SGH00027817]. This comes from Mr Bearhop. Is that assistant private secretary --

A. That is, yes.

Q. -- to the Minister of State, 26 July 1991.

Did Mr Forsyth always turn everything round in two days?

A. Yes, he was pretty quick, yes.

Q. "The Minister is content to endorse your recommendation and considers that a press release is appropriate. I would be grateful if this could be put in hand."

Can we go next to [SNB0027666], please? This is in connection with the possible decision for Scotland, maybe to have gone ahead. Sorry, can we just minimise that for at moment and go back to the statement so that we catch up? Going to -- yes, paragraph 32 and this is just your narrative of sending the submission.

You have highlighted a number of pieces of correspondence. Then 33, you think there was difficulty in moving the issue forward in the early part of 1991 in both Scotland and England. Actually, before we look at the question of Scotland possibly going ahead on its own, I should ask you about that question that we see there at 33:

"Why was SNBTS not to be told that there was an unofficial start date of 1 July 1991?"

That's in one of Mrs Falconer's notes:

"Why would this be confidential, to the extent of not informing the transfusion service?"

I think your answer to that, Mr Tucker is that you don't really know. You say:

"I don't think it's of any consequence since the date turned out to be inaccurate."

That's obviously correct, but I think we were wondering what the reasoning process was that underlay this wish to keep a chosen date from the transfusion services when the transfusion services would be required to put the system in place?

A. Well, I don't really know why it was regarded as secret but, on looking through the past papers, I see there is a letter dated 4 April 1991 from Dr Gunson to the NHS procurement and in that letter he says:

"Timing slipped because unavailability of testing kits ..."

And that Abbott was not available until mid-April:

"To accommodate slippage I have postponed introduction until 1 September 1991."

That was written on 4 April, it's [PEN0160166].

Q. Yes, we have that.

A. So that date was already 1 September to Harold Gunson, who was the national director. Also, I would assume, known to the Scottish Transfusion Service at the same time, since he was writing to the national procurement committee. So 1 July, to my mind was completely irrelevant.

Q. Yes. I suppose it does seem a little bit confusing, Mr Tucker. If the government departments -- one government department is saying to another, "Don't tell

SNBTS", but meanwhile the transfusion services are all in correspondence with each other and they are all aware of the thinking on start dates anyway.

A. Yes, but the officers concerned were junior officers, it wasn't, if you like a senior management decision being conveyed.

Q. Who was taking the decision as to what the start date should be?

A. The decision would have been taken, as I said -- Dr Gunson has already taken the decision on 4 April. I have taken the decision, he said. He would convey that to the Department of Health, that he thought he could not -- the RTCs in England could not proceed to introduce the tests, routine, until 1 September.

Q. Right.

A. If my memory is correct from reading the papers, the evaluation was still going on of the second generation of tests. The advisory committee had not said finally that these tests were as reliable as the current knowledge could make them.

Q. Right. Actually that other minute that we were looking at, that letter, is in our expanded preliminary report. Can we maximise the other document, please because it fits with what you are saying about Dr Gunson, except that it's for Scotland. So could we go back to that

[SNB0027666], please. That's the Blood Transfusion Service management board, 11/12 June 1991. On page 4, that records a decision of the Scottish directors, the one sentence decision:

"Agreed. Routine donation testing to begin on 1 September 1991."

So we have Dr Gunson speaking for England, the board meeting in June speaking for Scotland and then the submission going to the Scottish health minister in July 1991, asking for a decision. But, in reality, the decision has already been made, has it not?

A. Well, going to the minister to endorse it --

Q. So, the accurate description of the situation is that the transfusion services were the decision-makers and the minister endorsed it?

A. No, the minister endorsed the advisory committee's advice, through the Department of Health and ministers there. The transfusion people were the people on the ground who knew when they had the staff and the facilities to start routine testing with the test, whether it was Ortho or Abbott, that they would then use.

Q. Whose responsibility was it to say, testing will begin in the United Kingdom on X? Whose responsibility was it?

A. It would have been -- the Department of Health would have said, once they had known when their RTCs could do it.

Q. So are you saying that the responsibility belonged to the government departments?

A. Eventually, yes, but they had to be in a position to know that it was feasible to do and that the test was reliable.

Q. Right. It's just that in this period, which is a little difficult for newcomers to this story to follow, and by this period, I mean November 1990 to September 1991. It does seem a little bit difficult to work out who is taking the decision because we have Dr Gunson saying in one letter that the Department of Health haven't set a date, and then we have him writing to his fellow directors asking: what date would suit you? And Dr Cash is a writing to his fellow directors asking them what date they could achieve. I think all I'm trying to be clear about is whose was the responsibility of setting the date?

A. The date would have been fixed by the Department of Health when the evaluation of the second generation tests had been completed and the advisory committee had signalled that they were happy with that.

Q. Right. Do you think everybody understood the process?

A. Obviously not from all these different people that are now available to the Inquiry. They weren't available to everybody at the time.

Q. Can we go back to the statement, please? The last question that we put to you concerned a letter that was sent at the end of August 1991 by Mr McIntosh, who was the general manager of SNBTS. We will just have a look at that letter, it's [SNB0054822]. Did you see this letter at the time, do you think, or is this something you have just seen recently?

A. Just seen recently.

Q. Right. You have had a look at it?

Mr McIntosh is saying that the first alleged record of a clear UK policy in this regard came to their notice indirectly, unofficially and too late:

"We shall require to have much clearer official notification, timeously, in handling similar issues in the future."

Then saying that there is a need for more clarity about:

"To whom the advisory committee ... provides advice and what status that advice has;

"Who is ... responsible for turning that advice ... into actual policy, with authority to instruct action and/or inaction;

"Who is responsible for communicating relevant and authoritative instructions clearly and timeously to the relevant punters at the coalface."

We have looked at this before, Mr Tucker but just to look at the letter to its conclusion if we can go on to the next page:

"As you know, it is my belief that, thereafter, whatever policy decisions are ultimately taken about what developments are to be progressed and when should be conveyed to us very formally and very clearly by the relevant authorities in the NHS in Scotland. Where we are and where we are not free to do our own thing should also be made clear, that way we shall all know exactly where we stand.

"Clearly it may only be possible to achieve part of what I am looking for here. A certainly amount of inherent ambiguity will always be required by civil servants, partly to protect ministers and partly to protect themselves."

He thinks that a better outcome can be achieved next time.

You don't agree, Mr Tucker, with the comment about ambiguity? You think that's unfair?

A. I think -- I mean, I hadn't seen this. I thought we had a good relationship with the SNBTS. They were certainly

able to contact my staff and speak to them. I would not have thought that might have been the same position in England, having said that. I'm certain that my staff and myself were always trying to do what we thought was in the best interests of the NHS. So I don't see -- we are not protecting ourselves, or trying to avoid the responsibility of civil servants; we were working within the system that was operative in 1991.

Q. Yes, I don't think Mr McIntosh is saying that there was a bad relationship.

A. Well --

Q. I think he is maybe just saying that things weren't very clear.

A. I agree, but it's not clear why he didn't go through the Common Services Agency, who were his employers and who were the funders and the policy-makers for common services. It seems to have not had any direct link to them, and yet I assume they employed him and gave him his job description of what he was to do and where he could seek advice.

Q. I'm not sure that Mr McIntosh's comments relate to his own position. I'm not sure that he is articulating that he didn't really understand where he stood. It seems to be a bigger point: that it was difficult to know what the plan was maybe. Perhaps an example of that would be

this confusion about the starting date and people saying: don't tell anybody, but the starting date is going to be 1 July. That sounds to me a bit like ambiguity.

A. Well, you are suggesting that a junior member of staff has put on a minute and that Mr McIntosh is not aware of what's going on between John Cash and Gunson and all the rest of it and Ruthven Mitchell, all these people whom he chaired meetings with. I don't understand that.

Q. No, I'm not saying that, with respect, Mr Tucker. I'm just saying that, on this important question of everybody knowing what the aim was or what the planned starting date was; there was confusion. You yourself, if I may say so, in a very common sense suggestion, had mooted the idea of setting a date.

A. Yes.

Q. And that didn't happen?

A. At that stage I wasn't aware that the second generation of the tests hadn't been properly evaluated.

Q. One of the things you are suggesting is that the Common Services Agency could have become more involved. We have seen that, at one point, they did ask to be brought up to speed. But do you really think that the involvement of another body would have helped the position to become clearer?

A. They were the body responsible for the SNBTS. They were the pay masters, they were the employers. I mean, surely there must have been papers going up from the SNBTS to the managing committee of the Common Services Agency. If not, why not?

Q. Right. So I suppose that would be something that you would think was a defect, if people weren't following the properly understood channels of communication?

A. Yes, I would assume that the employer would have made it clear to the employee what the reporting system would have been.

Q. Right. You don't think it's fair to say that, on occasions, government departments perhaps -- and I know I'm wondering what Mr McIntosh was really meaning -- and I suppose we haven't heard from him yet -- but in that comment he makes about a certain amount of ambiguity, he is perhaps seeking to convey that one has more room for manoeuvre if one doesn't commit oneself publicly to taking a certain step on a certain date?

A. No, I think naturally the Civil Service was probably more cautious, the example being where he had been approached by Ortho and was ready to just buy their kit there, without that kit having been properly, scientifically, evaluated. Is that -- he would have jumped in, is my impression, whereas we said wait

a moment, let's have this properly evaluated. That's a different --

Q. So one person's ambiguity is another person's proper caution. Does it come to that?

A. If you say so.

Q. No, I'm asking you.

A. I'm just saying that we were probably more cautious than Mr McIntosh would have liked us to be.

Q. Right. Thank you very much, Mr Tucker.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Sir, thank you. Mr Tucker, I would like to go back to 1989 and the memo that you sent to Michael Forsyth. I think that's [SGH0028008]. The context of this is an article in the press, in The Guardian in particular, which we have seen. Can I ask you: in order to compile this document, did you take any medical advice?

A. Oh, definitely. We would not have put anything up to ministers without the CMO's office and staff giving us their views.

Q. Right. There is nothing in the article -- sorry, nothing in the memo that we see which mentions that contracting Hepatitis C could result in cirrhosis of the liver or liver cancer. In other words, it doesn't say

anything about the serious effects that Hepatitis C can have.

A. Can we have the rest of this --

Q. Yes, do, please.

A. I can't see if you are correct, but I'm sure Dr McIntyre is on record somewhere as saying that there were some minor effects -- not in every case obviously, but in the more serious cases, it was a serious matter.

Q. The point I'm making is that, in advising the minister at this stage, the minister does not appear to be being told about the more serious -- potentially most serious aspects of Hepatitis C. In terms of the -- in the context of this memo, that seems to be the case. Is that right? Do you agree with that?

A. Yes, but would he not have read The Guardian article that was attached?

Q. I don't know whether he would.

A. I would assume he would, because ministers are very keen to read what the press is saying about --

Q. The problem with that is that The Guardian article has been described as "alarmist" at one stage in this. I know it's -- the particular context for that is paragraph 4. That's not necessarily in the context of the potential, I understand, of hepatitis, more in the context of the likelihood of getting it from a blood

transfusion. But nevertheless, the thrust perhaps, or the emphasis on the memo is to suggest that the press article is over emphasising a problem, rather than under emphasising a problem. Do you see what I mean?

A. Yes, I do and all I could say there is that, at that stage in 1989, I'm not sure that Hepatitis C was fully understood by everybody.

Q. Well, it may not have been fully understood by government medical officers. That may be the case. But it may have been better understood by others at this time. We have heard evidence in this Inquiry that it was indeed -- I think it was reasonably well understood that, from about 1985 onwards, awareness was growing about the potential that Hepatitis C had.

If we look at the "line to take" section, if I can just take you through that, paragraph 8, what the minister is being -- what's being suggested to the minister, presumably if he is caught unawares by some bright spark of a journalist or interviewer on this particular issue and asked questions about it, then the line to be taken is set out there at 8(e), is that right?

A. That's correct, yes.

Q. The first thing it says is:

"Donors should not be deterred from giving blood."

Then it goes on to say:

"UK blood is still considered to be one of the safest in the world."

By whom was it considered to be one of the safest in the world, at that stage?

A. I assume that is the medical view -- our medical advisers.

Q. Then it goes on to say:

"The Ortho test is under review here, as in other countries."

Then it goes on to say:

"The prevalence of HPC [I take it that means Hepatitis C] in the population in this country has not been established nor has the role of blood in its transmission."

Can you explain what is meant by that:

"The role of blood in its transmission had not been established."

A. Again, that must have come from the medics. I'm not medically qualified. All I can say is my understanding would be that you can have hepatitis without having a blood transfusion.

Q. But I mean, I think The Guardian article is just simply concerned about the danger of blood transfusion in the context of Hepatitis C, in other words that you can get,

as a result of a blood transfusion -- you can be infected with the Hepatitis C virus.

A. Yes.

Q. I think that had been established and one shouldn't have any doubt about that, even by 1989.

A. Well, this -- if that is the case, this minute would have been seen in draft by our medics and, if they had signed off on it, then I assume that's what they thought.

Q. Another matter I wanted to ask you, in the context of the advice that was being given to ministers, or not, as the case may be, at or about this time, if we go to your statement, [PEN0172060], it's 2060 at 2063, paragraph 13. Just scan down this. There is a particular section I want to read to you:

"From our point of view it certainly made sense to be in partnership with the DHSS, and in any event both SHHD and DHSS obtained the same advice from ACVSB; their recommendations went to ministers in both countries, as well as Wales and Northern Ireland.

"I'm asked whether Scotland would simply follow England; the answer to this is yes and no. We would follow England if it was sensible to do so, for example in relation to the introduction of national testing where there was clear expert advice that this was the

correct thing to do. We would not necessarily have followed England if, for example, the ACVSB's recommendation had not been unanimous and had decided not to introduce testing; if we had contradictory Scottish expert advice, then ministers would have been consulted first."

Now -- sorry, I'll just complete that:

"We would certainly have looked at the issue further, in light of the information that other countries were testing and would not necessarily have followed ACVSB's recommendations."

What I want to contrast with you is -- I don't know whether you are aware of the position with surrogate testing, which we have been examining in an earlier stage of this Inquiry just recently but it does appear that, in relation to that, there was a situation where the Scottish National Blood Transfusion directors recommended to ministers -- sorry, to SHHD, rather -- not to ministers, but to SHHD that surrogate testing should be introduced. But that wasn't -- that recommendation wasn't communicated to the minister at the time. I don't know if you are aware of this, or not?

A. No.

Q. No. But would it be your position that, if

a recommendation of that kind was made by the Scottish National Blood Transfusion Service, whether it be in relation to surrogate testing or in relation to screening or whatever -- would it be your position that such a recommendation, if it were made, should have been put to ministers?

A. We would seek advice from our medical advisers on that.

Q. The question is: if you have expert advice from -- a recommendation from Scottish National Blood Transfusion Service, my question is: should that be put to ministers?

A. As I said, we would see what our medical advisers said of that advice. You are saying, "expert advice." Our expert advice lies in the medical advisers to the Secretary of State.

Q. What you say in your statement, however, is -- I don't think you introduce the element of seeking advice from your medical advisers. I think you -- what you seem to be suggesting in your statement here is that if you had advice from the body concerned, then you would put that to ministers.

A. Through our medical advisers.

Q. You would expect -- am I right in thinking --

A. If that was a clear -- advice which was possibly controversial advice, then, yes, I would have put it to

a minister.

Q. All right, thank you. Thank you, sir.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: I have no questions, thank you, sir.

THE CHAIRMAN: Mr Johnston?

Questions by MR JOHNSTON

MR JOHNSTON: I just have one or two points, if I may. The first one is this, Mr Tucker. I think you mentioned the financial position in 1991/1992 and that money was allocated in the budget for this screening, should it be introduced in that financial year. Is that right?

A. That's correct, yes.

Q. Can you tell us anything about the position in the previous financial year, 1990 to 1991?

A. Obviously there was nothing in the public expenditure survey, so it couldn't have been known in June/July 1989, when the public expenditure survey was being drafted. The only monies available in 1990 would have been from the contingency fund. Or from the monies already allocated to the Common Services Agency.

Q. Could I just follow that up by asking you to look at one document? This is PEN0172149. I'm sorry, that's the page number, rather than the document number. This is page number 4 of the statement given by Mr Hogg to the Inquiry: [PEN0172146]. In relation to a question you

were also asked about -- he makes some comments about a PES bid and I just wanted to be clear whether your understanding squares with his, where he says in his first sentence:

"Although an increased PES bid and subsequent revenue allocation for CSA/SNBTS for financial year 1990-1991 had been included, based on additional costs of £1.2 million."

Is it right to think that there had, indeed, been some thought given to this for the previous financial year? That's to say, 1990-1991?

A. Well, I don't recall it, but if Mr Hogg is saying it had been included...

Q. If you do not know --

A. I have sorry, no -- I can't understand, if we were only looking at it in -- the advisory committee was only looking at it in the last part of 1989, it wouldn't have been in PES because they would have missed the loophole there.

Q. Okay. I'll just leave it at that, thank you.

Just another small number of points then. You have just been looking at the memo you wrote in relation to the Guardian article. Do you recall that, in August 1989?

A. Yes.

Q. I think we saw that the focus in The Guardian article was on whether the government should decide that screening should be introduced, in relation to Hepatitis C.

Can you tell us what you were trying to achieve in putting the memo to the minister at this time, in light of that?

A. Basically, it was to alert him to the Guardian article and the possibility that there might be further press enquiries of him. To give him a position -- to give him information on that particular subject, because obviously that wouldn't have been in his mind at the time. Also to tell him where the department was and where the UK was and to indicate that the -- this was a UK matter, not a Scottish matter in particular, and therefore that we would be acting in unison with the rest of the UK.

Q. Would you expect him to convey that message more widely to the public?

A. Well, we gave him a form of words to use. Whether the minister would use that or use something else, that's for him.

Q. Right. You discussed with Ms Dunlop the question of the starting date for introducing routine screening of donations. Can you just tell us again quite clearly

what considerations you would take into account in order to decide -- rather, what considerations would be taken into account in order for a decision on the starting date to be made?

A. They would have needed to have had a reliable test. They would have needed to have had staff trained and ready to do it, they would have needed to have had the equipment and facilities and they would need to have worked out how they were going to counsel donors.

Q. From your perspective, how would you satisfy yourself that those criteria had been met?

A. Well, we would accept the good word of the SNBTS.

Q. Again on the question of starting date; if you had set a starting date, let's say 1 April, and widely publicised it and then it turned out that it actually wasn't going to be practicable; how do you think that would have played for government?

A. Well, they might have been criticised in saying that they were promising something which they couldn't deliver.

Q. Right. The only other question I wanted to ask was: in relation to the procurement of the various kits for testing, whether Abbott or Ortho, can you tell us which body would be responsible for the procurement decisions?

A. The national procurement body in the DHSS.

Q. Right. Does that apply to Scotland as much as to England?
A. Yes, because the Scottish branch, which was in the Common Services Agency, would be liaising with them and would arrange for the supply through them.
Q. I see. So it's a division of the CSA, but it has a counterpart in London. Is that right?
A. Yes.
Q. Thank you very much.
THE CHAIRMAN: Ms Dunlop?
MS DUNLOP: I have no further questions for Mr Tucker, thank you.
THE CHAIRMAN: Mr Tucker, thank you very much indeed.
MS DUNLOP: Sir, Dr Mitchell is here and I certainly don't want to keep him waiting much longer. Perhaps we could have our break now and keep it quite short?
THE CHAIRMAN: I think we have extended the stenographer's term a little bit on this occasion. We will try and keep it as short as possible.
MS DUNLOP: Maybe until quarter past?
THE CHAIRMAN: Take advice on it.
(3.10 pm)
(Short break)
(3.23 pm)

DR RUTHVEN MITCHELL (continued)

Questions by MS DUNLOP

THE CHAIRMAN: Good afternoon, Dr Mitchell.

MS DUNLOP: Thank you, Sir. Good afternoon, Dr Mitchell.

A. Good afternoon.

Q. We have kept you waiting and I'm sorry about that. Let's have your statement up to the screen. It is [PEN0171901]. What we are talking about now is the period, between 1989 and 1991, when there was a lot of discussion in the United Kingdom about the introduction of screening of donated blood for Hepatitis C.

I think we can perhaps go on a bit of a tour d'horizon, because you were in Rome and Durham talking about these matters at the time. But let's not leave the first page without looking at the question that is specific to you. We asked how you ended up on both committees. So, to spare your blushes, Dr Mitchell, I'll just quote from the points you have made in your response.

You have said that you think that the national medical directors -- that would be Professor Cash and others at SHHD -- would have some say in your nomination. Your reputation in the West of Scotland and elsewhere was high, following the work done on Hepatitis B. You presume your membership of both

groups -- that is the Advisory Committee on the Virological Safety of Blood and the Advisory Committee on Transfusion-transmitted Diseases -- was because you represented the largest transfusion centre in Scotland and you had considerable experience of transfusion matters.

Was it a bit of a strain attending all these different meetings?

A. Oh, yes, no doubt about that. I think from the largest centre it was important that someone should represent Scotland. I was either the longest serving director at that time -- and I used to say that, in Glasgow if you stood there long enough, you would see everything twice in blood transfusion. So I had a lot of experience at the technical side and also on the managerial and also the medical side. So that's one of the reasons, I think, that I was chosen.

I noticed a comment from Dr McIntyre that said that the first choice had been Dr Urbaniak. I rather think that was a mistake, but -- at least I hope it was a mistake, otherwise the first choice was anybody. I was a bit miffed at that, but I forgive Dr McIntyre for that remark.

Q. Dr Mitchell, I don't think anyone has ever couched it in those terms. Certainly there is a piece of paper

somewhere that had Dr Urbaniak's name on it, but no one has ever said that you were other than the first choice. So let's straighten that out here and now.

PROFESSOR JAMES: It was a typo Dr Mitchell.

A. I don't know. I presume it was. But I suppose...

MS DUNLOP: We shall on the second page and we are looking at the various meetings of the different bodies and I don't think I need to ask you about these --

A. I think it's important to realise that the Advisory Committee on Virological Safety -- the remit, although you have quoted it there, had many other things attached to it. It wasn't just dealing with blood transfusion, there were many others things that people -- other experts were called in on tissue transplantation, on artificial insemination, all sorts of people were being brought in: pharmacists, medicines control people and so on. They were all individually either brought in to give advice or gave their advice by correspondence.

Q. Right. I think, insofar as the two of them related to each other, if there was any confusion in the first months, that seems to have resolved into a position that the Transfusion-transmitted Diseases Committee was really subordinate to the committee on the virological safety of blood. Would you agree with that?

A. Yes, I think Dr Metters made that abundantly clear at

various times in the meetings; that the advisory committee was really a committee that dealt with the policy of things, taking advice from wherever they could or wherever they want to, whereas the blood transfusion one was the one that, as it were, effected the policy when it was given. They were the ones that actually made it happen. That's the essential difference between the two committees and, in a way, I was sitting wearing two hats --

Q. Yes.

A. -- in these committees.

Q. Yes.

A. Sometimes I had to keep my voice down: shut up, don't say anything; because you sometimes knew other work that was being done and other information which others were not privy to. Sometimes you were surrounded by what I would call the mischievous people, who were sort of what I would call "really interested", but only on the periphery. You know, the idle mischievous people that liked to know about things but didn't want to do much about it.

Q. That's outwith the committees?

A. Curious people. Yes, the idly curious, yes.

Q. All right. We talked about the first study that was undertaken in Scotland of these new kits and we can

see -- if we go to paragraph 6, we can see that that's mentioned; that Professor Cash was very keen to get his hands on some of these new Ortho kits and see what they were like.

We know, from the report of the study, in particular the first report that appeared in the autumn of 1989 that this was quite an ambitious study carried out in the West of Scotland, looking at a number of different aspects of the Hepatitis C problem. Do you remember that being carried out?

A. Yes.

Q. Yes. Can we move on to the next page, please? I think you made the point here that the two studies -- that is the study in Scotland and the study in England in 1989 -- were separate?

A. Yes.

Q. Actually, in your study -- I'm saying your study, the West of Scotland study, the sensitivity figure was a wee bit disappointing, down at about 33 per cent or even 21 per cent in donors. But different figures were obviously around and we have looked, with Dr Dow, at what some of the explanations might have been for these --

A. These were the early studies, clearly. There were two major ones done in 1989. 1989 -- remember there had

been one done prior to that by John Barbara following a meeting with Ortho in London, which none of us knew about. So we were moving in that direction. So John Cash was right to start bringing this stuff in. We will come to that later, I'm sure.

Q. You say, in answer to question 7, that the assessment of samples of special interest, you think that was part of a preliminary study to determine technical and handling procedures. But our understanding, gained from the other witnesses, is that samples of special interest were fed in to the study that Dr Dow and others were carrying out. So they were looking at some 2,745 blood donors and then some samples of special interest as well.

A. 2,742.

Q. Well. Right.

A. Yes, these were samples sent from the other transfusion centres in Scotland.

Q. Right. Then we are moving on through 1989, looking at the Virological Safety of Blood Committee and the fact that they looked at hepatitis, actually at their second meeting in May. Then, at the third meeting in July, Dr Mortimer is reporting that view that the Ortho tests were reliable and the chairman saying: well, let's look at all the information next time.

Do you think there was any sense, at that time, when you were going to these meetings, of how long it would take before you were able to screen the blood?

A. I did not have a lot of worry about when it would be ready.

Q. Right.

A. I thought we were on the right track. We had finally, as it were, come to the promised land. We had reached a position where we had a test which -- we had to knock the hell out of it to see that it was okay. So we were certainly progressing quite good at that time.

Q. Right. Moving on the next page, you think Ortho, no doubt for understandable commercial reasons, were seeking to encourage the commencement of testing in the United Kingdom.

A. Hm-mm, yes, that's right.

Q. Now, this is the summer of 1989 and we asked also about some early policy indications that this was going to be a common UK decision. I think we should just have a look at some letters that we haven't looked at already in elaboration of that early approach. Can we look at [SNB0061574], please?

A. Sorry, that's an extension of the English study that John Barbara started?

Q. Yes.

A. Yes, he added 5,000 to what they had done before, which was 3000-odd. So this is what Harold was talking about at that time.

Q. What I'm interested in particularly -- this is a letter of 26 July 1989 from Dr Gunson to Professor Cash and what I'm interested in is that part at the end, where he says:

"For the UK it is important that the SNBTS and the NBTS act in close collaboration, since I can foresee difficulties if one of one of us introduced the test unilaterally."

There is a very quick reply from Professor Cash, which is [SNB0082606]. This is another two day turnaround. 28 July 1989, Professor Cash writes back and, if it were needed, this is some support for the idea that the interesting samples fit into the main Scottish study at this point.

A. Yes.

Q. But we can see that Professor Cash has arranged for you to go to Rome. So you were taking his invitation because he was going to Australia. Professor Cash makes some points about the future:

"We will not move unilaterally, unless instructed to do so by SHHD. Thus close collaboration seems certain."

A. Yes.

Q. Then, lastly on this particular point, [SNB0061426]. Dr Gunson writing out to all his directors on 18 August 1989, and mentioning in that letter:

"It is important that we act in a co-ordinated manner nationally and also with Scotland with the introduction of these tests, with respect to the routine screening of donations."

A. Do you want me to comment on these as you go through them?

Q. Not particularly, Dr Mitchell. I'm looking at these because these illustrate the early desire to move together.

A. Yes, and obviously Dr Gunson had a major -- bigger difficulty than us -- you know, he had many more people to talk to and Scotland, being a small place, had a better chance of getting us all together at the one place and getting a decision. Whereas, I think Harold had a lot more trouble that way; of trying get all his team working together.

Q. Right. Did you think it was a good idea to aim to have a common UK starting date?

A. Oh, yes, I think that's very important, to avoid the old postcode lottery that we talk about. You know, the chap in Carlisle who comes up to Dumfries and vice versa. That was the thinking behind it.

Q. Now, can we go back to Dr Mitchell's statement, please? You met the Ortho representatives in London on 23 August 1989. You went down with Dr Follett and Drs Gunson, Contreras and Barbara were there as well. You reported back to Professor Cash on your meeting. That's [SNF0011449]. Can we just go to the last page of this, please, because that's the agenda. A half a day meeting, I guess. We can see what the different contributions were.

Then go back to the first page, please. You gave really quite a long resume of the meeting. We can see the reference to the press release in Wall Street. I suppose that's because of the colossal effect that all of this was having on the share prices of those involved?

A. Hm-mm, yes.

Q. We can see that reference to the fetters that had been put on Abbott. So Abbott weren't going to receive material until 1990?

A. Yes.

Q. I think you had a -- quite a well established working relationship with Abbott, did you?

A. Well, we were using their technology, you know, widely with our hepatitis testing, the other one, using their bead technology which we were good at, that particular

type of technology.

Clearly we would be interested in Abbott coming in, rather than us having to do Ortho, that would have been a major problem to have to go back and start all that again. It was a different set-up, a different way of doing it. The antigens were the same, but Ortho had a injunction to stop Abbott getting a licence and that was the major problem. But that was resolved later and, as I explained to you, I think everyone at that meeting, in fact I think Zuckerman was also there. I think he said this was very much a sales pitch, this particular meeting. That's really what this was meant for. It wasn't altogether very scientific.

Q. Right. Can we just have a look at the rest of the letter, please, just to remind ourselves of all the points you were making?

A. You can see how Ortho were pushing for a decision, have a decision, can we tell you ... because there were mega dollars riding on this kind of thing. If they came into the British market at that stage, clearly that would have a major effect on the world because people did have respect for the British opinion, whatever you may say about it. I think it would have been a very plus point for anyone who had the blessing of our Medicines Control Agency.

Q. Right. Yes. Although, in fact, the kits weren't having to go through a licensing process in the UK.

A. Oh, yes. There was no requirement in the UK at that time, but America was certainly waiting for their FDA, yes.

Q. Yes, and then there is that point made again -- we can see it on the screen -- that the UK would move in unity and there would be simultaneous announcement. Then on to the next page.

A. I think that was important to make sure that no manufacturer picked us off individually: united we stand.

Q. Yes. You seem to have been discouraging the idea of giving the transfusion directors in Scotland a set of kits until a decision had been made.

Then there was a video tape. Did that show how the testing was carried out?

A. Yes, that was again a sales promotion tape, which I sent to Professor Cash.

Q. Okay. Then Mr Davis has tried to tempt you with some financial deals?

A. Yes, that was interesting. I think the Directive in London took a very serious view of that and said: no, no, the procurement directorate will pay whatever is required for these tests, rather than being offered any

special deal. Because this chap was trying to say that it was towards the end of his financial year and if we can have signed up today, the prices next year would be the same as they were this year. You have got supermarket stuff: we will hold the price now, pending your decision. If you don't make a decision, the price will go up. Sorry, no blackmail, thank you.

Q. Okay. On to the next page, please. Talking about training and then some figures about the research, with the kits, that has been done so far in England; Dr Barbara. Then also from you, and I guess these figures that you were giving would have come from the study that Dr Dow and others were already undertaking. Mentioning the importance of having a confirmatory test.

A. Hm-mm.

Q. You gained the information that it was likely that, in Rome, a test using the Western Blotting technique will be discussed, albeit the genetic basis of this will be the original isolation procedures described by Michael Houghton.

A. In fact they never develop the Western Blot technique.

Q. I'm sorry?

A. They didn't develop the Western Blot technique.

Q. They developed a RIBA.

A. That's a different thinking. They did go for

a confirmatory system, that's right, RIBA-1.

Q. Yes.

A. Yes.

Q. Then on to the next page, please. Here we are. You had made very clear that you couldn't pre-empt the decision of ACVSB. You weren't representing them and you weren't representing the departments of health. Then you refer to the Guardian article. We have actually just been looking at that. You are explaining that you have made it very clear to Professor Cash what has been happening, so that he is well informed, given that it seems to be quite a topical matter.

A. Hm-mm.

Q. Right. Can we go back to Dr Mitchell's statement then, please, and move on? I actually wanted to go next to Rome. Can we go to paragraph 14, 14 and 15? Thank you. It's really a -- paragraph 14 talks about the need for a confirmatory test and I take it you would agree with the view that others have expressed that a test using a blotting format does give you extra benefit over and above the ELISA. Is that right?

A. That was the idea.

Q. Yes.

A. One member of the committee mentioned -- I think it was Dr Minor, one of the virologists -- a very important

point he made: supposing the FDA had not approved the test; we would have been left with egg all over our faces if we had committed to what Ortho wanted us to do.

Q. Yes. Can we look at Rome then, please? That's [SNB0018678]. We know you were there instead of Professor Cash. This has a cover sheet from the ACTTD but it's actually your paper. If we go into it, we can see it's actually headed, "Glasgow and West of Scotland Blood Transfusion Service". Then you narrate the proceedings in Rome.

You are:

" ... struck by the rapidity of this introduction [of the Chiron test]. Either it is an example of good marketing on the part of Ortho, or ... it is the test [everybody] has been waiting for ... "

Then you go on to explain some of the technical material?

A. I think I explained last time that there were other reasons that people went in quickly for a test, although it hadn't been recognised it was only a test system, it hadn't been fully validated. But I think -- as Professor Zuckerman said, a lot of this was being led by litigation.

Q. In an ideal world, you wouldn't want these sort of decisions led by litigation.

A. That was the point that we were trying to make, that a little knowledge is a dangerous thing. Going off like that -- as I say, we could have been left with saying: this test hasn't been approved in America, but by the way we are going to continue using it. Whereas the people that adopted it, took it on, had no means of checking. They had no confirmatory test whatsoever, but they wanted to look at something that they knew came from the virus.

The virus, in a sense, was leaving its footprints somewhere. So they said, oh, well, we will follow the footprints. That was an early, early stage, but nevertheless some of them did very rapidly go into the system because they had other reasons for wanting to do that.

Q. You say that. This is you commenting in September 1989 and you say that:

"At that point there seemed to be a never ending stream of workers give the results of screening programmes in their countries."

Can we move on to the next page, please. You have given quite a bit of background, Dr Mitchell. The danger of cirrhosis. Donor prevalence divided into three groups. That's interesting.

Certain parts of southern Italy having very high

rates of prevalence.

A. Yes.

Q. Some other interesting statistics.

A. It's worldwide. This was a substantial -- this was the first international symposium that was going on. So there was a lot of information coming from various parts of the world. I mean, I haven't mentioned the Japanese results but they are even worse than that.

Q. Yes. Go right down please. You are having some discussion of the links, if any, with ALT, as a marker and anti-HBc. Individual variations within individual countries: distinct north/south difference in Italy and Germany.

Then, on to the following page, please. We can see this is you preparing this report on 2 October 1989. That was for the Transfusion-transmitted Diseases Committee, which was looking, in October 1989, at what recommendations it might make to the next meeting of the VSB committee.

Indeed, Dr Gunson had done a report of his perception of the Rome meeting, and I think at the ACTTD meeting on 9 October 1989 you were discussing Dr Gunson's paper as well.

A. I think we were fairly -- much agreed on what had been found out.

Q. Yes.
A. Again a lot of it was the sales pitch going on.
Q. Then right down, please. You make the point about the good news as far as treatment of patients with haemophilia was concerned.
A. That's what I was saying earlier, that I think finally we had reached the promised land and things were improving.
Q. Right.
A. They had nothing for community HCV. You must remember that the test was brought in, not as a blood donor test; it was brought in for clinical management of patients --
Q. Well, indeed, yes.
A. -- who had hepatitis.
Q. Yes. We do know that it was available and used for looking after patients --
A. Oh, yes.
Q. -- quite a long time before the screening of donated blood began.
A. That's right, we could have just latched on to this. I think that was important.
Q. Then can we go back to the statement, please? We were at paragraph 15. We did narrate the Rome meeting, the preparation of a report which went from ACTTD to ACVSB, but there was no decision in principle by ACVSB that

screening should be introduced.

A. I think the advisory committee on virus never said: don't do it.

Q. No.

A. I think we had quite clearly said, "At the proper time, yes, it should be done."

Q. Looking --

A. You know, you don't want to waste a lot of money. You see, we had the advantage of people who were from the finance side of the departments and they had money to think about too. That goes a long way, the kind of money that would be needed to do various things. So clearly you had to be sure that this was money well spent.

Q. Right. But --

A. The principle was right, to get it done, yes, that's right.

Q. I suppose -- I mean, it has been interesting for us, Dr Mitchell, to look at the meetings of the VSB, November 1989, April 1990, July 1990. There does seem to be a bit of a delay before even a recommendation in principle is made to introduce screening. Do you think, looking back, it would have been a good idea to take a decision in principle a bit earlier on?

A. I thought a decision had been taken in principle early

on. If you read what Dr Metters said in some of his summing up, I'm fairly sure it was clear to everybody there that we would be keen to have a test that was reliable and specific.

Q. Yes. There isn't really anything that you would call a decision in principle until July 1990.

A. Well, I would need to look again at the minutes.

Q. Don't worry.

A. As I say, I don't think it's fair to say that they just kind of forgot about it. Eventually it would emerge, do you know -- I think there was a lot of discussion went on. That's what I'm saying about people -- the idly curious. It would seem to some people that nothing was happening.

I can assure you a lot of things were happening. Remember -- members of the committee were told in no uncertain terms that all the deliberations of the committee were confidential and were not to be discussed outside --

Q. Yes.

A. -- and there were reasons for that and --

Q. What do you think they were?

A. I don't think it's fair to say that they just ran away from it.

Q. No.

A. After a while they said: what were they there for?
Q. What do you think underlay the insistence on being so careful about confidentiality?
A. I think the real question was -- a lot of people would have loved to know: when are you going to start? What are you going to do? When are you going to start? And by the way have you got the money to do it?

That's what a lot of people wanted to know and I think that, when we said we would start would be when we had a test which could be validated and confirmed about some kind of supplementary confirmatory test because, at the moment, you were explaining one unknown in terms of another unknown. That's really where we were at that stage.

Q. Okay.
A. We knew, as I said to you, the footprints were there. There was something produced by the virus that we were able to identify, but it didn't necessarily say it was absolutely specific.
Q. Right. You were --
A. So that was the reason for the caution. We didn't walk away from it.
Q. Yes. You were in Durham as well, Dr Mitchell. Not long after Rome, you were at a meeting in Durham. Let's have a look at that, [SNB00024553]. This is a Durham meeting

of the British Blood Transfusion Society. Is that right? A meeting was organised with Ortho and you were there with Dr Gunson, Dr Contreras and Dr Barbara and you were talking about the Rome meeting.

A. Yes, that's right.

Q. Yes. At that point, Dr Gunson is thinking that the likely recommendation -- I think this means the recommendation from the TTD committee to the VSB committee -- would be that testing should be introduced in the UK, probably within the financial year 1990. That is some time after 1 April 1990.

You were all going to be meeting to finalise the details of the report and the recommendations. Then Mr Davis of Ortho saying that the FDA was likely to licence the test. Were you just thinking: well he would say that, wouldn't he?

A. Yes, all this bit about the lead-in times and so on, the 90 days to have kits available. That was really meant to put pressure on people. Tell us now. Even in fact when eventually a decision was made, they were still behind with the testing, they were still behind with the delivery. So it was not a question of: oh, we will deliver 100 per cent on day one. There was a lot of difficulty with getting terms from them.

Q. Right.

A. So there was a lead-in time as well as -- because they had to manufacture the things, the kits.

Q. Yes. Can we look at the next page, please? Then you were asking just those sort of logistical questions and:

"Dr Contreras expressing some reservations about the speed of the proposed introduction of the test."

As it turned out, she needn't have worried.

A. But her counsel was a very strong one. A very well-known transfusionist. A very high reputation.

Q. Indeed, an eminent figure in the transfusion world.

A. Absolutely, Dame Contreras.

Q. Reference being made to the need for a confirmatory test. Then there is a statement from Ortho as well. Can we just look at that? That's [SNB0024555]. That goes with it. So Ortho were alert to the desire for a confirmatory test.

A. I think that wasn't just the Brits that were saying that to them --

Q. No.

A. -- I think the whole world was saying that to them.

Q. So they are trying to keep you up-to-date with what they are doing in that area. Right.

Can we go back to the statement, please and on the next page, 1908, we asked you some questions, which you thought might be better answered by Dr Dow. Dr Dow and

Dr Follett. We think actually that that comment by Dr Barbara that Ortho were developing Western Blot assays may not be strictly right because that was a RIBA they were developing.

A. That's right, yes.

Q. Yes. Then the West of Scotland study was finally reported in December 1989. Can we go over on to the next page, please?

A. I think there is this other bit about the development kit and the difference. That's important too, again from the manufacturer's point of view. Some of this, you see, was actually the manufacturer doing field tests --

Q. Yes.

A. -- on his kits. He was sitting there getting all that information back: by the way your test doesn't work today. By the way your test isn't standardised. By the way it's easy to detect your positives because they are so strong that anybody could detect them, but what about the difficult ones? So they were getting accurate information as well.

Q. That's all very valuable information for the manufacturer?

A. Very much so. That's valuable to the manufacturer.

Q. Yes. On the top of this page that we can see, you say:

"To all the members of the various committees of which I was a member, it seemed self-evident that a test not approved in the USA, its country of origin, could not be approved in the United Kingdom."

That is back to the FDA. I just want to ask you: what about a decision in principle that screening should go ahead in the United Kingdom, provided that the FDA licensed the kits? Would that not have been an option?

A. That's exactly what Metters said. If we have a good confirmatory test, then we are talking business now.

Q. Right.

A. Yes.

Q. Okay. Then on to the next page. I think much of this is addressed to others, Dr Mitchell.

A. Shall I make the point about the hornet's test, I noticed people were asking about that. In actual fact what that refers to is a letter from John Cash to Dr McIntyre --

Q. Yes.

A. -- enclosing the recommendations that I brought back from America -- from Chicago in the middle of that year, which dealt with -- Ortho wrote it with NIH, American Red Cross and American Association of Blood Banks, giving a complete compendium of what would be done if the FDA was licensing the product. In other words, they

were pre-empting a decision that would made. So Dr McIntyre, remember, scribbled that note, "This will set the cat among the pigeons."

Q. It was a hornet's nest, but we get the idea.

A. Yes, a hornet's nest, the same kind of idea. This was something that was very important. But it was.

Q. We understand that you were responsible for the hornet's nest, but no one is blaming you for it.

A. He seemed to be wanting to know how this remark arose. That was the reason.

Q. Let's tease it out. What effect do you think it had on the Department of Health?

A. This is what Dr McIntyre wrote: come on, look, pay attention. Something is about to happen.

Q. So he is saying this is a significant development?

A. He is saying this is now real, this makes sense now. This is -- he, remember, was on the committee, the same as me.

Q. Yes.

A. So he was listening to what Metters and the others were saying and he was saying: if we can get a confirmatory test, then, okay. So he was more or less saying to the department in Scotland, now: it looks as if now the impediment has been or about to be removed.

Q. One of the impediments.

A. One of them, yes.
Q. Right, okay.
A. The scientific one, not the others.
Q. If nothing else, Dr Mitchell, I think we can be confident that we have got to the bottom of the hornet's nest comment.
A. I thought you would like to know.
Q. Yes, we do. Moving on, we did ask some questions which are really more directed towards Dr Perry and Dr Young. Then there are some questions about funding. On to 26. Yes, 26, 27, Professor Cash will respond, you have said and then 28. Then 29:

"The meeting of 2 July, did recommend that screening would be introduced, but not before the results of a comparative study."

Can we just have a look, please, at [SNB0061846]? There we have it. That's a report of the comparative study. Can we just look at the last page of that, please? Yes. That's -- I'm sorry, it's not the report, it's a document proposing the comparative study from Dr Gunson, dated 27 June 1990 and revised on 30 August.

In fact what had happened earlier is that you had been part of a subgroup drawing up a protocol for a large study and then the news came through that the FDA had approved the test in America and the ACVSB

meeting of July was brought forward to 2 July. So you were rather overtaken by events. So that's, I think, the first document in relation to the proposed study.

Can we then look at -- can we look at [PEN0160028]? This is the study as it was in fact undertaken.

A. This was first generation kits, yes.

Q. We have looked at this before, but this is Dr Gunson's final report, or a final report on that comparison of the first generation kits in 1990. What, in fact, happened was that there was -- I think if we have a quick look into it -- we have already looked at this but there was a phase 1, which was looking at large numbers of samples.

So each of the three participating centres looks at about 3,500 samples. Then phase 2 is that the positives go to a specialist laboratory, as I understand it and, to get a little more information on the progress of that, we can look at [SNB00053696]. This is you writing to Professor Cash after the November meeting of the VSB committee. We know, from the minutes of that meeting, that the Glasgow results of the phase 2 part -- that is the analysis of the positive samples -- had not come through, so you are writing to Professor Cash two days after the meeting and saying:

"Unfortunately, I did not have the results from

Dr Follett and none had been sent for the meeting. I understand that Edinburgh's report is imminent and he is awaiting PCR results from Edinburgh."

We have looked at this already and wondering if this is you blaming Edinburgh. That's just a flippant comment, Dr Mitchell, but anyway.

A. I can't possibly comment.

Q. Yes. We do have the Dr Follett report, if we look at [SNB0053727] and, if nothing else, I want to refer to this because I think it threw Dr Dow earlier that we didn't have the full story on this part of this study.

This report is from Dr Follett and dated 29 November 1990 and that's the Glasgow part of the phase 2 comparison of Ortho and Abbott. If we just have a quick look into it, please, we can see that this is an assessment of 69 samples and, as I understand it, the 69 samples were looked at at all three of the specialist laboratories.

So there we have the results of the Glasgow part of that.

A. Yes, this was phase 1.

Q. Well, the phase 1, as I understand it, is round about 10,000 samples. That's the 3,500 from each of three centres and then the phase 2 is looking at --

A. The same samples.

Q. -- the samples thrown up by phase 1?
A. The same total number of 10,000, which produced 61.
Q. Yes, or 69. Anyway.
A. Whatever.
Q. Yes. So there we have it. Then can we go back to the statement, please, because Dr Mitchell has actually discussed this exercise at 1911. You say that, in your view, it was necessary to compare the Ortho and Abbott kits. I think we were wondering that, given that the outcome of all of this exercise was to say that each centre could choose for itself, it might then have been time wasted but you don't really agree with that, or do you?
A. No, I don't agree with that, no. The way in which the kits would be examined and so on was pretty complicated. It wasn't really for the faint hearted, can I put it that way?
Q. Hm-mm.
A. Not wishing to be too pompous about it, but I can assure you that that sort of thing takes a lot of care and attention to do these comparative evaluations. I don't know, I think if you look at the results carefully, you will see that Ortho was missing things which Abbott was picking up, Abbott was missing things which Ortho was picking up.

If individual centres had been using one or other of the tests, they might well have been looking at stuff which -- we now know, from the comparative study, there was a concordance between certain tests but not -- certain specimens but not all of them are outliers. I think what I referred to Professor Cash as outliers, which really didn't fit into the confirmatory testing.

It was only when you did the confirmatory tests that you could show that those concordant results were, in fact, concordant. They gave the same results regardless of whether you were using Ortho, the RIBA-1 -- RIBA-2 or the PCR.

Q. Right.

A. That was what really clinched it, but to let people soldier on with a kit which -- they weren't really sure whether it was worth doing that because it would save an awful lot of time to be able to be told: this is the kit you can use.

Q. Right.

A. And you will not get it wrong very often: because there were a lot of false positives. That's the point I was making.

Q. Oh, yes, indeed.

A. That just wastes time and money and energy.

Q. Yes. We understand that you make matters a great deal

more specific by using the RIBA test?

A. Well, yes and when the Ortho 2, Abbott 2 kits, came available, that made a huge difference because, again, you had an entirely different set of proteins in the system. I mean in the generation 1, you had only the C100 and a C32, whereas the later ones had, remember, a whole string of different footprints.

Q. It had more antigens.

A. Much more specific, because there was a lot of false positivity with the generation 1, which we knew about, a lot of false positives, some of which you have read about; the question of other diseases and rheumatoid arthritis and all sorts of things, which is not uncommon in the population. These were just extraneous and causing a lot of unnecessary -- whereas -- you must remember that the reason that these people developed these additional tests, not because -- for us but because they realised that their tests were not specific enough. So they said let's try and tease out a bit more of these footprints.

Q. Yes.

A. I think that's really what clinched it was when they came along.

Q. Yes, the second generation kits were very much better because they included additional antigens.

THE CHAIRMAN: Ms Dunlop, the fourth last line on the screen at the moment, "That is the reason that a further phase 2 multi-centre trial was performed." Is phase 2 correct?

PROFESSOR JAMES: I think it's really a further phase 1 multi-centre trial.

MS DUNLOP: I think maybe what you are saying Dr Mitchell is that the exercise of comparing Ortho and Abbott was repeated in 1991, but with the second generation kits.

A. Hm-mm, yes, that's --

THE CHAIRMAN: Better just to take phase 2 out, if it's not right.

A. It's a bad expression, "phase 2". Some people use it in a different -- phase 1 and phase 2.

MS DUNLOP: It becomes difficult in 1991 because it's difficult to get hold of the Abbott kits, for intellectual property reasons. We can certainly firm up on that. We will look more at that.

A. They didn't become available until, was it, March.

Q. We have got the minutes of the meeting of ACVSB on 25 February 1991. Can we look just look at them? That's [SNB0018934]. This is taking matters on some more. Can we look at the discussion of further evaluation. Go on. Yes, the pilot study and then on to the following page, please:

"Ortho and Abbott 1 and 2 should, in principle, be available among others from 1 July for transfusion centres to choose."

Then can we go a little bit further down, please?

A. You can see how this is all rushing along, rushing along --

Q. Yes.

A. -- with no real commercial available confirmatory systems at that time.

Q. Yes.

A. The RIBA-2 really wasn't marketed --

Q. I think I have skipped past --

A. -- until early 1991.

Q. -- the relevant paragraph. Actually if we go back to paragraph 6, please, it's really here.

Professor Tedder's paper:

"The committee discussed the likely availability of the second generation tests."

Of course we are back to licensing by the FDA:

"Licensing of the tests by the FDA had not yet been finalised. Members agreed it was important for proper evaluation of the Ortho and Abbott 1 and 2 tests to be carried out before RTCs decide which test they should adopt."

The same 10,000 samples are to be kept so as to

evaluate the second generation tests.

A. That's right, that's the 10,000 whatever, 600-odd, these had been stored. I think Tedder was really suggesting there that people like Tedder had contacts in very many different places. They often had their ear to the ground and knew what was coming along and Zuckerman was the same. They were often sitting saying: I know that something else is on the horizon. So obviously we are paying attention to that.

Q. Yes.

A. So when we heard -- you see, when the Abbott 2 and the Ortho 2 became available, that was following a decision by the company that is the first kits would be discontinued.

Q. Yes.

A. Do you remember, in March, I think it was, they said there is a minute, a little note from Bob Perry, from a meeting that -- it must have been some of his people attended in London. In that, the last paragraph, it says that they have been told that the first generation kits will be discontinued.

So whatever you say about who is going to be doing what kit, if they were all doing it they would suddenly have found themselves with no kits at all. Or please just take our second generation kit and just use it,

please because we are telling you that it's okay. We were saying, no, you can't do that.

Q. We also have, just to follow that train of thought, we have the Glasgow part of that study at [SNB0064037]. This slightly alarming 84-page document. We only need to go to page 3. An awful lot of it is actually laboratory printouts.

A. It is just a whole range of results for anybody who wishes to look at them.

Q. Is that the report by Mr Hughes?

A. These were technical staff, these were scientific officers.

Q. Right. This is 15 May 1991. They are providing their evaluation. Can we just go up to the top there -- of the Abbott second generation test. That's what you were evaluating in 1991 in the West of Scotland?

A. Yes, and others.

Q. Yes.

A. That was the one where there was a second generation, there was -- also the second RIBA was in by that time.

Q. Right.

A. So you were able to compare --

Q. If we are using the same language, this is the phase 1. So, looking at 3,516 donor samples with the Abbott second generation kit and finding 11 repeat positives

and sending them to Ruchill for confirmation tests.

A. Yes, that's right.

Q. Yes. Can we just go back to Dr Mitchell's statement then, please. We will just move on to the next page. We asked you about this idea of not telling SNBTS what the -- the hoped for starting date was and you do not have any reason for that. Then we asked about Newcastle -- if we go on to the next page, please. When you heard about Dr Lloyd in Newcastle you wrote to him -- we have seen your letter -- and you say that:

"There was never any reason for Scotland to go ahead of other parts of the United Kingdom. The correspondence makes it clear how much regional and other authorities disagreed with the decision of Newcastle."

Did Dr Lloyd ever come to some gathering of the Scottish directors, have a lunch and make an apology?

A. No.

Q. No; you don't remember that?

A. I think it's fair to say that Dr Lloyd was not medically qualified.

Q. Oh, right.

A. Dr Lloyd succeeded, as you saw, as administrator director --

Q. Right.

A. -- when Anne Collins gave up. Anne Collins was the director who was trained at our centre in Law. Anne was the one who wrote the paper in 1983 on post-transfusion hepatitis following cardiac surgery. Do you remember that? That's the thing anyway.

So the difficult -- the problem with Hugh Lloyd was that, if you continue just to use the phase 1, the generation 1, when I wrote to him, I was saying to him: look Hugh, do you have a means of confirming these tests. By the way, what are you going to do with all the false positives that are queuing up and up and up? He didn't reply to my letter.

Q. Right.

A. So I mean, I don't know what you would judge from that, but it would seem to me that, to go ahead without -- remember, you showed me last time a correspondence for Newcastle about the setting up of a virus reference lab. Do you remember? I said to you, that's a public health issue and I don't know where Hugh was getting his confirmatory work done. Somewhere else; Manchester or wherever, I really do not know.

He certainly couldn't have been using the second generation test when he went ahead with the thing in May 1991, which is when he wrote to Harold Gunson because, at that point, the second generation tests were

only just coming in to the United Kingdom because Abbott and others had had a delay in supplying them. Harold made that quite clear in his compendium, which he sent out to all the directors, do you remember? Saying:

"I'm very sorry to tell you but we can't go ahead in July because we have got this other problem."

With a five protein chain, we were down -- we were back to square one because they had then to do that as well, albeit that we had some samples and so on still left. But once that was done, then Harold rightly roped in a lot of other English centres who would then start using second generation and so on. It was beginning to gel by that time.

Q. Okay.

A. Hugh Lloyd was brought in, more as a courtesy to Hugh to say well, look, Hugh, you shouldn't have gone off like that, but here we are. We will help you to draw back and introduce the test that everyone else is going to introduce, that can be confirmed and validated.

Q. I think --

A. That's how I read it.

Q. Right. Just lastly, Dr Mitchell, that question we asked about the near disaster that Professor Cash is referring to in a certain letter in June 1991. You thought he was maybe referring to the decision of Newcastle, but

actually I think the evidence suggests that what he was referring to was that Scotland nearly decided to go ahead in advance as well. In his view that would have been a near disaster.

A. Well, for the reasons that we have said.

Q. Or a disaster, sorry?

A. It would have been no more than if Wales had gone ahead or Ireland had gone ahead.

Q. You weren't in favour of Scotland doing an early introduction?

A. I think it's true to say Scotland could have gone ahead a bit faster. I think that's true. Dr Gunson did explain that, not from a scientific point of view but purely from the financial point of view, the ability to organise everything. He was dealing with 15 different people, different things. England was cross-charging.

It was minuted by some of the executive that the funding for the English centres would have to come out of the local regional budget. There would be no extra money and that would be passed on to the hospitals by increased charges. The only reason that I was affected by that was: what do I do for the private hospitals in Glasgow? Do we pass things on to them or do we just continue as we would for the National Health Service in Scotland. So there was a little bit of difference with

Glasgow -- in Scotland than in London. Scotland was good, we had the money available.

Q. Okay. Right.

A. But I still think that it would have been a bit churlish for us to go separately. I think we could have paid badly for that and I think John was right. Do you remember, when we started the test, when this big evaluation of it, RIBA-2 and the Abbott 2 and so on became available. We said let's extend it to five other centres to start building it up -- we built up about, I think, 108,000/109,000 donations that were tested.

John was saying to Harold Gunson in a letter, remember: please keep going, keep going, he said. That was said in May/June time. Keep going. That's what he was saying. He wasn't saying, oh, you can go your own way, don't worry about us we are quite happy, thank you, pull up the ladder, we are all right. He didn't do that. He was determined that we should still continue to go together. He did clearly say, he said to me -- I mean, I have got a letter from him saying please keep going because we have started, if you like, in terms of national things, we were screening from May --

Q. Yes.

A. -- right through to September.

Q. Yes.

A. But by that time we had built up a fair bit of information and so had other people.

Q. Okay. Thank you very much, Dr Mitchell.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: The one matter I wanted to ask you Dr Mitchell was in relation to question 37 in your statement, I'm not sure you actually answer the question you were asked, which -- the question that you were asked is concerning Dr McIntosh's views which are [SNB0054822] and Dr McIntosh -- I don't know if you have seen that document, maybe we should put that up on the screen. Have you seen this document?

A. Yes.

Q. Do you agree with Mr McIntosh's comments on that?

A. I think I know David very well and respect him very well and I worked closely with him. I think in a way it's a sort of, "Methinks he doth protest too much." I think that what David is saying is he did not get a piece of paper with Scottish Home and Health Department notepaper, signed sealed and delivered with a little stamp on it that said "this is approved."

I think it would be naive of him to say that he didn't know what was going on. He clearly did and if you look carefully at the minutes, I have pored over and

over these papers for goodness knows how many weeks now and David was kept informed about what was actually going on. I know he wasn't given, except through John Cash, the date when we would start but all he had to do was lift the telephone and say to Dr McIntosh or whatever: is this right, is it true? And please can I have it in writing.

I can understand, as an administrator, that was his view; that had to be given a complete absolute guarantee from the Scottish Office. I don't think it would be right to say that he was totally unaware of what was going on. He certainly wasn't.

Q. I don't think he is just complaining about not knowing about what's going on, he is also concerned about the time that's taken for screening to get reintroduced. Do you have any comment on that? Do you think it was --

A. Again, I think this is an example of perhaps someone not quite understanding what was actually needed, what was going on. I think I tried to explain, just a moment ago, just why it was that we had to move into the second generation because the first generation wasn't there. It was being withdrawn from the market.

Why was Abbott withdrawing that, why was Ortho withdrawing it? Because it was good? No, because they knew that it was useless, it was not up to standard, it

would not serve the purpose. So they rightly said, okay, we are going to improve this thing for you. But, at that point, we were almost back to square 1 because we had new technology, new techniques to develop, which we did. So I think when David said we were delayed, John Cash was saying, "Please keep going."

David was saying, "no, no, no, no", just -- you should have gone ahead like Hugh Lloyd. Oh, but David, do you realise the problem that you would have created with queues and queues of people queuing up asking you:

"Mr McIntosh, explain to me why am I not able to get insurance, why have I got to tell the dentist I have got this funny test."

Unfortunately the administrators don't have to face that problem. Howard had written a big document, you may have seen it, on how to deal with donors, early on. There was a big huge dossier on donor care. We have said it repeatedly, that the Blood Transfusion Service had an overwhelming duty of care to its donors.

Q. What about the patients, Dr Mitchell. Did they have a duty of care towards them?

A. Absolutely, yes, of course.

Q. It seems to have taken an inordinate length of time to introduce the screen, longer in this country than other countries. Do you think that was satisfactory?

A. I have already explained to you why other countries went ahead with this.

Q. Do you think it was satisfactory?

A. No, I think that we were correct in what we were doing, which is to make sure that, when the thing was put into the marketplace, put into our system, which, after all, was nothing like the hit rates that we were hearing from abroad -- under these circumstances, I'm sure patients would have been much happier saying, well, he has done the absolute best that he can do for me. He is not giving you something second-class, I'm getting the top of the range thing. I think that was the right way to go.

I think that, to be fair, this saga has not finished. I think that there may well be other tests coming along. There will be other transmissible things coming along. It's difficult to get everyone to agree to that. Archie Barr and I, very early on in the advisory committee, tried to start up a system of reporting of adverse reactions in transfusion centres. That had been notified to them and my major problem was to get everywhere else on side, because people just did not want to tell us about what they were hearing in their region.

So I mean, there was that sort of reluctance to work

collectively and, I think to go ahead and have individuals going off half cock would not be good in the patients' interests at all. I think we were still trying to -- every man's death diminishes me, everybody who is harmed diminishes me.

So it's not a question of saying, "Oh, well, just let them get on with it." No, we had to try and give the best possible service that we were capable of. As I say, our national director, all the Scottish directors were saying that's good, keep going, keep going. We were doing half of Scotland, half the donations here.

Do you remember, at this time too we were in the middle of a big conflict in the Falklands. One of the major sources of blood for the Falkland Islands was the Blood Transfusion Service in Glasgow. We were sending it out via Ascension Island. We had many other things to occupy our time but we certainly would not lose our main purpose in life, which was to supply an abundance of blood and blood products of a high standard.

We would not want to harm anybody. I said, way back I think on the first day of this Inquiry:

primum non nocere, first do no harm.

Q. Thank you, Dr Mitchell.

A. Blood is a dangerous drug, we have always said that answer.

MR ANDERSON: I have no questions.

MR JOHNSTON: I have no questions.

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

THE CHAIRMAN: Dr Mitchell, thank you very much indeed.

A. Thank you.

MS DUNLOP: No further witnesses until Tuesday, sir.

(4.35 pm)

The Inquiry adjourned until Tuesday 29 November at 9.30 am)

I N D E X