Friday, 3 December 2021

(10.00 am)

PROFESSOR DAME CARMEN MARCELA CONTRERAS (continued)

Questions by MS RICHARDS (continued)

SIR BRIAN LANGSTAFF: Yes?

MS RICHARDS: Professor Contreras, before we pick up where we left yesterday, I understand you might want to add a little more to what you were telling us yesterday afternoon about the educational work that was undertaken at the centre?

A. Yes, it was the -- thank you very much for allowing me to say that, but I think it's important. We published -- together with the National Blood Services in England and Wales and Scotland, published what is the successor to *Notes on Transfusion* that you showed for 1973, and that was more updated and expanded on appropriate use of blood and safe blood et cetera, on clinical transfusion medicine.

We also published, mostly from North London but also with the collaboration of colleagues in the UK Blood Services, and clinicians, the *ABC of Transfusion*. That was a book edited by me and published by the BMJ, and distributed by BPL to all hospitals, so that -- for free to all hospitals, so that they were aware of the risks of transfusion and

transfusion medicine.

Q. In relation to that second publication, the ABC, can you recall roughly when that was?

A. The first edition was 1989/90. 1990.

Q. Then the update on *Notes on Transfusion*, we've certainly looked at one version of that. I can't remember whether it was called the *Handbook [on] Transfusion* or something like that?

A. Yeah, the *Handbook*, yes.

Q. From 1988, does that sound about right?

A. Yes.

Q. So if we then pick matters up in relation to the issue of AIDS and issues relating to leaflets and questionnaires, where we left off yesterday afternoon you told us, as at October 1984, your centre essentially printed over the text of the original leaflet because you were still waiting for the Department of Health to issue the updated leaflet?

A. Yes.

Q. If we can then look at the circular regarding the updated leaflet that the Department of Health issued in '85, DHSC0002159, please.

So we can see this is dated January 1985. Paragraphs 2 and 3 -- sorry, paragraph 2 refers to the previous version. Paragraph 3 explains that:

"The leaflet has now been revised, most significantly in extending the high-risk groups who should not donate blood, and the opportunity has been taken to amend the layout and update factual matters."

Then paragraph 4 sets out "Revised distribution arrangements":

"Ministers have decided that it is essential that the revised leaflet be brought to the attention of each donor *on an individual basis*. This would normally be achieved by sending each donor a copy of the leaflet with his next call-up notification. It is realised that this may not be practicable for industrial sessions (or for new donors presenting at sessions) - in these cases alternative arrangements should be made to ensure that each donor is individually given the leaflet before any blood is taken."

Can you recall what the arrangement was at the centre in relation to this new leaflet in 1985 to ensure it was brought to the attention of each donor?

A. Unfortunately, we could not comply. You know, these rules are made by people who are not at the sharp end of blood centres, and unfortunately, we could not comply with the recommendation of sending the leaflet to every donor. As I said yesterday, we were sending

postcards to donors and that was a way of reminding them of the donor session.

We educated our donor attendants and receptionists on handing the leaflet, but I cannot say with certainty that it was handed to every single donor, I'm afraid.

Q. As I understand it, Dr Hewitt had some involvement in relation to -- around this time in relation, in particular, to issues regarding donor selection, so it may be that she will be able to assist in that regard.

Could we then just look briefly at the -- what I understand to be a third version of the departmental leaflet issued in September of 1985, CBLA0002255.

We see the date at the bottom of the first page of the leaflet, "September 1985" and then, if we look at the text on this page, we can see that the risk group in relation to being gay is now identified not as "practising" or as "having many partners" but simply being homosexual or bisexual, and then we have the addition of being "a sexual contact of any of these people".

If we go to page 3, please, I'm just going to draw your attention to the question:

"How is AIDS transmitted?

"The transformation of AIDS is not yet fully

understood, but it is known that one means of transmitting the disease is through blood and blood products. Because of this, all donations are now being tested for antibody to the AIDS virus, but people in the groups most likely to be at risk from AIDS still MUST NOT GIVE BLOOD."

The last four words in capitals.

That's obviously one means of ensuring that those who were donating blood understood that their blood would be tested, that their donation would be tested for in relation to HIV. Do you know whether, in addition to providing the leaflet to donors, donors were individually told that their blood was going to be tested?

A. Yes, yes. They were told and they had to sign that the blood was going to be individually tested and, in addition, we still had the self-exclusion questionnaire in isolation. So that they knew that they were at risk and they knew that they were going to be tested.

Q. We'll look at a document or two in relation to that.

A. If they were --

Q. Then if we just look at the question "Can donors get AIDS by giving blood?" The leaflet said:

"Absolutely not. Neither AIDS nor any other

disease can be contracted from giving blood."

Do you recall whether that was a concern that was voiced by donors or prospective donors within the area served by your centre, a fear that somehow by giving blood they could contract AIDS?

A. Oh, yes. There was a shortage of blood in the world. Not only -- you know, because I had contacts and I -- and because I'm foreign as well, there was a shortage of blood in the UK, nationally, and in other countries, like the USA and Europe, in European countries.

And we didn't know what to, and I said "Who could I call who is a public figure?" and I thought of Princess Diana at the time, but she was too slim and I don't think she was the right person, and I asked Prince Charles to come and donate. It took me a long time to get Buckingham Palace to allow me -- for him to come, and he came and gave his blood at Edgware; and he was in all the newspapers, and it's amazing how our blood stocks increased, not only in England, but in other countries.

I got letters from lots of parts in the world saying thank you, because it went round the world, this -- him giving his blood, showing that he was giving his blood.

Q. I was trying to work out, Professor Contreras, when that might have been and I've found, I think, a newspaper article in the Los Angeles Times, which would perhaps indicate the international attention, suggesting that that donation was given by Prince Charles at the Centre on 1 March 1985, and it quotes you saying that:

"He was invited to donate blood in an effort to allay public fears about AIDS and in the hope the visit would encourage other people."

It had that effect, did it?

A. It had more or less an immediate effect.

Q. If we can then just look at NHBT0092834, please. This is the "Minutes of the Meeting of the Eastern Division Consultants", 3 October 1985, and you were in attendance. If we just look down the bottom of the page, under the heading "AIDS" it says:

"Each Centre was using their own version of an updated 110 form, which were in the process of being printed."

At the bottom of the page, it says:

"The new AIDS Leaflet was criticised and most Centres were sending an [over the page] explanatory letter in addition.

"The most worrying aspect of the leaflet was

that it implied that anti HTLV III was a test for AIDS."

Do you recall that being an issue of concern?

A. I can't recall.

Q. If we just look at the next heading, under the heading "Blood collection and donor recruitment" it records Dr Darnborough saying that the publicity budget had been increased to £350,000.

Dr Darnborough was which Transfusion Centre?

A. Cambridge.

Q. Then it says:

"[You] said this was still grossly inadequate. It was generally agreed that it should be put to the Advisory Committee, via the RTD Meeting, that a larger proportion of available money should go to the London Centres."

In terms of the publicity budget, was that a nationally allocated budget from the Department of Health?

A. Yes, and managed nationally, you see.

Q. Why was it, if you can recall, that you thought that was grossly inadequate?

A. It was very little money. For example, we couldn't -- we had -- we couldn't advertise on television or on national radio, it was mostly for printing posters and

leaflets and a little bit of local advertising, but it's not like now when they're appealing for blood in the radio, daily.

Q. Now, just in relation to the exclusion questionnaire that you told us about, so that we can put some dates in relation to that. Can we look at JPAC0000140_143, please. Yeah, JPAC0000140 -- sorry, it's 043, my fault, Soumik.

This is a summary of a later publication from 1992. It's headed "Confidential Unit Exclusion: The North London Blood Transfusion Centre's Experience", and then it records that:

"A confidential AIDS Questionnaire has been in use at North London Blood Transfusion Service ... donor sessions since July, 1985. The purpose of the questionnaire is to encourage those donors whose behaviour puts them at risk of HIV infection to refrain from donating. In a situation where such individuals cannot avoid donating then they can indicate, in confidence, that their blood should not be used for transfusion."

Then it goes on to describe the process.

Now, other documents indicate, and I think it is consistent with what you told us yesterday, Professor Contreras, that you introduced this in July 1984 in

one centre --

A. Yes.

Q. -- as it were, on a trial basis and then this would suggest it was rolled out across the remaining donor sessions a year later; is that right?

A. Yes, yes. First at the plasmapheresis clinics and then to the sessions.

Q. Can you recall why it was a year before it was rolled out to the other centres or other sessions?

A. To the donor -- because it was very difficult to find sessions that were large enough, if we had to do it, we had to do it uniformly across all donor sessions, and sometimes we couldn't find a place for our screens to screen. We need -- some donor sessions are very tight. So until we were assured that we could do it, it took some time.

Q. Because it's right to understand, I think, that at this point in time, July 1985, testing of donations has not yet been introduced. That happened in October 1985.

A. Yes.

Q. So donor selection processes trying to deter high-risk donors or prevent high-risk donors from donating was essentially the only tool you had at that point?

A. Yes.

Q. Do you recall whether other Regional Transfusion Centres, whether in your division or nationally, introduced a similar measure or gave any thought to introducing a similar measure?

A. I don't think they did but I'm not quite sure.

Q. Then if we could look, please, at NHBT0000030_013. This is an article published in the British Medical Journal in March 1985, authored by you, Dr Hewitt, Dr Barbara and a scientific officer at the centre.

If we look at the heading "Comment", bottom of the left-hand column. So there's reference there to one of the published papers, I'm not going to ask you to go through the details of that, but if you go to the top of the next column then, this records that:

"Donors in the high risk category said that they had continued to donate despite the publicity about AIDS because the original (unrevised) leaflet had implied that homosexuals with stable partnerships were still eligible as donors."

Then last paragraph:

"It is alarming that some male homosexuals still donate blood, and it is vital that all possible measures are taken to discourage this."

So is it right to understand that your findings at the centre, which are discussed in a little more

detail in this paper that I'm going to go through, it indicated that the original leaflet hadn't deterred all high-risk donors because of the reason that they thought it didn't cover them?

A. Yes.

Q. Professor Contreras -- oh, actually, before I move on, let's just look at, I think, two versions of the questionnaire, just to get a sense of what you were introducing. PRSE0001398, please.

So we can see this is headed "National Blood Transfusion Service, North London Blood Transfusion Centre". The text is:

"Dear donor,

"Because of the current concern about the disease AIDS, which can be transmitted by blood products, we are asking all our donors, at each attendance, to complete the enclosed questionnaire in order to try and reduce this risk to a minimum."

So this appears to be a covering letter. Then it says:

"After booking in, would you please ...

"1. Read the AIDS leaflet.

"2. Enter the side-room on the left as you approach the main clinic. (One door at a time.)

"3. Complete your questionnaire in confidence.

"4. Post it in the special box provided.

"5. Take a seat outside, ready to enter the main clinic and donate."

This is the document with the questionnaire which would be provided at the sessions to the individual donors.

A. Yes. Yeah. But this is not the questionnaire?

Q. No. It refers to the questionnaire. Sorry, I thought we had a copy of the questionnaire but I'm not sure that we do.

Then there is a further document, a later one, I think, NHBT0085139_007.

So this post-dates October 1985 because it refers, in the second paragraph, to the blood being tested. But it explains:

"AIDS is a very serious disease caused by a virus HIV."

Then:

"There is no risk of catching AIDS through blood donation, but HIV can be passed on to a patient by the transfusion of infected blood. It is therefore very important that you read and understand what is said in the AIDS leaflet each time before you donate.

"Your blood will be tested for HIV. It is possible for the test to be negative in the early

stages of infection. All donors are therefore asked to read this form and complete it carefully.

"All information will be kept strictly confidential.

"You must not give blood ..."

And then there are a range of different exclusions there set out.

I don't think we have a date on this document but it's sometime in the second half of the 1980s I think, because the issue about having had sex at any time since 1977 with men or women who live or have lived in African countries I think is discussed at various meetings in the second half of the eighties.

This is the kind of document, is it, that was being provided by way of questionnaire to donors at the centre?

A. Yes. But that was not the self-exclusion questionnaire.

Q. And then -- well, it looks like this might have been a later version of the self-exclusion questionnaire, Professor Contreras, because if we look at the very bottom of the page, it says:

"Please fold this form and place it in the box provided."

A. Yes, sorry -- sorry, yes.

Q. This is -- sometime in the second half of the 1980s this is what was provided?

A. Yeah.

Q. Okay.

A. Yes, sorry.

Q. What I want to do next, Professor, is move on to the question of screening, testing of blood donations for HIV. Can we look first of all, before we go into the detail of that, at your witness statement, WITN5711001, and go to page 36.

So, paragraph 139 at the top of the page, you were here being asked a general question about the decision-making remit, for example, of Regional Transfusion Director meetings and you say this in relation to decision-making generally:

"With respect to the running of the centre, and meeting demands for products and services as well as for R&D, those decisions were made by me and my management team. So, at a local level, we made our own decisions with the Regional Health Authority as the overall body overseeing these. With respect to national standards, these were agreed by consensus at the Regional Transfusion Directors meetings."

Then you say this, Professor:

"Decisions on the national introduction of

screening tests for blood donations were made by the [Department of Health]."

Now I'm not going to suggest to you, Professor Contreras, that you're inaccurate there in what you say about decisions being made about national introduction of screening by the Department of Health, but what I wanted to try to understand is why it was that that category of decision was taken by the Department of Health rather than being an issue for Regional Transfusion Directors to decide for themselves.

A. As I understand it, it's because we were a national service. Although we were regionally managed and we did things different regionally, but there were matters of great importance, like the screening, that it was preferable that every -- that every patient in the country received the same type of screened blood for as many agents as were possible. But this needed funding, as well, from the Department of Health. So the Department of Health had to more or less instruct and inform regions that a new test was being introduced.

Q. Now, in relation to funding for screening for HTLV-III/HIV, your understanding is that was provided nationally by the Department of Health?

A. That's my understanding.
Q. As we'll see when we get on later in the day to the introduction of screening for hepatitis C, that wasn't funded by the Department of Health, was it? So --
A. That's correct, it wasn't.
Q. -- (overspeaking) -- fund it themselves through their Regional Health Authorities.

Can I just explore with you the different types of decisions that might need to be made in relation to the introduction of screening? This is a general discussion, Professor Contreras, before we look at the specifics of the decision-making in relation to testing for HIV or testing for hepatitis C or, indeed, surrogate testing for non-A, non-B hepatitis.

So there's a decision in principle, should we introduce screening for -- in relation to this condition. Would you accept that?
A. Yes.
Q. There's then the question of how that's going to be paid for?
A. Yes.
Q. There's the question of what form the screening will take, what particular tests to use, what arrangements, practical arrangements need to be made?
A. Yes.

Q. And then there's the question of what the actual date for implementation will be?
A. Yes.
Q. Was it your understanding that all of those decisions, all of those different categories of decision effectively fell to be taken by the Department of Health, albeit with Regional Transfusion Directors and Dr Gunson expressing views or making recommendations?
A. I don't think that all those -- the Department had a great influence in those. But the decision of whether we would test or not test was a Department -- it could have had advice from the Blood Services. But to test or not to test was a decision from the Department.

And then the details of what tests to use, we would do the kit evaluation test -- assays, and then recommend a certain test. And I cannot remember -- I think it was also -- it went to the Department, to that advisory committee, and then to -- from there to the Department.
Q. Now, if we leave aside for a moment the question of funding, was there in principle anything to stop a Regional Transfusion Centre, obviously with the approval of its Regional Health Authority, introducing screening at a time of its choosing?

A. No, apart from the fact that -- the conscience of the director and his or her team to give blood that's screened compared with the rest of the country, but --
Q. We'll probably pick that issue up when we look at the introduction of hepatitis C screening.

Okay, well, let's look, then, at the introduction of screening in relation to HIV. I'm not going to go through each and every stage of the decision-making process; I'm just going to look at a handful of documents which indicate the involvement of either you or the centre.

So if we start at CBLA0001914_007, we can see here a document dated November 1984:

"Advisory Committee on the National Blood Transfusion Service

"Working Group on AIDS"

Then paragraph 1 explains that:

"A Working Group on AIDS has been set up with the following terms of reference: 'To consider the implications for the National Blood Transfusion Service of testing blood donations for antibody to HTLV III and to report'."

Then we have number of members set out, including you, Professor Contreras, a couple of co-opted members, observers from Department of Health,

Welsh Office, Scottish Home & Health Department, Dr McClelland from the Scottish National Blood Transfusion Service, and then the secretariat being provided by the Department of Health, Dr Smithies and Mr Williams.

Can you recall whose idea it was to set this up? Was this a Dr Gunson or RTD initiative or was it a Department of Health initiative?
A. I don't recall.
Q. And what can you recall about the purpose of this working group, other than what we see set out in paragraph 1 terms in terms of the terms of reference? What was it that this working group was actually going to be doing?
A. I think it is what it states there: to consider the implications of testing for anti-HTLV-III, or anti-HIV, I think, *(unclear)*.
Q. Can you recall whether the plan was that this group would make recommendations that would then be considered by the Department of Health?
A. Yes.
Q. Can we then look at DHSC0001677, please. If we go to page 2, a letter from Dr Gunson to Dr Smithies, July 1984. We looked at this yesterday because one of the documents attached was about the organisation of

the National Blood Transfusion Service.

But if we go to the next page, what we have here is a document -- perhaps if we go over the page, we can see the authorship first of all. So authored by Dr Gunson, copied to a number of people, including you. The document itself is not dated, unfortunately, but if we go back to the preceding page, there's a plan set out, if we look at the first three paragraphs, Stage I is the sending of samples from the North West Thames Regional Transfusion Centre, so that's your transfusion centre, to the Middlesex Hospital:

"... where performance of the tests will be proved and evaluated.

"Stage II. The performance of the tests will be transferred to the [North West Thames Regional Transfusion Centre] and experience gained on its use."

Then Stage III was donations being tested at Manchester, Bristol and continuing at the North London Centre.

Do you have any recollection now of what work was undertaken at the North London Centre in terms of evaluating or contributing to the evaluation of the HTLV-III tests?

A. Yes, I can vaguely remember that the microbiology

laboratory was the first one to do the screening tests on this donations. It was the first generation assay, and we sent the repeatedly reactive samples to Professor Tedder at the Middlesex.

Q. So the work that was being undertaken by the North London Centre in that regard would have been under the auspices of Dr Barbara?

A. Yes.

Q. Well, no doubt we can ask him hopefully in relation to that.

Now, this is probably not a question you're going to be able to answer without looking at lots and lots of documents. Can you recall when the North London Centre was involved in the evaluations: did it start in 1984 or was it later in 1985?

A. I cannot -- no.

Q. Can we then pick matters up, then, in March 1985, at PRSE0004824. You'll see, Professor, this is The Lancet, 2 March 1985. If we go to the second page, right-hand column, about halfway down the page there's a letter there signed -- sorry, if we can have the list of names. So we can see it's signed by a number of Regional Transfusion Directors. We looked at this with Dr Napier, whose name appears, and we can see that your name is there as well, Professor Contreras.

Then if we look at the text of the letter, it refers to believing:

"... that the current commercial kits for HTLV-III antibody tests are likely to give a high rate of false-positive results."

Again, I don't know whether this is something you can remember without looking through lots of underlying documents. Do you recall what the evidential basis was for the concern that the tests were likely to give a high rate of false-positive results?

A. Yes, that I remember. It was for approximately ten initially reactive or positives on the screening test. We found one confirmed positive by Professor Tedder.

Q. Then you go on to say:

"We would therefore recommend that careful consideration be given before they are introduced for the screening of all voluntary blood donors, for the amount and degree of unnecessary stress and hardship that a fair number of our donors and their families would thus have to undergo is unacceptable."

So concern there about the impact of false positives on donors; is that right?

A. Yes.

Q. "This in turn could lead to a sizeable drop in the

supply of blood and blood products."

So there concern about the impact upon the Blood Transfusion Service. Then the next point, the third point that's made and described as being "for the safety of transfused patients", is that there should be essentially GUM clinics in the community where ordinary members of the population could get tested so they don't donate blood for the specific purpose of getting tested; is that right?

A. Yes.

Q. Again, was there an evidential basis for that concern, or was that just a fear that it might happen?

A. The -- in the USA they had -- they called it the magnet effect. Our colleagues in the USA who had started to test had evidence that people in high-risk groups for transmitting HIV were giving blood in order to know whether they were positive or negative.

Q. So the next paragraph says:

"We do support, strongly, the screening of all blood donors for HTLV-III antibody testing, but we would advise that this is delayed until test systems have been appropriately evaluated and efforts have been made to give all members of the public access to HTLV-III antibody testing."

In relation to those two points in that last

paragraph, evaluation of test systems and providing public access, can we just take those separately?
A. And providing ... sorry?
Q. Public access to testing.
A. Yes.
Q. In terms of providing public access to testing, whose responsibility would it be, essentially, to ensure that was available? Was that a Department of Health responsibility?
A. I believe the Department of Health asking regions to introduce alternative test sites.
Q. Do you have any knowledge or recollection yourself of what efforts were made by the Department of Health or what steps were taken, and when, in that regard?
A. I've read lots of documents that were sent to me by the Inquiry, and I believe I saw a memorandum or a letter to regional general managers to introduce alternative testing clinics and I think they said that this -- the best -- this best could be done at GUM clinics.
Q. Do you recall whether you or your colleagues, either your colleagues at the centre or your colleagues in the -- at other centres, do you recall whether you thought the Department of Health was moving quickly enough in that regard or whether you had concerns that

it was taking too long to sort out?
A. I think in some areas it took too long be set out. I think that my region acted quite promptly in establishing -- in offering HTLV-III testing but there were parts of the country, I remember some of my transfusion director colleagues, and I think that in Scotland, as well, it took some time for GUM clinics to be test -- alternative sites.
Q. Then the other point that you made in this last paragraph, you and your colleagues made in this last paragraph, was about the need for the test systems to be appropriately evaluated.

Can we just go, please, to PRSE0002078. This is a letter of 30 July 1985, from the Department of Health to Regional General Managers, Regional Medical Officers, Regional Transfusion Directors and others. It may be that this is the document you were referring to a few moments ago, Professor Contreras. It says in the first paragraph:

"In his press release dated 27 June the Minister for Health announced that a test would be introduced to screen all blood given by blood donors for antibodies to the virus which causes AIDS. Arrangements would also be made for Sexually Transmitted Disease clinics to provide a test for

people who fear they may have been exposed to the disease."

So that's -- this reads at least as though that's an announcement being made June/July 1985. Do you know of any reason why that couldn't have been done earlier?
A. No.
Q. Then the next paragraph of this letter talks about the evaluation of the test:

"The first stage of the evaluation of commercially available test kits has now been completed on behalf of DHSS by the Public Health Laboratory Service. The outcome of that evaluation has been considered by a panel of experts and a summary of their recommendations is attached. The National Blood Transfusion Service is now taking its own 2nd stage evaluation covering aspects peculiar to the use of kits in the blood donation screening context."

So we've got there a two-stage evaluation, with the second stage essentially only commencing in the summer of 1985. Do you know why it took until the summer of 1985 for that second stage evaluation to be initiated?
A. No, but I think it was too late.

Q. Just in terms of some dates, I'm not going to go to the detailed subsequent evaluation report, but we -- I'll just give the reference for the transcript, it's PRSE0002716. But it shows the North London Centre was one of the centres involved in that second-stage evaluation and, as I understand it at that point, what was being done in the North London Centre and, I think, Manchester was a comparison between different tests. So there was a testing or evaluation of the Wellcome Test and then of the Organon Test.
A. Yes.
Q. Do you know why what we see here is the evaluation being done sequentially? In other words, you've got the PHLS and then the evaluation being undertaken by yourselves and Manchester? Could that have been done simultaneously?
A. I don't think so because what the PHLS did was look at sensitivity and specificity but also at durability, the length of -- that the tests took. So some tests are good for diagnostic purposes in diagnostic laboratories but some tests are good for screening. So in screening donations you need sensitivity and specificity in order to get the right donors positive. With diagnostic testing, you try to get as much sensitivity as possible.

So -- and the length -- with diagnosis, it doesn't matter very much if you have a test taking three or six hours, but with -- in blood donations, if you're giving platelets. So there are several reasons why you should assess which tests are convenient for the Transfusion Service and then hand those one to the testing laboratories in the blood services.

Q. Although it might have involved more work for your centre under the auspices of Dr Barbara or Manchester or other centres to do it, as it were, simultaneously, is there any reason why there couldn't have been an evaluation of the practical implications, as it were, looking at all the diagnostic tests, whilst the PHLS was doing its own evaluation from its perspective? Did it have to wait until PHLS had narrowed it down to two tests, in other words?

A. Yes, it had to wait because we couldn't have been comparing, you know, a test that took too long with a test that was shorter. You know, they had to choose what was adequate for us, for the blood services. But it should -- it could have been done quicker.

Q. If we just, then -- if I can just ask you to have in mind again that March 1985 Lancet letter. We can put it back on screen if we need to but what I want to do, and indeed some questions I've been asked to ask you,

is to look at what Dr Gunson was asked about that letter in his oral evidence in the hepatitis C *A v National Blood Authority* litigation and ask you to comment on that.

So NHBT0000148_001, please.

So this is an extract from Dr Gunson's testimony. If we could go, please, to page 4, I'm just going to read -- starting from the third line, I'm going to read the passages and then ask you about it.

So this is a letter written in -- this is part of the question that's being put to him:

"This is a letter written in March 1985, just over six months before screening was actually introduced. Is that right?

"A. This is the Ala [that's a reference to Dr Ala] et al letter.

"Q. Yes. It is just over six months before screening for HIV is introduced?

"A. Yes.

"Q. It is about the time that other countries, France, America, Australia, the list we looked at yesterday, are, in fact, introducing screening?

"A. Indeed.

"Q. The signatories are probably all of the 14,

or however many it is, Regional Transfusion Directors?

"A. It is not all of them.

"Q. It is most of them?

"A. They are all transfusion centre directors in either England or Scotland."

Then there is a question about false positives, so there is a quote from the Lancet letter, and at line 173 the question is:

"Was that, in fact, the case?"

Dr Gunson says:

"There were false positive.

"Q. Was it a high rate?

"A. I am not sure at this time now whether you would describe it as a 'high rate', which is a rather indefinite adjective to put before it."

If we can see the rest of the page, please. Thank you.

Question -- this is line 179, there is then another quote from the letter:

"'We would therefore recommend that careful consideration be [I am not sure what it is, probably "given"] before they are introduced for the screening of all voluntary donors for the amount and degree of unnecessary stress and hardship that a fair number of our donors and their families will thus have to

undergo is unacceptable. This in turn could lead to a sizeable drop in supply'."

So there's the quote, Professor, from the March letter. Then the question continues:

"The importance of the supply is then stressed. Then the problems of the clinics, by which I mean the blood clinics, blood donation clinics, having to do the work. Really what they were really looking for was a different body to do the counselling?

"A. Yes."

Just pausing there, can you recall whether that was part of your thinking, that external support in relation to the counselling was required?

A. No, because we had -- at least from what I recall in my centre, we had a team of doctors that dealt with the counselling, and they went to St Mary's Hospital to -- you know, it's not the collection teams that were going to be doing the counselling, it's a group of experts at the centre.

Q. But the position may have been different in relation to other centres?

A. It may have been different.

Q. And then line 192:

"They [that's you and your co-authors of the letter] conclude:

"'We do support, strongly, the screening ... But we would advise that this is ask [I think it must be "delayed"] until test systems have been appropriately evaluated'."

Then the question continues:

"I simply wanted you to comment. Here we are with a much more serious condition [I think that's a comparison with HIV and hepatitis C that's being referred to there], other countries already introducing, but directors being primarily, apparently concerned about problems for donors and for practicalities within clinics. Is that a fair comment?"

If we go to the next page:

"A. Yes, I think the transfusion service is concerned with the health and welfare of their donors.

"Q. There's not any mention there about, as it were, the possible impact upon recipients, is there?

"A. Well, it does say, 'We do support strongly the screening of all blood donors'.

"Q. 'We are going to delay'. There is no, as it were, weighing up on the one hand the disadvantage of a donor being told, perhaps wrongly, that he had AIDS, and on the other hand a recipient getting AIDS while you delay. There is no balancing exercise done

in that letter, is there?

"A. In this letter there is not, no."

So you'll see from that exchange, Professor, that what was being explored with Dr Gunson was whether that March 1985 letter was essentially concerned with the impact upon donors and Blood Service in terms of the arrangements that would have to be made or loss of supplies, and insufficiently weighing into the balance the risks to the recipients of blood. Do you have any observations or comments to make on that?

A. No. I wished that, with hindsight -- but I wouldn't have known what to tell those nine donors that I couldn't confirm, you know. That -- you know, I would have created an army of worried well. You know, the people who, if they're told they've got something like cancer or a fatal infection, they might throw themselves in front of the tube, or anything. So it was those considerations. But perhaps we were wrong.

Q. I think you started to say, "I wished with hindsight" --

A. Yes.

Q. Do you wish with hindsight that the screening had been introduced earlier than October 1985?

A. Yes. I wish that that there had been a better test

because I had the problem of telling those ... you know, it's ... it's about which of the one in ten was the infectious one, was the one who was transmitting? That was a -- yeah, but I wished there had been a better test. It was a test that was done -- it was performed -- cultured in cells and lots of women have -- you know, young women who have had children have HLA antibodies, and this test was contaminated with HLA tissue antigens.

So women having anti-HLA antibodies, that are many, would have tested positive, having a very pure life. So I wished there had been a better test.

Q. Can I then turn to the specific arrangements that were made in the centre in relation to the introduction of the testing. Can we start by looking at a Regional Transfusion Directors meeting on 9 October 1985. So that's about a week before the date is set for the introduction of the testing nationally.

DHSC0002365_002.

So we've got there the meeting date, 9 October 1985, and we can see that you, amongst others, were in attendance.

If we go to the bottom of the second page, please. We have a heading "AIDS Update". Picking it up in the second paragraph:

"Anti HTLV-III screening is in hand and training completed. All RTCs will start full testing by the 14th October 1985. Discuss took place over fresh blood products in stock, ie FFP cryo and Frozen Blood. The matter had been raised at Divisions and RTCs differed. Some felt they would not support discarding untested donations. Wherever possible back-testing would be carried out on in-date material. It was felt important that BPL should accept and process FFP and time-expired plasma for heat-treated products. Dr Lane stressed that such material must be clearly identified and BPL given notice."

Before we look at the rest of this, is it right, Professor, to understand that the -- although there was the date of 14 October as the date upon which any donor coming into centres at that point in time, their donation should be tested, that left unresolved, and for individual centres to decide, what they did about everything they already had in stock?

A. Yes.

Q. So that question wasn't nationally mandated, it was left to be determined on a local basis?

A. Yes.

Q. And we can see here, in the fourth line of that paragraph, some directors not wanting to discard

untested donations. So it would seem from that, that in some parts of the country untested materials may have been supplied for use in patients after 14 October 1985; is that right?

A. Yes.

Q. Then we see, and the next paragraph is a contribution from you:

"Dr Contreras reported that all accredited donors of frozen red cells for boosting had been screened five months ago by a number of tests and expert opinions were that these were safe to use."

What does that refer to?

A. We had accredited red cells to -- it's something amazing that donors do, that they accept -- they are Rhesus negative or RH Negative volunteers who accept to be boosted with -- immunised with Rh positive red cells in order to produce anti-RhD or anti-D immunoglobulin. And these donors are injected with red cells regularly so that they maintain a very high level of antibodies and, in this way, we were self-sufficient -- this country was self-sufficient in anti-D immunoglobulin to protect RhD negative mothers from having children affected with haemolytic disease of the foetus or newborn.

So this -- because they were volunteers and they

were being injected with Rh positive donor cells, we accredited those red cells, and so we managed to ask them, and they were -- fortunately, they were all negative for HTLV and all the markers.

Q. But this tends to suggest that as long ago as five months before October 1985, there had been some form of HTLV-III testing that you were able to use in relation to this particular category; is that right?

A. Yes, it was the ones that we used in the screening assays, in the kit evaluation tests.

Q. Okay. And then there's reference to:

"Frozen donations -- many had been stored for years before high risk donors appeared in the population. Could perhaps testing of these people now clear their previous donations?"

Do you recall what that referred to, and what, if anything, was done in relation to that?

A. Yes, some centres, including ours, had frozen red cells in glycerol. They're very special red cells. For example, there's a blood group called Bombay that -- I think we have one or two subjects in this country, in the UK, in the 56 million population, that -- who are Bombay. So we have to freeze the cells from them, because if they need a transfusion they die if they get anybody's blood. So -- and we

had also especially typed cells for people with rare blood groups. Those were frozen and they could be frozen for 10 years.

So the only way to make sure that they were -- that those frozen cells were negative, unless they were going to be for an autologous donation, was to contact the donors of those frozen red cells and test them and, if they were not extremely special, they had to be discarded.

Q. And is that what was done at the North London Centre?

A. Yes.

Q. Do you know the extent to which it was done elsewhere at other centres?

A. No.

Q. Then if we go to the top of the next page, the first paragraph, it says:

"The role of the Department and the Press Releases over the next few weeks was the subject of discussion. Dr Smithies requested the advice of the meeting as obviously there would be much Press interest. Directors were concerned that in spite of publicity high risk persons were still coming to donor sessions in order to find out their HTLV-III antibody status. Many groups have made it clear that they will not attend STD clinics or GPs and most Districts have

not made clear arrangements for persons to have ready access to testing."

Then this:

"Dr Contreras reported her findings that GPs did not have clear instructions."

Can you recall what that refers to?

A. I don't recall clearly, but we had quite a lot of communication with GPs through Dr Hewitt's department, and I think that many of them said: no, we haven't received any instructions about HIV.

Q. And the responsibility to ensure that GPs or other clinicians outside of transfusion centres were fully aware of what was happening and able to offer whatever services were required, that would be the responsibility, would it, of the Regional Transfusion Centres and/or the Department of Health?

A. Yeah.

Q. That's not something over which the Regional Transfusion Directors would have direct control?

A. No, we had no control over GPs, just contact with some of them.

Q. Then if we could please next go to BPLL0010763, this is a letter you wrote in February 1986 to Dr Snape at BPL. You say in the first paragraph:

"We commenced total anti-HTLV-III screening of

our donor panel on the 23rd September 1985. From that date on, all donors L will have been screened for anti-HTLV-III."

So is it correct then that, in fact, you at North London didn't wait for the nationally agreed date; you brought testing forward by, I think, three weeks, that would be?

A. Three weeks, yeah.

Q. Why was that?

A. We were not the only ones. Because we had the facility to do it and because we knew that we had to issue HIV -- anti-HTLV-III negative blood by a certain date. So -- and I think that there were other centres that -- who did the same as us.

Q. So because you were ready you decided to go a little earlier than the national date?

A. Yeah. In order to have everything screened on the date that we were going to tell the public blood is tested. But we were not going to tell them the blood that we're giving today is negative.

Q. Then if we look at NHBT0057018_001, this is on the same topic, this a letter, 29 October 1985, to Dr Smithies at the Department of Health, and if we can just look at the second paragraph, you say:

"... we were able to start anti-HTLV-III

screening unofficially from the 23rd September 1985. Since we rarely have the luxury of too much blood gathering dust in the 'fridge and since our supplies of fresh frozen plasma get snapped up very quickly our only stored material is cryoprecipitate. We have been storing serum samples from donors for several months now and we are going through the records of our cryoprecipitate stocks to check which stored donors samples correspond to the stocked material. In addition we will be test those cryoprecipitate donors who return to give further donations so this problem is in hand."

You are, as I understand it, describing a situation in which, perhaps because of the location of the centre and the number of hospitals you serve, you didn't carry large numbers of stock that would be untested.

A. Yeah, most of our stock was in the hospitals and, as we've seen in other documents, I think, that you've sent to me, we -- although we were collecting a great -- much more per thousand population, we -- than the rest of the country, we still -- the demand was so high that it rotated very quickly. So only had cryo to --

Q. Do you know what the position was in other centres,

whether they had larger stocks of untested material than you did?

A. I do not know but I think I've seen a letter where at least one centre was -- did the same thing that we did.

Q. Then you referred a few moments ago to the fact that a lot of your stock would actually not be being held in the centre; it would have been supplied to the hospital so the hospitals would have stocks of blood/blood products that, as the 14 October 1985, may not have been tested.

A. Yeah, like fresh frozen plasma, for example, and if they had that and we asked them to return it.

Q. Can we just look at a couple of letters, in fact I think we probably any need to look at one letter. DHSC0101818. This is a letter you wrote in October 1985 to all consultant haematologists "Re: Anti-HTLVIII testing of blood donations":

"You will probably have heard that the date for the introduction of routine anti-HTLVIII testing of all blood donations has been announced as October 14th. All blood donations taken on or after that date will undertaken routine anti-HTLVIII testing, and no blood components taken on or after that date will be released in advance of a negative

anti-HTLVIII test, with one exception."

Then you describe the exception, as I understand it, it in the next sentence:

"The logistics of anti-HTLVIII testing combined with rapid release of fresh components (in particular platelets) are such that it will be difficult to continue our present practice of same-day release. We are trying our best to circumvent the problems, but the anti-HTLVIII test is more time consuming than other tests currently performed."

Then you go on to explain that platelets may not effectively be released on the same day for that reason.

Next paragraph:

"We have severely run down stocks of FFP and cryoprecipitate over the last month, in anticipation of the start of testing. It is impossible to retrospectively test all stock currently held at the RTC, but field trials of the anti-HTLVIII tests have been carried out over the few weeks, and a large proportion of the current stock of blood has already been tested."

Then you say this:

"There will be no facility for return of untested blood or components, but it is anticipated

that the overlap period will be short, except in the case of rare blood held as frozen units of red cells."

Which I think is the example you gave us few minutes ago.

So what was the expectation as to what hospitals holding untested stock should do with that, given that you say here there wasn't a facility for returning it?

A. I'm afraid it might have been if they had untested blood. Later on, we accepted fresh frozen plasma, and sent it as time expired plasma for production of PPF or albumin but, you know, I'm afraid that they would have been considered as perhaps suitable for transfusion.

Q. So after 14 October 1985, hospitals may have been using, to treat patients, products that had not been tested?

A. Yeah. Very few, but yeah.

Q. Do you know whether other centres operated any facility for return of untested blood or blood products?

A. I do not know.

Q. I'm going to ask you now to consider -- we can take that down, thank you -- the issue of surrogate testing for non-A, non-B hepatitis, and just so those who are following and, indeed, I am clear about what we mean

by surrogate testing, until the late 1980s, and we'll come on to this later, there was no test which could, as it were, directly test for hepatitis C. So surrogate testing refers to an indirect means of identifying donors who may be infected. Is that a fair summary?

A. Yes.

Q. There were two surrogate markers relevant in relation to non-A, non-B hepatitis: raised ALTs or antibody to hepatitis B core, anti-HBc; is that right?

A. Yes.

Q. You could, in principle, test both for ALT and anti-HBc, or you could test for one or the other?

A. Yes.

Q. Is it also right to understand that, in the 1980s, there wasn't a universal picture across other countries as to what they did but some countries used surrogate testing in the course of the 1980s; indeed, I think Germany had been using ALT testing for a couple of decades?

A. Yes.

Q. We'll see, when we look at some documents, that testing for both of those markers was introduced in the USA in 1986?

A. Yes.

Q. It wasn't introduced in the UK, was it, in the course of the 1980s at all?

A. No, it wasn't.

Q. Now, if we can then look at a handful of documents, again, ones which reflect meetings to which you contributed or letters which you wrote on this issue. I'm not going to go through the entirety of decision making or aspects of it that you weren't involved in. But, again, going back to some of the general questions I asked you earlier, whose decision did you regard it as being, as to whether surrogate testing should be introduced: Department of Health, Regional Transfusion Directors, Regional Health Authorities; who would be taking that decision?

A. Department of Health.

Q. Would that be because you would be looking to the Department of Health for funding or would it be for some other reason?

A. I think for -- especially for funding but also for uniformity across the UK.

Q. Can we look, then, first of all, at an article in 1984. It's at NHBT0000030_008. So we can see the date of publication, I don't think we have the precise date in fact but it's 1984, in any event, and it's entitled "Necessary Tests on Blood Donations to Detect

Infectious Agents".

You explain in the first paragraph that:

"Transmission of infectious agents is a major hazard of blood transfusion."

Then you go on to talk about the approach that could be taken in relation to screening and to identify a number of factors.

If we go on to page 3, we can see the heading, "Non-A, non-B hepatitis". You say there:

"Most cases of [non-A, non-B hepatitis] are mild or asymptomatic and there is no general agreement about the severity of the acute illness or its long-term effects."

We discussed that yesterday, Professor Contreras, so I'm not going to ask you about that again:

"There are no specific serological markers for the agent(s) of [non-A, non-B] hepatitis. There is an epidemiological association between HBV and [non-A, non-B] hepatitis. It has been estimated that up to a 50% reduction in [non-A, non-B] TTH [so transfusion transmitted hepatitis] could be achieved by eliminating units from donors with markers for past HBV infection; this measure could mean a 2-4% rejection of units. In the absence of prospective

randomised trials, no general recommendations can be made regarding routine use of anti-HBc tests."

You're dealing there, as I understand it, simply with anti-HBc and not with ALT testing?

A. Yes, I should have dealt with ALT as well.

Q. The last sentence of that paragraph would appear to suggest that your view was that a recommendation couldn't be made in the absence of further trials, prospective randomised trials.

A. Yes. For -- in each country, for each country, yes.

Q. Why did you think it was important to have prospective randomised trials?

A. To see whether there was, you know -- whether the incidence of non-A, non-B hepatitis was higher in recipients, like the TTV study in the United States, to see whether there was a higher incidence of non-A, non-B in people who retrospectively tested positive for anti-hepatitis B core. Because this was up to 50% but different countries had different estimations.

Q. So the purpose of the trials that you're talking -- or that you were envisaging could be undertaken here would be to establish what the extent of the problem for an individual nation of non-A, non-B hepatitis?

A. Sorry, could you repeat the question?

Q. What was the -- was the purpose of saying there needed to be these trials as at 1984 because you wanted to understand or you thought it was important for a country to understand the extent of non-A, non-B hepatitis in its population?

A. Of post-transfusion non-A, non-B hepatitis in the population. We did not know what the problem was in this country, with an all-volunteer donor. And so we did not know whether we had the same problem as the United States had -- or, I think, Spain, and I think there were some trials done in France as well, in Toulouse. But we did not know whether there was a correlation between anti-core or ALT testing and reduction of transmission in this country.

Q. I'm going to pick up what happened in the second half of the eighties, perhaps after the break, but as at 1984, in the first half of the 1980s, can you recall what, if any, studies were undertaken involving the North London Centre?

A. We did studies of anti-core and ALT, but -- to see what the prevalence was in blood donors, and it was lower than -- much lower than the United States. But we did not do studies of transmissibility, then. And this paper must have been written in 1983, as I said in my statement. I don't think I wrote it in 1984.

MS RICHARDS: I'm going to then pick matters up in 1986, but I note the time, sir, so perhaps we can take the break now and then I can do that after the break?

SIR BRIAN LANGSTAFF: Yes, well, we will take a break now until 11.45. 11.45.

(11.14 am)

(A short break)

(11.46 pm)

MS RICHARDS: Professor, if we can pick matters up in relation to discussion of surrogate testing in 1986 at NHBT0057025_001, please. This a letter dated 23 May 1986 from you to Dr Smithies at the Department of Health. If we pick it up in the third line of the first paragraph:

"Now that we have routine anti-HTLV-III screening of blood donations, which has reduced a very small risk of transfusion-transmitted HTLV-III infection even further, there is pressure to introduce screening to reduce the incidence of post-transfusion non-A, non-B hepatitis."

Just pausing there, from whom was there pressure and on whom was there pressure?

A. I -- if I remember correctly, it was from the liver disease specialists and from the haemophilia directors group.

Q. And then the letter continues:

"We know that there is under-reporting in this country, but it appears that there is a much lower incidence of post-transfusion non-A, non-B hepatitis than in the [US]. On the other hand, the reports of the sometimes severe sequelae of this type of hepatitis particularly in recipients who have received blood products originating from large donor pools, have caused concern."

Then you go on to talk about the position in the states:

"In the [US], the American Association of Blood Banks has announced this month that routine screening of blood donors for anti-HBc and ALT levels (as surrogate markers for donors at high risk of transmitting non-A, non-B hepatitis) has been approved as a requirement, and will be introduced into the Association's 'Standards'. The FDA is also considering this subject. Yet in this country we do not even know the current prevalence of anti-HBc in blood donors and we might predict that the rate has decreased since the introduction of measures to exclude 'high-risk' donors. We need to carry out a study of these surrogate 'high risk' markers in British blood donors -- and anti-HBc is a practical

marker to choose, as it relates not only indirectly to HTLV-III and non-A non-B hepatitis, but also very directly to Hepatitis B. We would also need to follow-up recipients of anti-HBc positive donations and this will entail a great deal of work and medical time. Once we had this information we could then start making informed decisions about the need for this surrogate screening and the implications in terms of cost, donations, lost, etc.

"I know that Dr Fraser of the Bristol RTC shares our concern over this matter, and would be willing to co-operate in a joint study of anti-HBc prevalence in donors. Could you let me know what your feelings are on this subject please? We can hardly start deciding policies on our approach to anti-HBc and ALT screening when we do not know the background data!"

I think it's right to understand from this letter that the approach you were urging on the Department of Health, in this document at least, is to say, before a decision is taken, there must be further studies of the type outlined in the letter; is that fair?

A. Before a decision is taken we need to know whether we have a problem in this country. We need to know what the problem is in this country.

Q. Was it not already the case that you knew there was a problem? You may not have been able to quantify it, but there could have been no doubt, could there, by 1986 that non-A, non-B hepatitis post-transfusion did occur with potentially, as your letter says, severe sequelae?

A. Yes, yes. It did occur, but we didn't know the magnitude of it. As I said yesterday, we had about four cases a year and not all of them were non-A, non-B. Some of them were hepatitis B.

Q. And the kind of study you were describing in this letter is -- it's not a study that could be undertaken quickly, is it? It would be something that would take place over -- if it was ever authorised and funded, would take place over quite a long period of time, would it not?

A. No, the first -- the original study was to know the -- to test donations for anti-core, and to see whether those previous donations had -- because most of our donors were repeat, to see if previous donations had -- go back to the patients and see whether they had transmitted.

Q. If we just look at the previous page, if we look at the last six lines or so. Seven or eight lines, sorry. So you talk there, I think, about two

different pieces of work: a study of the high-risk markers in British blood donors, using anti-HBc as your marker; but then you talk about also needing to follow up.

So let me take this in stages. That was to establish the extent of -- in which anti-HBc would be found in the donor population?

A. Yes.

Q. And then you say:

"We ... also need to follow-up recipients of ... positive donations ... [which] would entail a great deal of work and medical time."

The purpose of that, as I understand your thinking, was to see the extent to which it was being transmitted through donation?

A. Yes.

Q. That would not be a short exercise. You say yourself there it would entail a great deal of work and medical time?

A. Yes, yes.

Q. And what you were saying to the Department of Health -- obviously it was for them to make their own mind up, but you were saying was you needed both those before you could start making informed decisions?

A. I think that's what I meant.

Q. And that's what I'm suggesting would, as at 1986, mean you'd be looking at a decision-making process that would not be a matter of weeks or months; it would be a matter of years, would it not, before what you're describing could enable the Department to start making informed decisions?

A. I think that in a year we would have had -- not years, but in -- I remember discussing this, and -- because our Scottish colleagues had said that it would take many years, and I -- we believed that we could have a reply by -- in a year.

Q. If we go to PRSE0003557, this is a little later in 1986, September 1986. You wrote again to Dr Smithies at the DHSS enclosing a proposed pilot study of post-transfusion non-A, non-B hepatitis. You say:

"I have already had some semi-political questions asked about the lack of screening in the UK when compared with the USA ..."

Do you know what you were referring to when you talked about semi-political questions?

A. I can't remember.

Q. Then you say:

"Furthermore I am optimistic that a well designed trial may show that a surrogate screening for NANB hepatitis carriers in blood donations in this

country is neither indicated nor cost effective."

It might be said that's quite a curious way of putting it, "optimistic" that this wouldn't be required.

Why would that be a cause for optimism?

A. That if we were not transmitting it, that would be wonderful, if we are not transmitting non-A, non-B.

Q. Then you ask:

"If money is forthcoming, I would be grateful for an early reply. I leave any involvement of the Bristol RTC to you. The maximum number of RTCs involved should be two."

I'm not going to go to the details of the proposal but it's over the page. It continues for several pages. But that sets out there the provisional plan.

Perhaps I should just look at the bottom of the page, where item 7 is:

"To follow-up both donors and recipients with any evidence of hepatitis to assess the long term implications."

Now, did you receive funding from the Department of Health for this study?

A. I do not remember if it was this study or there was a three-centre study for -- to test for ALT and

anti-core, but I can't remember whether it was related to this letter or whether it was something different.

Q. And my understanding in terms of timing is that the funding for the study that was undertaken at the three centres was approved in 1988. Does that accord with your recollection? If you can't say, don't worry.

A. I think so.

Q. So it was -- again, it was a -- there's -- on any view, you didn't get a quick response and quick funding for this, for what you were asking for?

A. No, no.

Q. Can we then go, still in '86, to a discussion at an RTD meeting, CBLA0002345, please. This is 8 October 1986. You were in attendance and if we turn to page 7, bottom of the page, we can see the discussion under the heading "Anti-HBc and/or ALT Testing":

"The Chairman reminded Directors that the possibility of screening for anti-HBc had been discussed previously, and that studies of the incidence of anti-HBc in the donor population had been undertaken at Edgware, Bristol and Manchester about three years ago. Developments in America meant that this topic must be considered again as anti-HBc/ALT screening was soon to be essential for the

accreditation of Blood Banks in the USA. The Chairman proposed that the RTDs should approach the DHSS to fund a prospective study of 10,000 donations to see if the incidence of anti-HBc had changed since this was last examined. He added that Haemophilia Directors were pressing for plasma for fractionation to be tested for both anti-HBc and for abnormal ALT levels. It was agreed that a further trial should be taken at Edgware, Bristol and possibly Manchester and that an approach be made to Dr Smithies and Dr Moore for assistance with this. It was recognised however, that even if the incidents had reduced significantly since the last trial, because of self-exclusion or for other reasons, the introduction of anti-HBc/ALT screening seemed very likely."

Did you share the view in the autumn of 1986 expressed here, that whatever the study showed, the introduction of screening was very likely?

A. I cannot remember when my views changed.

Q. Then, if we go to CBLA0002358_0001. This is the next RTD meeting, January 1987, at which you were present. Now, the documents -- this document, the pages are out of order. So if we go first of all to the bottom of the second page, we've got the heading "Anti-HBc and ALT screening":

"Dr Gunson reported that the Working Party on Transfusion Associated Hepatitis was due to meet on the following day to finalise a proposal to the DHSS to fund a limited study of 12,000 donors, looking for anti-HBc and abnormal ALT with follow-up of selected donors and possibly recipients."

Then there's a further discussion in relation to that. Dr Napier raises a question about a study beginning with transfused patients:

"Dr Gunson reported that this had been discussed, but it was felt to be costly, difficult, and not practical. The proposed approach would give information [can we then go to page 4, please, because page 3 is out of order] about the effect of anti-HBc and ALT screening on donor panels and blood collection."

So if we can just go back to the bottom of the second page, if we just look at those last couple of lines, as far as you can recall, had you been party to discussions about -- the discussions that Dr Gunson refers to about it being costly, difficult, and not practical to undertake a study beginning with transfused patients?

A. I don't recall having discussed it with him.

Q. In any event, we're now, it's fair to say, in

January 1987 and what's being talked about is still the making of an approach for funding for a study to be undertaken, the study hasn't yet been funded or begun. Looking at it now, do you think this was being considered quickly enough or was it all taking far too long?

A. The latter. It was taking far too long.

Q. Can we then, please, go to PRSE0001444. If you look at the bottom half of the page, right-hand side, you'll see, Professor Contreras, there's an article by Professor Cash and his colleagues, or a letter, about non-A, non-B surrogate testing, with the "irrational, perhaps, but inescapable" heading. I'm not going to go through it because we've looked at it already in the Inquiry and you've seen it in advance of your evidence, but the purpose of putting it on screen is I think you and Dr Barbara wrote a response to this and that's what I want to ask you about?

So if we have PRSE0003767, 1 August 1987, right-hand column. "Testing of blood donations for non-A, non-B hepatitis". We'll see when we go over the page that it's authored by you and Dr Barbara. You say:

"In their contribution to the current debate in *The Lancet* our Scottish colleagues ... argue the case

for surrogate testing of blood donations for non-A, non-B hepatitis ... We take issue with several points."

Then this is your first point:

"Has the time for a prospective study already passed? This seems to imply that the longer an unproven test is used, the greater becomes the pressure to use it. This is not an argument that should commend itself to those practising transfusion medicine. Why should we have to wait 3-4 years for an answer? If the problem is serious this will be revealed, in *acute* [non-A, non-B hepatitis], within a year of initiating the study. The need for controlled studies of the incidence of [non-A, non-B] post-transfusion hepatitis will not disappear with the introduction of routine screening of blood donations with tests of unproven value. Indeed, trials are necessary in different countries where the incidence of [non-A, non-B] post-transfusion hepatitis is likely to vary as widely as does the incidence of positivity for putative markers such as anti-HBc."

In fact, I'll read the whole letter, Professor Contreras, and then ask you about it. So that's your -- the first question that you pose. Next paragraph:

"How far can the arguments stretch that 'all known methods' should be used to avoid the risk of [non-A, non-B hepatitis] after transfusion? The bulk of [non-A, non-B hepatitis] may still be transmitted even after surrogate screening. Are we certain that patients would succeed in a legal action if they contract [non-A, non-B] hepatitis after the transfusion of blood untested for anti-HBc? Why should [non-A, non-B] post-transfusion hepatitis be such a special case that we have to make tremendous efforts to prevent occasional infections? What about the transmission by transfusion of agents such as cytomegalovirus or HTLV-I for which they are *specific* tests but which are not screened for routinely?

"With regard to pooled plasma products, can anyone really feel confident that the 30% decrease in virus load predicted from US studies as a result of surrogate testing would have any obvious impact on transmission of [non-A, non-B hepatitis] when 70% of virus remains in the plasma pool?

"How can the impact of transfusion-transmitted AIDS be compared with that of transfusion-transmitted [non-A, non-B hepatitis], whose consequences seem minor? We doubt if the public (since consumer reassurance is being invoked) sees [non-A, non-B

hepatitis] in the same light as AIDS. The significance of HBV and HIV infection are well known; the clinical importance of [non-A, non-B hepatitis] has to be sought.

"Transfusion services must not bow to irrational pressure for measures whose efficacy is unproven. In the UK, transfusion centre directors resisted commercial pressure for premature introduction of unsatisfactory screening tests for anti-HIV; they show the same resolution with [non-A, non-B hepatitis].

"At our transfusion centre 400,000 blood components are available for transfusion per annum. We have received an average of only 4 reports of [non-A, non-B] post-transfusion hepatitis annually for the past 10 years, and we repeatedly remind clinicians of the need to report infective complications of blood transfusion. A realistic estimate of the annual cost of surrogate screening for [non-A, non-B hepatitis] in the UK would be £9 million. Our colleagues' estimate of £2 per test (which test?) seems too low, and to it must be added the cost of counselling 3-4% of blood donors.

"It is vital to extend the few available studies of transfusion recipients with more complete follow-up of untransfused patients to find out what role

sporadic [non-A, non-B hepatitis] has in the hepatitis attributed to transfusion. And before we accept that 50% of cases of [non-A, non-B] post-transfusion hepatitis progress to chronicity and that 10% of chronic cases progress to liver cirrhosis, larger studies must be done. New studies are also essential because the published data on [non-A, non-B hepatitis] transmission by transfusion relate to transfusions given before the 'clean-up' of donor panels in the wake of the AIDS epidemic."

Over the page, last paragraph, top of the page:

"Even those arguing most forcefully for the significance of [non-A, non-B] post-transfusion hepatitis, recognise that studies on the natural history of chronic [non-A, non-B hepatitis] have been limited both in size and duration of follow-up and that the ultimate prognosis of this disease has not been established."

So if we just go back to the previous page, you appear to be -- you and Dr Barbara -- very clearly advocating here that surrogate testing should not be introduced until such time as further studies had been undertaken; is that fair?

A. Yes.

Q. One of the reasons you articulate for that is one of

the issues to which you've already referred, that there was more that -- there was a lot that was unknown, if I can put it that way.

A. **(Witness nodded)**

Q. You were also concerned about costs and about the potential to lose donors, and the need to make arrangements for counselling donors found to be showing one or other of the surrogate markers; is that right?

A. Yes.

Q. Was it right to say, even in -- given everything you told us yesterday about your evolving understanding in relation to non-A, non-B hepatitis, that, in relation to non-A, non-B hepatitis as at 1987, the consequences seemed minor. Was that not underplaying, on any view, the risks in relation to non-A, non-B hepatitis?

A. Yes, I admit -- yeah.

Q. Can I suggest, Professor Contreras, that a problem with the approach described in this letter, of undertaking more studies and only then deciding whether or not to introduce the screening, would be that you would be perpetuating a state of affairs in which there was no screening or testing whatsoever in relation to non-A, non-B hepatitis. You're running the risk of people continuing to be infected, while

you wait for a more complete understanding of the problem.

A. Yes. I have to admit that.

Q. Can I then just ask you to look next at a comment in a Regional Transfusion Directors meeting, July 1987. CBLA00028 -- CBLA0002383.

A. Can I just say that, unfortunately, perhaps, we did not see the problem, and you know -- and also I don't know when the study by Seeff and by Harris, those studies of the long-term effects and survival, were done. But that confirmed what we were thinking at the time, that apparently it wasn't causing more problems in the general -- from the point of view of mortality, more problems in the general population.

I admit that I was wrong in not having introduced screening before but, unfortunately, we were not seeing the problem.

Q. This is the minutes of a meeting, July 1987, of the Regional Transfusion Directors. So it's after Professor Cash's and his colleagues' letter has been published in The Lancet but before the response that we were just looking at from you. If we go, please, to page 8, bottom half of the page, there's a heading "Letter to Lancet from SNBTS":

"The Chairman referred to both his own

reservations and those of other Directors about the letter recently published in The Lancet to which all the Scottish Directors were signatories on the subject of anti-HBc and ALT screening of all donations. There was disappointment that unilateral action had been taken and it was this, rather than the contents of the letter, to which exception was taken, though it was pointed out that the costings quoted in the letter could be challenged. Professor Cash indicated that although he was concerned about the views being expressed that he had had no alternative. Dr Whitrow indicated that he perceived a different attitude to product liability by SHHD north of the border which was one of the factors which had prompted the letter."

Now, I don't know whether you've got any independent recollection of this meeting at which you were present, Professor Contreras, but the way in which the first half of that paragraph is expressed tends to suggest that the mood of the RTDs was not profound disagreement with what the Scottish -- their Scottish colleagues were saying but just disappointment that there had been, as it were, a breaking of ranks by the letter being sent.

Do you have any recollection of whether that is an accurate reflection of the mood of the meeting?

A. I might -- it might have been the mood of the meeting but I cannot remember.
Q. We've got a couple of letters that you wrote to Dr Rotblat at the Department of Health in late 1987. I'm not going to go to them because they're on a similar theme to the materials we've already looked at, I'll just give the reference for those who might wish to look at them. They're NHBT0000187_008 and NHBT0000187_010 and they're letters from you to Dr Rotblat 14 and 22 November 1987.

I want to then pick matters up in 1988, if we go to NHBT0000187_024. Again, I'm not going to go through the detail of this but we can see it's headed "Multi-Centre Study of ALT and anti-HBc Screening of Blood Donations, Minutes of meeting of steering committee, Manchester, 8th June 1988". We can see a number of people in attendance, including from North London yourself and Dr Barbara, and then there's an invitation just below the list of attendees for you to chair the steering committee. Then we can see at paragraph 3:

"Centres participating in the study:

"Manchester ...

"Bristol

"Edgware

"(Edinburgh has withdrawn ...)"

Then there's a discussion about how the study is going to be undertaken. I'm not going to go through the detail of it but is it right to understand that, essentially, it's taken until the middle of 1988 for the funding to be made available to enable the study to even commence?
A. Yes.
Q. Can you recall what the scope of the study was? We can look at the documents if we need to but do you have any broad recollection?
A. It was that three centres would test donations from males and females for the prevalence of anti-core and ALT raised above a certain level. I think it was 45 international units per litre but, yeah.
Q. Is it right to understand that it was a more limited study than the bigger two-stage prospective study --
A. Yes.
Q. -- that you'd been discussing earlier?
A. Yes, it was just the prevalence in donations.
Q. Then if we move on to 1989, NHBT00000 -- sorry, I should just say I'm going to give a reference and not go to it. There's an RTD meeting in October 1988 at NHBT0018189, which says that the results of the trial won't be available until the late spring of

1989. I'm not going to go to it but just so we can get the chronology right.

Then if we go to NHBT0000043_002. This is the first meeting of something called the UK Advisory Committee on Transfusion Transmitted Diseases. If we go over the page, we've got the date of the meeting, 24 February 1989, and those present: it's Professor Cash, you, Dr Follett, Dr Gunson, Dr Mitchell and Dr Mortimer, and Dr Wagstaff giving an apology for absence.

Then if we can look at paragraph 2:

"Dr Gunson introduced the meeting by saying that he had, about a year ago, discussed the forming of a UK Group to determine policy with respect to transfusion transmitted diseases with Drs McClelland and Pickles. The Department of Health were in the process of forming such a group but its brief would be wider than blood transfusion medicine, embracing transplantation and other aspects of disease transmission.

"This present Committee had been formed to discuss transfusion transmitted diseases and to provide advice to the Departments of Health."

So this committee, the Advisory Committee on Transfusion Transmitted Diseases, was a new committee,

set up, as described by Dr Gunson there, to provide advice to the Department of Health.

What was, as far as you understand the interrelationship between this committee and its work, and the work of the Advisory Committee on the Virological Safety of Blood, which you didn't sit on?
A. Yeah.
Q. Did you have a clear understanding of their relative roles?
A. As far as I can remember, the Advisory Committee had more power, more teeth, and this was just an advisory committee to the ... to the main Department of Health committee.
Q. So this committee that we're looking at, the ACTTD, would have discussions, but its thinking might then be communicated to the Advisory Committee on the Virological Safety of Blood?
A. Yes.
Q. And then the latter's recommendations might then go to the Department of Health?
A. Yeah. Well, that was chaired, the advisory committee, I learnt later, because the information from the ACV --
Q. ACVSB.
A. -- was never shared with us as transfusion directors,

but I learnt that the Department was -- it was the Deputy Chief Medical Officer who chaired those meetings. I learned from my reading.

Q. Was that Dr Metters?

A. Dr -- first it was Dr Harris and then Dr Metters.

Q. And so is it right to understand that what was happening in the Advisory Committee on the Virological Safety of Blood might get reported back to you by some extent by Dr Gunson?

A. Yes.

Q. But there was no -- its minutes, its recommendations, its thinking, wasn't formally shared with you?

A. No, they were secret minutes.

Q. And do you know why that was? It doesn't seem necessarily conducive to the most joined-up decision-making?

A. I wish knew, but there's so many things on the Department of Health I never was able to understand.

Q. Then if we go in this meeting to page 5 and we can look at the discussion about surrogate testing. So we've got the heading "Non-A, non-B hepatitis":

"Dr Contreras outlined the results of the study in England and Wales ..."

So that's the three-centre study in which North London had been one of the participants.

At 7.2:

"Dr Mitchell reported that in a Glasgow study of 5,000 donations the ALT exceeded 50 iu in 2.8%. With respect to anti-HBc tests in a separate study, 17 out of 2,000 donations were found positive, of which 15 were reproducible."

So there was a study being undertaken in Scotland which was largely in parallel with the study that you were taking in England and Wales?

A. Yes.

Q. Then there's a report from Dr Cash about the methodology for ALT testing, and then 7.4:

"It was agreed that there would be no recommendation to institute ALT testing until the current study was completed in England. However, there was a degree of inevitability about the introduction of the test which was required by regulatory authorities in other countries to determine the acceptability of fractionated plasma products. This would be discussed with BPL in the near future."

So at this stage, in February 1989, it's right to understand from this, I think, that this committee is not making any recommendation that a decision be made to introduce ALT testing. The plan was: complete the study. But there seems to be a recognition that

this was something that would inevitably have to come.

A. Yeah.

Q. And then we see paragraph 7.5:

"Dr Gunson reported that Ortho Pharmaceutical Company had approached him with respect to trials with the Chiron Test in the UK."

Now that's not talking about surrogate testing but about the newly developed test for hepatitis C.

A. Yes, anti-HCV.

Q. Anti-HCV.

Although paragraph 7.4 refers to the inevitability about the introduction of -- at least for ALT testing, that didn't happen, did it?

A. No.

Q. The -- is it right to understand that active consideration in relation to surrogate testing essentially fell into the background because the focus then shifted to anti-HCV testing?

A. Yes, that's correct.

Q. Can I then just ask you, just a little, in terms of reflections, about surrogate testing more generally in relation to non-A, non-B hepatitis.

It's right, I think, to understand that in relation to both ALT testing and anti-HBc testing, those were tests which were relatively well known and

understood?

So you weren't -- when I say "you", the Blood Transfusion Service, the Department of Health, wasn't in the position that it had been with HTLV-III testing and that it might be with anti-HCV testing, where there had to be an evaluation of how well tests worked. It was known that ALT testing and anti-HBc testing could be undertaken relatively simply and straightforwardly.

A. Yes.

Q. And other than through donor screening, which we've already discussed in some detail, it would be right to understand that there was no other way, was there, of reducing the possibility of transmission of non-A, non-B hepatitis at this point in time, other than using either ALT or anti-HBc or both?

A. Well, as we showed later on with John Barbara and my team, the introduction of self -- of exclusion of donors -- prospective donors in high-risk groups, that decreased the prevalence of anti-core -- anti-HBc in blood donations. But that was like a benefit that we didn't expect, or -- yeah, but --

Q. As an incidental benefit of what was already being done?

A. Incidental, yes.

Q. I absolutely understand, Professor Contreras, that donor selection, donor screening measures, in relation to high-risk groups, introduced for other reasons, might then have incidental benefits in terms of non-A, non-B hepatitis. But if one leaves aside those measures in relation to selection and screening of donors, there was nothing else available in the 1980s, until we get to the anti-HCV test, other than surrogate markers. So if anything was going to be done, it would have to have been one or other or both of those?

A. Yes. And I -- with hindsight, I would have chosen anti-core, because it was more specific, and because we later showed with -- well, the virologist, the microbiologist showed that anti-core was also beneficial to exclude the transmission of hepatitis B that was still occurring.

Q. Yes. And if time permits, we might come on to anti-HBc as -- in relation specifically to hepatitis B this afternoon.

But before I turn to ask you about, then, the decision-making in relation to anti-HCV screening, can I just ask you about two matters relating to registers? So there came a point -- let's -- if we look at the letter it will give us the date.

BPLL007760_001.

This is September 1987. You were writing to Dr Fraser, who was the Regional Transfusion Director in Bristol but also chair of the Regional Transfusion Directors, I think, at this point in time.

You were writing suggesting the formation of a national register for hepatitis B, and Dr Barbara had volunteered to be the central coordinator of that.

Now I'm not proposing to go through the detail of what you set out here and how it could work, but could you just set out for us your recollection of why you thought that this would be a useful idea, and whether it was established in due course?

A. Yes. I supported firmly the idea of a national register, because we should have national registers for all transfusion-transmitted diseases, infections, particularly transmission by labile blood components. So -- and we did not know what the extent of -- we knew in our centre, but what the extent nationally of hepatitis B transmission was. And this register did take effect, although not all centres contributed in the same way, but it had -- I thought it was a very, very good proposal, and it would have taught the country a great deal.

Q. And then in relation to hepatitis C there was --

obviously at a later stage, because as at 1987 the anti-HCV test hadn't yet been identified -- there was a hepatitis C register.

If we just look at your statement, at WITN5711001, page 83. It's paragraph 328, bottom half of the page. You refer there to the HCV National Register collecting data from transfusion recipients traced during the HCV look-back exercise.

Did you have any direct involvement with the establishment or operation of the HCV register?

A. I believe we had, because we had meetings with the CDSC and the PHLS. So Dr Barbara and Dr Hewitt and myself were always in conversation with the CDSC and the PHLS.

Q. And the question I've been asked to ask you about the HCV register, I don't know if you'll know the answer to this or not, was about patient consent, whether patients were told that their details were being entered on the register or whether it was done without patient knowledge?

A. I cannot remember, but -- I do not know whether they were, no.

Q. If we then come to the question of hepatitis C screening, and I think if we pick matters up with a letter that you wrote to Dr Gunson in January 1989,

it's at NHBT0000187_042, please. So 15 January, you to Dr Gunson, and you say:

"On Thursday I had a meeting with my Treasurer who said that it would be very difficult to find the monies for the introduction of anti-HCV screening of blood donations in 1990. He asked whether the provision of central funding would be considered by the Department of Health. Most districts in the North-West Thames region are overspent and he is doubtful whether the 2% growth given to all Regions for 1990/91 will cover most of the immediate programmes in the North-West Thames Region. He asked whether I would consider anti-HCV testing as top priority (ie more important than shortening of the waiting lists) and I had to admit that I do not.

"As you well know the sums of money involved for anti-HCV screening are considerable and it would be very difficult, if not impossible, to find the funding within existing resources."

Now that's one of a number of letters that -- or occasions over the course of the next three years in which you raised the concern about the cost of anti-HCV screening and your view that it should be funded by the Department of Health. We know it never was. It wasn't funded by the Department of Health.

Why was it that you thought this should be a Department of Health centrally funded initiative?
A. Because it was a central decision, and because that had happened with previous screenings. For anti-HIV there was money for everything, and for anti-HCV there was no money.
Q. And did you ever learn why it was that the Department decided that funding for this testing programme was to be met regionally rather than centrally?
A. I don't know what -- how the Department saw it, but I -- you know, I would be speculating that ...
Perhaps they didn't see it as they saw HIV, and as they later saw variant CJD.
Q. Now, in the course of 1989 there were a number of things that happened in relation to consideration of anti-HCV screening. There was, I think, some participation by the North London Centre in the course of 1989 in evaluation of the Ortho assay, is that right?
A. Yes.
Q. And then --
SIR BRIAN LANGSTAFF: Can I just for a moment understand the dates here. My understanding is that it wasn't until May 1988 that the Chiron Corporation announced that it had cloned the -- a virus which was -- became

known as hepatitis C, it was the cause of non-A, non-B hepatitis. And it wasn't then reported quite what the details were until the following year, and it wasn't until, I think, April of 1989, my earliest note is, of any report to there being an assay, a test which could be used to screen.
But the letter we've just been looking at NHBT0000187_042 comes from January 1989 and is talking about the costs of screening, without an actual test being marketed at that stage. When was the test marketed, as far as you can recall? Was it before the details of the cloning were ever published or not?
A. No, no.
SIR BRIAN LANGSTAFF: And plainly it would seem Ortho had been working on what an assay would look like without the details having been published, except to them, by the Chiron Corporation. Is that probably right?
A. I think perhaps yes, sir, I ...
SIR BRIAN LANGSTAFF: So they would, as it were, corner the market?
A. Yes, sir.
SIR BRIAN LANGSTAFF: Yes. But the question then is what happened in -- when, in 1989, after April, when the first -- or the assay was announced or announced available for sale or whatever it actually was at that

stage.
MS RICHARDS: Yes. We don't, unfortunately, have a single witness with whom -- who was involved in every aspect of it with whom we can go through a comprehensive chronological account. There will be some gaps that Dr Barbara may be able to fill in and there will be, no doubt, I think, Department of Health witnesses next year who we'll be able to, again, fill in a lot of the gaps with.
Perhaps the figure most centrally involved in terms of attendance at committees and involvement in discussions and so on was Dr Gunson.
SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: And we have, of course, his written and oral testimony to Mr Justice Burton in *A v National Blood Authority*, but there isn't a single witness with whom we can, I'm afraid, give the overall chronology. But there are meetings in which I know Dr Barbara was involved in the course of 1988 in which the Chiron discovery was being considered and discussed, and he may be able to assist us with how his knowledge of it developed over the second half of 1988 and the course of 1989.
SIR BRIAN LANGSTAFF: Well, it would certainly seem that without there being the test actually physically

there, everyone was anticipating there would be one.
THE WITNESS: No, I don't think that was the case, sir.
SIR BRIAN LANGSTAFF: Right.
A. I think that they had a test, but it hadn't been approved in the USA --
SIR BRIAN LANGSTAFF: I see.
A. -- by the FDA. And so they more or less secretly had a test, you know? But I think that was the case.
SIR BRIAN LANGSTAFF: Right. I understand.
MS RICHARDS: Yes. And at the meeting that we looked at a few minutes ago, the first meeting of the advisory committee in relation to transfusion-transmitted diseases in February 1989, Dr Gunson described there an approach he'd received from Ortho with respect to conducting trials of the test in the UK.
SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: I only looked at the surrogate testing when we looked at it earlier but there is a passage in those minutes which record Dr Gunson's conversations.
SIR BRIAN LANGSTAFF: It was -- this is a comment, really, but it was curious that that should come immediately after a discussion of whether there should be a surrogate test -- or a study to see if there should be a surrogate test, rather.
A. Yes.

SIR BRIAN LANGSTAFF: Because you might have thought the purpose of the surrogate test is to identify something which you're now going to trial direct test for.
A. Yeah.
MS RICHARDS: And, sir, you're right to think in relation to -- April 1989 was the publication in Science.
SIR BRIAN LANGSTAFF: Yes, 21st April, was it?
MS RICHARDS: I've only got April, I'm afraid, written down in my notes, sir, but the publication in the articles in Science about the -- the details of the specific screening test.
Dr Gunson had, in advance of that, drawn up protocols for a proposed trial of the Ortho test.
SIR BRIAN LANGSTAFF: Yes. So there was, if I can summarise it this way: is it a fair summary to say there was developing appreciation that a test was likely and there were candidates or a candidate under consideration in early -- from the beginning of 1989 onwards? Would that be fair?
A. Yes.
SIR BRIAN LANGSTAFF: Thank you.
A. Yes, sir.
MS RICHARDS: And, sir, my notes again record, April 1989, Dr Gunson meeting with Chiron, at which it was agreeing that Ortho test kits would be supplied to the

North London Regional Test Centre to enable the trial and evaluation to be undertaken.
Perhaps -- well, again, I think we can probably pick this up with other witnesses but we know one of the things that happens later in 1989, Professor Contreras, was a symposium in Rome in September 1989, which I think Dr Barbara attended. Do you recall whether you attended that or not?
A. No, I did not.
Q. Okay, well, then we can pick that up hopefully with him.
And then if we get to October 1989, NHBT0000043_034, this is the Advisory Committee on Transfusion Transmitted Diseases, 9 October 1989. If we go to the bottom of page 2, we can see the heading "Anti-HCV testing of blood donors". So this gives us a sense of the way in which the decision-making process was being undertaken.
"The Committee were informed that the Department of Health's Advisory Committee on the Virological Safety of Blood had requested a briefing paper on policy regarding Anti-HCV testing of blood donors.
"The Committee considered two papers summarising the first international meeting on the Hepatitis C virus prepared by Drs Gunson and Mitchell, and a paper

on the results of an anti-HCV UK study on surrogate markers for NANB post-transfusion hepatitis in blood donors ..."
If we go to the top of the next page:
"After a wide ranging and careful consideration of the many problems regarding the test and its introduction for routine screening of donations, it was agreed that Dr Gunson's paper should be used as the basis of the paper to be submitted to the Department's Committee.
"It was also agreed that Dr Gunson's paper should incorporate information from the papers prepared by Drs Mitchell and Raafat as well as a number of textual amendments proposed by the Committee."
It might be said to be a somewhat laborious decision-making process but what we appear to have here is Dr Gunson putting together a paper with -- I'm not going to take you to the details of his paper, but putting together a paper with his views, recommendations, in relation to testing.
That's, as it were, considered by this committee upon which you sit, the ACTTD, but then it's going to go then to the ACVSB, because, is this right, it's the ACVSB which is charged with -- not making the decision

but making with formal recommendations to the Department of Health?
A. Yes.
Q. And then it's the Department of Health that makes the decision. Is that your understanding of it?
A. Yes.
Q. Whether at the time or having looked back at the material now, do you have any thoughts or observations upon the speed or lack of speed with which the decisions were taken over this period from 1989 through to 1991?
A. Yes, the lack of speed.
Q. We can then, I think, see you reporting back to a divisional meeting in October '89 at NHBT0017553_001. So this is a meeting of the Eastern Division of Consultants, chaired by you.
And if we turn to page 6, at the bottom of the page:
"Anti-HCV testing
"Not yet licensed by FDA, but the UK is likely to commence testing around June/July 1990. Concern was expressed that there is no confirmatory test. Dr Contreras informed the meeting that Dr Gunson's recommendation to the DHSS were that the UK should start testing (i) only after FDA licensing, (ii) when

confirmatory testing is available and (3) there is provision for counselling. The financial implication for the UK is likely to be over 5 1/2 million pounds. It's been estimated that it would cost the [North London Blood Transfusion Service] over £600,000 per year at the rate of £1.70 [plus] VAT per test. This cost excludes the replacement of the 1% or so donors who would be lost."

If we leave aside the financial issue, Professor Contreras, there are three pre-conditions here identified in terms of what's going to be, it's said, recommended through Dr Gunson to the Department of Health. The first relates to FDA licensing. Why was the UK's commencement of testing to be dependent upon the grant of a licence from the FDA?

A. Because they, like the MCA, can -- they're very strict in the approval of a test. So they would have, very sensibly, looked at all the aspects of the testing before approving it for use in the United States, and we didn't have that mechanism here.

Q. The second pre-condition is when confirmatory testing is available. Is this because of the concern about false positives?

A. Yes.

Q. Then (3), "provision for counselling". Counselling

would take what form in relation to an anti-HCV positive test?

A. It would -- we would have to contact the donor, ask him to come to the blood centre or to go to somewhere where he could be counselled. We would have to test him -- tell him that he or she was anti-HCV positive, that he might be carrying an infection, that he would not be able to donate again, and we would refer that patient -- we would advise that patient to go to hepatologist that we would have contacted.

Q. Now, I can see that there are obviously resource implications in relation to that. But it's not a particularly complex system, is it, to set up? Leaving aside the question of obviously funding and it'll take a certain amount of time, and you need to have the doctors who have the capacity to do that, but it's not a difficult system. Indeed, it's a system you'd have been familiar with --

A. -- (overspeaking) --

Q. -- at other centres because of other testing?

A. Yes.

Q. So is there any particular reason why the need to make provision for counselling should have held things up?

A. The cost, again. It's always cost. Because we would have needed a great deal of manpower to -- and it's

doctors.

Q. Can you recall -- bearing in mind this is a meeting as at October 1989 and the expectation at this point is the UK is likely to commence testing in mid-1990. Can you recall when at the North London Centre you started making the arrangements or putting in place the arrangements for counselling?

A. As -- I think it must have been as soon as we knew that we were going to start testing.

Q. Because is it right to understand that, perhaps in contrast with the position relating to surrogate testing, there was never any doubt, was there, that testing for HCV would be introduced, really? The question was always going to be --

A. When.

Q. -- when. So centres would know, on any view, that this was coming?

A. Yes.

Q. Then if we look at -- again, there are various publications, some of which you contribute to over the following months but I don't think we need to go through the details of them all, and we've got them in the papers that the Inquiry has.

Perhaps we could pick it up at NHBT0071870_002, which is January 1990. So we've now got the National

Directorate established for the National Blood Transfusion Service and this is its National Management Committee of which you were a member, and the meeting is 4 January 1990, and you were present at the meeting.

We can see what's happened in relation to anti-HCV at page 4 under the heading "Pilot trial on anti-HCV testing", bottom half of the page:

"Dr Gunson tabled a report which summarised the findings of the pilot studies on anti-HCV tests in the [North East] Thames, Trent and [West] Midlands Regions and which included comments on the test from [North East] Thames and Trent."

So some pilot studies, obviously, by this point in time have been completed. I'm not going to go through the detail of the discussion then.

If we go to the top of the next page, the first paragraph tells us Dr Gunson was going to:

"... prepare a more comprehensive report for distribution to all RTCs and to the [Advisory Committee on the Virological Safety of Blood]."

He then advises that:

"... the [Advisory Committee on the Virological Safety of Blood] was to complete a cost benefit exercise on the introduction of anti-HCV testing."

There's then reference to the Abbott test, so there's a second test now available for evaluation, is that right?
A. Yes.
Q. Then, if we go just to the next paragraph further down, it says:
"With regard to the absence of a confirmatory test, Dr Gunson advised the Committee that the ACVSB did not see this necessarily as a barrier to the introduction of routine screening, but the ACVSB would insist that any test for routine use must have been licensed by the FDA."
. You have told us already, I think, that you didn't see the minutes of the ACVSB meeting, those were regarded as secret or confidential.
Did you have any particular understanding, through Dr Gunson or through any other means, of the ACVSB's approach to the question of confirmatory testing?
A. No.
Q. So you don't know whether their thinking was: well, we can start screening and perhaps deal with the availability of confirmatory testing as and when it becomes available, but it shouldn't hold up the introduction ofscreening? You don't know if that's

what they were thinking?
A. I think that's what I read.
Q. Then if we go further down the page there's a reference to you:
"Dr Contreras said that about 1% of those tested in the [North West] Thames region had found to be repeatedly positive, but that not all of these were found to be infectious and it appeared to be that not all of those who had received blood donated by such people had developed HCV."
So is it right to understand that's a finding it from the pilot study that was undertaken in your region?
A. It must have been, yes.
Q. Then it's described:
"The prevalence of HCV in England and Wales appeared to be similar to that experienced in some states in the USA, but lower than the estimated prevalence in Denmark, Italy, Spain and about the same as in Finland."
Now, I'm not going to go through the details of all the countries which introduced hepatitis C screening before the UK did, but you would have presumably have become aware, particularly in the course of 1990, that a number of other countries had

introduced or were about to introduce anti-HCV screening into their nations?
A. Yes.
Q. Do you recall being concerned or your fellow Regional Transfusion Directors being concerned that the UK was taking longer, was lagging behind what was happening in other developed nations?
A. Unfortunately, I wasn't concerned at the time, if I remember correctly, unfortunately. Because of the nature of the beast, because the test was -- had no confirmatory assay, and because it had so many false positives. I should have been concerned, but I wasn't.
Q. Then -- again, without taking you, I think, unnecessarily to meetings, if I just give a couple of -- or a reference for the transcript -- NHBT0000043_047 is the March 1990 meeting of the Advisory Committee on Transfusion-Transmitted Diseases, which reports that the ACVSB had deferred making a decision until its next meeting at the end of April.
Then the next, I think, date of significance, again, I'm not going to take you to the underlying documents because it relates to a meeting you didn't attend, but the ACVSB, I think, in July 1990 decided

that there needed to be a pilot study of both the Ortho and the Abbott tests.
So what I want to do, then, is just pick matters up with a document or authored by you at the end of 1990, Professor Contreras. It's NHBT0000190_067, so it's 17 December 1990 from you to Dr Barbara and Dr Brennan.
"I have read the FDA regulations for anti-HCV and the revised recommendations for the prevention of HIV transmission.
"I must admit that the Americans have put themselves in a very awkward position regarding anti-HCV testing with no recommendations for supplementary tests."
Is "supplementary" there a synonym for confirmatory tests?
A. Yes, yes.
Q. "When will they learn? I pity those physicians who will have to explain the 'possible significance of positive test results' to repeatably reactive donors."
Then the next paragraph deals with an issue relating to HIV. Then in the last paragraph you say:
"I am bemused after reading these two documents. I just cannot understand the FDA thinking."
Looking at that now, Professor Contreras, why

were you so bemused or perplexed at what was being done in the USA?

A. If I remember correctly, at that time, I said this -- we knew that the test had a lot of false positives or that there were too many positives to the number of real positives, and that there was no way of knowing which one -- which of those units/donations was the one that was transmitting HCV. So I was bemused that the FDA was not insisting on a confirmatory test or not mentioning it.

Q. I'm going to then pick the chronology up in 1991 with a series of letters.

Sir, rather than do one of them now and then come back to the rest of them after lunch, perhaps we can take lunch now, a couple of minutes early and then do them as a coherent sequence.

SIR BRIAN LANGSTAFF: Well, we'll do that and come back at two o'clock. So two o'clock, please, for lunch. After lunch.

(12.56 pm)

(The Luncheon Adjournment)

(2.00 pm)

MS RICHARDS: Professor Contreras, we'll pick up the chronology of decision-making in relation to the introduction of hepatitis C screening, in 1991, with

You replied the same day to Dr Gunson saying:

"I am unable to give you a date in which we could commence testing for anti-HCV, until we have definitive information on financial arrangements to cover screening, supplementary tests, counselling, follow up, etc. We are extremely busy with our Business Plans and contracts as well as dealing with the extra workload incurred as a result of the Gulf War and we cannot give anti-HCV screening the priority required by the Department of Health."

That wasn't, I think, probably what Dr Gunson was hoping for by way of response. He did write to you later saying -- later in 1991, saying, "We can't really start without you", because the North London Centre was a big and important centre.

Why did you feel unable to give Dr Gunson a date by which you could start?

A. Because in fact we were really, really busy with our business plans. I don't know whether it was true, cross-charging the internal market that had been introduced, or that we were introducing notional charging to hospitals. So everybody was working, and then the Gulf War on top of that.

So, you know, we were coming to work at 8.00 in the morning and leaving after 10.00 in the evening.

NHBT0000076_006.

This is a memo from Dr Gunson to all Regional Transfusion Directors, 22 January 1991, and in paragraph 1, he says:

"The Department of Health have agreed that routine testing of all blood donations for anti-HCV can be put into operation."

Looking at it now, and bearing in mind this is now January 1991, had it taken too long to get to that stage?

A. Yes.

Q. Then we can see, paragraph 2, Dr Gunson says:

"I have been asked to try and ensure that testing starts simultaneously in England and Wales ... coordinated with ... Scotland."

Then he asks, in paragraph 3, directors to advise "what you consider to be the earliest date that you could commence testing".

Then he explains in 4 that:

"Financial arrangements to cover routine screening and supplementary tests have still to be concluded ..."

If we then look at your response, Professor Contreras.

NHBT0000073_030.

We were really -- we were not coping with the work we had and I think I must have shot from the hip.

Q. And it would appear -- no, let me put it a different way.

When you said, "until we have definitive information on financial arrangements", did you mean by that "until we know if the Department of Health will pay"?

A. Yes.

Q. In relation to the comments in the last sentence, "we cannot give anti-HCV screening the priority required by the Department of Health", it's right to note -- I don't think we need to put it up on the screen -- that Dr Gunson wrote back to you and said, "The Department of Health has not asked for any priority to be given to anti-HCV screening."

The reference for that, just for the transcript, is NHBT0000073_039.

Now if we look at NHBT0000073_047 -- oh, we've got it. Thank you.

So this is a letter from you, 12 February 1991, to Dr Sheila Adam, the public health director at the Regional Health Authority, and the second paragraph says:

"As you can see from the attached copy of

Harold Gunson's letter of 5 February, the Department of Health proposes that the costs for anti-HCV screening should be charged onto products issued from RTCs and be borne by users. At NLBTC, we think that this is simply appalling."

Then if we skip down a few lines, you say:

"The additional £600,000 or more needed for anti-HCV screening are just not there."

Bottom of the page, last two lines you say:

"We feel that the Department does not understand the full implications of screening for anti-HCV."

Then, over the page -- sorry, in fact, can we go back to the bottom of the previous page. I should have read the whole of the last two lines.

You say:

"It is not only that the blood derivatives [go over the page] will be more expensive but donors who are found to be positive will have to be counselled and, if necessary, referred to liver specialists who will treat them with expensive drugs such as Interferon. Who will pay for this?"

Then you continue to set out a number of concerns in relation to the funding.

You, I think, sent this letter to the chair of the various Blood Transfusion Service divisions, for

them to circulate to others in the hope that there would be a reconsideration on the part of the Department of Health about its refusal to fund the cost, is that right?

A. Yes.

Q. But that didn't get anywhere in terms of getting a different decision from the Department?

A. No. They insisted that the hospitals -- that users had -- that we had to add it to the price of blood.

Q. If we then go to NHBT0000191_089, please. This is from you to Dr Gunson, 22 February 1991. Second paragraph you say:

"When I spoke to you regarding anti-HCV screening, I said that if forced we would be able to start on 1 July 1991 <u>if the money was available</u>. Apart from having to employ additional staff and make modifications to our computer and release systems, we are confident that we could start screening, but if we have to find the monies ourselves, this will be later than 1 July 1991. So far I have not received instructions from my Regional General Managers to add on the cost of screening to the handling charges for blood derivatives.

"Hence, I repeat that if we are forced to start screening, we would be able to start but very

reluctantly."

Why were you reluctant to start screening, as described in that letter?

A. Again, it's the cost, you know. I had to juggle with all the things -- the expenses of the centre, and I didn't have those 600,000.

Q. If a decision had been taken by the Department of Health at a rather earlier stage, a different decision, whereby they said the costs would be met out of central funds, do you think that could have accelerated the whole programme overall?

A. Yes, evidently.

Q. Were other centres, to your knowledge, also struggling to find the finance to pay for the cost of establishing screening?

A. They must have been.

Q. Now, when we get to March of 1991 -- perhaps we'll look at NHBT0000073_063. Minutes of the Advisory Committee on Transfusion Transmitted Diseases at its meeting of 25 March 1991. If we go to page 2 we can see under the heading "Introduction of anti-HTLV tests into NBTS and SNBTS":

"4.1. The starting date and its definition.

"4.11. The proposed starting date of 1st July presented difficulties since it was considered

essential that the second generation test from both Orth and Abbott should be evaluated prior to the commencement of routine tests."

Then if we go to the next paragraph it refers to preliminary results obtained by Dr Barbara, and it was agreed that further testing at all three RTCs was essential.

Now, without going to lots of other materials, in around March 1991 it appears the Department of Health agreed there should be a second round comparative evaluation of the tests at the three centres.

A. I think it was of the second generation tests.

Q. Yes, sorry, I've got my second in the different -- in the wrong place. An evaluation of the -- so a further evaluation, now of the second generation tests, to be carried out at all three of the Regional Transfusion Centres there. That caused further delay, did it not, in the introduction of the screening?

A. Yes.

Q. It meant it was put back from July to September?

A. Yes.

Q. Why was it thought necessary to undertake the evaluation of the second generation tests?

A. Thinking about it now, I think we could have started

in July. But again, with hindsight.
Q. I just want to ask you about a letter you wrote to Dr Gunson in April of 1991. NHBT0006421_002.
This is a letter, 22 April. You say in the first paragraph, in the second line, that:
"[You] have ... consulted with Pat Hewitt and John Barbara and the three of us are of the opinion that we are going 'over the top' with the proposed screening of anti-HCV."
You then say in the next paragraph that you accept that the Blood Transfusion Service has no option but to introduce screening of blood donations, and then you talk about being disappointed about the issue in relation to costs.
If we go over the page, I don't need to go through the detail but you set out a number of observations about the procedure for confirmatory testing and various other matters.
And then if we go to page 3, under the heading "Monitoring test results", you say:
"The more we think about it, the more we think we are going over the top with this testing for a virus that has not been shown by anybody to cause immense healthcare problems in the UK. Why should we monitor anti-HCV results when no-one has been the

slightest bit interested in monitoring HBsAg results?"
You were asked about this in your statement, Professor Contreras, and what you said in your statement was that when you talked about going "over the top" for the proposed screening, you were not talking about the principle of introducing screening but the particular arrangements that were proposed; is that right?
A. Yes, it was so, so complicated that, you know, the patients needing platelet transfusions, for example, would have suffered. We would have made mistakes because Philip -- I respect Philip Mortimer a great deal, he is a great scientist and a great microbiologist, but he never worked in a transfusion centre. So to take aliquots of frozen -- you know, it was so, so complicated that we would have certainly made mistakes and we would have wasted a lot of units unnecessarily.
Q. So is it right to understand this letter as seeking to influence the way in which the screening would be undertaken, not whether, and not the date of its, introduction?
A. Yes, certainly the way.
Q. Did the way in which it was originally proposed that it would be introduced, did that contribute to further

delay or was it resolved relatively expeditiously?
A. I think it was resolved quickly when we suggested that RIBA -- RIBA is the confirmatory test for anti-HCV, the first confirmatory test, that could be done at Transfusion Centres and then you could go -- a very few would go for PCR. So that, I think that Philip realised that his method was totally impractical and expensive.
Q. In relation to the confirmatory test, the RIBA test, am I right in understanding that that was a test that had in fact been available for some time, that was a test available from 1990?
A. Yeah, but not really as a routine test as an experimental or confirmatory assay.
Q. Can we then look at a letter that Dr Lloyd wrote to all directors of transfusion services on 2 May, NHBT0000076_041. Dr Lloyd referred in the first paragraph to the original July date having been changed to a provisional September date and then said in the second paragraph:
"In view of the fact that we [so in Newcastle] were already set up for testing, I have decided to keep to the July date. By 1st July, all units of blood for transfusion in the Northern Region will be negative for Hepatitis C antibody."

Now, you and number of other transfusion directors wrote to Dr Lloyd disagreeing with his course of action. If we can look at NHBT0000192_009. You wrote the next day, 3 May, describing yourself as "very sad and disturbed to receive your letter":
"Your decision will erode the concept of a National Blood Transfusion Service. The majority of Regional Transfusion Directors have decided to start testing when the data on the current national comparative studies of the available test are accessible to analysis.
"With the national consensus approach, the threat of Product Liability should not arise. We think under current legislation it would be defensible to postpone testing. Moreover a national approach might well have prompted the [DH] to provide appropriate funding for testing with all its ramifications such as confirmatory assays, counselling, and donor referral. Now, I can see no hope of presenting a united front in pursuit of central funding."
Then you describe it as a "potentially divisive step", if we just go over the page. You then talk about surrogate testing, and say your view:
"... has always been that this would be a waste

of resources, especially with the imminent introduction of a specific assay for anti-HCV."

So if we just go back to the first page, you weren't alone in writing to Dr Lloyd in terms such as this but Professor Contreras, why was Dr Lloyd's decision one that triggered such a reaction from you?

A. I really do not know why, because thinking about it now, I recognise that I am really sorry to have written this letter, because I think we could have introduced anti-HCV testing in July.

Q. It could be said that the Regional Transfusion Directors who expressed their concern to Dr Lloyd -- we've looked in earlier hearings, for example, at the terms in which Professor Cash wrote to Dr Lloyd, and there were others. It could be said that the Blood Transfusion Service was prioritising the importance of consensus over considerations of patient safety. Do you have any comment in relation to that?

A. I didn't see it like that. Now, I could see it but, at the time, I didn't see as prioritising consensus over safety. Yeah, but now, you know, externally, I could see it like that and, for us, it was, you know, the national service and the costing. But as I said, we -- if we had -- if we could introduce it in September with no funding, we could have introduced it

in July with no funding.

Q. You did, I think, then, at the centre, make the arrangements for its introduction at the beginning of September 1991.

A. (Witness nodded)

Q. It's clear from the evidence you've given, Professor Contreras, that you think hepatitis C screening could have been introduced earlier than it was. If you leave aside the position of your own centre and the difference between July and September, if funding had been different, if the decision-making process had been quicker, do you have a sense of how early testing could have been introduced, in your view, bearing in mind a number of other countries had introduced it really in the early part of 1990 and then some others later in 1990?

A. I do not know whether my -- my thinking at the time and my position at the time, and that of my colleagues, would have induced me to introduce the first generation test because, as I said, you know, I didn't -- the same as with HIV. I didn't want to create an army of worried well. So -- but perhaps we could have introduced it as soon as their second generation test had been tried and was available.

Q. Then, just if I can pick up the point of the "army of

worried well", this is the point about false positives?

A. Yes.

Q. Perhaps if we look at the way you put it in your witness statement, WITN5711001. If we go to page 97, the last paragraph on that page. So you say in paragraph 389:

"It is unsafe to inform blood donors of a false positive test that would label them for a lifetime, hence the need for confirmatory testing."

Then, if we go to page 104, paragraph 415, you say:

"As I have said above the false positive rate was seven to every one donor who actually had the virus; therefore we would have to be telling potentially seven people that they might be carrying a virus which they did not have and discarding their blood unnecessarily."

Can I ask you to look at it in this way, Professor Contreras: why would the prospect of telling people they might have a virus that they didn't have, and once confirmatory testing was available you could tell them they didn't have it, why does that outweigh the risk of infecting people with a virus that they would not otherwise have, with potentially serious

and, indeed, fatal consequences?

A. I do not think that it outweighs the risk but, you know, as somebody who was collecting this blood or in charge of the collection of blood, I cared for patients and for donors, and I did not want to create a psychological illness in those donors. But, yeah, perhaps I should have weighed the risks.

Q. Can I then just ask you, still on this topic, just to look at a couple of further materials. The first is an email from you in 2000, NHBT0086471. So you say here:

"Just a short note to remind you that Harold Gunson is very hurt and disillusioned with the [Department of Health] and [National Blood Authority] after the 'grilling' during the HCV litigation court case. I have spoken to him twice and he felt he was defending the [Department of Health] and Dr Jeremy Metters, previous Chairman of MSBT for decisions that he was not party to."

Then you go on to talk about him as someone who dedicated a lifetime to the National Blood Service. Are you able to recall further any conversations that you had with Dr Gunson about this issue and about how he felt about the litigation?

A. You know, I can't remember any of this, and I'm proud

of this email, but I cannot -- you know, because he took the brunt of the criticism there at the Penrose Inquiry when it was no fault of his own, more or less. But I do not remember either this email or the conversations.

Q. Then I just need to ask you about some observations Dr Barbara made in the note of a meeting in the context of the litigation, and then one aspect of Dr Gunson's evidence, because there's some observations from both of them about your approach to hepatitis C screening that I want to give you an opportunity to comment on.

If we look, first of all, at NHBT0036250_025. It's an attendance note of a solicitors meeting with Dr Barbara. I'm not going to ask you about what he says about his own personal views, on issues relating to screening, but just about some observations he made about your thinking.

So if we go to page 2, fourth paragraph:

"He [Dr Barbara] said that he thought we should get a statement from Marcela Contreras because she was very vocal in her reluctance to introduce screening."

Then the last paragraph of that paragraph:

"He said that Marcela Contreras still believes that Hepatitis C infection was overrated."

Do you -- let me show you one other paragraph and then ask you. If we go three paragraphs further down:

"Dr Barbara said that Marcela would give a vigorous account of the perception at the time that Hepatitis C was not worth the candle."

Those are his words but do you have any comment to make upon what's being said was your approach at the time?

A. Well, unfortunately, at the time I did not see it as a major problem in the transfusion of labile blood components, you know, I saw it as a problem in the transfusion of concentrate. But we were not -- we had no evidence of the problem, and perhaps I was wrong, but ...

Q. And then if we look at -- just one further extract from Dr Gunson's oral evidence in the NBA litigation.

NHBT0000148_001.

A. Sorry, and there John Barbara quotes Seeff again about -- you know, Seeff -- that's in the USA -- followed up for over 20 years the recipients, the patients who acquired hepatitis C or non-A, non-B, by transfusion, and didn't find any difference in -- the mortality was the same in controls and in the patient groups.

Q. So this is the same extract -- sorry, the same transcript we looked at earlier, but if we go to page 66, and it's the first ten lines or so.

So this part of a question to Dr Gunson:

"By this time, early 1991, the Department had taken over the evaluation process. We looked at that letter.

"A. Yes. I now know what you are referring to.

"Q. There is local resistance still, is there not?

"A. There are some centres who were not happy even with the July start date.

"Q. Some people still wanted to fight the battle as to whether it was worth doing at all, did they not?

"A. There is correspondence to that effect available.

"Q. Particularly from Dr Contreras?

"A. Yes.

"Q. Let us be plain about this, because we can look at the letter and indeed I think perhaps we should: unless Dr Contreras agreed, nobody else could do anything; that is the position, is it not?"

Then there is a further discussion about some of the documents we've looked at.

So it might be said that Dr Gunson regarded there as being some directors, including you, who still in 1991 were unconvinced that hepatitis C screening was worth doing at all. Was that your view in 1991?

A. At the beginning of 1991, unfortunately, yes.

Q. And am I right in understanding your evidence that you -- looking at it now, you think you were wrong in that regard?

A. Yes.

Q. Can we then just move away from hepatitis C screening to an issue relating to anti-HBc screening. Not now as a surrogate marker for non-A, non-B hepatitis but, as it were, in its own right in relation to detecting possible hepatitis B infections.

If we look at NHBT0000044_095, this is a short discussion paper prepared by you and Dr Barbara, Professor, for the ACTTD. It's dated 23 January 1992. I just want to ask you to look at the first paragraph, where you say:

"The question of the likely benefit of anti-HBc screening of blood donations continues to reappear, especially so in the light of the introduction of anti-HCV screening. The attitude towards transfusion safety has veered away from the concept of 'maximum

benefit at minimal cost' towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced. The latter approach is reinforced by loss of Crown Immunity, the introduction of Product Liability and the emphasis on Quality, Audit and licensing by the MCA."

Then you go on to talk about the potential for introducing routine anti-HBc screening.

Can I just ask you about what you describe there as a shift in attitude from a concept of what you've termed "maximum benefit at minimal cost" towards the idea of, "Well, if there is a measure that reduces risk, we should take it". Are you describing there a shift simply in your own thinking, or it was your understanding that there was a wider shift in attitude?

A. It was both, I think. It was my own thinking and my team's thinking, and general thinking as well, that we had to introduce any testing, regardless of cost.

Q. And the concept you've described of maximum benefit at minimal cost, and that attitude to transfusion safety, is it right to understand that describes essentially the approach that you and colleagues had taken previously in the eighties in relation to issues such

as surrogate testing and anti-HCV testing, but now you were convinced of the need to be more proactive?

A. Yes.

Q. And then if we can just look at and see, in relation to then the particular issue of anti-HBc screening, I'm going to give a reference that we don't need to go to, and then pick up a couple of documents.

So at the ACTTD meeting of 7 May 1992 -- for the transcript it's NHBT0017532:

"The Committee agreed that the introduction of anti-HBc donor screening had a high priority."

So that was May '92. Then I want to ask you to look at a meeting of the same committee in January 1983 at DHSC0006982_049.

So we had Dr Gunson in the chair. You are there, it's 12 January 1993, and then we have the heading "Anti-HBc screening". There's a reference to results from Glasgow, Cambridge and North London not being available, but then it says this:

"However, on the basis that

"(i) the knowledge from the trials to date have revealed that potentially infectious donations for hepatitis B were being transfused.

"(ii) that patients who had suffered from transfusion associated hepatitis B (when the blood was

HBsAG negative) were being reported.

"It was agreed that a recommendation to ACVSB for the introduction of routine anti-HBc screening of donations should be made."

Is it right to understand that there is exemplifies the shift in attitude that you had described in that earlier document?

A. Yes.

Q. And the committee of which you were a member was now advocating the introduction of anti-HBc screening because you were conscious that there were still hepatitis B infections being transmitted through blood?

A. Yes.

Q. If we then move on -- so that's January 1993. We can see the recommendation to the ACVSB is going to be made. We then move to NHBT0018427. This is you writing to Dr Gunson on 3 June 1993.

"In your letter of 3 June 1993 you reported that the Advisory Committee on Transfusion Transmitted Diseases will advise ACVSB that anti-HBc testing of blood donation should commence."

You say that:

"On logistical and scientific grounds, we could commence screening as soon as funds are available,

but ..."

Then there's an issue in relation to funding.

You refer in the next paragraph to having discussed the matter with Dr Hewitt and Dr Barbara, and then you say:

"We firmly believe that anti-HBc testing of blood donations is the necessary and logical step to reduce further the already small number of HBV transmissions by blood transfusion. We feel that this is the obvious progression for reduction of PTH, given the implementation of HCV screening almost 2 years ago."

So is it right to understand you are continuing, with Dr Hewitt and Dr Barbara, to advocate for anti-HBc screening to be introduced?

A. Yes.

Q. Then if we move to DHSC0004709_151.

DHSC0004709_151.

This is October 1993, you to Dr Gunson. Second paragraph:

"I was dismayed that the DH Advisory Committee on MSBT ..."

That was, I think, the successor to the ACVSB:

"... has decided not to introduce routine testing of all donations for anti-HBc. I have had

a long discussion with Dr David Dane and John Barbara and we have concluded that some of the reasons that the Committee has given are very difficult to defend ..."

The first deals with false positives and then the second you say:

"The primary object of donor testing is to provide safe blood."

Then you go on to make a number of other points in the course of the two-and-a-half-page letter. I'm not proposing to go through all of those.

Do you recall what happened after that in terms of anti-HBc screening? You obviously were disappointed with the decision that had been taken not to introduce it. Was that resolved, and if so, how?

A. No, it wasn't resolved, we never introduced anti-core screening. But it was later on superseded by the PCR, the very sensitive test that would have excluded those donations that were carriers for hepatitis B -- most, not -- most but not all. So it was never totally solved.

Q. Because the reason, as I understand the documents, that you were advocating anti-HBc testing and the hepatitis B infections were still occurring was because, although the sensitivity of testing had

improved since the early seventies, the tests were still not sufficiently sensitive to detect all cases.

A. Yeah, because the tests were for surface antigen.

Q. Yes.

A. And surface antigen in -- what we were transmitting was what we call -- well, what Dr Dane and Dr Barbara called tail-end carriers. So those carriers of hepatitis B that have lost detectable surface antigen but still have anti-hepatitis B core antibody, and still have some virus in the body. So you cannot detect it in a small tube, but you can transmit it by the pint.

Q. Now I'm going to move now to a different topic which concerns an issue about the supply of what was sometimes called fresh warm blood, for the purposes of certain forms of significant cardiac surgery.

Can I start with a letter you wrote to the Medical Defence Union because it contains, I think, a useful summary of the history. It's NHBT0093056. You wrote this letter, 19 May 1988, to Dr Beresford at the Medical Defence Union. You say:

"Following our telephone conversation and your helpful advice, I am writing with relevant information on my saga with Mr Yacoub."

Now, that is Magdi Yacoub, now Professor Sir

Magdi Yacoub, and I should say, sir, we do have a witness statement from Professor Yacoub which sets out his perspective in relation to his use of blood, and it may be an issue which we explore in future hearings. In any event, Professor Contreras, you say:

"For a very long time, Mr Yacoub has insisted on the use of 'fresh, warm blood' for his difficult cardiac surgery operations. A large proportion of the operations performed by Mr Yacoub seemed to be of a difficult and complicated nature and, in his opinion, when the patients bleed, the only form of effective therapy is the use of 'fresh, warm blood'. I have tried to convince him that there are alternatives to 'fresh, warm blood' in these times of blood component therapy, but to no avail.

"Only quite recently, Mr Yacoub's team was bleeding large number of donors at Harefield hospital and was not complying with the routine pre-transfusion testing required by the National Blood Transfusion Service. He was bleeding donors and transfusing their blood within minutes of collection. Hence, all microbiological screening of blood donations was done retrospectively in the Pathology Laboratory at Harefield. The Haematologist at Harefield approached us for help since this practice was against her

principles, and her laboratory was unable to cope with the increasing demands for testing imposed by Mr Yacoub's team. In view of this, I attended several meetings with Mr Yacoub, the General Manager at Harefield, the Anaesthetists and Dr Amin, the Consultant Haematologist at Harefield. I said that I would try to do everything possible for Mr Yacoub's difficult cases and that, whenever it was impossible for us to supply same-day blood, that had been screened and tested, one of the Consultants at this end would authorise the issue of same-day unscreened blood, (ie not tested for [hepatitis B surface antigen], HIV and syphilis). The issue of unscreened blood could only be authorised by one of the 4 Consultants at this Centre. Although the issue of unscreened blood is totally against the good practice of Blood Transfusion Medicine and against my own principles [over the page], I gave in in order to avoid the collection of blood by Dr Yacoub's team. I found that it was better to supply blood from established blood donors who had gone through our verbal screening procedure and who had answered a confidential questionnaire stating they did not belong to a group at high risk of HIV infection. However, despite all our efforts, Mr Yacoub continued

bleeding people at Harefield and requesting 'Fresh, warm blood' more often than he had previously anticipated at our meetings."

You were asking for advice from the Medical Defence Union about your own position, I think, in that regard. Now, am I right in understanding that by this time, May 1988, this was an issue that had been ongoing for a couple of years?

A. Yes.

Q. I'm not going to go to the documents themselves but I'll just give a couple of references. You'd written in February 1988 to the National Heart and Chest Hospitals -- to Dr Berman at the National Heart and Chest Hospitals expressing your concern about this issue. The reference for the transcript is NHBT0085681_039 and you'd written to Mr Yacoub himself, copied it to the Department of Health. Again, we don't need it on screen, DHSC0002841.

Can I, however, then put up on screen a letter you then wrote to the Department of Health because you wanted the Department's assistance, I think, in helping you to resolve this issue, DHSC0002841_009. So 19 July 1988, you wrote to Mr Harris at Department of Health, second paragraph, you say:

"Since I was appointed Director of this Centre,

I have had to deal with problems regarding the use of fresh blood by Professor Yacoub. I have expressed to Professor Yacoub on numerous occasions my concern and disapproval of this practice which I consider to be against the best principles of blood transfusion medicine. Unfortunately, Professor Yacoub continues bleeding members of staff, visiting doctors and members of the Armed Forces for his numerous 'emergencies'. I have told him that am not prepared to issue from this Centre any more untested blood unless the DHSS is prepared to agree to this."

Then you continue in the next paragraph:

"We have had three cases of HIV infection apparently transmitted by blood transfusion that we have been unable to follow-up fully since the three patients concerned were given, in addition to blood supplied by the Transfusion Service, fresh warm blood collected at Harefield hospital. We have followed up the donors of the units issued by this Centre but it will be impossible to follow up the donors who gave the fresh blood in view of the poor record keeping by Professor Yacoub's team."

Then, just before I ask you about the issue overall, the reply from the DHSS is at DHSC0006312_0036. It's entirely conceivable I've

written that down wrong, Soumik.

Oh, no. What I'm going to do, because I don't think the text of the letter is terribly material, I'll read out:

"We in DHSS share your general concerns but the local problem as described you at Harefield is essentially a problem for the Regional Health Authority to tackle and we are in contact with them."

Then there is agreement with a number of your concerns. I just want to get an understanding of what the problem was, as you saw it, and then how you sought to resolve it. Because Professor Yacoub thought that the use of what was termed in the correspondence "fresh, warm blood" was a necessary and appropriate course to take in relation to some of the complex cardiac surgery he was undertaking, I think it came to your attention that staff at the hospital, and on occasion others, were effectively being bled there and then at the hospital and the blood immediately used for the patient without it having undergone any testing whatsoever; is that right?

A. Yes.

Q. You were very troubled by this, and there's a range of other correspondence and communications. I'm not going to go into all of them. I'm going to paraphrase

but is this right: you essentially went for the lesser of two evils, in your view, to avoid completely untested unscreened blood being taken there and then from nurses and doctors, and so on, at the hospital and immediately transfused, you reluctantly made available same-day blood on occasions to Professor Yacoub, which also hadn't been tested fully, but which at least came from your established donor panel with the donor screening and selection procedures in place. Is that right?

A. Yes, it was -- first of all, I have to start by saying that I was convinced by -- although I say in my letters that it is against my principles, but I was convinced, when I went to several meetings with Professor Yacoub and I went to theatre, and I remember going once at 2.00 or 3.00 in the morning when he was asking for -- so, and I could see that little babies, you know, newborn babies were -- that were -- had to be done through the extracorporeal machine, they were bleeding, and bleeding, and he gave them this fresh, warm blood and it was like a miracle, the bleeding stopped. And that happened with babies and with heart/lung transplants, difficult heart/lung transplants as well.

So I had -- although I believed in component

therapy but, for these cases, I thought, well, he's right, in what he's -- he's the expert. He was doing surgery that nobody else in the world was doing.

He was saving life -- you know, I went to see those patients in the wards and, you know, they wouldn't have had a chance to live for more than a month, perhaps. They were on respirators or the babies -- you know, the babies would have died within days and I saw this, like miracles in medicines. So he convinced -- that convinced me that I had to help in some way.

So the best of both evils was to give him blood from known donors that we knew, from lots of publications, by us and Dr Barbara especially and everybody, that repeat donors, known donors, carry a much lesser risk of transfusion-transmitted infection than new donors or family replacement donors, or donors who are not volunteers.

So I said, well, it's better to give him blood that in the majority of cases might have been tested when we issued it, because we were testing daily. So very few case, very few units were untested when they went to -- when they went to -- when they were issued to Harefield, but most of them were tested before they were transfused to the patient because we tested them

as soon as possible, but if we issued them in the middle of the night something that had been collected that evening, we might not have.

But all the units that we gave to him, that we gave to Harefield, as fresh blood, it was never warm, in our case, it was room temperature. All those units were tested on the day of transfusion if they hadn't been tested prior to transfusion.

Then, from product liability came -- you know, I couldn't continue providing him. But I -- when I think retrospectively, I wish I had been able to help him with fresh, same-day blood, tested.

Q. In relation to the blood or blood components that you supplied to Professor Yacoub on those occasions when you did, am I right in understanding that they were -- where they weren't tested before use, there was testing after use?

A. I think the majority of them were tested during -- were tested either on -- before they were issued, the majority of them, but some of them were tested immediately after issue or when they were on transit, or when they were being -- some of them might have been when they were transfused. But they were all tested and they were all found negative for all the markers.

Q. Is it right to understand that, in relation to any blood that was used in surgery from people who were bled within the hospital, over which you and your colleagues had no control, you've no way of knowing whether any of that was infected?

A. Yeah. No way. And also, we do not know whether all those units were -- samples from all those units were sent to Dr Amin, the pathologist.

Q. Now the correspondence we looked at was from 1988. There's a document from Dr Hewitt in 1995 showing it's still an ongoing issue. I can ask her about that. But can I just ask you to look at a document in 1999. NHBT0101360.

The date here is 18 March 1999, and it's a memo from you and it refers to having attended a meeting at Harefield with Professor Yacoub and others.

It would appear from this that the use of untested fresh warm blood from volunteers' blood at Harefield Hospital was still happening, is that right?

A. Yes.

Q. It wasn't, as I think we see in the last two lines of that paragraph, happening at the Royal Brompton Hospital but it was still happening at Harefield.

And then if we go over the page, if you look at the last paragraph, it would appear that at this stage

you came up with a different solution, which was the supply of apheresis platelets and leucodepleted red cells.

Do you know whether that then resolved this issue or donors continued to be bled and untested blood used?

A. I do not know but I think that he continued to bleed the occasional donor.

Q. I should say again, for the benefit of the transcript, that the statement that we have from Professor Sir Magdi Yacoub, it's at WITN4129001 and explains his reasons for proceeding in the way that he did.

A. May I say that the older I get, the more I think that the use of fresh -- of whole blood, that perhaps we might have gone, with component therapy, a little bit too far, and for acute haemorrhage or for the type of operations that Professor Yacoub was doing and that I am not alone in -- and he is not alone in thinking that fresh warm blood -- fresh blood -- full, whole blood, is a better option. Because it decreases the number of -- it decreases the risk, instead of giving three components, of giving one, and it doesn't add to the volume also, and it doesn't add so many additive solutions. So there is some reason for using.

Q. And it's right to point out that you've referred to some of that literature, I think, in your witness statement.
A. *(Nodded)*
Q. To some of the literature that post-dates the events that we've been talking about.
A. *(Nodded)*
Q. I've then just got a small number of, as it were, miscellaneous topics to ask you about now, Professor Contreras.

If we could have your witness statement on screen, WITN5711001 again. If we could go, please, to page 77, paragraphs 308 and 309. You say there:

"With regard to donors found to be HBsAg positive, we included them in a panel of donors who were seen annually with full medical examinations and LFTs. If alterations were found, they were referred to a hepatologist at their local hospital. These investigations contributed a great deal to our understanding of Hepatitis B carriers and the long-term effects of the infection ..."

Then 309:

"We also collected, under strict isolation conditions, plasma from subjects with high levels of HBe antigen, in a collaborative effort with

Professor Arie Zuckerman ... in a project to make an HBV vaccine."

I've got a handful of questions I've been asked to ask you on this issue.

In relation to the practice described in 308 of taking blood from this panel of donors found to be HBsAg positive, what was done with the donations that were collected from them?
A. No, it was samples. We followed them up and took samples from them, annually, because we didn't know the natural history of hepatitis B. You know, when -- for how long were they carriers, when they cleared the virus, et cetera and, since we were so strongly associated with Dr Dane, then we could follow these donors -- with their consent, because they want to know as well whether they had cleared the --
Q. So it was only samples. You weren't collecting further donations for use in the manufacture or processing into products to -- for --
A. Oh no, no, no.
Q. -- transfusion?
A. No, no, never, no. This was separately, and they were not done with the routine donors, not bled with the routine donors, because we knew that they were infectious donors.

Q. And then in relation to paragraph 309, where you talk about collecting plasma from subjects with high levels of antigen with Professor Zuckerman in a project to make a hepatitis B vaccine, at what period of time are you talking about there? Do you know?
A. I cannot remember. I think it was before I became professor of the Royal Free. I cannot remember.
Q. Do you know how that plasma was used in the production of a hepatitis B vaccine, or was it simply provided to Professor Zuckerman?
A. It was provided to Professor Zuckerman, who was an expert in hepatitis. But it never came to anything.
Q. And then if we just turn on to page 91, paragraph 363, you say there:

"We had a panel of donors with high titres of microbial antibodies, such as anti-HBV, anti-Tetanus, anti-VZ, who we plasmapheresed regularly for the production of specific immunoglobulins by BPL."

Were any products other than immunoglobulins produced from that panel of donors?
A. I don't think so.
Q. And were there processes in place to ensure that such plasma did not enter the -- in a general pool?
A. I do not think so, but -- because these are very safe donations, they've got antibodies, they -- they were

not infectious. They were -- it was -- you know, we wanted to concentrate the antibodies in those donations. So it's not antigen. These were not infectious donors. They were the best donors you could find, because they were protecting people from hepatitis B. So if you knew that you were transfusing -- that somebody was at risk, you would give them a concert, an immunoglobulin containing antibodies to hepatitis B or to tetanus or to varicella-zoster or to rabies.
Q. And then on a completely different topic in your statement, if we go to page 88, the paragraph at the bottom of the page. This now in relation to the look-back. I'm not going to ask you any detailed questions about it, Professor Contreras, because I think Dr Hewitt is more likely to be able to assist with the detail of it.
A. Yes, she is the expert.
Q. And we're hearing from her next week. But you say here in paragraph 351, your recollection was that you wanted to start the look-back earlier but that the Department of Health would not provide the funding for the programme at an earlier point in time.

And you've pointed to a memo where you talked about a -- you suggested to colleagues applying for

a grant.

Can you recall any more about that, about any approaches to or discussions with the Department of Health about a look-back?

A. No, what I remember is that we applied and we were not successful. But I don't remember discussing it any further with the Department of Health.

Q. Now, the national look-back began in 1995. We know, of course, that the hepatitis C screening was introduced in 1991. What's your view, if any, on the appropriateness of the delay between the introduction of routine screening, the availability of testing, and the start of the formal look back?

A. Totally inappropriate.

Q. The last question, Professor Contreras, from me for the time being, is just in relation to SHOT, Serious Hazards Of Transfusion, I think that's the right description of the acronym. You were involved in its inception and until, I think, 2007, when you retired from NHSBT. Could you just tell us in broad terms what the purpose of SHOT was, why it was set up?

A. The purpose was -- it had been started in a very rudimentary way in Italy and I was invited to a meeting in Italy by Dr Marconi and I couldn't go (I think I had surgery, or something like that) and

I asked two of my colleagues, Dr Williamson and Dr Love to go to Italy and then we discussed -- SHOT was the Serious Hazards Of Transfusion Haemovigilance, it means the vigilance, the follow up, or the knowledge on the risks, the real risks of transfusion in the patient population.

So it was for us to learn what was happening with our blood, and collating it throughout the UK, and reporting it to a central reporting base, secretary and then follow and analyse those risks of transfusion, and we realised that, you know, our main problem at the time when we started SHOT, and I think still is, was errors, giving the wrong blood to the wrong patient.

Q. Again, looking at it now, with the benefit of hindsight, would it have been beneficial, do you think, to have something like SHOT established at a rather earlier stage so that it would have been available as a forum for decision making in, say, the 1980s when some of the key decisions fell to be taken in relation to blood safety?

A. Yes, definitely, yes.

MS RICHARDS: Sir, those are the questions I currently have for Professor Contreras but we obviously need to give the opportunity to Core Participants through

their legal representatives to suggest any further lines of questions. So perhaps we could take a break now, and I can consider any questions that I am asked to put to Professor Contreras.

SIR BRIAN LANGSTAFF: Yes. Let me just explain to Professor Contreras, there are a lot of Core Participants in an Inquiry. An Inquiry is rather different from a legal case, because participants have no particular case to put to you, they have perspectives. Each may very well be different from the other but they're all entitled to ask questions through counsel to the Inquiry. We just want to know what happened as best we can from the witnesses.

To let that happen, we take time for them to discuss with counsel what additional questions they may want to ask.

So we'll need, what do you think, about 40 minutes?

MS RICHARDS: Yes, 40 minutes would be ideal.

SIR BRIAN LANGSTAFF: So 3.50, do you think?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: It is likely, I can't promise at all -- it depends how many questions there are, there may be quite a lot, there may be very few -- but I think you are likely to be away from here by 4.30 or

thereabouts, just to give you some idea.

But for the moment, would you like to go and have a cup of tea.

THE WITNESS: Thank you, sir.

SIR BRIAN LANGSTAFF: 3.50.

(3.09 pm)

(A short break)

(3.50 pm)

MS RICHARDS: Professor Contreras, just a few further questions. In the course of your evidence, you've referred on a handful of occasions to "labile blood components" as contrasted with, for example, fractionated with concentrates. Could you just assist us in understanding what you're talking about when you talk about "labile blood components" and what the significance was of the distinction you were seeking draw.

A. Labile blood components are those components that are taken from a unit of blood and processed at the transfusion centre, that means red cells, platelets -- you know, if you spin a unit of blood in the centrifuge, then you get the heaviest particles at the bottom and those are the red cells. Then there is a layer that we called the buffy coat, because it's got a buffy colour and that buffy coat is rich in

platelets and white cells. White cells are the ones that defend us against infections and -- particularly bacterial infections, but at the same time, they cause lots of febrile transfusion reactions, so they've got two edges to it and on top of it, is the plasma.

And the plasma we use it either as fresh frozen plasma, that we freeze immediately within 8 hours of collection, ideally, or 6 hours of collection, and -- or we make cryoprecipitate out of it, and that means processing the plasma and freezing it and then thawing it, very slowly, and getting a concentrate of Factor VIII. That is the precipitate, the cryoprecipitate, that is in a much smaller volume than a unit of plasma that will have 200 or -- or 250 or 300 millilitres, and the cryo will have all the Factor -- or most of the Factor VIII and fibrinogen in it for coagulation, and it will only have 50 to 55 millilitres.

Q. So when you talked about labile blood components, that's what you're describing as a --

A. Yes.

Q. -- group of components, as distinct from the fractionated products that might be produced at BPL from the plasma sent there for fractionation?

A. Yes. And the fractionated products are factor --

albumin, that used to be called, in all of this, PPF, Factor VIII, Factor IX, immunoglobulins, et cetera.

Q. Yes, thank you.

Now, completely different topic, I asked you yesterday about the organisation of the National Blood Transfusion Service, and you talked about your view that there should have been a properly funded National Blood Transfusion Service, as I understand it, earlier than there was.

When do you consider that a properly funded national service should have been established?

A. As early as possible. You know. In the 1980s, perhaps. Yeah, when we saw that there were so many -- there was evidence of discrepancies and also of some centres being -- having lots of blood and some centres collecting more blood than others and not being able to supply the demand. So yes, as early as possible.

Q. And then I asked you yesterday about the discontinuance of the regular Regional Transfusion Directors' meetings, which came to an end in January 1984 -- sorry, '89, after the National Directorate was set up.

If Regional Transfusion Director meetings had continued beyond January 1989, do you think that would have made a difference to or possibly improved

decision-making as regards the introduction of hepatitis C screening?

A. I do not think so. I think it would have been even more complicated, you know. It was 15 decisions, and there was a national management committee. I don't think -- no, because it was not a directors' decision. It was ...

Q. Next I'm just going to ask you about some matters arising out of the introduction of the hepatitis C screening in September 1991.

Do you know whether all Regional Transfusion Centres adopted a hundred per cent HCV testing of all blood on 1 September 1991, or whether it was rolled out with effect from 1 September 1991?

A. I believe, but I'm not totally sure, that we all introduced anti-HCV screening on the same day or around the same day.

Q. In terms of use-by dates for blood, blood components, there's guidance about that in a handbook of transfusion, and other sources. I don't need to ask you about the detail of that, but do you know whether those dates were always followed in practice or was there a variable position in terms of whether they were adhered to or not?

A. I don't think that anybody used blood beyond its

expiry date. So it could have been 28 days or 38, 35 days, depending on the anti-coagulant and the additive solutions and, for fresh frozen plasma, as well, you know, a year. And platelets, they wouldn't -- I believe that most hospitals would not have taken the risk of using it after -- I know that some of the private hospitals that we supplied tried to return blood to us as soon as possible so that they were not charged.

Q. Just for the sake of clarity, that would have been decision-making by the hospitals that had the products in storage and were actually going to use them. It wouldn't necessarily come to your attention if hospitals were using stocks beyond their --

A. No, it wouldn't come to our attention. But that's where education was so important.

Q. In terms of the possibility of untested blood, blood components, being in the NHS system in the weeks or months after 1 September 1991, are there reasons why there might have remained untested components in the system beyond that 1 September date? Are there types of frozen components, for example, that would have already been in stock?

A. Yes.

Q. Are there any other reasons you can think of as to why

there might have been untested components still in use beyond 1 September '91?
A. Because the hospitals had stocks. Platelets not, but, you know, red cells, cryo and fresh frozen plasma.
Q. In terms of frozen red cell concentrates, I think that's something you referred to at an earlier stage of your evidence, how long could they be stored in the frozen state before being used?
A. 10 years. Or perhaps more, if -- very rare.
Q. This is then the final cohort of questions, again on a completely different topic. This is about apheresis donors. How were apheresis donors selected or identified?
A. First of all because they had been donors in the past. So at least for our centre, they should have given at least two donations before they became apheresis donors. And usually it was their interest, when going to a static clinic, one of our three static clinics, and seeing other donors connected to these machines, they say, "What is he or she doing?" And so it was -- they volunteered. Sometimes we asked a donor who was large enough and a good donor, who had given several donations, "Would you be interested in plasmapheresis?" So we tried to increase the number of apheresis donors.

And they needed to have very good veins, have a certain size, and have a good history of donation, and -- yes.
Q. Is it right to understand that apheresis donors were ALT tested?
A. Yes.
Q. How frequently was that the case?
A. At every -- so there were a number of plasma donors and platelet donors who gave blood fortnightly. They were amazing. But you couldn't collect more than 15 litres a year -- of plasma a year. But until they reached the limit they donated every fortnight.
Sorry, what was your question?
Q. The first question was how often they were tested, which I think you've answered: each time they donated.
A. Yes, each time.
Q. Why were apheresis donors ALT tested when standard donors, if I can use that term for the moment, were not?
A. Because they went into pools, into plasma pools. But if one unit had the possibility, remote possibility, of infecting somebody, it could be distributed to thousands of Factor VIII concentrates.
Q. If an apheresis donor attended to donate as part of the apheresis panel and had raised ALTs and were asked

to defer donating, would they also be advised not to give blood by way of standard donation?
A. The problem -- not problem but the thing that apheresis donors, once they became apheresis donors, they hardly ever -- we hardly ever asked them to give a unit of blood because every time they came to give their donation we had to take samples, so we had to control their red cell levels to control that they were not anaemic. So if they gave plasma or platelets, they did not give whole blood.
MS RICHARDS: Sir, those are the questions I am proposing to ask from those put forward by Core Participants.
Do you have questions for Professor Contreras?
SIR BRIAN LANGSTAFF: I don't. Thank you very much, no.
MS RICHARDS: Professor, do you have anything you would wish to add?
THE WITNESS: Yes, if you could bear with me --
MS RICHARDS: Of course.
THE WITNESS: -- and yes, I would like to say a few words.
I know it's Friday evening, and everybody wants to go home. But, you know, I fully appreciate the IBI efforts and enormous amount of work that has gone into tying to thread all this complicated matter together, for the benefit of those infected and affected.
I am very sorry that this Inquiry has come so

late when many of the infected and affected have died, are too ill, or too old to benefit in any way from the conclusions arrived at by Sir Brian.
The same applies to the witnesses. It would have been better for all concerned if this Inquiry had taken place 30 years ago. The UK blood services have always been risk averse but the tragic incidents in the 1970s and 1980s that led to this Inquiry have changed the services beyond recognition, making the blood services one of the most risk averse services in the NHS.
I have always lived by the principle of what all doctors say: first, do no harm. And I am sincerely sorry if any of my actions, decisions or omissions harmed any patients or their relatives. That was never my intention.
This has been difficult for us all but I hope what I have said, and I tried to remember, has thrown a little more light into the Inquiry's efforts to arrive at the truth. Thank you for listening to me.
MS RICHARDS: Thank you, Professor.
Sir Brian?
SIR BRIAN LANGSTAFF: I have to say I am rather surprised that you haven't been asked to give evidence before, either in a case or in an inquiry. I think there may

be a lot of people now who realise what they've been missing, because what they'll have missed is the straightforward, honest, helpful way in which you've given your evidence.

A lesser person may have been more defensive about past decisions by the various bodies of which they were part, so I just want thank you for your courage and your intellectual honesty in not ducking the question of whether mistakes were made and unacceptable delays caused in the past. But I think it goes further than that.

It is truly refreshing for me, for us, to see someone who has so obviously thought about what happened in the past and has been candid enough to admit that, on some matters, they themselves were wrong.

I'd just like to thank you for having had the strength of character to do that. It is really appreciated.

THE WITNESS: Thank you so much, sir.

MS RICHARDS: Sir, that's obviously it for today.

We will resume next week, sitting every day next week, so we resume on Monday with the evidence of Dr Entwistle, yes. Then we have a full day of different witnesses, for the rest of the week.

SIR BRIAN LANGSTAFF: Yes, so it's ten o'clock on Monday, and I expect it will be ten o'clock every other day next week.

(4.07 pm)

(Adjourned until 10.00 am on Monday)

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