Friday, 14 October 2022

(10.00 am)

THE HONOURABLE RICHARD SETON TEDDER (continued)

Questioned by MS RICHARDS

MS RICHARDS: Professor Tedder, I'm going to pick up the chronology of events in relation to HIV screening in November 1984 by looking at a document with you.

It is PRSE0004191.

If we look at the top of the page we can see this is described as "Report on Meeting of Advisory Group on AIDS, 27/11/84". This report doesn't have a name attached to it but it looks like it was probably produced by Dr Bell, who was an observer from the Scottish Home and Health Department, at the meeting that took place on 27 November 1984.

Sir, for your note and for the record, I don't have a reference number for the formal minutes of the meeting but the agenda and details of membership, including Professor Tedder, can be found at CBLA001985.

SIR BRIAN LANGSTAFF: If you just give me a moment. I don't know if you've got reference DHSC0002551_011?

MS RICHARDS: I'm not sure whether we have it on the system today.

SIR BRIAN LANGSTAFF: Because that's a note, certainly, a very long note, of what happened at the meeting.

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MS RICHARDS: Could you give the URL again, sir?

SIR BRIAN LANGSTAFF: Yes. DHSC0002251_011. I can't tell you whether it is minutes or --

MS RICHARDS: Apparently we do have it. Yes, this is Dr Abrahams' note to Dr Harris at the meeting. In fact, I'm going to go back, if I may, to the document at PRSE004191 just because there is a comment in there that I wanted to ask Professor Tedder about.

If we go to the second page. Bearing in mind, of course, this is somebody else's comments on the meeting, Professor Tedder, but we have the paragraph:

"(d) Development of HTLVIII Test Facility.

"- Weiss now has an isolate and cell line which produces virus suitable for assay. Tedder has used this antigen successfully for 2 weeks. This has no licensing problems.

"- DHSS has been informed by US DHSS that access to Gallo isolates and cells can only be via the manufacturers to whom they are already licensed."

Then this:

"- Weiss/Tedder/DHSS appear to be negotiating as follows:

"Wellcome ('interested')

"Celltech ('no interest')

"Unilever/Seward (?)"

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We know from your statement and other documents that Wellcome obviously was approached to assist with the scaling up, the commercialisation, effectively, of the test. Before I ask you anything further about Wellcome, do you recall any interactions either that you had or Professor Weiss had or that you know anyone else had with any of the other companies named there?

A. To be quite truthful, no, I don't. I think it's probably unlikely that I would have been involved with that because, as I say, this fell under the remit of Professor Weiss and the Chester Beatty Laboratory. I should have known about it but I wasn't directly involved with putting it forwards as an area of commercialisation, because it was not my remit.

Q. In terms of the collaboration with Wellcome, and we will see further documents that refer to that over the coming months, do you have any recollection now as to how that came about? Whether the Department initiated it or you did or Professor Weiss?

A. I think it would have probably come about through the relationship which our department in the Middlesex Hospital and medical school had with Wellcome in relation to hepatitis B diagnostics. Their particle agglutination test was something that David Dane was very interested in, and used, and we adapted that. And

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as one of the British manufacturers of diagnostics, Wellcome would have been the people who Chester Beatty Laboratory would have gone to. Probably on our recommendation, because we knew people there, but I was not directly involved in that.

Q. If we then move to December 1984.

HCDO0000394_117, please, Lawrence.

These are the notes of the meeting that took place at BPL on 10 December 1984. We looked yesterday at an advisory document that emerged out of this meeting but these are the notes taken, I think, by Mr Pettet, from BPL, of this meeting, which involved, as you will see, a wide range of people: reference centre directors, Dr Craske, Dr Mortimer and others, and of course, then, yourself.

If we look at the bottom of the page, please. In relation to HTLV-III antibody screening, it records:

"Dr Tedder reviewed the current situation by saying that the Gallo cell line was available for investigation although the USA had made isolates difficult to obtain. The British isolate required an organisation to handle the bulk virus culture: Porton (PHLS) and Wellcome are the only ones so far interested. There are problems in obtaining the antigen. Dr Tedder's test uses a cruder antigen."

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Do you know what that refers to, "problems in obtaining the antigen" and then a reference to yours?

A. I can surmise what it was due to. I can't give you gospel because I don't know exactly what they are saying. The difficulty was that you had to have a protocol which allowed you to have expanded cells and then infect them and then take the supernatant, the fluid from around the cells and use that diagnostically. And if you didn't do that, and you tried the more conventional way of having infected cells and expanding infected cells -- I think we touched on this yesterday -- the antigen was not shed by the infected cells into the supernatant the same way as if you had a lot of cells, put the virus in and then harvest it. That was the difficulty.

I'm not sure why the comment is a "cruder antigen". It may be that we used an antigen which didn't have to be purified. And I think that was the advantage because, if you recall from yesterday, I was saying we had an antibody on the solid phase which then pulled down the antigen, so you actually did your purification on the solid phase rather than having to do it in a more conventional way.

Q. Then just to go down the page, under the heading "Availability of tests", it records:

"Dr Craske advised that currently, the reagents were only available on a research basis, and that substantial resources would be required to enable the proposed workload to be undertaken."

Then there is a reference to routine testing in the next paragraph, and then this:

"Some discussion took place on which organisation would be best placed to organise the testing, and whether DHSS financial support would be forthcoming. Dr Lane ... suggested that if resources were available BPL would play a part coordinating the endeavour. Dr Smithies [who was the successor to Dr Diana Walford] advised that she would take all these points back, to the DHSS for consideration."

Then the next page under the heading "Blood donor testing":

"It was suggested that the testing of donors requires either 1) mass commercialisation of a British test or 2) application of a current commercial test. Confirmed that testing would be introduced at two centres early in 1985 prior to widening availability to the rest of the NBTS.

"Dr Gunson advised that it would be preferable to test all donors. However if resources were limited it might be better to concentrate testing at the major

'risk' centres."

Then this:

"Dr Cash was concerned that no central organising body was being contemplated for the test programme. This view was confirmed by Dr Tedder who was concerned that the pace of test advancement was so fast that the scientists were left to introduce a test as soon as possible. There was also considerable concern expressed over the lack of financial support from the DHSS."

Now, I think the latter point, in terms of lack of financial support, it is obvious from this note what's meant by that.

Can you assist us in understanding the concern about the absence of a central organising body, and the comment that's attributed to you about the pace of test advancement?

A. It was not something that I was aware of, the concern of that. I mean, I think Dr Cash was wanting to have his organisation to have a significant role in this, and I think that may have been one of the feelings that he was saying, "Well, you know, who is going to do it? Why don't we do it?"

Whoever was going to do it, at that time, there would have been a need to use cultured antigen, which means that you have to have the ability to handle what

is called a category 3 pathogen under control conditions, to make sure that it was safe. And that would have required a considerable investment in the laboratory to be able to expand that.

That, I think, is indirectly why we talked to colleagues at Porton at one stage.

Q. Then following this meeting, just over a week later, there is a letter from you to Dr Smithies.

PRSE00011177.

This is a letter of 18 December 1984, and we can see you make a number of points in the paragraphs of the letter. So:

"i. We urgently need to be able to scale-up of the Middlesex Hospital/Chester Beatty radioimmunoassay ...

"ii. The MH/CB RIA has been designed to be compatible with the current BTS hepatitis testing. Pilot studies are of the utmost priority in selected centres to confirm that this is indeed the case.

"iii. Until the ... assay has been routinely used for a considerable time, it is very important that reactive sera are referred to a designated laboratory for confirmatory testing and that donors and their blood products are followed up."

Then there is a reference to an "initial need to monitor the efficiency" with which the -- your assay, if

I can put it that way, and the "forthcoming commercial kits detect anti-HTLV III".

Then there is a request for financial support. So a sum for a basic grade MLSO, a sum for a secretary and a sum for what's described as a predicted disposables.

Then over the page you say in the third line:

"... we would be unable to take up this work without support and that we would not be able to continue it here at the end of the support period. Further this work could only have been possible with the co-operation of Professor Weiss and his colleagues ... [at] Chester Beatty ..."

If we can go back to the first page.

So it is clear you are asking the DHSS to provide what looks like a relatively modest amount of financial support to enable work to continue.

But the reference there is to scaling up of the RIA. As I understand it from your statement, you are slightly perplexed by that because by this time your understanding would be that scaling up would be something being undertaken essentially by Wellcome? Is that correct? And that they would be using an ELISA rather than a RIA?

A. It's difficult for me to recall exactly. The -- at that time the transfusion services were able to handle

radioimmunoassays because the hepatitis B testing was based on radioimmunoassays, so therefore it would not be difficult for them to -- they would have the gamma counters, they would have the washing facilities, they would have the safety of dealing with radio labels. So it would be -- from a Health and Safety Executive point of view, it would be relatively easy to give them a radioimmunoassay which would fit to all the hardware that they currently had.

I'm not sure that I have answered your question.

Q. Your statement suggests that, by this time, if any commercial company was going to be involved -- and we have seen the reference to Wellcome, and you have explained that it would need someone like Wellcome to be able to scale up -- that you would not be able to do it within your facilities?

A. Correct.

Q. Wellcome would be using an ELISA test rather than an RIA?

A. I think, at this time, there was a move towards coming away from radioimmunoassays to a more stable platform, which would be an enzyme-linked immunoassay. And if one had -- in the discussions with colleagues in Wellcome, they would not have entertained running a radioimmunoassay because it was not their expertise,

but this is why I think Dr Lane was anxious to -- that it be recognised that BPL could produce radioimmunoassays for this. But yet the general move was away from an RIA to an EIA, and that would have precluded one working with the BPL, because they did -- I'm looking at it now -- I think they were not experienced in making enzyme immunoassay labels and dealing with an EIA version.

Q. If we then just pick up a handful of documents, which are Departmental documents and not ones you'd have seen at the time but which just show how the Department was dealing with the matter.

If we start at PRSE0003287. This is a minute dated 2 January 1985 from Dr Smithies. It is to the Department STB, so scientific and technical branch, and it refers to a draft paper and a copy of your letter of application, which I anticipate refers to the letter that we have just looked at.

Dr Smithies says:

"I hope the proposal will meet with approval."

Over the page we can see what Dr Smithies here is saying:

"A [RIA] for HTLV III antibody believed to be a causative agent of AIDS has been developed at the Middlesex Hospital and used there on a research basis.

Plans are going ahead to scape up production of the test reagent and it is hoped that tests for blood donors could be ready to be used in the National Blood Transfusion Service in the early part of 1985.

"In order to monitor the sensitivity and specificity of the test, to validate positive tests and generally to develop the accuracy of the test a reference centre for problems experienced by Regional Transfusion Centres is mandatory. Dr Tedder ... who developed the radioimmunoassay test in collaboration with Professor R Weiss ... is willing to undertake this function for further development of the test. If he does so he requires support to cope with the extra work."

Then we see the figures that were in your letter. Then the last paragraph:

"In view of the important role in ensuring the safety of blood donations and limiting the spread of AIDS into is the wider community than is currently the case there is an urgent need to use this test in the [NBTS] and its success will depend on its accuracy which needs to be monitored. MED SEB [that is Dr Smithies' branch] see this request as a priority in needing support."

This would appear to suggest that the Department's

understanding of what you were anticipating your role was going to be was to act as a reference centre for problems experienced by regional transfusion centres in piloting or rolling out the test. Was that your understanding of what you were -- the role you were going to be undertaking?

A. It is very difficult for me to recall that at this distance. Looking at it now, I would be surprised that I would have been put in this position without the involvement of colleagues in Public Health Laboratory Service because they were also expert in the field, and particularly Dr Mortimer's team already had access to our radioimmunoassay and was using it as one of the tests that he had at his disposal for doing reference work at Colindale.

This is very radioimmunoassay oriented and we already -- if this was 1985, we were already thinking that we need to get away from RIA to EIA, and that is why I'm slightly puzzled that we don't have more of reference to enzyme immunoassays with colleagues in Wellcome, because that would have been the natural way to go. Because we did not have the experience for making enzyme conjugates and BPL didn't have the experience of making enzyme conjugates.

Q. If we just then look at a document from a couple of days

later, 4 January, which is DHSC0002255_039.

If we just go to the third page, first of all, to see who has produced this. It is DA Kennedy, who may I think have been Dr Kennedy, but I can check whether I'm correct about that or not, again in the Scientific and Technical Branch of the DHSS, 4 January '85.

If we go back to the first page we can see what Dr Kennedy's understanding of the position appears to have been.

If we go to the second paragraph, where it refers to you:

"[Dr Tedder] ... and [Professor Weiss] have, with colleagues, developed [an] RIA for HTLV III antibodies. This RIA ... was developed with the intention that it should be suitable for routine use in blood transfusion centres. Accordingly, the basic test protocol is identical to that of an RIA that is widely used for screening for hepatitis B surface and the same range of equipment is used."

A. That is incorrect.

Q. In what respects?

A. The basic test protocol is not identical to that of an RIA used for screening hepatitis B surface antigen. The hepatitis B surface antigen is a two-step immunometric assay which pulls the antigen onto the solid phase and

then detects the antigen with a radio label. That is a very different format from the assay which we're talking about conceptually for HIV, which is, yes, you have a solid phase, it's got an antibody to HIV on it and you pull the antigen onto there. That then becomes the whole re-agent for the assay, that you then use this solid phase with the captured antigen to give you an opportunity for blocking an antibody which sticks onto that antigen with the patient's serum, which is a completely different protocol from the RIA that one's talking here for surface antigen.

Q. Is it however correct that the same range of equipment is used, so the second part of the sentence?

A. If it is for a radioimmunoassay, yes --

Q. For an RIA?

A. Yes, it would be, ma'am.

Q. And then there's reference to the Middlesex having played a big part in the development of the hepatitis test, and then this:

"Antiserum for the ... RIA is being produced by Wellcome Reagents Ltd in collaboration with Porton Down [the PHLS Centre for Applied Microbiology and Research]. This is being done on a 'costs only, no profits' basis. There has been a Patent application in the names of the Middlesex Hospital and Chester Beatty Laboratory, where

Professor Weiss is based, and commercial exploitation is likely.

"The ... RIA is thus a product of the co-operation of British Science and British industry. There is general agreement that it is the most sensitive RIA for HTLV III presently available."

Again, just pausing there. You've already told us about the involvement of Wellcome, the involvement of Porton Down. Was that correct that it was being done on a costs only, no profits basis? Or do you not know?

A. I can't comment on that because this would have been agreed with the Chester Beatty Laboratories and I had no involvement with that. I think there would have been a general feeling from colleagues in PHLS and elsewhere that this was so urgent that this just needed to be done and cover costs and get on with it.

Q. Then the next paragraph begins by saying that:

"There are firm plans to produce the ... RIA in kit form -- the same form as the hepatitis test -- at BPL. However, work to scale up production will be needed before routine supply to BTCs can be started."

So again, just pausing there, is that right given that the scale up and the production of the tests kits, as I understand it, if they're going to be done by Wellcome would not be in the RIA form but would be in

the EIA form?
A. I think that is correct because I do not recall Wellcome having any experience in handling radioisotopes.
Q. Then's then a reference to:
"Pilot studies on use and performance will have to be undertaken and throughout these studies the Middlesex Hospital will have to monitor the results."
And then there's some more detail as to what that might entail. If we go over the page, picking it up in the third line:
"Commercial kits for HTLV III are expected soon from the USA. It has been predicted that these will cost between £1 and £2 per test. This is considerably more than the [Middlesex Hospital/Chester Beatty] RIA will cost. It is likely that USA manufacturers will wish to use the UK as a proving ground for their products and thereby to gain support for performance submissions to the US Food and Drugs Administration. It is very important therefore to be able to assess these kits to ensure that the NHS can be told about unsatisfactory ones. Clearly, the Middlesex Hospital is uniquely qualified to assess HTLV III kits."
Then there's a reference to "proposal" from you and Professor Weiss, which I think we may have somewhere but isn't on this document. Then it says this:

"After it was submitted discussions were held with Dr Tedder to clarify some of the points made. As a result, some changes to the costings can be made and more information can be given."
Now, I don't propose to read through all that but we can see it's a request for two-year funding, not one-year funding, and then there's some equipment and consumable items and so on referred to. Then point 6 says:
"Given that funds are made available, it should be possible to start the pilot studies by June, 1985."
Then if we just go to the next page:
"The proposal, which is strongly supported by Medical Division and STBA, offers the opportunity to develop further a very sensitive British test for HTLV III antibodies and to establish it for routine screening of blood donors for AIDS. The proposal also offers the opportunity to follow up in depth donations of blood from HTLV III antibody-positive people. Finally, there is an opportunity to assess commercial products which will inevitably be introduced to capitalise on an established need."
Do you have any general comments about what's set out here, Professor Tedder?
A. No, ma'am, I don't. I mean, I think it was -- at the

end of the day, the move to EIA opened up very successful collaboration with colleagues in Wellcome Diagnostics and this was generally recognised to be a major step forward for British industry, as you know.
Q. Would it be -- this document appears to suggest that at this point in time two things were, amongst others, contemplated: first, that the Middlesex Hospital would be involved in the production of kits that would be used for pilot studies; and, secondly, that the Middlesex Hospital would be used or involved in assessing the kits more widely. Was that correct?
A. I think we would not have been involved with the EIA development because we did not have the technology for that. We would have advised and helped with the generation of antigen, or characterisation of the antigen, and we would have certainly been involved in dissecting the meaning of a reactive sample in any assay in terms of whether the reactivity was specific for HIV, we can call it now, or was not a specific reaction.
Q. Then if we just move on in January to a document produced by Dr Smithies at DHSC0000562, it's 11 January 1985. It's Dr Smithies to Dr Alderslade and she's sending this so it can be submitted to the Chief Medical Officer. We can see that from the first paragraph:
"CMO wished to consider this submission prepared

with administrative colleagues for Ministers to obtain approval in principle for the introduction of a screening test for AIDS antibodies in the [NBTS].
"The UK test is currently being used at the Middlesex Hospital and at ... Colindale ...
"[A] scale up of production of the reagent is necessary before the test can be applied more widely."
Then if we go over the page, we've got the text of the submission. I don't need to read through any of that, but if we could go to the bottom of the third page, just under the heading "Financial Implications", the submission says this:
"No tests are yet available for use in Regional Transfusion Centres. They are expected to be ready in the Spring. Both American and British tests are still being developed but the likely cost will be between 75p to £2.00 for each donation. The British test is more sensitive and more suitable to install at Transfusion Centres and is likely to be cheaper."
Then there's a reference to what the resource implications may be.
Now, can I just invite your observations on the suggestion there that the British test is more sensitive and more suitable to install at transfusion centres. Would that be correct if Dr Smithies is talking about

your RIA to start with?

A. I'm not sure what in this particular point in time the "British test" refers to. I do not think it would be the RIA because there was no desire to build an RIA. Although we had the BPL RIA for the hepatitis B surface antigen, that was at a time when there was a move away from the RIA to an EIA.

I'm not sure if they are talking about the competitive enzyme immunoassay as the "British test", which I think is where we would have been here, not talking about a competitive radioimmunoassay but a competitive EIA.

I think indeed it was more sensitive but it was -- or as sensitive but it was very much more specific, which had considerable implications because if you have a test which has false specificity at a measurable and easily detectable level, every donor who's picked up has to go through a rigorous investigation, not only of the donor (who they are, what they are, their behaviour, et cetera), but also you have to have all the samples have to be put through confirmatory testing to make absolutely certain that what you're detecting is genuinely antibody against, in this case, HTLV-III.

So the competitive EIA, or indeed if it had been the RIA (but I don't think it was), the competitive assay

would have been much more specific. I'm not sure it was necessarily more sensitive than the American indirect immunoassay -- probably similar. It had the advantage that it would detect -- can I just go into a little bit of immunology, ma'am?

Antibodies can be IgG, IgA and IgM. The American assay used an anti-IgG detector, so would only detect IgG antibody. A competitive assay will react with and detect antibody of any specificity, any class specificity, because that antibody will get in and block the available epitopes, the available antigen sites, for the conjugate to come in.

So you have an advantage of sensitivity to all types of IgG, IgA and IgM, which is an advantage. It was easier to use because it was a one-step assay. Basically you have your well, you put your sample in, you put your conjugate on, you set it incubating, you go away, you come back after the incubation period, wash it and develop it; whereas the indirect immunoassays, you have to do your dilution, you put it in, you incubate it, you wash it, then you put the conjugate in, incubate it, wash it and then come to the colours. So there are two steps in a sequential -- in the indirect immunoassay.

Whereas the one-step assay is everything goes into

the well, incubate, then wash and develop.

Q. As I understand it, at this point in time, January 1985, the American kits had not yet been evaluated. It's suggested here they're still being developed. So in terms of an ability to say the British test (and assuming that's a reference to the British EIA that was being developed with Wellcome) would have greater specificity, would that be based upon an understanding of the advantages of the competitive assay over the indirect assay, in general?

A. That would be an aspiration. I suspect my colleagues in the PHLS would have done work on this to also look at the sensitivity of the competitive assay. It would have been easier to install in the sense that you just have one incubation and then one wash and develop (you don't have to have two sequential incubations) which makes it technically easier.

Q. Just for the sake of completeness, there is an annex to this submission which begins on page 5 and paragraph 3, bottom of the page, has a heading:

"Development of the Screening Test for AIDS Antibodies."

There is reference there to the five pharmaceutical companies in the US who have been licensed. Then reference to Professor Weiss having isolated a virus

from a British patient and that this was being developed to provide a test by Wellcome who subcontracted Porton to scale up its production.

Then if we go over the page, if we look at the last paragraph on this page, it says this:

"The UK test is sensitive and specific and particularly appropriate to introduce into RTCs who are using a similar technology to detect Hepatitis B carriers."

That would appear to suggest there's still an understanding on the part of the department that it's going to be an RIA test rather than an EIA test.

A. I think you're right, ma'am. But what I don't know is when there was a move away from the radio -- the BPL RIA for hepatitis B surface antigen to a commercially-available assay for -- enzyme immunoassay for hepatitis B surface antigen.

Q. If we then just move to the end of January 1985 and the first meeting of the Expert Advisory Group on AIDS, of which you were a member. That's at PRSE30 --

SIR BRIAN LANGSTAFF: I'm sorry for interrupting, but can I just be clear. If we go back to the previous page that we were looking at, page 3 of this memo -- thank you -- what it says --

MS RICHARDS: That's page 5.

SIR BRIAN LANGSTAFF: It is the third page of the original. Page 003. Thank you.

Under 6, the fourth line:

"The British test is more sensitive and more suitable to install at Transfusion Centres ..."

On the face of it, if one is asking is what is in the mind of the Department at this stage RIA or EIA, this is ambiguous because the sensitivity of the test does not depend upon whether it is RIA or EIA. That's plain from your evidence. And you are saying, well, it is more suitable to install because it involves a simple one-step process as opposed to the American two-step process. So you could say it is more suitable to install. So that language doesn't help with knowing precisely what's in the mind of the author.

But if we go then, please, to where we were at page 5. The annex. Thank you.

MS RICHARDS: I think it is probably the next page.

SIR BRIAN LANGSTAFF: It is the next page. Thank you.

Where it talks about -- yes, it is the last paragraph on the page:

"The UK test is sensitive and specific and particularly appropriate for introduce into RTCs who are using a similar technology to detect Hepatitis B carriers."

Now, you have said to counsel you think that must be, in context, a reference to the RIA process and not to the EIA?

A. Correct.

SIR BRIAN LANGSTAFF: So probably it would follow, if that's what's in the mind of the author here, that the earlier ambiguity is resolved: it is looking at RIA and not at EIA. Would that be fair?

A. I think the comment on sensitivity and specificity and the ease of a one-step assay is applicable both to having a radioimmunoassay label and having an enzyme label. The overriding issue is what platform the transfusion service had at the time. And if they are using a radioimmunoassay, an RIA competitive assay would fit very well. If they were moving to an EIA, a one-step competitive EIA would also fit. So, it depends on tailoring the need -- or tailoring the feature of the assay to fit with the need of the transfusion service and whatever the infrastructure was at that time.

So, in either way the sensitivity and the specificity as an RIA was similar to the sensitivity and specificity of an EIA in competitive format.

SIR BRIAN LANGSTAFF: Yes. One of the questions for me will be: what was in the mind of Government at this time and

was it a justified view? That, of course -- we've had some evidence, oral evidence, but will largely be a question of interpretation -- or may well be a question of interpretation of documents.

I think by this stage, this is mid-January, 11 January, there isn't a document coming from the Department which refers in terms to an EIA test being that which is linked in the writer's or author's mind with the British test.

MS RICHARDS: I think that's right. And the document that we are about to look at, which are the EAGA minutes, does start talking about ELISA tests for the first time, but it seems to be referring to that as being what the American companies are producing. But again, it is all a matter of inference from documentation.

SIR BRIAN LANGSTAFF: But it does look as though that is the mindset at any rate?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Rightly or wrongly.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: And from what you're saying, they may not have picked up what the latest developments in the -- the trends of the tests which virologists would provide?

A. I can't comment on that. I'm not in their mindset,

so -- but, yes, I mean, I think that's possible. It depends what you -- the way you perceive the technology of testing is moving, and at this time it was clearly -- and the American assays were using chemiluminescence, which is an emissions system, which is more like a radioimmunoassay except in this case it is emitting photons, and we were using a colorimetric assay as an inhibition assay. It is slightly different but they are all forms of enzyme-linked assays.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Sir, if we move to the end of January and the first EAGA meeting, PRSE0002734.

We have the date of 29 January 1985, and we can see it is chaired by Dr Abrams and a list of attendees, including Dr R Tedder.

Then if we go to page 4, we have the heading "The Availability of the AIDS Screening Test".

Paragraph 18 refers to:

"Professor Weiss said that work was currently being carried out with Wellcome Diagnostics to develop a screening test, but there were still problems to be solved and he was not able to say when the test would become available. Professor Zuckerman said that the tests were also being carried out at his laboratory and that the results of the American Dupont and Travenol

test might be available within a few months. Comparisons would be made with the test being developed by Professor Weiss and Dr Tedder.

"19. The Chairman reminded members that the November meeting of the BTS Advisory Group on AIDS had concluded that a screening test for all blood donors should be made available as soon as possible. He asked whether the EAGA endorsed this view.

"20. There was general support for the introduction of a blood donor screening test as soon as practicable.

"21. On the type of test to be used, Dr Gunson said there was an overwhelming preference for the use of the radioimmunoassay test in the NBTS. Whilst Professor Zuckerman stressed the need, first, for evaluation of other tests, including the ELISA test. The Chairman said that DHSS would ensure all tests were evaluated."

Paragraph 22 is about the availability of testing for GUM clinics, and then 23 talks about a subgroup being set up, which you'll remember, Professor Tedder, to consider various aspects of the screening tests.

It might be thought paragraph 21 indicates an understanding at this meeting that RIA tests were still an option. By this time, end of January 1985, to your mind would there have been any prospect of

an RIA test being used in the National Blood Transfusion Service?

A. In the sense that the infrastructure was already in place for radioimmunoassays because of the hepatitis B antigen detection requirement, yes. But, if you recognise that all the evolving commercial assays for antibody to HIV -- or HTLV-III -- if we may call it HIV, because that's what we are talking about?

Q. Yes.

A. All the anti-HIV assays that were commercially available were EIAs, so even if the NHSBT and Harold Gunson had wanted to maintain RIA, he would not have been able to do so on the commercial assays, because they were all EIAs.

So I think this is -- I'm not sure, there may be an overwhelming preference to use RIA, because they had that in place, but it was unsustainable in the eventuality because the assays for anti-HIV were all enzyme-linked.

Q. Then, we can look at the first meeting of the subgroup that's referred to in paragraph 23.

It is at DHSC0000425.

So it is a note of a meeting on 15 February and we can see those in attendance, including you, Professor Tedder. Then paragraph 2:

"It was recorded that Travenol, Dupont, Ortho, Abbotts and Electroneucleonics were licensed to use the Gallo isolate. Apparently all the US companies were using an ELISA test. None had been given FDA approval. Wellcome were developing a test based on the British isolate which might be available for use in Regional Transfusion Centres within three months."

Doesn't tell us whether that is going to be an ELISA or an RIA.

Then under the heading "Evaluation":

"The Chairman said that in the absence of statutory marketing controls the DHSS had invited companies developing test kits to take part in a Departmental evaluation."

Just pausing there. This is more an observation than a question. It would appear from this that by 15 February the invitation to companies to participate in the evaluation had already been issued.

Then it says this:

"An *ad hoc* panel of experts with DHSS officers would agree a protocol and arrange for a PHLS virologist to carry out the evaluation."

We know that was, in due course, Dr Mortimer.

"The British test underdevelopment would be included in any evaluation."

Professor Tedder, I just wanted to ask you this, in terms of agreeing a protocol for the evaluation, how long, broadly, would you expect that to take? Would that be a difficult task or would that be a relatively straightforward task?

A. Can you differentiate between the -- setting up the structure from the valuation from the setting up the access to the antibody assay, because I think those are slightly different.

The development of a competitive ELISA by Wellcome Diagnostics would require them to make the components, get access to a supply of HIV antigen from culture, which, in the very early stages, would have been through collaboration with the Chester Beatty Laboratories, but very quickly would have had to fall to the Porton group to produce it because of the containment you needed to grow up large quantities of a category 3 pathogen.

I'm not sure how quickly I was expecting anything to happen. I was probably pretty busy providing serological testing for clinics and for -- as you know, for Haemophilia Centre Directors at this time, and I was doing -- we were pretty much pushed to our limits in providing that serology. So I would not have been close to Wellcome at that point in time but I'd have been asking them to put -- expedite everything as fast as

they can.
Q. Would it be right to understand that at this point in time, so mid-February 1985, Wellcome were not yet at the stage that the American companies were at?
A. I think that has to be correct, because Americans -- the American companies were saying: we have assays which you can purchase and they're ready for use. They were indirect immunoassays of questionable specificity.
Q. Just going back to the reference to a protocol. That, I think, is the protocol for the evaluation rather than describing what it was that Wellcome and the others --
A. I think that is correct.
Q. Would you expect it to take long for a panel of experts with DHSS officers to agree a protocol or should that have been a relatively straightforward exercise?
A. You know what panels of experts are like. There is a lot of discussion. I think it would be relatively easy, particularly in collaboration with colleagues in Colindale, to define what would be a suitable panel. The difficulty was to have a sufficiently large volume of the start material to be able to divide it into panels of samples for people who were interested in having access to a panel. And that's the role of NIBSC. Such an important role that they have.
Q. I'm going to move then to March 1985.

Could we have on screen, please, USOT0000016_144.
Now, if we look at the top of the page, we can see this is a meeting between CMO, so that is Donald Acheson, and Dr Tedder, Professor Weiss and Professor Adler, Middlesex Hospital, 22 March 1985.
This document is divided into two stages. There is a meeting of a note with you and Professor Weiss and then there is a note of a meeting with Professor Adler. I don't need to ask anything about the meeting with Professor Adler.
It says this:
"1. The availability of antibody screening tests was discussed. A number of companies from the [US] were entering the market. The screening parameters of these tests were not yet established. Professor Weiss had some reservations about the practicality of mass usage of the confirmatory test now approved by the FDA in the United States.
"2. The evaluation of the screening tests to be available for use in the United Kingdom was discussed. CMO asked whether a recognisable and organised system for this evaluation had been set up. In reply it was explained that the PHLS would be responsible for the mechanism of evaluation, under the direction of a working group chaired with this responsibility."

Paragraph 3:
"Sera from patients with various defined categories of AIDS presentation would be used to identify tests which appeared to perform well. It was to be anticipated that the bulk of the commercially available tests would pass this initial assessment:
"4. It would then be necessary for initially successful kits to be evaluated in services in the BTS, preferably for more than the 1,000 tests probably now being proposed.
"5. Dr Philip Mortimer ... was mentioned as a possible organiser of the evaluation.
"6. CMO asked whether there were any practical or financial blocks to this programme being implemented. In reply it was stated that more staff would certainly be required within the Virus Reference Laboratory - with associated revenue consequences.
"7. The Tedder/Weiss test was discussed. Naturally they hoped that this would [prove] to be scientifically and practically acceptable in routine use. At the moment it worked reasonably well as a laboratory tool, but adequate scaling up was still to be achieved. Some delay with the delivery of the bulk antigen from Porton was being experienced.
"8. It was agreed that it would probably be

necessary for the BTS to go ahead and use the first successful test that became available. This was unlikely to be the Tedder/Weiss test, in the first instance. They themselves were essentially laboratory scientists. They must inevitably now leave the bulk of the commercial exploitation to Wellcome and Porton."
First of all, do you have any recollection of meeting the Chief Medical Officer on this occasion?
A. No, I'm afraid that at this distance in time, ma'am, I don't.
Q. Now, this would appear to suggest that, again, the US kits are at a more advanced stage than what I'm going to refer to as the British test. It is referred to here as the Tedder/Weiss test, but what appears to be being discussed here is the test that you and Professor Weiss had devised which was now being scaled up by Wellcome and Porton.
A. The competitive one-step EIA, yes.
Q. And it would appear to be recognised that that was -- there was still quite a bit of further work to be done in terms of that exercise, and there's reference to Porton -- delays with the delivery of the bulk antigen from Porton. Is that a fair reading --
A. I think that we were disappointed with the first products from our colleagues in Porton, because they had

not adhered to our protocol for cell expansion, then infection; they had gone a different pathway and it did not produce an antigen which worked. Or there was an insufficient -- putting it into correct terms -- there was insufficient shedding of virus envelope protein from the cell culture when the cell culture was set up the way that Porton did it, as opposed to the way that we set up the cell culture.

Q. So if it were to be the case -- this is a hypothetical -- if it were to be the case that the evaluation wasn't going to take place until the British test was available, that would mean a delay in the evaluation because the British test, as it would appear from this document, was some way behind, at this stage, the US tests?

A. I can't comment on that because I was not involved, but I think what you say is correct. It would have been uncomfortable to be associated with a development which was going to lead to a delay in investigation of the performance of other kits.

What they are actually referring to in the earlier part of that comment was the Western blot kit as the confirmatory test, which people were really fairly nervous about, and we can explore that if you wish, but I think there should have been -- I like to believe

there would have been an investigation at the performance of the indirect immunoassay, which is the various American or the Pasteur assays, and determining the sensitivity and specificity of those.

Q. Just for the benefit of those listening, in terms of the evaluation process, although I think that some of the earlier documents anticipate that you might have an involvement in that, there is a document that makes clear that you were not to have an involvement with that nor was Professor Weiss, because there could be a conflict of interest --

A. Absolutely.

Q. Or there would be a conflict of interest --

A. There would be.

Q. -- because you were involved with the development of the Wellcome test?

A. Correct.

Q. So you yourself were not directly involved in the evaluation process. You were on the subgroup of EAGA but you weren't undertaking the evaluation --

A. We would have probably looked at other people's data and poked it around, but no, I specifically stood back from that. At the Middlesex Hospital Medical School we were not involved.

Q. Then, again, just for benefit of those following the

evidence, there is a follow-up minute from Donald Acheson, which I will just put on screen briefly.

It is USOT0000016_143.

Where he says this in the minute to Dr Abrams on 25 March:

"1. I visited Dr Tedder, Professor Weiss and Professor Adler at the Middlesex Hospital on 22 March 1985. During our discussion it became clear that unresolved technical challenges facing the UK test mean that it is unlikely to be first in the field. We are likely to need to evaluate a number of other tests largely from the United States, over the succeeding months.

"2. I would be grateful to know what organisation exists within the Department and the PHLS to meet this challenge, and who is to be both responsible and accountable for the completion of what will be a demanding series of evaluative tests.

"3. I would also like to know what arrangements are planned to put into effect recommendations resulting from the evaluation when they emerge."

Then in paragraph 4 he says he'd like to take forward and urgently work on the resource implications of the introduction of the test and its consequences."

So that is the position as at 22 and 25 March 1985.

If we then move forward to the end of May 1985, to PRSE0002837.

This is a meeting of the Expert Advisory Group on AIDS on 29 May 1985. We can see again you are listed there, Professor Tedder.

Then if we go over the page, we have the heading at 5:

"Introduction of a screening test for antibody to the AIDS related virus."

I don't think we need to look at paragraph 5.1.

Paragraph 5.2 then explains what the position is in terms of evaluation:

"Dr Smithies says that the PHLS had been asked to evaluate all available screening test kits. Three produced in the USA had been licensed by the FDA and there were at least two being manufactured in Europe. Dr Mortimer said that the initial evaluation would be undertaken at Colindale involving 350 sera, half of which were from blood donors. Two kits would be tested in the next 2 weeks and a third in the next 4 to 6 weeks. It was hoped that at least three sets of data would be available for discussion by an ad hoc group of experts in mid July."

Then the paragraph continues, and in the last sentence of that paragraph:

"The Chairman said that while it was important to introduce a reliable screening test as soon as possible, an effective evaluation of the test was essential and should not be rushed."

Now, this indicates that as at the end of May the evaluation process by the PHLS had not begun, and it is anticipating it will be undertaken essentially in June and July of 1985.

Do you have any knowledge, Professor Tedder, as to why, as at the end of May, the PHLS evaluation had not yet started?

A. No, I don't. I have no recollection of that. All I would say looking at it now, the difficulty -- not the difficulty -- but the requirement from a valuation like that has two components. It has the -- evaluation has to look at what the sensitivity is, i.e., if you have 100 genuinely (you assume) HIV samples, does the test detect 100, does it detect 95, and what do the other tests do in terms of detecting the real reactivity, on the one hand, and that's, if you like, the term sensitivity: how many out of the positives? Does it detect them all, mostly all, some, et cetera?

The other side of that component is if you have 100 or 200 or something negative samples, does it correctly ascribe those as being negative or does it

ascribe 1, 2, 3, 5 per cent as being reactive because that, in itself is -- both of those are problems. If you have an insensitive test, you're missing genuine positives. If you have a non-specific tests, you're generating positives which are not real and you have to be able to sort those out because the individuals, whether it is a donor or somebody in an STD clinic, you're telling them, "You have a reaction in an EIA". The next question is "What does that mean?" and, unless you do a whole range of subsidiary testing, you have no idea what it means.

Q. But are you aware of any reason why the PHLS evaluation could not have begun earlier than June 1985?

A. Well, I think probably, no, I don't. But I think it would have taken a certain amount of time to gather enough samples that were genuinely positive and enough samples that were genuinely negative and have those categorised so you have a panel of known probity to put the commercial tests, or anybody else's tests, through because it's -- we're a little bit retentive in terms of data as virologists, we like to make sure we've got it right, and you would have to collect a panel of known positives and a panel of known negatives and that might take a bit of time.

Q. The paragraph below, so paragraph 5.3, records what

I think is a discussion about confirmatory testing. We see the reference there to the "Western blot and/or RIPA." What's "RIPA" refer to?

A. Well, that would be a radioimmunoprecipitation assay and I have no experience of those.

Q. In terms of confirmatory testing --

SIR BRIAN LANGSTAFF: Might it be RIBA?

A. Sir?

SIR BRIAN LANGSTAFF: Should it be RI"P"A or RI"B"A?

A. I think it's a PA. RIBA? I'm not -- well, it could be either. It could be both. Recombinant immunoblot assay would be one --

SIR BRIAN LANGSTAFF: That's what I was thinking of.

A. -- or a radioimmunoprecipitation assay would be a RIPA. And I'm not sure -- at this point in time, I'm not sure quite what they meant.

SIR BRIAN LANGSTAFF: Because RIBA was used quite a bit, was it not?

A. Yes.

MS RICHARDS: Is it right to understand that the confirmatory procedure that you were I think most familiar with, most confident in, was the indirect immunofluorescence antibody test?

A. It was one which would be -- because of using the immunofluorescent assay for respiratory viruses, it's

something that a laboratory, a diagnostic virology laboratory, would find it easy to deal with because all you do would -- all you do -- you would replace the film of influenza-infected cells with a film of HIV-infected cells, and then the procedure would be exactly the same. You'd put the diluted serum on there, you incubate it, you wash it, you come in with a conjugate of antifluorescent-labelled anti-antibody, incubate it, wash it, and then put it under a UV microscope.

Q. Was that the test that you had used for the study that had been reported in The Lancet in September 1984? There were the two tests: your competitive assay and the immunofluorescence test?

A. Yes, it would have been an indirect immunofluorescence assay.

Q. You mentioned, I think, having reservations about the Western blot test. Why was that?

A. In principle, a Western blot, what it does is it takes recombinant proteins and, one way or another, it separates them on size or charge and layers them onto a solid phase so that you have an array of proteins on a solid phase.

You then bring the patient's serum and you put that over the solid phase and the patient serum, antibody from the patient serum, will bind with various

components of the virus which are laid out by size in the Western blot.

The difficulty with Western blot is that many of us who use them felt that there were only two types of Western blot that were useful: one where you had multiplicity of lines and one where you had no lines at all -- so completely negative or completely positive. And the difficulty with Western blots, as some people in the audience may recall, the virologists here, was you were getting a Western blot with one line positive or two lines which were weakly positively and how do you relate that to the portfolio of antibody that you see in a real -- when I say "real", that's an inappropriate term -- a known positive sample where you have a multiple stack of lines, you have four or five lines in a Western blot.

When you've only got one line in the Western blot, you have to say, "Well, I'm not quite sure what that means", especially if it's weakly reactive. Two or three weak reactions in a Western blot were not uncommon and one then was a major difficulty of interpretation of that.

So it was -- a Western blot in our book, if it was all positive, yes, there would be no difficulty with that. If it was all negative, that was comforting. But

then these frequent findings of one or two lines which seemed to be, depending on which sample you had (you'd have a line there or a line there or two lines there, as opposed to a whole stack of positives), they were difficult, they were not easy -- in fact, they were difficult to interpret, especially when you've got these partial reactions.

Q. Do you recall which confirmatory test was in due course used, once testing was introduced in October --

A. Well, I think laboratories in testing would have had a range of assays. They would have had an indirect immunofluorescence assay, as we used. They could have had a competitive assay if they used the Wellcozyme, and that was very unlikely to give you a false positive reaction.

I don't know. Each laboratory would have had its own protocol for building a range of two or three assays and knowing if they're all positive, that's one thing, if they're all negative, that's another, and then puzzling about the idiosyncratic single reactions.

Q. Then there's just two further documents to bring the chronology to the point of -- at the end of the summer 1985.

If we start with DHSC0000551 and if we go to the second page, we can see this is a meeting on 10th June

1985 of the Screening Test Sub-group of the Expert Advisory Group on AIDS attended by you. If we go a little further down this page, there is a heading:

"Progress on Evaluation of Diagnostic Kits of HTLV III Antibody."

I don't think I need read through paragraphs 4 to 7, but if we go to the next page and just pick it up at paragraph 9:

"Dr Mortimer reported that three manufacturers' kits would be tested by the end of June including the Wellcome kit. The protocol could be amended to allow the field trials to go ahead earlier than presently planned. However Dr Mortimer had reservations about such action before PHLS had evaluated more tests including that of Wellcome but appreciated the NBTS position."

Then paragraph 11 records two Regional Transfusion Centres being particularly anxious to start routine testing in advance of a national commencement date.

Paragraph 12 refers to the Western blot test and there's a record of some discussions by you and a proposal to consult you and Dr Mortimer about that.

A. Sorry, which section was --

Q. Paragraph 12.

A. 12.

Q. Then it is really paragraph 14 I wanted to ask you about, but I might need to read paragraph 13 to make sense of it:

"Dr Gunson then reported on the protocol for the field trials."

There's a further discussion there set out. Then you're recorded in paragraph 14 as saying this:

"Dr Tedder considered the sample size might not produce a single genuine positive: the evaluation was therefore about how to employ in the NBTS rather than a 'field trial'."

Are you able to assist in understanding what that means?

A. If you're going to do an evaluation, you need to have known reactive genuinely -- I don't like the term -- but a genuine positive. You have to have samples which you know have genuinely got antibody in there. You have to have a panel of those and you have to have a panel of negatives.

So I would have been nervous about any transfusion centre introducing these tests until the STD clinics nationally had access to the appropriate serology for their patients because of the danger of saying "we're going to be testing in a transfusion centre for HIV" and then drawing people in to get their test by default.

I think the processing 580 specimens a day on average, if the prevalence was 1 in 1,000 to 1 in 2,000, you would have to do a large number of those to find the one genuinely sera reactive in your field trials.

That's why, looking at what I'm -- what I said at the time, I think you need to have a big enough sample in a very low prevalent situation to find one or two genuine positives, rather than -- if you can follow my concerns --

Q. Yes.

A. -- you have to have a big enough panel to give you a small number of real positives to look at the performance of those in relation to the performance of the negatives.

Q. In any event -- and, again, this is an observation rather than a question -- it would appear from this that the Wellcome test is now, by the middle of June, available for evaluation.

The last document then is PRSE0002628. This is the Expert Advisory Group on AIDS meeting on 30 July 1985 and if we go to page 3 -- this is really just to complete the sequence of events, Professor Tedder -- we've got evaluation of AIDS screening tests and there's reference to a paper being tabled, Dr Smithies reporting it would be issued on health authorities as a report on

the evaluation of the kits:

"The kits had been tested against a panel of sera from unselected blood donors from groups of patients with AIDS or AIDS-related diseases, and from groups of patients in which false positive results were a possibility. The kits recommended as most suitable for use in diagnostic laboratories were ..."

Then we have the Organon kit, the Wellcome kit, and the Ortho kit, and various matters set out in relation to them, and then the Wellcome and the Organon kits are:

"... considered to be particularly suitable for use in blood transfusion centres and were easy to use. Both these kits would be the first to be investigated in the second stage of the evaluation which was designed to investigate performance in large scale screening of blood donors."

In terms of that second stage of the evaluation, did you have any involvement in that process? So we've got the evaluation that had been undertaken by Dr Mortimer and concluded by this point in time, end of July, and then an anticipated second stage, which as I understand it from this, was expected to look at how things -- how the testing actually worked in the Regional Transfusion Centres on a large scale.

A. It's difficult for me to recall at this point in time.

I would be surprised if we were not involved in terms of identifying appropriate positive and negative sera for some of our colleagues to use but, at this point in time, I really, really can't say how much if we were involved at all in that.

Q. Just to note, if we look at the bottom of the page, there's a discussion in paragraph 7.3.2, which is the last paragraph, about the timing of introduction of the tests, and the reference there in part is to the issue that you've raised, Professor Tedder, about the risk of people turning up at blood transfusion centres effectively to get an AIDS test.

I want to pick that up with you as part of a number of most general questions, but we can note that that's being set out there.

Sir, I see the time. Those are all the documents on this issue that I wanted to take Professor Tedder to, but I wonder if I could pick up after the break the handful of additional further questions on this issue that I have.

SIR BRIAN LANGSTAFF: Yes. Well, let's do that and come back at 11.50 am.

MS RICHARDS: Thank you, sir.

SIR BRIAN LANGSTAFF: 11.50 am.

(11.19 am)

(A short break)

(11.50 am)

MS RICHARDS: Professor Tedder, we heard from you yesterday that by around July 1984 you and Professor Weiss had a successful, a working test for HIV.

We know that testing was introduced in the National Blood Transfusion Service mid-October 1985. Looking back now, do you have any reflections on how long it took to get the test introduced into the National Blood Transfusion Service, and do you feel able to express an opinion on whether it could or should have been done more quickly?

A. There are two questions in there. I would not have been in a position to influence, positively or negatively, the introduction of a commercial kit, wherever it came from. That was not my role.

I think one's desire to have a test in the transfusion service has to be measured against the need to have testing available routinely in the GUM clinics to avoid covert movement of people presenting as blood donors in order to get a HIV test.

Even now, looking back on it, I don't know whether we were -- I don't think we were too quick, but were we too slow? And if we had been faster at introducing the testing at the transfusion service, would we have done

more damage by drawing in young men at risk of HIV who wanted to have a test who couldn't get it in their GUM clinic? It's ... I don't know what the answer to that is.

Q. Can I just ask you to look at something you say in your statement. If we could have WITN3436003 and it is page 87.

In fact, if we just pick it up at the bottom of the previous page, just to see the issue that you were addressing. So you were asked whether any other factors affected the date on which routine screening was introduced.

Then if we go to the top of the next page, you say this:

"I have already explained that with a disease that at the time was thought invariably fatal -- considered a death sentence -- you need to be sure that a positive was a true positive and negative a true negative. Evaluation was essential. Also essential was providing for counselling ..."

Then you develop that and say that would have taken some time to arrange.

I just wanted to put a different perspective to you for your comment. You say there you need to be sure that a positive was a true positive and a negative

a true negative. It might be said if you wait until you are sure, you may let months go by in which infection may be transmitted?

A. I don't think that's necessarily true because I'm just saying you need to be sure in your own mind that what you are saying is positive is positive and what you are saying is not positive is therefore negative.

I don't think that would necessarily delay one very much, because by the time you had investigated -- by the time a test had come forward and investigated, say, by the Public Health Service, you would have a good idea of what the -- in a low risk population, which would be the blood donors, what the meaning would be of a low level reaction. Was it real or was it not?

Q. Then I asked you yesterday about whether the position might have been different if you had had access to an isolate, from whatever source, earlier. I should have referred you to something you said in writing to the Penrose Inquiry, Professor Tedder. My apologies for not doing so, but can we just look at that.

PRSE0001069.

So this is your written statement, as it were, your response to questions posed in writing by the Penrose Inquiry, September 2011. If we could just look at the penultimate paragraph on this page. You say this:

"Interestingly, and in retrospect how unfortunately, Luc Montagnier had already offered CBL access to IDAV and arranged for a courier to bring the material to London in the autumn of 1983. A ferry and trains were delayed, the contact was not met as anticipated and the cell culture was left over the weekend with the result that the culture had died."

Then this:

"Things might have been different had we had access to this culture ..."

I just wanted to draw your attention to that, Professor Tedder, and invite again any reflections you have now on whether things could have been different if, in the course of 1983, you had had access to the culture that you and Professor Weiss ultimately had access to in 1984?

A. It is difficult to know because it would have been -- I might have been a few months earlier in developing a competitive assay because I might have had antigen from that culture. In relation to that, I don't know how soon Robin Weiss had the CBL1 isolate of that year. I think it is -- it's galling in the way to know that somebody has offered you an important culture system and it got delayed in the post and by the time it came to you it was not viable.

Q. Thank you. Again, for the benefit of those following and listening, we do have a fairly detailed statement from Professor Weiss, who obviously sets out his own involvement and perspective in relation to these matters.

I'm going to move away now, then, from HIV screening, Professor Tedder, and move to hepatitis C screening. I'm going to take this rather shortly because we have explored the documentation relating to the decision-making of the ACVSB with a number of witnesses in the course of the Inquiry's hearings.

You say in your statement at, I think, paragraph 317, we don't need to put it on screen, that you have little if any recall of the decision-making in relation to the introduction of hepatitis C --

A. I don't think I was -- I was not involved with it as such. I mean, I would have been involved in looking at the performance of some of the kits, how you would confirm a positive. We would have had -- fairly early on in '85 we would access to -- or at some stage in '85, to PCR test looking for a viral genome, which would have been a confirmatory test of -- a confirmation of infection rather than confirmation of serology. And there is a difference between those two.

Q. I'm thinking here specifically of the period between

spring 1989, when hepatitis C has been identified and the Advisory Committee on the Virological Safety of Blood has started deliberating upon the introduction of hepatitis C screening into the Blood Transfusion Service, through to September 1991 when hepatitis C testing of donations was introduced.

In relation to that period of time, one of the things that we know from an array of documentation is that a number of other countries introduced hepatitis C screening earlier than the United Kingdom. Do you have any recollection of how -- of that being noted, of it being a matter of concern, any sense that the UK was lagging behind other countries?

A. Not at the time. I think I -- what I was aware of, the concern of what you are going to do to know whether a reaction in an indirect immunoassay, such as all the assays were out there, what that meant in terms of the donor, the specificity of the reaction in the donor, whether you needed to do a follow up on every recipient who had had components or blood from that donor retrospectively. And the difficulty -- unless you knew that your test was giving you an accurate marker for the presence of antibody to HCV, and therefore that the person was likely to have been infected with HIV(sic) at the time they donated, it is very difficult to do

a look-back and try to contain the damage if you don't know whether your initial marker is real or not.

So you have to be able to convince yourself that this donor truly was infected and therefore has presented a risk to recipients of their components.

Q. Can I invite you to look at one paragraph in your witness statement and just see whether you have anything to add to it.

It is WITN3436003 and it is page 105, please.

So, again, in fact I should put it in context, if we just look at the question, which is on the previous page. You were asked this, it is in bold print towards the bottom of the page:

"In your view, was it necessary to delay the start date of routine anti-HCV screening to September 1991 in order to evaluate the second generation Ortho and Abbott test kits? Has your view changed over time?"

Then, in paragraph 343 you talk in general terms about the problems of introducing a test to a transfusion service where there are questions in relation to specificity and sensitivity.

Then if we go to the next page, I just wanted to read paragraph 344 and see whether you had anything to add:

"I can see that viewed retrospectively, the studies

that were being undertaken kept being overtaken by events; a new test, second generation, a confirmatory test and then two further such tests, and the need for approvals, funding, and logistics. I can understand a reluctance as things unfolded not to introduce something too quickly without knowing what it meant and potentially causing harm through both false positives and false negatives and possible impact on the safety and sufficiency of the blood supply. I can also understand why someone who became infected with HCV when a test was available and sequential studies were being conducted, would find it difficult to see why it could not all have been done more quickly. It is a risk benefit analysis. I think that if a more pragmatic approach had been taken with the seropositives and counselling, and we could have quarantined it until testing was available, loss of a low percentage of donors would probably have been acceptable."

That, as I understand it from your statement, is in retrospect your reflection looking back at the material you had reviewed for the purposes of your statement on the issue of hepatitis C screening.

Is there anything else you would like to add to that on the issue of how long it took?

A. Well, everything is a balance of risk and benefit, and

I don't in any way step back from the sadness that people may have been infected with HCV during that time.

The introduction of a screening test when you are uncertain of its specificity and its sensitivity could do more harm. It could reduce -- it could have reduced the availability of blood because of donors being unprepared -- not prepared to subject themselves to this. And we are seeing at the moment -- in this country we currently have a shortage of donors not for any particular reason but you are always on the knife edge of having enough blood to be able to control the requirements -- to cover the requirements, not to control, to cover the requirements of the Health Service.

I can understand why there might have been concern in the transfusion service not to risk introducing something which could do more harm, through rendering blood unavailable for use, rather than making people safer in the sense of removing people out of the donor panel that you don't want.

Looking back on it, perhaps it should have been introduced more quickly, but then the question is would you have done more harm to your acquisition of donors coming forwards. I can't answer that question. I just do not know.

Q. Can I then move, again briefly, to questions relating to surrogate testing, and look first of all at surrogate testing as a possibility in relation to HTLV-III/HIV, and then separately at surrogate testing in relation to non-A, non-B hepatitis.

In your statement you've dealt with the documentation relating to surrogate testing at paragraphs 366 onwards.

Can I ask you to look at paragraphs 387 to 390.

So if we could have the statement back on screen, Lawrence, and pick it up at page 116.

You say this at paragraph 387, and this, as I say, is specifically about the surrogate testing in relation to HIV:

"At this time there was the recognition on both sides of the Atlantic that AIDS was likely to be caused by an identified virus. Once that concept was accepted, and the virus was out there to be identified, it would then be strange to spend time on using surrogate markers of unknown specificity and sensitivity rather than put effort into developing and applying appropriate serological tests for the agent.

"388. Looking now at how the work went, I think there was a belief that this retrovirus which the French called LAV I and Gallo called HTLV III was going to turn

out to be the agent that caused AIDS. Although that was the belief, it was by no means a certainty. The focus of the research changed as knowledge moved on ..."

Then you refer to some specific matters in the rest of that paragraph. At 389 you say:

"In summary, I do think there was value in surrogate studies for identifying AIDS and AIDS infected persons when that was the best that was available, but these were superseded when the actual virus was clearly identified, and a serological test was in development."

Then there is a reference to a paper published in transfusion in September/October 1984.

I just wanted again to ask you a handful of general questions on this topic, Professor Tedder.

First of all, would it be right to understand that there was a possibility of anti-HBc being a marker surrogate in relation to AIDS?

A. It is not a marker, because that would mean a specific thing for HIV, but as an indicator of -- you would be saying it's an indicator of a lifestyle that may make you more risky, and that could be applicable to that particular -- those particular lifestyles which were associated with a higher prevalence or higher incidence of hepatitis B virus infection, which would be recreational use of injecting drugs where you are

sharing equipment would be one area where anti-HBc might be useful. And in the same context of a marker of a lifestyle, it might be in the homosexual male who has partners, in whom hepatitis B is more common.

In both those situations you could use anti-HBc as a correlate of people who fall into those two risk groups. But you would also be -- in some countries it would be devastating because 25% of your donor population may be naturally anti-HBc seropositive because of acquisition of hepatitis B within that human population.

Q. But that wouldn't be the case in the United Kingdom?

A. No, it wouldn't, but you would still militate against people from those countries being donors in this country, and that could lose donors.

Q. Viewed in the way you describe it, could it be said that anti-HBc testing in that way is another way of, to paraphrase Dr Dane, "knowing your donor"? It gives you information about your donor that helps you reach an assessment as to whether that is a donation that should be used?

A. Indeed but it doesn't tell you -- you don't "know your donor" about the large number of people who are anti-HBc negative. So, yes, you would have a tiny glimpse, a tiny population of your donors, you say, "Ooh, I don't

like -- I don't want to use your blood because you're anti-HBc positive" but what's the false negative rate of that? Would anti-core testing actually have made much of a difference? I just don't know. It depends.

If all your young men who are donors, who were HIV infected were also a positive for hepatitis B anti-core, then that argument holds veracity. If it's only a small proportion, it's a false sense of security and I really don't know where the risk benefit would fall on that.

Q. Then, as you say in these paragraphs, your focus, and no doubt the focus of some of your colleagues, was on the developing of the test specifically in relation to the virus causing --

A. For HIV, ma'am.

Q. For HIV.

A. Yes.

Q. Do you know whether -- as it became apparent that it was going to take a while before there would be a workable test on a scale that could be evaluated and introduced into the National Blood Transfusion Service, do you recall whether there were any deliberations to which you were party as to whether, given the length of time it might take, surrogate testing should be seriously considered?

A. I don't recall that. What I do recall is the

alternative approach is to try and contain within your -- or remove from within your donor panel people who were likely to be at risk of a particular infection, in that case HIV. So that would be getting to know your donor panel and excluding men who have sex with men.

Q. And then turning to surrogate testing in relation to non-A, non-B hepatitis, and it's an issue we've explored with other witnesses, in particular Dr McClelland. Your statement, if we go to page 119, suggests at paragraph 399, picking it up in the third line:

"I worked closely with John Barbara, Marcela Contreras [both of whom the Inquiry's heard from] and other Consultants at the North London RTC, but have no recollection of any involvement in the debate over surrogate testing for non-A, non-B hepatitis."

Does that remain your recollection, that it wasn't an issue that was prominent in terms of your own work and involvement?

A. I'm not quite sure what the term "surrogate testing for non-A, non-B" actually means. Non-A, non-B would have been screened for by the introduction of antibodies against a causative virus, in that case hepatitis C; so you'd be looking for anti-hepatitis C antibody. Do you consider elevated liver function tests?

Q. So there are two forms of surrogate testing that

certainly had been explored in evidence with other witnesses: anti-HBc again --

A. Yes.

Q. -- and then ALT testing.

A. Certainly, I mean the former relies on the coincidence of hepatitis B infection in people who are at risk of HIV through sharing of recreational drug equipment or through being -- a male having sex with males, and anti-HBc would be more common in those two groups.

Elevation of liver function tests would be, again, a feature of a virus infection which causes persistent low grade inflammation of the liver. I'm not sure whether that's actually a surrogate test or whether it's a correlated test for the presence of mild hepatitis.

Q. But in any event, as I understand it from your statement, you refer to a statement from Dr Gunson, you've set out various documents, but you don't recall much, if any, involvement in deliberations about these issues?

A. Personally, no. No, I don't.

Q. In that case, I don't think it's probably sensible for me to ask you anything further about it.

Can I then just pick up really one final issue by reference to, first of all, a document from 1984 and then to your statement. So the document from 1984 is at

PRSE0004532. This is a note taken by someone; it's not clear who. If we go to the second page -- sorry, third page, someone's handwritten on the bottom: "Cc, BMCC" which might be cc Brian McClelland. I'm not sure what the "PLY" might refer to. But, in any event, it might be that these are some notes taken by Professor Cash or it might be something completely different.

But if we go to the first page, in any event, it's some notes of a talk given by you at a haemophilia meeting in Cardiff. Now, do you have, first of all, any recollection yourself of this meeting?

A. Embarrassing to say, no, I don't.

Q. Then I just wanted to pick up what you say -- if you go to the bottom half of the page -- there's a -- we can see set out there the data from the publication in The Lancet, which I think helps us understand roughly what the date of this would be; so it's going to be after 1 September '84. Then it's this:

"The UK seropositivity rate is now apparently exponentially rising."

Then this:

"Dr Tedder made the comment that in veterinary medicine, products from one country would not get through incoming Customs of another country in the way that concentrates have come into the human market for

haemophiliacs in the UK."

So that's somebody recording your comments in the latter part of 1984.

Can I then, before I ask you about that, take you to your statement.

It is towards the end of the statement, please, Lawrence.

Page 132 of the witness statement. Page 139.

You say this, so it is paragraph 464, top of page 139. It is on the left-hand side of the screen:

"I note with interest and disquiet my comments about how easy it was to bring human material for therapy across international boundaries and yet my colleagues in the veterinary fraternity simply would not have entertained this for animal-to-animal material therapy and it would not have been allowed."

As I understand it, the human material that you are there referring to are imported factor concentrates?

A. I think it is true, in terms of animal material, you would find it very difficult to bring a therapeutic animal material from one country into another country without running into all sorts of regulatory requirements, but I'm not a vet, but I know that vets are very nervous about cross-species transmission through introduction of something into a population

where it's not there.

The pressure to bring material in for therapeutic purposes overrides that in human terms. And I don't think I can question that. There are reasons for having access to human material from populations which are not endemic in this country, and that is the nature of the medicine.

Q. Then if we just look on the right-hand side of the screen at paragraph 440, which is the bottom of page 132. And recognising, of course, that you were not a haematologist treating patients but nonetheless, obviously, you are both a doctor and a scientist involved in relation to viruses, you said this:

"Personally, I would have recalled, prevented or very strictly controlled the use of imported commercial blood products, especially those from the USA, which were known to have a significant risk over and above the expected. If the same was to occur with a British product, then clearly recall would be appropriate. At the Middlesex, we would only have used such products if it was the only option to avoid serious harm to a patient. That was David Dane's teaching."

And we explored that yesterday.

I just wanted to put that up on screen so that those listening understand the views that you'd set out there.

Is there anything further that you would add to what you record there?

A. Well, I think it's the -- when you put the pressure on a source to provide plasma from which you are deriving a therapeutic agent, you've got to question how the source of that plasma is made available under the criteria of which the donors are selected.

We know at the time that there was no compunction about using prisoners to give plasma to the American manufacturers of concentrate. And that would fly directly in the face of David Dane's very, very strong edict: know your donors. Because in that particular case, incarcerated males, you cannot know your donor. And I think that speaks for itself.

MS RICHARDS: Sir, those are the questions I'm proposing to ask Professor Tedder. But we obviously need a break to enable Core Participants to suggest, through their legal representatives, any further lines of questioning. I don't anticipate that that is actually going to require a huge amount of time. I don't think, from what I understand, there are going to be vast numbers of questions. I was going to suggest that we took a half hour break now, come back, and I don't expect to be longer than 10 or 15 minutes.

SIR BRIAN LANGSTAFF: Let me just explain to

Professor Tedder what's involved and then we will take a break until not before 12.50 pm.

MS RICHARDS: Thank you, sir.

SIR BRIAN LANGSTAFF: Professor, as you will appreciate, this is not a court case where there are two different sides. It is an Inquiry in which there may be a number of different interests, and those of Core Participants are represented by their lawyers, those who have lawyers, and those lawyers are entitled to put questions to counsel for her to ask you.

Plainly they don't know what the questions will be until they have heard everything you have had to say and how you have said it.

A. My role, sir, is to be as helpful and as forthcoming as I can be in an area where there is immense sadness for the harm which has been inadvertently caused, and if I can do anything to help, I just have to be asked.

SIR BRIAN LANGSTAFF: Well, I'm going to ask you in the first place to wait until not before 12.50 pm. I say not before just in case counsel may need more time, so however few questions she has to ask you, it won't be before 12.50 pm. If there are more questions, you will be told you will be delayed a bit. I can't tell you quite how long you will be delayed after that; it all depends how many questions there are.

So 12.50 pm.

(12.25 pm)

(A short break)

(12.50 pm)

MS RICHARDS: Professor Tedder, just a handful of further questions.

The first arises out of your study published in The Lancet, September 1984, and the finding that 63 out of 184, so 34%, of the haemophiliacs tested had the antibodies for HTLV-III. Were those results provided to the Haemophilia Centres that had supplied the samples?

A. I would be devastated if they hadn't been.

Q. So your expectation would be --

A. Oh, absolutely. Because, I mean, if we were referred samples from any clinical area for any serological test, irrespective of what it was, in the department of virology, if we generated results, those results are owned by the people who sent us the samples from their patients, and indirectly owned by the patients.

Q. Would you have expected those 63 haemophiliacs to have been informed of their results, obviously not by you but by their centres?

A. I would have anticipated -- I would have hoped but I don't know. I would have hoped they would have been, because that would have been the responsible thing to

do, no matter how difficult and appalling it is.
Q. Next question on a different topic. Hepatitis B. After the introduction of the first generation tests in 1972, what was your impression of the prevalence of hepatitis B over the following years, in the '70s and '80s?
A. In objective terms I can't give you a response for that. Low. But whether it was lower than predicted or higher than predicted, I don't know. It's not an area I was deeply involved with.
Q. Then picking up on Dr Dane's theme of "know your donor" and the importance of donor exclusion criteria, and obviously we discussed that yesterday, Professor Tedder. But from your perspective as a virologist, are you able to comment on what would be effective donor exclusion criteria for hepatitis B and for non-A, non-B hepatitis, hepatitis C?
A. Parenteral exposure to other people's blood, which would mean recreational drug use, prior history of transfusion receipt. Those were the two principal criteria. Obviously having mild -- having hepatitis, clinical hepatitis of any type, or known or suspected, would be another reason for excluding such an individual.
Q. I asked you about your recollection of the test results for the Edinburgh cohort and the communication of that

to Dr Ludlam. In relation to testing of samples from Treloar's, so the school -- the Haemophilia Centre there run by Dr Aronstam, do you have any recollection of testing samples from Treloar's or of any communications with Dr Aronstam about test results?
A. I'm afraid I do not.
Q. Then, in relation to the evaluation process for the HIV screening, you referred to needing to have panels of known positives and known negatives. Do you know whether samples from people with haemophilia were used in the evaluation of tests?
A. No.
Q. Last question is this, I don't know if you can answer this but it is a matter I have been asked to raise with you and it may be you can assist. Is it possible for a person who has achieved a sustained virological response to hepatitis C to have the virus reactivated following cancer treatment?
A. Are we talking about hepatitis B?
Q. Hepatitis C.
A. C?
Q. Yes.
A. Is it possible to reactivate?
Q. So if somebody has reported a sustained virological response and is effectively told they have cleared the

virus, to have the virus reactivated following cancer treatment, is the question I'm asked to pose.
A. Well, if the sustained response equates to virus clearance from the liver, then that should not be possible. If, on the other hand, the sustained response is inducing a period of suppression of detectable viraemia and the assumption is made that the patient is then cured of the infection, that infection could re-establish it if you subject that host and that patient to immunosuppression.

But, you know, it is like so many things, you can think you have got rid of a virus infection in a human host and then you do something to them and if there's any residual virus it may reactivate. But on the whole if you are saying somebody is cured, and the assumption -- and the belief is that there is no virus left, then it would not reactivate.

MS RICHARDS: Thank you.

Sir, those are the questions I am proposing to ask from those put forward, and I understand that Professor Tedder's representatives have no questions to request. Do you have any questions?

SIR BRIAN LANGSTAFF: Just one, really. It arises out of your discussion with counsel this morning about the question of testing via surrogate means.

Let me approach it in this way; so far as hepatitis is concerned, so far as HIV is concerned, before it was identified as HIV, the principal defence, as I understand it, was knowing your donor and excluding what you might call "risky" donors from the donor pool; am I right?
A. I think that is a precept -- know your donors is true whether or not you have serological testing, sir, yes, broadly.
SIR BRIAN LANGSTAFF: What that means is that you exclude people you identify as having a lifestyle which might give rise to infection. It might not. So if you are, for instance, asking men who have sex with men not to donate, you may be excluding and probably are excluding a majority of that group who don't have infection, it is because of the size of the -- potential size of the minority that you want to exclude any member of the group. Am I right about that?
A. Correct, sir. Yes.
SIR BRIAN LANGSTAFF: And that was done and there appears to have been no violence done in the course of it to the blood donation service -- the donation side of the Blood Transfusion Service. No unsustainable violence anyway.
A. I'm sorry, I'm not entirely following that last question.

SIR BRIAN LANGSTAFF: It was done without losing too many donors?

A. Well, yes, by definition, because it was a policy which was put in place to exclude a risk population. The same as we would exclude somebody who had come from a malarial country; within a certain time frame you would not wish them to be a donor. You would not wish people who have a risk of acquiring certain infections through certain behaviours. And you can expand that as much as you wish. One would not want that particular individual or individuals to offer themselves as donors.

SIR BRIAN LANGSTAFF: Now, when you were discussing testing by means of anti-HBc, you indicated that that might be a marker or indicator of a risky lifestyle, because it may give rise to aspects of life which might put you into one of the high risk groups for not donating.

A. Yes.

SIR BRIAN LANGSTAFF: Your concern, as I understand it, about that test generally was that it might exclude too many from donating?

A. I think it depends on the population in which you are going to introduce anti-core testing. There are some countries where 15-20% of your population may be anti-core seropositive, and in that situation, to introduce that as a surrogate testing would be damaging.

SIR BRIAN LANGSTAFF: But talking about the UK?

A. You could introduce anti-core screening.

SIR BRIAN LANGSTAFF: In fact, that would be doing no more than using a biological test to identify a "yes" tick in the box which says, "Yes, I have one of these life styles which might be risky so I won't donate"?

A. In a proportion of those but, equally well, a significant proportion from a donation point of view would be people who had been brought up or emigrated from countries with a high prevalence of hepatitis B.

SIR BRIAN LANGSTAFF: And people who were brought up in a country and came from a country with a high rate of whatever the disease was (say, a country where an epidemic is ranging), you might want to exclude those, might you, from your blood donation pool?

A. No, not necessarily because the -- you remember that the population in this country who you are collecting blood for is multiple phenotypes of people of different racial groups, each of which have a requirement for matching their blood group of the person from whom you're taking the blood with the blood group of the person who's receiving it. So if you start distorting the population, you might find it's very difficult to find a blood group match for somebody who's in an ethnic group where hepatitis B might be a common marker.

SIR BRIAN LANGSTAFF: I see. So in those cases where you have a small proportion of the population, a rare blood group, if you want to call it that --

A. You might do some harm like that. Again, it's all a question of balance and I'm not sure quite where the benefit and loss -- where you would put the appropriate benefit and loss in that.

SIR BRIAN LANGSTAFF: It's to establish in my own mind where that balance should properly have been drawn and where it is to be drawn that I've been asking you those questions and thank you very much for those answers.

MS RICHARDS: Sir, I should just say I think Professor Tedder had referred a couple of times during his evidence to the current shortage of donors and I have been asked to point out that, as I understand it from the news, and my knowledge is no more than what is set out in the news, that it's not a shortage of donors that had led to the amber alert being issued by NHSBT, but staff shortages. That is at least what is reported and of course reported that there has been an immediate response of multiple numbers of donors coming forward as a result of that amber alert.

SIR BRIAN LANGSTAFF: We do not have to enquire into that situation but there are mixed messages, perhaps, which are coming out. One of the interesting features may be,

this is just a comment and it may be wrong, for others to pick up, but the ease with which a large number of donations was obtained once the call went out.

But that's for others to argue about in due course. Thank you very much.

MS RICHARDS: Professor Tedder, is there anything else that you would wish to add?

A. Well, I think yes. As a virologist, I'm sometimes seen to be just interested in virology and not much else, but I have a deep sadness for the harm, unexpected and unintentional harm, which has occurred through allowing a virus to become loose in a population, and particularly the harm which has happened to people who, through therapeutic -- well-meaning therapeutic invention from the Health Services, have actually become infected with HIV and other agents. And all I can say to those people, I feel desperately sad and desperately sympathetic to the well-being of those people who are harmed. And I'm just very sorry, as a virologist, that it brings me to a position that says an object of my interest, which is HIV, has caused so much damage to so many people, and people in the room, you have my deepest sympathy. And all I can say is, if another agent ever comes around like that, we will be very, very careful to limit its damage.

I say that, but what have we got? We have got a coronavirus at the moment. But that is a slightly different issue. But, again, we need to try and control the introduction of these agents into the human population.

MS RICHARDS: Thank you.

Sir?

SIR BRIAN LANGSTAFF: It is often said, and maybe rightly, that it is never too late to learn. You have taught us, Professor Tedder, that as an Inquiry, perhaps we should have learned some time ago but you have taught us now, that for any expert witness we might usefully have installed a whiteboard and a marker.

A. I think, sir, it is nice to use your hands and demonstrate shapes like this, but these are transient and it is sometimes useful to have a whiteboard or a blackboard and actually be able to draw things out. That is assuming that the person behind the instrument is able to draw accurately and precisely. But it would be helpful but not absolutely --

SIR BRIAN LANGSTAFF: But I would like to thank you for using words and hands to educate us in some of the subtle mysteries of viruses, their transmission and their effects and how they might be tested for. It has been very valuable. Particularly since you were

referred to so often in many of the documents we have been looking at in the rest of this Inquiry.

So thank you for coming as a scientist and exploring those mysteries for science with us. Thank you.

MS RICHARDS: Sir, that completes our evidence now until 8 November, and I can now set out what evidence we are going to hear what we return.

SIR BRIAN LANGSTAFF: Let us do that, shall we. This is Tuesday, 8 November, onwards?

MS RICHARDS: Yes. We will be hearing on 8 November from Brian O'Mahony, chief executive of the Irish Haemophilia Society. On 9 November, we will be hearing the re-arranged evidence of the statistical group; so that will be Professor Sheila Bird, Professor Stephen Evans and Professor Sir David Spiegelhalter.

On 10 November, we will be hearing from Professor Ian Roberts, who is Professor of Epidemiology at the London School of Hygiene and Tropical Medicine and co-founder of the Joint Colleges Tranexamic Acid in Surgery Implementation Group. That's to look at some particular issues about the use of tranexamic acid and minimising the need for blood transfusion.

We'll be hearing from Professor Derek Manas, Medical Director of the Organ and Tissue Donation and Transplantation Clinical Team at NHS Blood and

Transplant.

On 11 November, we will be hearing from Alex Chisholm, Chief Operating Officer for the Civil Service and Permanent Secretary for the Cabinet Office in the morning of 11 November. In the afternoon of 11 November, we will be hearing evidence about the availability of specialist psychological support for those infected and affected. The witnesses will include: Dr Caroline Coffee from the Welsh Infected Blood Support Scheme; Dr Belinda Hacking, director of psychology services for Lothian and chair of the Heads of Psychology Services across Scotland; and Caroline Leonard, director of Cancer and Specialist Services at the Belfast Health and Social Care Trust. We anticipate there will be an additional witness or witnesses as part of that session but those are the ones currently confirmed.

Then in the second week, 14 November, on the Monday, we will hear from Andrew Goodall, the Welsh Government Permanent Secretary, and Lesley Fraser, Director-General Corporate for the Scottish Government in the morning.

In the afternoon we will be calling Dame June Raine, chief executive of the Medicines and Healthcare products Regulatory Agency.

On 15 November we will be hearing from

Dr Susan Hopkins, Chief Medical Advisor for the UK Health Security Agency, in the morning that is. And in the afternoon Professor Colin Melville, Medical Director and Director of Education and Standards for the General Medical Council.

Then on 16 November we will be exploring evidence relating to haemovigilance and pharmacovigilance through hearing from Professor James Neuberger, Chair of SaBTO, the Advisory Committee on the Safety of Blood, Tissues and Organs, Professor Mark Bellamy, and from Dr Alison Cave, Chief Safety Officer for the MHRA.

On 17 November we will be exploring issues relating to the extent to which there is still undiagnosed hepatitis C and how to address that, and we will be hearing from Professor Graham Foster, the national clinical lead for hepatitis C for NHS England, Professor John Dillon, professor of hepatology on behalf of the Scottish Health Boards, Dr Brendan Healy, the blood-borne virus clinical lead for Wales, and Dr Joanne McClean, Director of Public Health in the Public Health Agency, Northern Ireland.

That will be in the morning. In the afternoon we will be hearing from Dr Michael Mulholland from the Royal College of General Practitioners. That will be to explore issues in relation to GP knowledge and training

in relation to hepatitis C.

On 18 November, the Friday, we will be hearing from Professor Jonathan Van-Tam, relatively recently Deputy Chief Medical Officer and recipient of the Royal Society David Attenborough Award for Outstanding Public Engagement with Science.

So those are the witnesses currently scheduled. It may be that there will be an additional witness or witnesses added in to the timetable and so participants should keep an eye on the published timetable on the website.

SIR BRIAN LANGSTAFF: And participants will be aware that the main focus, the exception perhaps being the statistics group, is on the future.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: That is on the recommendations and what it might be in due course suggested I should recommend which will lead to improvement in the future and make a difference.

MS RICHARDS: Precisely.

SIR BRIAN LANGSTAFF: Thank you. Thank you all.

(1.15 pm)

(The Inquiry adjourned until 10.00 am on Tuesday, 8 November 2022)

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