

Wednesday, 26 January 2022

(10.00 am)

**SIR BRIAN LANGSTAFF:** Professor Barbara, can you hear me?

**THE WITNESS:** I can indeed, Sir Brian.

**SIR BRIAN LANGSTAFF:** You can see me?

**THE WITNESS:** Yes, I can.

**SIR BRIAN LANGSTAFF:** Good. In a moment or two,

Ms Fraser Butlin will start asking you some questions

after Mary has asked you to take the affirmation.

But, first, you can tell me you are at your home, are you?

**THE WITNESS:** I am, Sir Brian.

**SIR BRIAN LANGSTAFF:** At home there's, what, your wife and others?

**THE WITNESS:** Yes, and my dog --

**SIR BRIAN LANGSTAFF:** And your dog, right.

**THE WITNESS:** -- who is being kept securely out of the way so that he doesn't join in.

**SIR BRIAN LANGSTAFF:** I was just going to ask that. You are talking to a room here in Aldwych, in which there is a select and small group of people. We have no more because of the restrictions we are observing because of the current virus. Beyond this room, however, there are something in the region of 100 or so people who will be listening to everything that you

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Professor Contreras that she became director of the centre in 1984. When that happened, is it right that you and Dr Patricia Hewitt shared responsibility for the scientific and clinical microbiology work at the centre?

**A.** Yes.

**Q.** Would it be right that Dr Hewitt took on the clinical aspect of the work and you the scientific aspects?

**A.** Yes, she was dealing with the medical side and I was dealing with the clinical science.

**Q.** Just to complete the overview of your career, you then became microbiology consultant at the National Blood Authority in 1994?

**A.** Yes, and reported to Angela Robinson at that time, as well as to Marcela Contreras.

**Q.** You remained in that role until 2001?

**A.** Yes.

**Q.** At that point, you became an emeritus consultant?

**A.** Yes, I went back to London two days a week for just over five years.

**Q.** You remained there until about 2005; is that right?

**A.** Yes, about that, 2006.

**Q.** I just want to talk with you, to begin with, about your role at the North London centre. You had responsibility for everything to do with microbiology;

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have to say today. So that's the audience that you

have, the public that you are speaking to.

Now, Mary would you invite Professor Barbara, please, to take the oath.

**PROFESSOR JOHN ANTHONY JAMES BARBARA (affirmed)**

**Questioned by MS FRASER BUTLIN**

**SIR BRIAN LANGSTAFF:** Yes.

**MS FRASER BUTLIN:** Thank you.

Professor Barbara, can you see and hear me?

**A.** I can indeed, very clearly.

**Q.** Good. Professor, you hold a PhD in microbiology; is that right?

**A.** Yes, yes.

**Q.** So it is right, isn't it, you are not a medical clinician, rather you are a scientist?

**A.** No, I'm a consultant clinical scientist.

**Q.** In 1974 you became the head of microbiology at the North London Blood Transfusion Service?

**A.** Yes.

**Q.** That was about the same time as when Professor Contreras also joined the North London service, isn't it?

**A.** Yes, I have it in my mind we joined on the same day but I can't be sure of that.

**Q.** The Inquiry has heard evidence, as you know, from

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is that right?

**A.** Yes, including the provision -- the detection and provision of high titre immunoglobulins, like for HBIG, hepatitis B immunoglobulin, things like that.

**Q.** Can you tell us more about what a microbiologist works entails?

**A.** I suppose the call was the screening of the 1,000 or so donations a day that we would receive for an ever-increasing number of microbial agents, and then the confirmation of any reactives, the dealing with the donors who were found to be positive and, because our honorary consultant was Dr David Dane at the Middlesex, who had discovered what was known as the Dane particle, the actual infectious particle of hepatitis B virus, with his advice, I was able to set up counselling for HBsAg positive donors.

And we also did any follow-ups of possible post-transfusion infections. We did bacteriological screening of plasma before it was returned to the plasma -- before the red cells were returned to plasmapheresis donors, and we did a variety of projects associated with the development of microbial aspects. I kept registers of infected donors. We followed up -- I think I have already said -- things like jaundice enquiries and, eventually, I was

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1 a founder member of Serious Hazards of Transfusion.  
2 And so it was quite a wide-ranging set of remit,  
3 also developed automation, computerisation, because  
4 obviously when you are dealing with 4,000 or 5,000  
5 tests a day, the more you can streamline it, the more  
6 you can ensure an error free pathway and proper  
7 quality control, then the better.

8 Forgive me for sniffing. I'm afflicted with  
9 catarrh. I think it is the slight change in the  
10 weather.

11 Q. Please, don't worry.

12 I can see that something's happened with the  
13 picture. I just want to check that you can still see  
14 and hear us and that we have not lost you?

15 A. Yes, perfectly.

16 **SIR BRIAN LANGSTAFF:** We had a message that the bandwidth  
17 was low. That's Professor Barbara's bandwidth is low.  
18 I hope that will be rectified.

19 **MS FRASER BUTLIN:** Indeed.

20 A. I fear that we are at the end of the line in the  
21 country.

22 Q. Would it be fair then from that description of what  
23 your role entailed, would it be fair that you were  
24 then focused on the science involved in the testing of  
25 blood and in securing the best data in the issues of

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1 someone with a PhD, with a doctorate, in microbiology,  
2 to lead their microbiology laboratories?

3 A. Yes, that is correct. This was initiated by  
4 the previous director, Dr Tom Cleghorn, who very early  
5 on engaged Dr Dane as honorary consultant.

6 I think in my statement I may have described  
7 Tom Cleghorn as visionary because he recognised that,  
8 rather than being a nuisance that you had to get  
9 round, the problem of transfusion-transmitted  
10 infection, if anything, would grow bigger. So he was  
11 very far sighted, you know. And along came the whole  
12 range of agents that I have listed in one of the  
13 slides from my lectures that I have appended.

14 And I think Dr Cleghorn, with Dr Dane's advice,  
15 decided to have a bespoke microbiologist, or  
16 virologist, to head the department.

17 Q. That visionary view of Dr Cleghorn must have been in  
18 the early 70s, because your appointment was in 1974.  
19 Did he ever talk to you --

20 A. Yes.

21 Q. -- about what it was and why it was he felt this was  
22 something that was coming down the road?

23 A. Yes, in various conversations, the details of which of  
24 course I really don't remember, I became aware that  
25 he was certainly aware that the microbial aspect of

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1 testing that you were dealing with?

2 A. Yes, that was mainly the thrust of things but there  
3 were a whole variety of associated projects. I was --  
4 because of our help from Dr Dane, I was able to set up  
5 panels of infected donors, which other centres didn't  
6 do. We were able to, for example, plasmapherise high  
7 titre HBsAg positive donors so the plasma could be  
8 used for a project that was started by  
9 Professor Arie Zuckerman, to derive a British plasma  
10 derived hepatitis B vaccine, which didn't actually  
11 come to fruition. But there were those -- a lot of  
12 those sort of things.

13 Q. But would it be fair that your focus was on the  
14 science rather than the clinical side of the North  
15 London centre?

16 A. Yes.

17 Q. And you weren't, in your role, charged with making  
18 decisions about the broader policies that were in play  
19 in relation to which tests to introduce and when at  
20 the centre? That would have been for the director?

21 A. Yes, with the input from the evidence, the data we  
22 collected, the kit assessments. But the decision  
23 would be from the director, yes.

24 Q. It is right, isn't it, that the North London centre  
25 was the only Regional Transfusion Centre to employ

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1 transfusion was not going to be limited to bacterial  
2 screening of blood before it was returned to plasma  
3 donors, the syphilis testing that had been in place  
4 for donkey's years and, in the early 70s, the newly  
5 set up hepatitis B surface antigen testing. I think  
6 he was aware that blood was an ideal portal of entry  
7 for blood-borne infections to be transmitted to  
8 a patient, with blood being infused directly into  
9 their bloodstream.

10 Q. I have also been asked to ask you whether it would be  
11 fair that, because you were the only head of  
12 microbiology with a doctorate, that made you something  
13 of an anomaly within the Blood Service?

14 A. In that respect, I guess I was anomalous, yes.  
15 I didn't think of it that way.

16 Q. And, therefore, whether you were effectively working  
17 alone, with somewhat limited peer-to-peer interactions  
18 and engagement?

19 A. No. The people who headed the other blood centre,  
20 what used to be called AU testing labs, Australia  
21 antigen, were senior technical staff, initially known  
22 as technicians but then more appropriately called  
23 medical laboratory scientific officers, and I was in  
24 close contact and had various projects and derived  
25 a lot of good information and ideas from these

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1 colleagues and all the other 13 or so centres around  
 2 the country.  
 3 **Q.** Are you aware of any discussions with other Regional  
 4 Transfusion Centres about them also employing  
 5 postdoctoral microbiologists?  
 6 **A.** No, not in the early stages at all.  
 7 **Q.** In terms of the physical location of the North London  
 8 centre, it was physically very close to the PHLS,  
 9 wasn't it?  
 10 **A.** Crossed a fence, yes.  
 11 **Q.** And also --  
 12 **A.** To PHL.  
 13 **Q.** -- the CDSC?  
 14 **A.** Yes.  
 15 **Q.** How much interaction was there, firstly, between you  
 16 and the PHL?  
 17 **A.** A lot. And it grew considerably as the list of  
 18 potential microbial risks of transfusion also grew.  
 19 So I would be across the fence a lot and they would be  
 20 across the fence to us. The Public Health Lab, the  
 21 Communicable Disease Surveillance Centre, a lot of  
 22 interaction. That was one of the benefits of being  
 23 where we were.  
 24 **Q.** And those interactions, were they informal discussions  
 25 about things you were looking at or were they more

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1 around the same time.  
 2 **Q.** Just so that those who are listening understand what  
 3 a microplate is, it is a plate with wells in where  
 4 a small sample of serum can be put into each well and  
 5 labeled and then frozen down?  
 6 **A.** Yes. And the archive microplate I spotted in the  
 7 manufacturer's catalogues, what was called a deep well  
 8 microplate which took one millilitre, 1ml, and of  
 9 course that was a godsend. And you could cap it as  
 10 well.  
 11 **Q.** Did the North London centre seek to encourage other  
 12 centres to set up a similar archive of samples?  
 13 **A.** I don't think there was formal encouragement. There  
 14 was a lot of interaction and contact between the  
 15 microbiologists at the centres, and we would set up  
 16 seminars and we would discuss things like  
 17 serum archives. So I think that ideas did catch on.  
 18 And it was a two-way thing: we took on ideas, other  
 19 centres took on ideas.  
 20 **Q.** Moving on then to post-transfusion hepatitis and the  
 21 screening test for hepatitis B.  
 22 In the late 1970s, if your lab identified  
 23 a donation as testing positive in a screening test for  
 24 hepatitis B, can you talk us through the process that  
 25 was then followed? Just broadly.

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1 formal meetings?  
 2 **A.** It was a mixture. There was lots of informal kicking  
 3 ideas around. There were also formal committees,  
 4 which I know you have got listed and I have forgotten  
 5 most of the ones I was on or chaired, and there were  
 6 joint projects that we would set up. For example, the  
 7 kit evaluation group involved Dr John Parry, now  
 8 Professor John Parry, in doing the seroconversion  
 9 panel assessments that I have described in my  
 10 statement.  
 11 **Q.** Before we get there, I want to discuss with you  
 12 a little bit more about some of the things that were  
 13 set up in the North London centre. At some point in  
 14 the centre you set up an archive of serum samples.  
 15 **A.** Yes.  
 16 **Q.** Do you recall when that archive was established?  
 17 **A.** Not exactly. It was reasonably early on and it was  
 18 facilitated by automation, automated samplers, and  
 19 the use of a microplate, 12x8, a 96-well microplate --  
 20 again, there is a slide in my package of stuff --  
 21 which meant that we could store large amounts of  
 22 samples securely but in a small space, and with data  
 23 retrieval because they were barcode labeled. So it  
 24 was quite early on and it did serve as a model,  
 25 I know, for other centres. The Scots had started it

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1 **A.** Broadly, okay. Do stop me if I get carried away by my  
 2 pet subjects.  
 3 You would do a test for HBsAg and if it was  
 4 initially reactive -- we never called them "positive"  
 5 until they were confirmed -- if it was initially  
 6 reactive we would repeat on that sample in duplicate  
 7 and if one or both of those were also reactive, we  
 8 would get a snippet of bleed line from that pack and  
 9 test the bleed line as well to make sure that we got  
 10 the right sample for the right pack. Then, those  
 11 samples at that time, before we had our own reference  
 12 lab set up, they would go to the Middlesex Hospital  
 13 for confirmatory testing. There would be  
 14 neutralisation tests done that would confirm that, by  
 15 ablating the reaction with specific anti-HBs, you  
 16 could say that that reaction was definitely HBsAg.  
 17 You would do anti-HBc testing and you would check if  
 18 it was of the IgG or IgM antibody class and if it was  
 19 IgM, you would know it was a recent or an acute  
 20 infection.  
 21 **Q.** At some point in that process would the donation be  
 22 held so that it didn't leave the centre?  
 23 **A.** As soon as there was a repeat reactive result, which  
 24 came within the same day, that donation would be held.  
 25 No donation would be released until my lab would have

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1 cleared them and any initial reactive would not have  
 2 been cleared. A repeat reactive would have been held  
 3 and my staff would collect the donation from the blood  
 4 bank and store it securely in the fridge.  
 5 **Q.** Thinking back to the archive sample, once that archive  
 6 was available, if a donation tested -- was repeatedly  
 7 reactive, would you then go back to the stored samples  
 8 to check them for the same donor?  
 9 **A.** No.  
 10 **Q.** Why not?  
 11 **A.** No, we would save the stored sample for any future  
 12 use. If there was a discrepancy between the test  
 13 sample and the snippet from the bag, then we would go  
 14 back to the archive sample.  
 15 **Q.** Sorry, Professor Barbara, that was my question that  
 16 wasn't clear enough. If you have a donor who is  
 17 a repeat donor and the current donation has tested --  
 18 **A.** Sorry, not a repeat reactive?  
 19 **Q.** You have got a current donor who has tested positive,  
 20 would you go back to their historic prior donations in  
 21 the archive? Apologies, my question wasn't clear.  
 22 **A.** Forgive me. I thought you were meaning a repeatably  
 23 reactive sample, I'm sorry.  
 24 Yes, absolutely we would go back to the archive  
 25 sample and we'd, first of all, re-test in my lab in

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1 **A.** Yes. We would ask the clinician if they wouldn't mind  
 2 sending us a sample. We would also ask if they got  
 3 a pre-donation or pre-transfusion sample because,  
 4 sometimes, we would be following up a potential case  
 5 only to find that the recipient had a pre-existing HBV  
 6 infection and then, when we received those samples, we  
 7 would do the battery of tests I've described to check  
 8 whether they were infected, and because the serology  
 9 for hep B was so extensive, had been worked out early  
 10 on, we would be able to say what stage of the  
 11 infection that recipient was in.  
 12 **Q.** When you say the "battery of tests", that would  
 13 include a hepatitis B core antibody test?  
 14 **A.** Yes, IgG, IgM and Hl antigen and anti-HBe. They would  
 15 also do ALT and AST.  
 16 **Q.** Could we turn, then, to WITN6989011, please.  
 17 **A.** Sorry, will this come up on my screen?  
 18 **Q.** It should come up on your screen, Professor Barbara.  
 19 Just give it a moment and please say if it doesn't.  
 20 **A.** Forgive me, I will take my glasses off so I can read  
 21 it more easily.  
 22 **Q.** This is a document, an article, that you wrote with  
 23 Moya Briggs. It is dated at the top September 1982,  
 24 headed "Post-transfusion hepatitis in North London in  
 25 1981; a review", and we can see in the first

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1 case we had made an error and I'm happy to say --  
 2 another topic -- but we could show that we made very  
 3 few testing errors. If we couldn't find any HBsAg, we  
 4 would send the archive sample to the Middlesex and  
 5 they would, in the early days, have access to  
 6 radioimmunoassay, which subsequently we were able to  
 7 develop for our own use, they would have that more  
 8 sensitive test, they would check it for anti-core and  
 9 anti-core IgM and then, if there was any hint that it  
 10 was infectious, I would inform the hospital and we  
 11 would -- I or Dr Hewitt -- and we would request  
 12 samples from the recipient of that donation,  
 13 preferably samples, rather than them testing it,  
 14 because our reference laboratory had a good range of  
 15 specialist tests to get to the bottom of the problem.  
 16 **Q.** Thinking about the reverse situation,  
 17 Professor Barbara, the centre also operated the  
 18 J system that the Inquiry has heard about, didn't it,  
 19 in relation to post-transfusion hepatitis reports?  
 20 **A.** When you say "J", there was "JH", jaundice history,  
 21 and "JE", jaundice enquiry. So, yes, we operated  
 22 a JE system.  
 23 **Q.** So if a clinician reported that a recipient of  
 24 a transfusion had post-transfusion hepatitis, you  
 25 would then make enquiries into what had happened?

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1 paragraph:  
 2 "At the hepatitis workshop held in Scotland last  
 3 year we presented a review of post-transfusion hepatitis  
 4 in North London during the previous ten years. The  
 5 present report provides details of our 1981 PTH  
 6 enquiries."  
 7 Then, in the next paragraph, we can see that  
 8 there were 16 PTH reports received in 1981.  
 9 **A.** Yes, "Two of the 16".  
 10 **Q.** Then, if we turn onto page 6 of the document, and we  
 11 have the heading "Conclusion" --  
 12 **A.** Yes.  
 13 **Q.** -- could we just zoom into the conclusion part. We  
 14 will just zoom into the conclusion so it is a bit  
 15 easier to see.  
 16 It reads this:  
 17 "Our enquiries into PTH during 1981 illustrate the  
 18 diversity and complexity of this work."  
 19 You were referring there, weren't you, to the  
 20 number of tests that were involved and the  
 21 difficulties in tracing what the root cause of the PTH  
 22 was, weren't you?  
 23 **A.** Yes, and the differentiation of which agent may have  
 24 been responsible, if at all.  
 25 **Q.** Then we see this, at the bottom of the page:

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1 "We are trying to encourage the hospitals we  
2 supply to report all PTH in the hope we can get more  
3 information about non-A, non-B as a cause of PTH in the  
4 UK."

5 A. Yes.

6 Q. Is it fair then, Professor Barbara, that in 1981 you  
7 recognised that not all cases of post-transfusion  
8 hepatitis were being reported to you?

9 A. Yes. If I could amplify slightly, I think even  
10 earlier we were aware of two things, that not all  
11 post-transfusion hepatitis was due to hepatitis B and  
12 also that not all cases were necessarily being  
13 reported and so with Marcela -- with  
14 Professor Contreras and Dr Hewitt and other  
15 colleagues, we did set about quite regularly updating,  
16 doing seminars for our hospitals, to impress on them  
17 the value of telling us about any possible cases, in  
18 part so that we could prevent any infectious donor  
19 from infecting other recipients.

20 And, if I could also add that you asked about my  
21 remit earlier, this aspect of education and this  
22 aspect of R&D, for example, to analyse the cases of  
23 post-transfusion hepatitis B reports, that was  
24 an important part of what I did and, of course, this  
25 was helped by being a bespoke virologist or

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1 So if we carry on to page 3 we have a table which is  
2 much more helpful, I think.

3 A. Okay.

4 Q. If we can look at that table, we can see the totals  
5 across 1976, 1977, 1978, 1979 and 1980, the totals of  
6 the post-transfusion hepatitis reported cases?

7 A. Yes.

8 Q. It is right, isn't it, Professor Barbara, that this  
9 study depended on the post-transfusion hepatitis being  
10 reported to you?

11 A. Yes, absolutely.

12 Q. If we then go down to the next paragraph, please,  
13 below table 2.

14 A. May I add that that, of course, was why we encouraged  
15 hospitals to report anything that they were suspicious  
16 about, so that we would get a clearer picture of what  
17 the situation actually was.

18 Q. We can see in the paragraph highlighted:

19 "Most of our cases of post-transfusion hepatitis  
20 are based on reports of clinical jaundice: of 15 cases  
21 reported during 1977-80 this was the presenting factor  
22 in 13. In two of the cases where the patient was not  
23 jaundiced one had chronic hepatitis and subsequently  
24 became [hepatitis B surface antigen] positive, while the  
25 other recipient 'felt unwell', and had raised bilirubin

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1 microbiologist.

2 Q. We saw there a moment ago a reference to a study that  
3 looked at the -- at a longer period of  
4 post-transfusion hepatitis reports. I just want to go  
5 to that document.

6 CBLA0001301, please. If we zoom into the top of  
7 it, so it is a little bit easier to read on the  
8 screen, we can see that it is a short communication in  
9 the Medical Laboratory Sciences journal 1981 by you  
10 and Moya Briggs again.

11 Then if we go down to the body of the text on  
12 this page, please, we can see that you are presenting:

13 "... preliminary results of [your] approach to  
14 the examination of the extent of post-transfusion  
15 hepatitis of the non-A, non-B type in the region  
16 served by the North London Blood Transfusion Centre."

17 If we go further down in this paragraph, we can  
18 see it reads:

19 "The numbers of cases of post-transfusion  
20 hepatitis reported to us during the last 10 years are  
21 shown in [Figure] 1."

22 A. I'm afraid I don't have that.

23 Q. It is okay, we are going to just turn the page, where  
24 we see Figure 1, which is at the top of the page,  
25 which is rather difficult to read, Professor Barbara.

18

1 and liver enzyme levels. In two cases where blood from  
2 donors incubating hepatitis B was transfused, both  
3 recipients became [hepatitis B e antigen] positive  
4 'inapparent' carriers of [the surface antigen] though  
5 with raised liver enzymes."

6 Just pausing there. It is right, as well, isn't  
7 it that, as well as being entirely dependent on  
8 post-transfusion hepatitis being reported to you,  
9 those reports would only be made if someone had  
10 clinical jaundice or something else to cause the  
11 clinicians to suspect there was an issue?

12 A. Yes.

13 Q. Then if we go to the final paragraph of this paper, we  
14 can see that the conclusion in the last paragraph is:

15 "The clinical importance of chronic aspects of  
16 non-A, non-B hepatitis is not yet clear, and much  
17 chronic non-A, non-B hepatitis resolves itself within  
18 2 years. Probably post-transfusion hepatitis B is more  
19 important than the non-A, non-B variety, since not only  
20 does it appear to be the more severe infection but, if  
21 transmitted to a patient in hospital, it may be the  
22 source of more obvious infections among the staff. Even  
23 with sensitive screening methods currently available for  
24 testing donor blood, the hospital reports of  
25 post-transfusion hepatitis are still important for the

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1 prevention of further cases caused by the same donor."  
 2 A. Yes.  
 3 Q. Your conclusion there, that post-transfusion  
 4 hepatitis B is more important than the non-A, non-B  
 5 variety, was that based on the number of  
 6 post-transfusion hepatitis cases that were being  
 7 reported to you, where it wasn't hepatitis B?  
 8 A. Sorry, I couldn't quite catch the last part of your  
 9 question.  
 10 Q. Let me re-phrase it. Your conclusion here is that  
 11 post-transfusion hepatitis B is probably more  
 12 important than non-A, non-B hepatitis. Given that you  
 13 were reliant on reports of post-transfusion hepatitis  
 14 and given that the majority of those post-transfusion  
 15 hepatitis reports indicated hepatitis B positivity,  
 16 was that part of the reason why you concluded that  
 17 hepatitis B was more important than non-A, non-B?  
 18 A. Yes, I understand what you are saying now.  
 19 Yes, I suppose the clinicians were more -- would  
 20 more readily report a possible post-transfusion  
 21 hepatitis if their laboratory had found hepatitis B  
 22 surface antigen. So there might have been a bias in  
 23 terms of the number of cases of post-transfusion B  
 24 reported. I think also that non-A, non-B, as we knew  
 25 it then, would often generally be milder and might not

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1 about the seriousness of non-A, non-B shifted?  
 2 A. I can't pinpoint that. Forgive me, my memory is not  
 3 that clear. What I would say is that as the first  
 4 serological tests became available from Chiron and  
 5 Ortho, although their specificity and predictive value  
 6 in a low incidence and prevalence population was poor,  
 7 in a patient proportion it had more predictive value  
 8 and one was able to read reports of hepatitis C being  
 9 detected in patients with hepatocellular carcinoma or  
 10 chronic liver disease. So it was latterly that the  
 11 awareness of the significance of what we knew as  
 12 non-A, non-B became clearer.  
 13 Sorry, does that make sense?  
 14 Q. Thank you, Professor. Can I take you to a paper that  
 15 the Inquiry has looked at a number of times,  
 16 PRSE0003622, just to see if this assists.  
 17 It is a paper that was published in The Lancet  
 18 on 16 September 1978 by Professor Preston, headed  
 19 "Percutaneous Liver Biopsy and Chronic Liver Disease  
 20 in Haemophiliacs", where it was reported that there  
 21 had been systematic screening of 47 haemophiliacs in  
 22 Sheffield and liver biopsies had been carried out. We  
 23 see in the middle of the paragraph that:  
 24 "A wide spectrum of chronic liver disease was  
 25 demonstrated, including chronic aggressive hepatitis and

23

1 have been picked up, unless they were doing liver  
 2 function tests.  
 3 And certainly there was quite a general feeling  
 4 in Blood Service circles that hepatitis B was more  
 5 severe, could kill you, you could get fulminant  
 6 hepatitis because of the very vigorous antibody  
 7 response that, paradoxically, would prove fatal in  
 8 a small number of cases. So I think those were the  
 9 factors that made us feel that B was more severe than  
 10 non-A, non-B.  
 11 Q. It is right, isn't it, that asymptomatic non-A, non-B,  
 12 at least initially asymptomatic non-A, non-B cases,  
 13 would be missed entirely or potentially missed  
 14 entirely by this study?  
 15 A. Yes. The American studies would have funded  
 16 prospective work, some brilliant work by Dr Harvey  
 17 Alter, who would follow up recipients with liver  
 18 enzyme studies. So they would see the evidence for  
 19 non-A, non-B.  
 20 Q. You have said in your statement that, at that time,  
 21 you didn't consider non-A, non-B as something that was  
 22 particularly serious in terms of the clinical  
 23 condition; is that right?  
 24 A. Not as serious as hepatitis B, yes, I felt that.  
 25 Q. Do you have any sense of the timeframes when your view

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1 cirrhosis."  
 2 Was that a paper that had crossed your desk that  
 3 you were aware of in the late '70s?  
 4 A. It may well have. I have to be honest, I didn't  
 5 recall it until I saw it in the documents that you  
 6 kindly sent to me.  
 7 Q. So you are not sure if, at the time, that was  
 8 something you were familiar with, Professor Preston's  
 9 work?  
 10 A. It was very likely I was but there were an enormous  
 11 number of publications that I would have been involved  
 12 with and reading, so I certainly was aware of  
 13 Professor Preston and the work he was doing and I have  
 14 a feeling, a sort of recollection, that there was  
 15 a general -- I had a general awareness but I can't say  
 16 definitively that I read that paper; I probably did.  
 17 Q. I'm asked to ask you whether, with the benefit of  
 18 hindsight, do you think that the North London centre  
 19 or you were too slow to recognise the seriousness of  
 20 the non-A, non-B hepatitis?  
 21 A. I think that once a specific test -- and I say  
 22 specific in the general term -- was able to identify  
 23 the virus in patients significantly affected, I think  
 24 we were pretty quick to be aware then. I think  
 25 beforehand, yes, there may have been a feeling that it

24

1 was less important than hepatitis B.  
 2 And, I have to be honest, in terms of severity,  
 3 chronic condition, carrier state, sexual transmission,  
 4 transmission from mother to child, I still feel that  
 5 hepatitis B is a more aggressive virus.  
 6 **Q.** Can we then look at some of the testing that the  
 7 centre was doing in relation to post-transfusion  
 8 hepatitis. If we look at NHBT0000030\_007. It is  
 9 a short communication in Vox Sanguinis in 1983 that  
 10 you wrote in Dr Contreras and Dr Moya Briggs.  
 11 **A.** Moya didn't have a doctorate, although she would have  
 12 deserved one.  
 13 **Q.** Apologies.  
 14 It is headed "A Donor Implicated in Two Cases of  
 15 Post-Transfusion Non-A, Non-B Hepatitis". I will read  
 16 some of it and then I'll pause and ask you questions  
 17 about it:  
 18 "In the absence of specific tests for non-A, non-B  
 19 hepatitis viruses, evidence for their involvement in  
 20 [post-transfusion hepatitis] can only be  
 21 circumstantial."  
 22 The report then discusses a particular donation:  
 23 "A UK-born male had donated one of only two units  
 24 given as whole blood to a patient who became jaundiced  
 25 6 weeks after transfusion. Serum taken from this

25

1 opinion, the permanent exclusion of this donor from  
 2 donating blood."  
 3 **A.** Yes.  
 4 **SIR BRIAN LANGSTAFF:** You add at the end of that --  
 5 **MS FRASER BUTLIN:** I'm going to come to that in a moment,  
 6 sir.  
 7 **SIR BRIAN LANGSTAFF:** You are going to deal with the last  
 8 sentence?  
 9 **MS FRASER BUTLIN:** I will, absolutely.  
 10 **SIR BRIAN LANGSTAFF:** Very well.  
 11 **MS FRASER BUTLIN:** Before we get there, I want to deal  
 12 with one other point if I may, sir.  
 13 Just before we look at the last sentence, I just  
 14 want to be clear, Professor Barbara, that when you  
 15 were dealing with post-transfusion hepatitis,  
 16 situations like this, you were testing samples for  
 17 hepatitis B core antibody, hepatitis B surface  
 18 antigen, ALT and AST; is that right?  
 19 **A.** Yes.  
 20 **Q.** And would it be fair --  
 21 **A.** That would be -- sorry.  
 22 **Q.** Go for it.  
 23 **A.** I'm sorry. I was going to say, because there was, if  
 24 you like, a higher level of potential -- sorry, I'm  
 25 tongue-tied for the moment.

27

1 patient at the time of jaundice was negative by RIA for  
 2 [hepatitis B surface antigen, hepatitis B core antibody  
 3 and hepatitis A], but weakly positive for [hepatitis B  
 4 surface antibody]. After notification of this case of  
 5 [post-transfusion hepatitis], the two donors involved  
 6 were resampled ... Serum from the other donor was  
 7 negative by RIA for [hepatitis B surface antigen] but  
 8 positive for [hepatitis B core antibody] (IgM class  
 9 negative) and [hepatitis B surface antibody]. This  
 10 donor had also mildly elevated enzyme levels."  
 11 You give the figures for the ALT and the AST:  
 12 "Although the implication of the second donor was  
 13 only presumptive, he was asked to refrain from blood  
 14 donation until further notice ..."  
 15 You then explain that, because of an error where  
 16 the donor was told he was safe to donate again, he  
 17 then donated seven months later, and the recipient of  
 18 that donation was identified as having  
 19 post-transfusion hepatitis.  
 20 Then if we go over the page you set out the  
 21 testing of that subsequent donation and you conclude  
 22 at the bottom of the page:  
 23 "Nevertheless, the situation described (a donor  
 24 who is both anti-HBs and anti-HBc positive and is  
 25 suspected of a possible link with PTH) justifies, in our

26

1 Because it has been a report of post-transfusion  
 2 hepatitis, there was, if you like, a smoking gun that  
 3 made it more indicative to do these supplementary  
 4 tests, which is why we would have done those. They  
 5 wouldn't have been tests that we would have done on  
 6 any donor, it was just because this donor had been one  
 7 of those, and potentially implicated in a case of  
 8 post-transfusion non-A, non-B in a recipient.  
 9 Forgive me for interrupting.  
 10 **Q.** No, I think there is a slight delay on the system  
 11 which is making it slightly difficult, so please don't  
 12 apologise for interrupting at all.  
 13 Essentially, what we see here is, isn't it, that  
 14 you are using those tests as a surrogate for non-A,  
 15 non-B hepatitis testing?  
 16 **A.** Yes.  
 17 **Q.** Then, if we come to the last sentence of the article,  
 18 you note that:  
 19 "This procedure is reminiscent of measures taken  
 20 for the prevention of PTH B before HBsAg tests became  
 21 available."  
 22 **A.** Yes. I of course wasn't in service then, but I was  
 23 aware from the literature and from the discussions  
 24 with Dr Dane and Dr Moya Briggs that -- just this kind  
 25 of thing, that an indirect surrogate approach would

28



1 have been the only thing they had when investigating  
 2 post-transfusion hep B. Or likely hep B.  
 3 **Q.** But it is right, isn't it, that these tests weren't  
 4 used by the centre across the board to screen  
 5 routinely on a surrogate basis?  
 6 **A.** That is right. Because, if you like, the report of  
 7 possible transmission or infection of a recipient  
 8 enabled you to focus on a very small number of donors  
 9 that would benefit from these indirect non-specific  
 10 and surrogate tests.  
 11 **Q.** I want to pick up that point a little bit later  
 12 because it comes later in the chronology again. And  
 13 we will address it again in relation to hepatitis C  
 14 a little bit later today.  
 15 Can I move now to your understanding of HIV.  
 16 You have said in your statement that  
 17 your understanding of HIV shifted over time, but that  
 18 at first you didn't link it to blood transfusion. Is  
 19 that right?  
 20 **A.** That is correct. Do you want me to expand on this  
 21 slightly?  
 22 **Q.** Yes, please do.  
 23 **A.** When an immune deficiency syndrome was initially  
 24 described with reports in MMWR, Morbidity Mortality  
 25 Weekly Reports from the US CDC. It was very difficult

29

1 they'd heard that two haemophilia patients had  
 2 developed AIDS -- or I think it was called GRID5 at  
 3 the time, gay-related immune deficiency syndrome. And  
 4 I immediately said, "Well, I suppose they are  
 5 homosexual men", and he said, "No, don't think so,  
 6 married with kids", and the chill realisation that  
 7 this was a virus and, as such, would have been  
 8 transmissible by blood and even by fractionated  
 9 products, because the process of fractionation to make  
 10 Factor VIII would inactivate parasites and bacteria  
 11 but didn't inactivate the acellular virus particles,  
 12 any acellular virus particles. So it was, I think --  
 13 I don't know, about 1983, that -- this was a phone  
 14 call that absolutely stuck in my mind, and still does.  
 15 I don't remember the date. I'm not good on dates  
 16 I suppose.  
 17 **Q.** Can I try and assist you with the date,  
 18 Professor Barbara? The Inquiry has heard evidence of  
 19 that CDC report being on 16 July 1982.  
 20 To the best of your recollection, do you think  
 21 that Dr Roger Dodd phoned you fairly swiftly after  
 22 that CDC report.  
 23 **A.** That seems very likely.  
 24 **Q.** So it is more likely to have been around in July 1982  
 25 than the 1983 that you have taken a guess at?

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1 to know -- to make sense of that. It appeared to be  
 2 eventually due to an infectious agent. Certainly it  
 3 was indirectly picked up by CDC because of the  
 4 increased incidence of pneumocystis carinii and the  
 5 increased dispensing of pentamidine, which was a drug  
 6 used to treat pneumocystis.  
 7 Initially people wondered whether it could be  
 8 some sort of agent like swine fever that had gone  
 9 rogue or whether it was due to the use of recreational  
 10 drugs called poppers, or even if it was due to  
 11 a suppression of the immune system in the passive  
 12 partner in a male homosexual relationship, being  
 13 exposed in delicate mucosal areas to large amounts of  
 14 the active partner's semen.  
 15 **Q.** Your view shifted somewhat, didn't it,  
 16 Professor Barbara, when you received a call from  
 17 Dr Roger Dodd?  
 18 **A.** Yes.  
 19 **Q.** He was the head of American Red Cross transfusion  
 20 infection laboratories?  
 21 **A.** Yes, he was sort of my "oppo", my opposite number over  
 22 there. And I knew Roger very well, he was  
 23 an expat Brit, a virologist, and we had worked  
 24 together and he was somebody that I knew and could  
 25 talk to freely. And he phoned me one day to say that

30

1 **A.** Yes. Looking at it with the report data, yes.  
 2 **Q.** And so at that point I think your evidence is that you  
 3 understood HTLV-III, AIDS, the name that it was given  
 4 at the time, to be transmitted by blood to the best of  
 5 your understanding?  
 6 **A.** To be potentially transmitted by blood, yes. It  
 7 seemed a real possibility. A frightening possibility  
 8 but a real one.  
 9 **Q.** Moving forwards in time. You were involved in the  
 10 drafting of the first AIDS leaflet together with  
 11 Dr Tom Davies; is that right?  
 12 **A.** Dr Davies, yes.  
 13 **Q.** Could we have NHBT0020668, please. We have a letter  
 14 from Dr Wagstaff from July 1983 enclosing a copy of  
 15 the final form of the leaflet. If we then go over the  
 16 page we have a copy of the leaflet.  
 17 Is this the version of the leaflet that you were  
 18 involved in? As far as you recall?  
 19 **A.** Can I have it a bit bigger, please?  
 20 **Q.** Of course.  
 21 **A.** Yes, I believe I was involved in this, and more  
 22 specifically in the little fold-over leaflet, the  
 23 smaller-sized one, about, I don't know, eight or nine  
 24 inches by four inches, that continually evolved. But,  
 25 yes, I would have had involvement in this.

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1 Q. If we look under the heading "Who is at risk from  
2 AIDS?", we see three groups of people who are said to  
3 appear to be particularly susceptible:  
4 "(1) Homosexual men who have many different  
5 partners.  
6 "(2) Drug addicts, male and female, using  
7 injections.  
8 "(3) Sexual contacts of people suffering from  
9 AIDS."  
10 Firstly, in relation to the first category,  
11 "Homosexual men who have many different partners", was  
12 that something that you were involved in drafting,  
13 that wording?  
14 A. Yes, I would have been involved. That wording  
15 wouldn't have been down to me. There was a reluctance  
16 amongst RTD transfusion centre directors to be prying,  
17 if you like, into donors' sexual habits.  
18 And as an aside, I must say that, since the  
19 majority of transfusion directors had a haematological  
20 background, they didn't, as it were, think like  
21 a microbiologist or a virologist, where sex and drugs  
22 were something that I would have always been aware of  
23 as potential routes of transmission of agents, and,  
24 you know, the overlap of sex and drugs and blood  
25 donation I was aware of. So there was a reluctance to

33

1 the word "drug addict", male and female, and I agree  
2 the phrase "using injections" implies now or currently  
3 or recently. So, again, with hindsight, I would have  
4 preferred something stronger. But as I've said,  
5 I would have been a part input into this document,  
6 which would have had a lot of input from various  
7 people, often more senior than myself.  
8 Q. Then if we go down to the heading "Can AIDS be  
9 transmitted" --  
10 SIR BRIAN LANGSTAFF: Just before you do that. We picked  
11 up yesterday when Dr Wagstaff was giving evidence that  
12 the first of those categories, "Homosexual men who  
13 have many different partners", is just as you have  
14 described in respect of the word "using", it is  
15 talking about now, as opposed to the past. It is in  
16 present tense.  
17 So also, arguably, is sexual contacts of people  
18 suffering from AIDS. From your perspective, would  
19 the risk actually be not just those who are currently  
20 engaged in sex with (a) many different partners,  
21 men -- being homosexual, those who are currently using  
22 injections, and those who are currently a sexual  
23 contact of someone who has AIDS, but people who have  
24 been, to their knowledge, in the past?  
25 A. Absolutely, Sir Brian. I think I would have preferred

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1 pry too deeply. And also it made sense at the time to  
2 recognise that, on a statistical basis, the more  
3 partners you have the more likely you are to encounter  
4 a partner who is infected with HIV.  
5 Q. But it is right, isn't it, that this might suggest to  
6 a man in a stable partnership with another man, that  
7 they were still eligible to donate?  
8 A. Yes.  
9 Q. With the benefit of --  
10 A. Yes, I --  
11 Q. Sorry, go ahead.  
12 A. Sorry. No, I would certainly have had that feeling  
13 myself, yes.  
14 Q. And whether at the time or with the benefit of  
15 hindsight, do you think it would have been better for  
16 this to have said "Men who have had sex with men"?  
17 A. Yes, I do.  
18 Q. If we then look at the second group "Drug addicts,  
19 male and female, using injections", might this also  
20 suggest that those who have perhaps injected drugs  
21 once or twice, would similarly not be caught by this  
22 definition?  
23 A. Yes, I think -- again, with hindsight -- intravenous  
24 drug users, either male or female, would have been the  
25 cover-all, but at that time one was able to use just

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1 to have that element strengthened. Of course, going  
2 back to a time when we now know that HIV was  
3 circulating from the early 80s, in smaller numbers  
4 probably even earlier, but for me it wasn't a current  
5 or a recent because a past event might have caused the  
6 damage of infection. So yes, I totally agree with  
7 you.

8 SIR BRIAN LANGSTAFF: It was a question really, rather  
9 than an observation, but it is, I suppose, also  
10 an observation.

11 Thank you.

12 MS FRASER BUTLIN: If we can go down to the heading "Can  
13 AIDS be transmitted by transfusion of blood and blood  
14 products?"

15 The answer there is given:  
16 "Almost certainly yes."

17 The Inquiry has heard evidence from Dr Walford  
18 about the original draft of the leaflet that she and  
19 Dr Gunson prepared, just before you worked on it, and  
20 they had answered that question simply as "Yes, it  
21 can". Can you recall why that wording was changed  
22 from "Yes, it can" to "Almost certainly yes"?

23 A. I have to be honest, no, I can't recall that at this  
24 stage, or even whether I was involved in changing that  
25 particular aspect. I'm sorry.

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1 Q. Again, with the benefit of hindsight, or perhaps from  
 2 your understanding at the time, it would have been  
 3 more accurate, wouldn't it, if it had simply said,  
 4 "Yes, it can"?  
 5 A. Yes. I mean, you might have couched it as "There are  
 6 reports of transmission by transfusion".  
 7 **MS FRASER BUTLIN:** Thank you.  
 8 Sir, I'm about to move on to another topic and  
 9 I note the time. I wonder if now is a good time to  
 10 take a break?  
 11 **SIR BRIAN LANGSTAFF:** Yes. We will do that and come back  
 12 at 11.40 am.  
 13 Can I just say, Professor, what I say to all  
 14 witnesses at this stage which is that you are giving  
 15 evidence, what you may not do is talk about the  
 16 evidence you have given or anything which you think it  
 17 you may yet be asked about in evidence with anyone,  
 18 whoever it is, you can talk about anything else you  
 19 like. But I hope you have a satisfying break and we  
 20 will be back at 11.40 am, if you please.  
 21 A. Yes, sir. I understand that. Thank you very much.  
 22 (11.10 am)  
 23 (A short break)  
 24 (11.40 am)  
 25 **SIR BRIAN LANGSTAFF:** Yes.

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1 such as [hepatitis B core] antibody will detect some  
 2 patients early enough in the stage of their disease to  
 3 remove the risk of transmission of infection by  
 4 transfusion."  
 5 There is then reference to what has become known  
 6 as the San Francisco baby case. Then he says:  
 7 "I think it will be worthwhile investigating the  
 8 possible use of screening tests which might be found to  
 9 be suitable at a later date, but I think the only  
 10 effective way will be to use some sort of questionnaire  
 11 to donors, and to rely on their altruism and honesty  
 12 with regard to homosexual exposure."  
 13 You, as I understand it, Professor Barbara,  
 14 didn't agree with Dr Craske's view of the utility of  
 15 hepatitis B core antibody testing in relation to  
 16 screening for AIDS; is that right?  
 17 A. Could we just go back to that bit of the para where he  
 18 makes that comment?  
 19 Q. Indeed, it is the second paragraph.  
 20 A. Because the wording is important:  
 21 "... I am doubtful whether the use of  
 22 a screening test such as [anti-HBc] will detect some  
 23 patients early enough in the stage of their disease  
 24 ..."  
 25 **SIR BRIAN LANGSTAFF:** I think he must mean, must he not,

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1 **MS FRASER BUTLIN:** Thank you, sir. Could we have  
 2 NHBTO017448\_004, please. This is a letter, perhaps if  
 3 we can just zoom into the top half, thank you. This  
 4 is a letter from Dr Craske to you dated 12 May 1983.  
 5 Then if we go down to the second and third paragraphs,  
 6 please, we can see that Dr Craske tells you that:  
 7 "From a recent review of the literature I have  
 8 made, I am doubtful whether the use of a screening test  
 9 such as [hepatitis B core] antibody will detect some  
 10 patients early enough in the stage of their disease to  
 11 remove the risk of transmission of infection by  
 12 transfusion."  
 13 In relation to -- sorry, let me start again.  
 14 (Pause)  
 15 **SIR BRIAN LANGSTAFF:** Take your time.  
 16 **MS FRASER BUTLIN:** If I might just get a glass of water  
 17 that will help. Thank you.  
 18 Apologies, Professor Barbara. This is a letter  
 19 from Dr Craske to you in May 1983 and it is headed  
 20 "Screening of Blood Donors to Remove the Risk of  
 21 Transmission of the Acquired Immune Deficiency  
 22 Syndrome AIDS", and Dr Craske writes, in the second  
 23 paragraph:  
 24 "From a recent review of the literature I have  
 25 made, I am doubtful whether the use of a screening test

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1 some donors? Because this is talking about the risk  
 2 of passing it on, isn't it? Have I got it wrong?  
 3 A. Sorry, Sir Brian, I missed the first part of your  
 4 question.  
 5 **SIR BRIAN LANGSTAFF:** I'm sorry. I will just remove my  
 6 mask. I was just wondering about the use of the word  
 7 "patients". Because what he is talking about,  
 8 I think, is avoiding the risk of a donor with AIDS or  
 9 with HIV infection -- with an infection which may  
 10 transmit AIDS, passing it on, and when the word  
 11 "patients" is used here, it is talking about donors  
 12 presumably, is it?  
 13 A. I think so, Sir Brian. I think John Craske is using  
 14 the word "patient" as a sort of generic term,  
 15 a potential donor who might actually be a patient.  
 16 **SIR BRIAN LANGSTAFF:** Yes.  
 17 A. But my -- what I didn't agree with is the aspect that  
 18 we are not aiming to detect a donor who is undergoing  
 19 hepatitis B infection, but we are looking at anti-HBc  
 20 in the context of a phrase that virologists use about  
 21 viruses running in packs, a common source of infection  
 22 for various agents, like intravenous drug use. And my  
 23 feeling was that there was some possible merit,  
 24 certainly worth considering, of anti-HBc as  
 25 an indication of past or present infection with

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1 an agent that could, as it were, co-infect with HIV.  
 2 **MS FRASER BUTLIN:** We have already heard --  
 3 **A.** Sorry -- does that make sense?  
 4 **Q.** Thank you, Professor Barbara.  
 5 We have already heard that the North London  
 6 centre introduced confidential questionnaires given to  
 7 their donors and that those questionnaires included  
 8 a box that a donor could tick to say "Please, don't  
 9 use my blood for donation".  
 10 You then tested those donations, didn't you,  
 11 that came from those donors who ticked that box?  
 12 **A.** Yes, and we would have looked at anti-HBc.  
 13 **Q.** What did you find in relation to the correlation  
 14 between people ticking that box and the results of  
 15 hepatitis B core antibody testing?  
 16 **A.** I don't remember the exact figures. Doubtless it is  
 17 in our literature somewhere, either yours or mine or  
 18 both, but there was an increased rate of anti-HBc in  
 19 donors ticking the box.  
 20 **Q.** So it might suggest that hepatitis B core antibody  
 21 testing was a useful marker to eliminate donors who  
 22 shouldn't have donated?  
 23 **A.** In the context of HIV, it was a potential surrogate  
 24 test that could be considered but you would have to  
 25 also consider the numbers that didn't test positive

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1 people who had been infected at birth early in life or  
 2 soon after, maybe because they were in areas of high  
 3 hepatitis, came from countries of high hepatitis B  
 4 incidence.  
 5 **Q.** Once HTLV-III screening tests were introduced, in  
 6 the North London centre, it is right, isn't it, that  
 7 when a sample tested positive initially then you would  
 8 test it in duplicate to assess whether it was a repeat  
 9 reactive?  
 10 **A.** Correct.  
 11 **Q.** And if it was, then the blood would be collected and  
 12 held?  
 13 **A.** The blood would be withdrawn from inventory and kept  
 14 in my laboratory in a designated secure fridge.  
 15 **Q.** And at that point is it right that it would then be  
 16 tested using the Western blot test?  
 17 **A.** We would send the samples to our reference  
 18 laboratory -- this was 1985 and before we had our own  
 19 reference laboratory -- and they would do repeat  
 20 tests. There would be a Western blot test. And also,  
 21 in my laboratory, I had developed a modified  
 22 haemagglutination assay, using re-agents from  
 23 a Japanese company, Fujirebio, where you could dilute  
 24 the cells, the red cells, used in the assay, and then  
 25 put them into V-weld microplates, centrifuge, and you

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1 and the possibility that, if someone had anti-core, it  
 2 wasn't caused by a factor that would put them at risk.  
 3 They may have been born, you know, with an early  
 4 infection of hepatitis B.  
 5 So it was an idea but it wasn't a clear cut  
 6 idea.  
 7 **Q.** But your view at the time, Professor Barbara, as  
 8 I understand it, was that that would have been  
 9 a useful surrogate test?  
 10 **A.** It could have been a useful -- I don't think I ever  
 11 formulated it in my own head as something that I would  
 12 definitely want to press ahead with but it was  
 13 an idea, it was a concept that might have some  
 14 utility.  
 15 **Q.** And in centres where there was not the opportunity to  
 16 tick a box on a confidential questionnaire to say  
 17 "Please don't use my blood", might the hepatitis B  
 18 core antibody testing have been of particular use?  
 19 **A.** Yes, in the absence of a self-exclusion questionnaire,  
 20 it may have had some value.  
 21 **Q.** Because it would have picked up those people who you  
 22 identified where there was a correlation between  
 23 ticking the box and testing positive on the  
 24 hepatitis B core antibody testing?  
 25 **A.** Yes, but unfortunately it would also have detected

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1 would get a dot. You would put the plate at a slope  
 2 and if the dot stayed as a dot, it was agglutination,  
 3 and if it formed a teardrop streak as those red cells  
 4 fell down the well, it was a negative. And that  
 5 enabled us quite economically and rapidly and very  
 6 sensitively to titrate the positivity. And if you got  
 7 a titre by this assay of, say, over 1 in 32 or 1 in  
 8 64 -- and they could range out to 1 in 1,000 -- you  
 9 could be -- gives you a lot of confidence that it is  
 10 a real positive.  
 11 **Q.** And when did that set of testing in your laboratory  
 12 become available?  
 13 **A.** It was soon after the ELISAs became available, and it  
 14 was something that we found very useful as an adjunct  
 15 to the ELISA testing, so it would have been sort of  
 16 mid to late 1980s.  
 17 **Q.** Do you recall if that testing that you developed was  
 18 available before or after the first generation of  
 19 screening tests?  
 20 **A.** It was after.  
 21 **Q.** Can you help us in relation to the Western blot test.  
 22 In the documents, and we will come to it in a bit more  
 23 detail in a moment, there is a lot of discussion about  
 24 confirmatory testing that I understand was done at the  
 25 Middlesex Hospital?

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1 A. Yes.

2 Q. Was that the Western blot test or was that some other

3 form of confirmatory testing?

4 A. I'm pretty certain now that it was the Western blot.

5 And as I have said elsewhere, a straightforward ELISA

6 gives you a yes/no: there is antibody or there isn't

7 antibody.

8 The Western blot, if I put it this way, allowed

9 you to see the anatomy of the antibody response so you

10 could see which antibodies to which components of the

11 virus were present. And the more -- you would want at

12 least two antibody lines, so the more components of

13 the virus could be detected by the antibodies in the

14 Western blot, the more confident you were of the

15 genuineness of the reaction.

16 Q. Is it right the Western blot test had been available

17 for some time prior to the ELISA testing?

18 A. No, I don't think so, because you would have needed to

19 have the virus isolated and in the Western blot you

20 would break up the virus, run it down

21 a polyacrylamide gel, blot off that tube of gel, and

22 get a series of viral antigen lines stuck onto the

23 blot. Then you would add your sample and the

24 antibodies would bind to that.

25 So you needed to have isolated the virus and

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1 buds through the infected cell and takes with it cell

2 wall antigens, which will contain HLA antigens and

3 when you do your test, anybody who has HLA antibodies

4 would come up as reactive and the reactivity rate

5 could be anything from 2 per cent to 10 per cent of

6 tests and only about 1 in 10 of the reactives would be

7 confirmable as real.

8 Q. At the time of the first generation screening tests,

9 was your understanding and expectation that

10 confirmatory tests were in the pipeline and likely to

11 arrive pretty soon?

12 A. We knew they were working on them but, to be honest,

13 I didn't have a timeframe for when they might become

14 available.

15 Q. You have talked us through your concern about the

16 false positive rates and the possible numbers that

17 were involved. Would you accept that by waiting for

18 confirmatory testing to be available it meant that

19 blood that was infected with HTLV-III was entering the

20 blood banks and out to the hospitals and on to

21 recipients?

22 A. Yes, I would accept that but I would also make the

23 comment that, initially, the feeling was -- and this

24 was because there was such a long, if you like,

25 incubation period between infection and the

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1 defined it.

2 Q. But in terms of the technique of the Western blot

3 test, that technique had been developed, albeit in

4 relation to other viruses?

5 A. Indeed, yes. Western blot was a recognised form of

6 assay.

7 Q. The first generation screening tests were available

8 from March 1985, but you had concerns about those

9 first generation screening tests in relation,

10 particularly, to false positive rates; is that right?

11 A. Absolutely.

12 Q. Given that the technique of the Western blot test was

13 available prior to March 1985, why was that not

14 a solution to the concerns about false positive rates?

15 A. That's a good question. I presume because

16 laboratories or manufacturers hadn't formulated the

17 Western blot around HIV. But that is my presumption

18 at this time. I can't remember. I -- yes, I -- that

19 is the best answer I can give to that question.

20 Q. In terms of your concerns about false positive rates,

21 can you help us with what they were particularly?

22 A. Yes. With the ELISAs that Dr Robert Gallo licensed

23 when he had discovered "HTLV-III", the manufacturers

24 had to use his cell line, which was rich in HLA

25 antigens. I have described elsewhere how the virus

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1 development of immune suppression and the various

2 diseases that that allowed into the patient -- there

3 was a feeling that only a small proportion of infected

4 people would go on to become ill and symptomatic.

5 Q. Was that a feature of your thinking when you were

6 raising concerns about false positive rates?

7 A. Yes, that would have been in my mind, as well, yes.

8 Q. With the benefit of hindsight, might it not have been

9 better to use the first generation tests to enable

10 blood to have been put on hold and then to be

11 re-looked at when confirmatory testing came on stream?

12 A. With the benefit of hindsight and knowing what we now

13 know about the severity of HIV, I think we could maybe

14 should have examined how we might do that without

15 totally disrupting the management and the supply of

16 donors and donations, because the same considerations

17 apply to HCV, which doubtless you will come onto, and

18 the problem was that, in the UK, certainly we wouldn't

19 exclude a donor without telling them.

20 If we were to exclude a significant number --

21 remember just at North London it was 1,000 donors

22 a day -- and if we were excluding 10 to 50 say, just

23 as a figure that might have been, the practicalities

24 of doing that safely and securely would have been very

25 difficult. Then you have got the knock-on effect of

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1 the impact on the supply of available blood for the  
 2 hospitals and then you would have to work out what you  
 3 told the donors.  
 4 **Q.** That issue of what you tell the donors was something  
 5 that was Professor Contreras' role; is that right,  
 6 rather than yours?  
 7 **A.** I was able to counsel donors -- as I told you, I had  
 8 initiated the hepatitis B counselling in the service,  
 9 it was about the first in the country -- with  
 10 Dr Dane's advice and with any input and help that  
 11 I needed from clinical colleagues, but mainly  
 12 Dr Hewitt and a team of other medical doctors would  
 13 have been doing the talking to the donors. And this  
 14 would have presumably included talking to donors who  
 15 may have been infected but we couldn't be sure, which  
 16 would have been a very difficult discussion to have  
 17 had.  
 18 **Q.** I want to move on then, Professor Barbara, to  
 19 hepatitis C at surrogate testing, we picked up some of  
 20 that earlier this morning and we discussed the  
 21 centre's use of hepatitis B core antibody, ALT and AST  
 22 testing in a case of post-transfusion hepatitis.  
 23 We move forwards now to 1987. If we could have  
 24 PRSE0003767, please.  
 25 We have here a letter that you wrote with

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1 patients would succeed in a legal action if they  
 2 contract [non-A, non-B] hepatitis after the  
 3 transfusion of blood untested for [hepatitis B core  
 4 antibody]? Why should [non-A, non-B] post-transfusion  
 5 hepatitis be such a special case that we have to make  
 6 tremendous efforts to prevent occasional infections?"  
 7 Is it a fair reading of this letter, Professor  
 8 Barbara, that the premise of your argument, yours and  
 9 Professor Contreras's argument, is that non-A, non-B  
 10 hepatitis infections were occasional?  
 11 **A.** Yes. I think our understanding at the time was that  
 12 they were occasional. As you know, we did try and  
 13 monitor any post-transfusion hepatitis infections that  
 14 might relate to non-A, non-B. We also had the feeling  
 15 that non-A, non-B was not as severe as hepatitis B.  
 16 **Q.** Then if we carry on down through the letter to the  
 17 final three paragraphs --  
 18 **A.** Remind me of the date of this, please?  
 19 **Q.** August 1987.  
 20 **A.** Yes, thank you.  
 21 **Q.** It picks up:  
 22 "Transfusion services must not bow to irrational  
 23 pressure for measures whose efficacy is unproven. In  
 24 the UK, Transfusion Centre Directors resisted commercial  
 25 pressure for premature introduction of unsatisfactory

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1 Professor Contreras to The Lancet, dated  
 2 1 August 1987, discussing the testing of blood  
 3 donations for non-A, non-B hepatitis. It is  
 4 responding to a letter from Scottish colleagues that  
 5 the Inquiry has seen previously. In the second  
 6 paragraph, you and Professor Contreras says this:  
 7 "Has the time for a prospective study already  
 8 passed [in relation to surrogate testing]? This seems  
 9 to imply that the longer an unproven test is used, the  
 10 greater becomes the pressure to use it. This is not  
 11 an argument that should commend itself to those  
 12 practising transfusion medicine. Why should we have to  
 13 wait 3-4 years for an answer? If the problem is serious  
 14 this will be revealed, in acute [non-A, non-B  
 15 hepatitis], within a year of initiating the study. The  
 16 need for controlled studies of the incidence of [non-A,  
 17 non-B] post-transfusion hepatitis will not disappear  
 18 with the introduction of routine screening of blood  
 19 donations with tests of unproven value."  
 20 Then you carry on to say:  
 21 "How far can the argument stretch that 'all  
 22 known methods' should be used to avoid the risk of  
 23 [non-A, non-B hepatitis] after transfusion? The bulk  
 24 of [non-A, non-B hepatitis] may still be transmitted  
 25 even after surrogate screening. Are we certain that

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1 screening tests for anti-HIV. They should show the same  
 2 resolution with [non-A, non-B] hepatitis."  
 3 Before we pick up about the non-A, non-B  
 4 hepatitis, can you help us with what you were  
 5 referring to in relation to the commercial pressure  
 6 for premature introduction of HIV testing?  
 7 **A.** Yes, companies would have been very keen -- the  
 8 initially licensed companies would have been very keen  
 9 for the Blood Service to introduce the anti-HIV  
 10 testing because, of course, it was a huge market.  
 11 **Q.** Then the letter goes on:  
 12 "At our transfusion centre, 400,000 blood  
 13 components are available for transfusion per annum. We  
 14 have received an average of only four reports of [non-A,  
 15 non-B] post-transfusion hepatitis annually for the past  
 16 ten years, and we repeatedly remind clinicians of the  
 17 need to report infective complications of blood  
 18 transfusion.  
 19 Again, was your view of the value of surrogate  
 20 testing based on your understanding of the limited  
 21 number of post-transfusion hepatitis reports from  
 22 clinicians?  
 23 **A.** Yes, the limited number of reports, our perception of  
 24 the limited clinical benefit and our awareness of the  
 25 diversion of resources that introduction of surrogates

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1 would have entailed: cost, in other words.  
 2 **Q.** Given that the centre was using these tests to decide  
 3 whether to exclude a donor from the panel when there  
 4 had been a report of post-transfusion hepatitis, why  
 5 was that not then good enough to apply to the  
 6 screening of all donations?  
 7 **A.** If you consider the whole range of donations and then  
 8 concentrate on a report of possible post-transfusion  
 9 hepatitis, you are, if you like, narrowing down the  
 10 focus where you can concentrate your efforts and get  
 11 the most value out of the surrogate testing. So, it  
 12 is what I said before: you got the smoking gun, so it  
 13 merited that concentration of effort and that really  
 14 didn't apply for the whole range of donations.  
 15 **Q.** Was that a resource question, Professor Barbara?  
 16 **A.** It was partly a resource question and that wasn't just  
 17 in terms of the cost of the test but, of course, the  
 18 staffing, but it would also involve a diversion --  
 19 sorry, a reduction in the amount of available blood  
 20 for issue and, of course, it would also that mean  
 21 donor management and donor counselling -- you would  
 22 have to take that into account because there would  
 23 have been considerable implications for that as well.  
 24 **Q.** Then if we move forwards to June 1989,  
 25 NHBT0000076\_037, please.

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1 centre during the meeting for anti-HCV rates in anti-HBc  
 2 positive donors. The revised figures for this data  
 3 following repeat testing is 4.4% of anti-HBc positive  
 4 donors have given positive results for anti-HCV  
 5 (1 in 23).  
 6 "To date, the anti-HCV test provided consistent  
 7 results and was convenient to perform."  
 8 So as at June 1989 it appears to have been your  
 9 view, Professor Barbara, that the anti-HCV tests were  
 10 producing consistent results. Is that your  
 11 recollection?  
 12 **A.** In terms of repeatability of reactivity. So whether  
 13 the reaction was real or false positive, it was  
 14 consistent in as much as it would come up again when  
 15 you re-tested it.  
 16 **Q.** If we then turn to page 4 of the document, please. We  
 17 have:  
 18 "3.7.4. Donors positive for anti-HCV  
 19 "Repeatable anti-HCV positive or 'grey-zone'  
 20 donors should be flagged, without counselling or  
 21 notification. Plasma to be stored frozen. Future  
 22 donations to be treated similarly pending decision on  
 23 the significance of the anti-HCV assay."  
 24 Next to the word "counselling" we can see  
 25 a little asterisk. And the asterisk takes us to the

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1 We have a meeting on 9 June 1989 of the  
 2 "National Study on Surrogate [Non-A, Non-B] Markers in  
 3 Blood Donors", and we can see just under the stamp on  
 4 the right that you were present and you were acting as  
 5 the secretary at that meeting.  
 6 Then if we go over the page, as part of the  
 7 progress reports we see -- sorry, back one page.  
 8 Should be page 2.  
 9 Sir, I'm afraid we have had a difficulty. We  
 10 don't have pages 2 and 3. It is a very short part of  
 11 page 2 that perhaps I can simply read into the  
 12 transcript.  
 13 **SIR BRIAN LANGSTAFF:** I think read it out but take it  
 14 slowly so that Professor Barbara can follow.  
 15 **MS FRASER BUTLIN:** Absolutely.  
 16 **SIR BRIAN LANGSTAFF:** And if he wants you to repeat it,  
 17 please just ask, Professor.  
 18 **A.** Thank you.  
 19 **MS FRASER BUTLIN:** There is a heading "NLBTC". So the  
 20 North London centre. And you are -- it says this:  
 21 "Dr Barbara, report F.  
 22 "1 in 150 anti-HBc negative donors were repeatedly  
 23 anti-HCV positive. 2.2% of 64 NLBTC donors with  
 24 elevated ALT were anti-HBc positive.  
 25 "Dr Barbara received additional data from the

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1 bottom of the page.  
 2 **(Pause)**  
 3 Keep going further down, please. There's a  
 4 further heading under the name "Dr John Barbara".  
 5 Yes, it's at the very bottom there, the heading  
 6 "Anti-HCV reactions and donor counselling". Thank  
 7 you.  
 8 It reads:  
 9 "On reflection and after discussion with  
 10 Dr Hewitt, consultant in medical charge of Microbiology,  
 11 and Dr Christine Moore we feel that the anti-HCV results  
 12 should not be withheld from the donor at counselling,  
 13 especially if they corroborate one or both surrogate  
 14 marker findings. Notification would include emphasis  
 15 that the test is still in the research phase, as they  
 16 were informed at the beginning of the trial. Findings  
 17 may not be 'absolute' but are extra evidence suggesting  
 18 that the donation is unsuitable for transfusion. We  
 19 think this will reduce rather than increase doubt and  
 20 worry on the part of the donor. Provided  
 21 Ortho Diagnostics allow us to do so, we think that the  
 22 GP should also be informed of these results, as research  
 23 findings."  
 24 **A.** Yes, I have read that, thank you.  
 25 **Q.** This view that you had taken, together with Dr Raafat,

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1 Dr Hewitt and Dr Moore, appears to suggest that in  
2 the --  
3 A. Sorry, could we have that back again so that I can  
4 keep -- be able to look at it?  
5 Q. Of course. There we go.  
6 A. Sorry to interrupt. Yes.  
7 Q. It appears from this note in these meeting minutes  
8 that you and others had taken the view that, in the  
9 context of a research trial, donors could be told  
10 about results that were you weren't entirely sure of  
11 the significance of; is that fair?  
12 A. Yes. In fact, in a research trial one might argue  
13 there was less ethical pressure to inform donors of  
14 any, if you like, positive findings, because this  
15 wasn't an extant part of our testing repertoire. But  
16 obviously on reflection here, even though it was  
17 a research trial -- and this emphasises the importance  
18 we attach to keeping our donors informed -- even  
19 though it was a research trial we obviously had  
20 recommended that the donors would be told, with all  
21 the emphases that you can see presented here.  
22 Q. And so in the face of uncertainty, you and your  
23 colleagues had found a formulation that you felt was  
24 appropriate to use with donors?  
25 A. In the limited context of a trial with numbers of

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1 Page 4 is missing. It is two bullet points that  
2 I wanted to take Professor Barbara to, so if I may  
3 I will simply read it into the record.  
4 On page 4 there is a heading "General comments":  
5 "1. Test seems reproducible, robust and  
6 meaningful.  
7 "2. Confirmation of some sort is obviously  
8 required."  
9 Does that accord with your recollection of your  
10 views in June 1989 of the hepatitis C testing?  
11 A. That it was reproducible --  
12 Q. Robust and meaningful.  
13 A. As I said previously -- certainly with any test, if  
14 you tested and got a result and re-tested and got  
15 a different result, you would be very unhappy with it.  
16 And that wasn't the case with this, with the assay.  
17 So the results you got, whatever they meant, were  
18 reproducible, and therefore robust.  
19 Sorry, what was the second point?  
20 Q. It was reproducible, robust and meaningful. And then  
21 the second point was the need for confirmation  
22 testing?  
23 A. Oh, yes. Yes, that was important.  
24 Q. Can we then pick up NHBT0000188\_017, please.  
25 This is a letter to The Lancet from yourself and

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1 donors that would then be involved. And if you -- you  
2 can't really extrapolate that to routine donor  
3 screening because the numbers would have been far more  
4 enormous. And also, because it was a trial, one would  
5 be able to say to the donors, "As a clearer  
6 understanding evolves, we will inform you."  
7 Q. In thinking about extrapolating it to all donors, was  
8 the difficulty a matter of resources for that  
9 counselling to happen?  
10 A. Extrapolating to all donors, yes, the resources would  
11 have been an important factor. And as I have said  
12 before, the impact on the blood supply would have been  
13 significant as well.  
14 Q. Can we turn now to NHBT0000017\_006, please.  
15 We can see at the bottom of this page the  
16 initials "DH/JAB" and "RME", "23.6.89". The JAB there  
17 is you, isn't it?  
18 A. Yes, and the DH is the late Dr Howell.  
19 ^Name Check Yes.  
20 Q. So this was a "Preliminary report No. 2" on the HCV  
21 assay?  
22 A. Yes.  
23 Q. And if we -- there's then a couple of pages of some  
24 tables of results, but if we carry on to page 4 ...  
25 There is another problem with documents, sir.

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1 Professor Contreras. It is dated 8 August 1989. If  
2 we can then carry on down to the body of the letter,  
3 please. You say this -- there has been a flurry of  
4 publications on hepatitis C in The Lancet:  
5 "We agree that the new Ortho ELISA for anti-HCV  
6 clearly appears to be a specific assay for the major  
7 agent causing post-transfusion non-A, non-B hepatitis.  
8 It is obviously incomparable with any of the previous  
9 attempted assays for NANB virus and provides a welcome  
10 advance over surrogate markers for infection with this  
11 virus. However, in the context of donor screening,  
12 precipitate action should be avoided. As in other  
13 assay, the predictive value of a positive result  
14 hinges on the prevalence of the marker in a given  
15 population. While the test scores well in panels of  
16 well characterised NANBH sera and in samples from  
17 patients with a diagnosis of NANBH, we do not know the  
18 predictive value of the test in low prevalence  
19 populations such as UK blood donors. In this context,  
20 it is essential to have confirmatory assays to  
21 eliminate, for example, the possibility of cross  
22 reactivity with yeast antigens, before sensible  
23 policies for generalised screening of blood donations  
24 are implemented."  
25 It carries on. You discuss an evaluation that

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1 has been undertaken and you say:  
 2 "Between 0.5-1% of blood donations have been found  
 3 to be repeatedly reactive (unpublished observations).  
 4 Excluding this proportion of blood donors might appear  
 5 to be a minimal problem. However, when related to the  
 6 annual 2.5 million blood donations in the UK, the  
 7 problem is certainly not trivial."

8 You also highlight the enormous and costly  
 9 undertaking that would be required of contacting and  
 10 counselling blood donors.

11 Then, over the page:

12 "Considerations of the cost-effectiveness of  
 13 routine donor screening must await the advent of  
 14 reliable confirmatory tests as well as faster screening  
 15 tests."

16 Professor Barbara, this letter was written in  
 17 August 1989. In relation to confirmatory testing, at  
 18 that point, were you aware of confirmatory testing  
 19 being developed?

20 **A.** I was aware that people were working on confirmatory  
 21 testing. I didn't know what stage it was at.

22 **Q.** Was your sense that it would be available very soon?

23 **A.** In all honesty, I can't recall.

24 **Q.** If we just look again at that final sentence of the  
 25 letter, the considerations of the cost effectiveness

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1 anti-HCV clearly appears to be an assay specific for  
 2 the major agent causing post-transfusion non-A, non-B  
 3 hepatitis. And certainly all -- myself and my  
 4 colleagues were excited at the realisation that this  
 5 assay would be doing very well in Harvey Alter's panel  
 6 which was used to test candidate assays.

7 Previous to this assay, none of them showed any  
 8 correlation with the status of the samples. So when  
 9 this assay came it was -- it gave us considerable hope  
 10 that there would be the ability to specifically  
 11 detect. But I'm making this point because it wasn't  
 12 an assay of high specificity, it was an assay specific  
 13 for that agent.

14 Thank you for your patience.

15 **Q.** Following on from that, given that it was, as you  
 16 understood it, specific to that agent, would it not  
 17 have been better to introduce the testing at this  
 18 stage, even if that had meant that you couldn't have  
 19 any confirmatory testing?

20 **A.** The same arguments applied to what we discussed  
 21 previously with HIV and, again, the question of the  
 22 severity and the clinical impact of non-A, non-B was  
 23 still something that hadn't been fully elucidated.

24 **Q.** If we move forwards --

25 **SIR BRIAN LANGSTAFF:** May I just ask a question about

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1 of the donor screening. That appears to rather sum up  
 2 your concerns about the hepatitis C tests. In  
 3 relation to the cost, both in terms of the cost of  
 4 doing the tests, the loss of blood donors and the  
 5 difficulties in relation to counselling donors; is  
 6 that fair?

7 **A.** Yes. It is worth remembering that roughly all  
 8 previous screening tests would have cost -- for each  
 9 test for the up to 2 million donations a year in Blood  
 10 Service -- would have cost anything up to -- with HIV  
 11 it became 50 pence a test. The economical assay  
 12 I developed for hepatitis B was actually pennies per  
 13 test and Ortho would be charging £2 a test. So, in  
 14 terms of the overall impact on budget, it would have  
 15 been enormous.

16 So I think cost effectiveness did figure very  
 17 highly in our considerations. Could I also -- if we  
 18 go back to the beginning of that letter, is that  
 19 possible?

20 **Q.** Page 1.

21 **A.** This letter here. If we go right back to the first  
 22 paragraphs --

23 **Q.** NHB0000188\_017.

24 **A.** -- second paragraph, if we could, please. Again, with  
 25 hindsight, our wording would have been better, that

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1 this. Can we just highlight, please, the second  
 2 paragraph again?

3 Prior to the cloning of what became known as  
 4 hepatitis C by -- I think it was by the Chiron  
 5 Corporation, there had been significant discussions  
 6 about surrogate testing on non-A, non-B, had there  
 7 not?

8 **A.** Yes, sir.

9 **SIR BRIAN LANGSTAFF:** There was a difference of view, as  
 10 I understand it, between those who thought it was  
 11 worth introducing and those who thought it might not  
 12 be. Here, the second sentence:

13 "It is obviously incomparable [that is the Ortho  
 14 ELISA test] with any of the previous attempted assays  
 15 for NANB virus ..."

16 Then this:

17 "... and provides a welcome advance over surrogate  
 18 markers for infection with this virus."

19 It might be thought to follow, that, if it was  
 20 an advance over surrogate markers -- I mean, do you  
 21 agree that it was an advance over surrogate markers?

22 **A.** Yes, Sir Brian.

23 **SIR BRIAN LANGSTAFF:** It would make the case for  
 24 introducing some sort of test, which otherwise  
 25 surrogate markers would have indicated, rather

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1 stronger, one might have thought. Would that be  
2 a fair conclusion?  
3 **A.** Yes, I think that is a fair comment.  
4 **Q.** Perhaps you can help with this, one of the downsides  
5 of introducing a test with -- aimed at identifying  
6 non-A, non-B, rather than hoping to eliminate non-A,  
7 non-B by identifying other markers, is that you would  
8 wish to talk to the donor concerned because, plainly,  
9 they may have a problem and they have to know about  
10 it. Suppose you had had surrogate testing, would that  
11 have involved talking to donors whose donations were  
12 excluded? You did say earlier, I think, that if any  
13 donation was not accepted you would expect to tell the  
14 donor that that was the case and broadly why.  
15 **A.** Yes, Sir Brian. If we were say to have introduced  
16 combined raised ALT and anti-HBc testing and then one  
17 of the options was to consider anyone who had raised  
18 ALT and who was anti-HBc positive as a higher risk for  
19 non-A, non-B, then the donations would have been  
20 excluded and we would have then told the donor that we  
21 were excluding future donations and we would try and  
22 explain why, which would have been a bit difficult  
23 because we would have to tell them that we were trying  
24 to err on the side of safety while we regretted having  
25 to lose their current and future donations.

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1 **MS FRASER BUTLIN:** I want to move on to the second  
2 generation testing.  
3 Could we have NHBT0000191\_011, please. It is  
4 a letter from Ortho to you, dated 11 January 1991. It  
5 says:  
6 "In order that I can ship you the Second  
7 Generation RIBA-HCV assay for clinical evaluation, I am  
8 required by the US Food and Drug Administration to have  
9 you sign and return the attached declaration."  
10 Then, over the page, we have the signed forms  
11 that we don't need to go to.  
12 Do you recall whether or not you were, in fact,  
13 sent the second generation RIBA assay?  
14 **A.** I'm sorry, I can't recall. I presume I would have  
15 been if I signed it and sent it off and we would have  
16 been keen to see it but I can't specifically recall.  
17 I'm sorry.  
18 **Q.** Do you recall doing any testing of the second  
19 generation RIBA?  
20 **A.** I am sure we did but details, no, I cannot recall.  
21 **Q.** Then if we turn to NHBT0000073\_065, please.  
22 We have a letter from Dr Gunson to all RTDs  
23 dated 3 April 1991.  
24 Then if we go to the body of the letter please,  
25 it says this:

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1 It also would raise the question of whether we  
2 then needed to do look-back on the recipients of  
3 previous donations from that donor.  
4 **SIR BRIAN LANGSTAFF:** So if indeed, as you think it was,  
5 this was a considerable advance on surrogate assays,  
6 is it likely that there would probably be less  
7 counselling of those who were not infected than would  
8 have been the case with surrogate testing, had it been  
9 introduced?  
10 **A.** Do you mean there would be fewer donors as candidates  
11 for counselling because there would have been fewer of  
12 them detected by the assay?  
13 **SIR BRIAN LANGSTAFF:** Yes, I do.  
14 **A.** I can't work those figures out offhand.  
15 **SIR BRIAN LANGSTAFF:** Don't try and do it now. If you  
16 have a moment after this to think, well, what would  
17 the comparative figures probably have been, as best  
18 you can tell, do please let us know. I think it is  
19 better to do that than try and say something now which  
20 may not be right.  
21 **A.** Yes, so comparing the donor loss with first generation  
22 HCV and surrogate testing. It is a very interesting  
23 point and I can't remember if it ever came up, it may  
24 have done but, yes, thank you for that.  
25 **SIR BRIAN LANGSTAFF:** Well, thank you.

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1 "You will recall that in my letter to you of  
2 15th February I suggested that the 1st July 1991 might  
3 be an appropriate date to commence anti-HCV screening  
4 of blood donations.  
5 "You may be aware that since the three-centre  
6 trial of anti-HCV tests was completed, Ortho and Abbott  
7 have produced second generation test kits which have  
8 additional antigens to the C-100 of the test we have  
9 evaluated. There may also be other companies supplying  
10 anti-HCV tests."  
11 Then the final paragraph on this page:  
12 "It is undoubtedly in our interest that this  
13 evaluation takes place. However, to complete this study  
14 and become operational by 1st July 1991 is too tight  
15 a schedule. It is difficult to state precisely  
16 a revised date, but I think we should aim to commence  
17 routine screening for anti-HCV by 1st September 1991."  
18 As I understand it, Professor Barbara, you  
19 agreed with Dr Gunson's suggestion that evaluation was  
20 required?  
21 **A.** Yes, I think evaluation would have been required. If  
22 we could go back to the beginning, so that I can get  
23 my head around the dates again --  
24 **Q.** Of course, it is --  
25 **A.** -- and which tests --

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1 Q. It is dated 3 April 1991.  
 2 A. And it is in regard to which generation of ELISA?  
 3 Q. If you just go to the second paragraph of the  
 4 letter --  
 5 **SIR BRIAN LANGSTAFF:** I think it is actually a RIBA test  
 6 rather than an ELISA.  
 7 Q. It is a RIBA test.  
 8 A. Ah, sorry, forgive me, I'm getting fuddled.  
 9 **SIR BRIAN LANGSTAFF:** Am I right in thinking that the  
 10 first generation test was an ELISA test --  
 11 A. Yes.  
 12 **SIR BRIAN LANGSTAFF:** -- and the second --  
 13 A. And the second generation too.  
 14 **SIR BRIAN LANGSTAFF:** The second generation was a RIBA  
 15 test, RIBA assay?  
 16 A. Sorry, Sir Brian, the second generation test was also  
 17 an ELISA but it had more antigens on the solid phase  
 18 of the microplate of the ELISA. The RIBAs were always  
 19 confirmatory tests.  
 20 **SIR BRIAN LANGSTAFF:** So when we saw the original  
 21 letter -- if we just go back to it for a moment --  
 22 NHBT0000191\_011, that we looked at a moment or two  
 23 ago.  
 24 The second generation RIBA HCV assay, the RIBA  
 25 is a confirmatory test that comes with it or what?

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1 we would have been much more comfortable.  
 2 Q. Was there any reason why the testing of the second  
 3 generation tests couldn't have occurred in parallel  
 4 with the introduction of testing for all donations?  
 5 A. In hindsight I believe not. I have to add, provided  
 6 we got the RIBAs, yes.  
 7 Q. Can I turn now to NHBT0088770, please. That's the  
 8 fifth page, I need the first page, please. Do we have  
 9 any further pages?  
 10 Dr Barbara, I cannot show you the first page,  
 11 but there is nothing I want to particularly address on  
 12 it other than to introduce the document, which is  
 13 a document published in Reviews in Medical Virology in  
 14 1991, the heading of which is "Blood Transfusion  
 15 Services should have begun screening for Hepatitis C  
 16 when an antibody assay first became available".  
 17 And it is described as a debate I think "for"  
 18 with Dr Brown and Professor Thomas --  
 19 A. I -- yes, I remember --  
 20 Q. -- and you wrote the "against" bit of the article.  
 21 A. Yes.  
 22 Q. What I'm going to do is pick up the journal article  
 23 from page 3, please, which is where your writing  
 24 starts.  
 25 A. Okay.

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1 How do I understand that?  
 2 A. Yes, Sir Brian. The RIBA, the recombinant immunoblot,  
 3 is the assay that gives you the anatomy of the stark  
 4 antibody response that the ELISA will give you. So  
 5 this was the second generation confirmatory assay from  
 6 Ortho.  
 7 **SIR BRIAN LANGSTAFF:** Thank you.  
 8 **MS FRASER BUTLIN:** In relation to the second generation  
 9 ELISA tests in April 1991, is it fair that you and  
 10 others from a scientific perspective fully expected  
 11 those second generation tests to show significantly  
 12 improved sensitivity and specificity?  
 13 A. Yes, because the range of antigens on the solid phase  
 14 was better, we would have expected not only increased  
 15 sensitivity but increased detection range, so the  
 16 ability to detect more types of antibody positive  
 17 samples.  
 18 The specificity we wouldn't have known about.  
 19 It was still on the same basic format, so the  
 20 potential problems that the first generation assay had  
 21 could still apply to the second. But if we had  
 22 confirmatory tests, the supplementary tests really of  
 23 RIBA -- because RIBA wasn't totally confirmatory, it  
 24 was supplementary, it was giving you a clearer picture  
 25 of what the antibodies were. But with that in place

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1 Q. We can see at the bottom left against the proposition  
 2 and your name.  
 3 A. Yes.  
 4 Q. And if we go to the top of the second column we can  
 5 read this -- what I will do, Professor Barbara, if  
 6 I may, is read some of it and then I will ask you  
 7 a question about it.  
 8 A. Okay.  
 9 Q. "One single crucial factor in any decision concerning  
 10 the introduction of a new (and in this case, very  
 11 expensive) pre-transfusion screening test for blood  
 12 donations must be examined: in the absence of  
 13 screening, can significant transfusion-transmitted  
 14 disease be associated with the agent in question?  
 15 This is often the factor that is most obviously prone  
 16 to geographical variation. Although the data relating  
 17 chronic liver disease (CLD) to transfusion history are  
 18 very sparse, striking differences are apparent between  
 19 different countries."  
 20 Then you address a study from Japan which showed  
 21 what you described as very high figures suggesting  
 22 an aetiological connection between transfusion and  
 23 liver disease. Whereas you indicate there that wasn't  
 24 present in UK studies.  
 25 Then if we go down to the next heading, please:

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"The rates of PTH in Japan and the UK mirror the extent of the association between CLD and a history of transfusion; while PTH rates in Japan are high, they are very low in the UK."

Then if we go over the page. Under the heading "HCV seroprevalence" you note that:

"Surprisingly, the seroprevalence in, for example, Japan (1.5%) is not markedly different from countries such as the UK (0.3-0.7%) although the rates of PTH differ enormously."

Again, in this article you were making the same link, weren't you, that chronic liver disease is caused by post-transfusion hepatitis. So again in this article you were relying on the reports of post-transfusion hepatitis to get to those seroprevalence -- sorry, to get to the rates of post-transfusion hepatitis?

**A.** Yes, the incidence of post -- yes. Yes.

**Q.** Then if we see under the "Assays for anti-HCV" you say:

"The first-generation assays for anti-HCV employed solely the C-100-3 antigen derived from a non-structural region of the virus. Antibody responses to this protein may be more likely to reflect chronic rather than short-term acute infection with the agent. These assays

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And in terms of tests for detecting antibodies to a viral infection, you get better antibodies to the actual virus bits itself, the structure. You have -- you know, if you imagine the virus floating around in the bloodstream, it is going to elicit more of a vigorous antibody response than the little bits of non-incorporated, non-structural antigen that are left in the infected cell.

So, that was one point I wanted to make, that although the antigen was specific to hep C, it wasn't the best -- it wasn't the choicest antigen to have derived.

Because of what I've just said and -- the fact that you haven't got the vigour of antibody response, if you had an acute infection you are going to be less likely for an antibody to C-100 to be positive than if you had a chronic long-term infection where cells would have been continually producing the non-structural proteins. So, I just wanted to make that point clear there.

**Q.** Picking up on that issue of antibody responses maybe more likely to affect chronic infection, did that give you pause for thought that perhaps acute symptomatic post-transfusion hepatitis was not a good marker to use for future issues with chronic liver disease?

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suffered from the following disadvantages:

"1. Low predictive value in the absence of supplementary tests, which were not available until some time after the screening tests were marketed.

"2. Short-lived antibody in a significant proportion of subjects; in some cases this may reflect false-positive, rather than genuine transient reactivity."

**A.** Did you want me to just talk to that briefly?

**Q.** If I just go through to point 4 so that we have it. 3 is the:

"Long delay until seroconversion, following infection ..."

**A.** Sorry.

**Q.** And 4 is the:

"Low titre of the anti-C-100-3 response."

What did you want to add to that,

Professor Barbara?

**A.** Sorry, if we go back to the first two, points 1 and 2.

Yes, the C-100 antigen, this point about it being from a non-structural region, this is the -- relates to the fact that when a virus replicates in its host cell, there will be proteins, antigens made as part of the virus production process that are not then incorporated into the actual structure of the virus.

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**A.** That's a good point. I'm not sure that I'd worked through that logic.

**Q.** Particularly in light of the disparity between the rates of post-transfusion hepatitis in Japan and the UK?

**A.** Yes, I suppose that could have been a factor that one would have to consider. I would really have to think about that.

**Q.** If we carry on then in this article to the conclusions, page 5, please, we can see that you have summarised the reasons for not initiating anti-HCV screening as soon as tests first became available as follows:

"1. No evidence for an association of transfusion and [chronic liver disease]."

Was that your view in 1991, that there was no evidence for an association of transfusion and chronic liver disease?

**A.** Yes. I think that it was. One didn't link chronic liver disease with transfusion in any significant degree.

**Q.** Then:

"2. Very low rate of [post-transfusion hepatitis] and transfusion-transmitted HCV infection."

I think we have already talked about the rates

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1 of PTH a number of times:  
 2 "3. Defects of the first available assays (low  
 3 predictive value in low-prevalence populations;  
 4 possibility of false negatives).  
 5 "4. Absence of supplementary tests initially.  
 6 "5. Enormous workload and cost implications  
 7 with the risk of diversion of resources from existing  
 8 screening programmes and the resulting dilution of  
 9 their efficiency."  
 10 Did these remain your views as to why tests were  
 11 not introduced when they first became available?  
 12 A. Yes. As to why tests were not introduced when they  
 13 first became available, yes.  
 14 Q. Can I then turn to NHBT0036250\_025, please. This is  
 15 an attendance note taken by solicitors in  
 16 December 1999. We can see that you attended their  
 17 offices from 12.25 until 4.30 in the afternoon and  
 18 what we have got here is a six-and-a-half-page note,  
 19 so it is a very condensed note of what I understand  
 20 was a lengthy conversation; is that right?  
 21 A. I guess so. It is a way back, so these would have  
 22 been condensed notes, yes.  
 23 Q. Can we put up the third, fourth, fifth paragraphs,  
 24 please. "He said", I think that's you,  
 25 Professor Barbara:

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1 view, and also from a scientific point of view, my  
 2 personal feeling at that time was that a gap between  
 3 the introduction of second generation tests when they  
 4 became available, and then when actually screening was  
 5 started, would have been indefensible in the  
 6 legalistic term but also in the scientific term, that  
 7 if we had a more specific test then why weren't we  
 8 using it?  
 9 Q. You go on to say they did -- or the note records  
 10 a summary of your conversation as follows:  
 11 "They did not go for first generation tests  
 12 because of the cost benefit, the lack of scientific  
 13 evidence and the disruption to the blood supply.  
 14 "First there were the first generation tests and  
 15 there was a lack of confirmatory tests and then the  
 16 second generation tests. There would not have been any  
 17 reason other than a timetable as to why the second  
 18 generation tests were not used and he found that hard to  
 19 justify."  
 20 A. Yes.  
 21 Q. Then:  
 22 "He would say that they never believed that  
 23 Hepatitis C was that serious but he thought it would be  
 24 difficult to hold to that view when the 'rarities' were  
 25 in front of him."

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1 "He said that he felt that they were an open  
 2 target [this is in the context of the litigation]  
 3 because he thought they could make an issue of the  
 4 decision not to use anti-HBC and ALT, again about the  
 5 decision not to use the first generation tests. He  
 6 thought that the gap between the introduction of the  
 7 second generation tests and screening which had been  
 8 introduced was indefensible. He did not know what he  
 9 could say about that."

10 Just pausing there, is that still your view?

11 A. This is the summary that a legal individual would have  
 12 made of our quite protracted discussions, yeah? This  
 13 is what was summarised?

14 Q. It is an attendance note with the solicitors and, as  
 15 I said at the beginning, we recognise it is a very  
 16 condensed note of a lengthy conversation.

17 A. Okay.

18 SIR BRIAN LANGSTAFF: Just for my interest, the interview  
 19 took about four hours but how long is the note, how  
 20 many pages?

21 MS FRASER BUTLIN: Only six and a half pages, sir.

22 SIR BRIAN LANGSTAFF: I see.

23 A. It really is hard for me to remember at this stage but  
 24 I think this would be a fair summary of what I would  
 25 have said and both from a strictly legal point of

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1 Is that your recollection of what you explained  
 2 at that time?

3 A. Yes. I mean, I think that's a fair recollection of  
 4 what was -- what I was -- was there at that time, yes.

5 Of course, when you concentrate -- if you  
 6 suddenly bought a Skoda car, you begin to notice that  
 7 everyone else seems to be driving Skodas. And so if  
 8 you home in on a specific issue like serious cases of  
 9 hepatitis C, it then becomes a more significant  
 10 question. I can understand that.

11 MS FRASER BUTLIN: Sir, I'm about to move on to  
 12 a different topic. I have three short matters I need  
 13 to address with Professor Barbara and then obviously  
 14 we will need to invite any further questions from the  
 15 Core Participants.

16 SIR BRIAN LANGSTAFF: When you say short matters?

17 MS FRASER BUTLIN: I think I will be more than ten  
 18 minutes, sir, perhaps 15 or 20, but my timing, sir,  
 19 unfortunately is, as with many counsel, never very  
 20 reliable. I may be shorter, I may be longer.

21 SIR BRIAN LANGSTAFF: Yes. I think in the light of that,  
 22 what we will do is we will take a break now for lunch,  
 23 come back at 2.05 pm, if that's all right with you,  
 24 Professor, and finish off those questions. Chances  
 25 are we will have another break some time after 2.30 or

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1 thereabouts, and that will probably be the last break,  
 2 as such, in the day I would expect.  
 3 **A.** I hope I'm not adding to any delays by my somewhat  
 4 confused responses.  
 5 **SIR BRIAN LANGSTAFF:** No, no, no! Good heavens me, don't  
 6 worry about that at all! The important thing is to  
 7 get your evidence as clearly as we can and as well as  
 8 we can, and we have the day set aside to hear you, so  
 9 you need not worry. We are making very good progress  
 10 I think. So, thank you.

11 **A.** Thank you, sir.

12 **SIR BRIAN LANGSTAFF:** 2.05 pm.

13 **MS FRASER BUTLIN:** Thank you.

14 (1.08 pm)

(Luncheon adjournment)

16 (2.05 pm)

17 **MS FRASER BUTLIN:** Before we pick up, Professor Barbara,  
 18 the three final topics I want to discuss with you, we  
 19 were discussing earlier today various matters  
 20 addressing sensitivity and specificity of the testing  
 21 and I have just been asked to highlight that  
 22 Professor Barbara's witness statement deals with the  
 23 scientific details of that to quite a considerable  
 24 extent. I'm not going to take him to it but just to  
 25 highlight for Core Participants that it is there in

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1 the decision of the MSBT not to pursue routine testing  
 2 of all blood donations for anti-HBc.  
 3 The letter then says this:  
 4 "This decision was reached after consideration of  
 5 the following:  
 6 "(i) All ELISA tests for anti-HBc gave false  
 7 positive results; even the more specific tests the false  
 8 positivity rate appeared to be in the order of 10-fold.

9 "(ii) There were no agreed, satisfactory  
 10 confirmatory tests which means that there be an  
 11 inability to provide definitive health information to  
 12 a considerable number of donors."

13 A question arose in earlier Inquiry hearings  
 14 about this point, if there were no confirmatory tests  
 15 how could it be known that the ELISA tests gave false  
 16 positive results? Is that something you can assist us  
 17 with?

18 **A.** Yes, I have written an email to the solicitors helping  
 19 me, Vicky Morris, and I believe they were trying to  
 20 get this through to Sir Brian.

21 **Q.** Perhaps you can just explain for us now verbally, if  
 22 you can, how it comes to be said that you have false  
 23 positives without a confirmatory test?

24 **A.** Yes. There is no single confirmatory test for  
 25 anti-HBc and laboratories working on this would have

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1 his statement.

2 **SIR BRIAN LANGSTAFF:** Yes, thank you.

3 **MS FRASER BUTLIN:** The first matter, Professor Barbara,  
 4 I want to ask you about relates to hepatitis B core  
 5 antibody testing not as a surrogate test for  
 6 hepatitis C but in the context of a study that was  
 7 being undertaken in relation to its use to reduce  
 8 hepatitis B transmission.

9 Firstly, were you aware of that study taking  
 10 place in the early 1990s?

11 **A.** Sorry, to reduce the risk of hepatitis B?

12 **Q.** That is right.

13 **A.** There were lots of studies in that regard and I was  
 14 certainly very interested in the idea of anti-HBc to  
 15 detect what I called tail end carriers who were at the  
 16 end of carriage but might have some residual  
 17 infectivity especially in a large volume of  
 18 a donation.

19 **Q.** Can we turn then to DHSC0004709\_153, please.

20 **A.** You will forgive me if I have this heated wheat bag on  
 21 my neck. I have developed a very stiff neck.

22 **Q.** Of course.

23 We have a letter here from Harold Gunson dated  
 24 7 October 1993 sent to all RTDs/Chief Executives about  
 25 anti-HBc testing of blood donations and it addresses

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1 had access to a battery of tests, they would have  
 2 initially tried to detect any HBsAg with as sensitive  
 3 a test as possible, which eventually of course became  
 4 PCR. They would also titrate the anti-HBc to see how  
 5 strong the reaction was and of course the stronger  
 6 reactions were more likely to be real. They could  
 7 then also test for anti-HBs because the presence of  
 8 anti-HBc could either reflect continuing infectivity  
 9 with undetectable HBsAg or it could reflect clearance  
 10 of virus with undetectable anti-HBs. But if  
 11 an anti-HBc positive donor had anti-HBs at a level of  
 12 20 milli-IU per ml that would be considered protective  
 13 or immune and it would also confirm the anti-HBc  
 14 result.

15 You could also test for this other marker,  
 16 anti-HBe, which is -- e antigen is part of the  
 17 different antigens in hep B and e antigen is  
 18 associated with the icosahedral virus with the core  
 19 of -- the icosahedral core and because it is  
 20 associated with the virus, it is also associated with  
 21 infectivity. And anti-HBe is what develops when the  
 22 virus is cleared.

23 So with this range, this battery of tests, you  
 24 could get a pretty good idea if an anti-core reaction  
 25 was real. Now, of course, you couldn't do this in

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1 a routine setting because it is not a single  
 2 confirmatory test and indeed, for research purposes,  
 3 you could even ask the anti-core positive individual  
 4 if they'd agree to be vaccinated when hep B vaccine  
 5 became available and if there was undetectable  
 6 anti-HBs that would, of course, have been boosted. So  
 7 it was this battery of laboratory and almost research  
 8 tests that could give us the handle on what was real  
 9 or not.

10 **Q.** The second topic I want to discuss with you is --

11 **SIR BRIAN LANGSTAFF:** Can I just summarise for the sake of  
 12 perhaps the understanding of those who may not have  
 13 had the advantage of reading your statement first, in  
 14 which you set out quite a bit of this.

15 What I think you said, but tell me if I have got  
 16 it wrong, is that there wasn't a single test that you  
 17 could use, ie as a confirmatory test, but there were  
 18 a number of different tests which shone a light upon  
 19 different aspects of it, together, if you used those  
 20 tests you could say with a fair degree of certainty  
 21 you have got the virus, or the antibody?

22 **A.** That's absolutely right, Sir Brian, yes.

23 **SIR BRIAN LANGSTAFF:** Thank you.

24 **MS FRASER BUTLIN:** Moving on then, Professor Barbara, to  
 25 my second topic. You have said in your statement that

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1 sample to 100 microlitres of diluent, you couldn't be  
 2 sure you had added that, and manufacturers  
 3 developed -- they tweaked their assays so they could  
 4 add chemical reagents that didn't affect the test but  
 5 that changed colour when you added sample. And also  
 6 they added colour to all the other reagents so that  
 7 you could tell that you had performed each stage, the  
 8 five stages or so of an ELISA assay.

9 So the relationship -- I never thought of "them"  
 10 and "us", I always felt that we were working together  
 11 and the more help we gave them, the better the test  
 12 would be. You know, to enhance patient safety.

13 **Q.** Can I turn now to a letter.

14 SBTS0000067\_087.

15 It is a letter written by John Cash to  
 16 Harold Gunson dated 7 September 1992. The substance  
 17 of the letter reads as follows:

18 "As a consequence of a number of consultations  
 19 over the last months it is clear to me that throughout  
 20 the UK BTS, and perhaps beyond, there is growing concern  
 21 that there may have emerged a small cartel which is  
 22 manipulating the development of microbiology donation  
 23 screening test evaluation (and the to some extent  
 24 confirmation testing).

25 "This manipulation is perceived to be directed

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1 you built and maintained relationships with  
 2 the manufacturers and suppliers of test kits. Can you  
 3 help us with what that involved, how you built and  
 4 maintained those relationships?

5 **A.** Well, of course, for hepatitis C because we had --  
 6 I could identify some donors who were very likely to  
 7 have transmitted non-A, non-B, and we detected that  
 8 through surrogate testing, the fact that they came up  
 9 in at least one, sometimes two post-transfusion non-A,  
 10 non-Bs -- we saw that paper about a donor implicated  
 11 twice -- we were able to provide plasma to  
 12 Professor Richard Tedder and, working with  
 13 Wellcome Laboratories, as they were then, they  
 14 produced an independent British clone. So that was  
 15 a close working relationship with a commercial  
 16 company.

17 Then, for enhancement of tests, for tweaking of  
 18 tests, for any feedback that we could give to  
 19 manufacturers to make tests better, easier, quicker,  
 20 we would certainly want to do that, and I also got  
 21 companies to put in reagents to show us when a serum  
 22 sample had been added to a diluent. For a surface  
 23 antigen test you just added undiluted serum and you  
 24 could clearly see the sample in the microplate well.  
 25 But when you were adding, say, 10 microlitres of serum

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1 towards the personal research interests of Dr Barbara,  
 2 Professor Tedder and Dr Mortimer and not necessarily the  
 3 best interests of the UK BTS. More recently concern has  
 4 been expressed that some or all of these individuals may  
 5 be inappropriately associated with certain commercial  
 6 manufacturers of microbiology donation test kits, such  
 7 that their professional advice is being influenced by  
 8 the interests of the commercial organisations with which  
 9 they are associated.

10 "These are weighty matters and of a very serious  
 11 nature and I'm bound to advise you that very recent  
 12 events have led me to share many of these concerns."

13 Then over the page:

14 "It is my earnest hope that as we move forward to  
 15 an NBA that the concerns expressed above can be  
 16 appropriately dealt with."

17 First of all, were you aware of this letter at  
 18 the time or shortly after?

19 **A.** No.

20 **Q.** And were the concerns --

21 **A.** Harold Gunson never showed it to me. Never brought  
 22 the issue up.

23 **Q.** That was my next question. Did he raise any of the  
 24 concerns that are written in this letter?

25 **A.** No. And with all due respect to the late

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1 Professor Cash, I think Harold thought they were  
2 rubbish. I can honestly say they were totally  
3 unfounded. Myself and the colleagues mentioned there  
4 did indeed work with manufacturers for the reasons  
5 that I have already said. As a patent holder -- as a  
6 co-patent holder for hepatitis C, I never received any  
7 of the royalty monies. They went to the centre,  
8 actually into my laboratory, to purchase enhanced  
9 bacteriology screening test, which eventually became  
10 the basis of our bacteriology reference work.

11 It is also of interest, I can't remember when,  
12 but Professor Cash offered me the job of running the  
13 Scottish National Micro lab. Without interview. It  
14 was just a straight offer. So I don't think he could  
15 have thought too ill of me. But when I saw this  
16 first, it came as a total surprise. And totally  
17 unfounded as well. Sorry if I'm a bit passionate  
18 about that.

19 **Q.** I want to then move to my last topic,  
20 Professor Barbara, and that is in relation to  
21 organisational matters across the Blood Transfusion  
22 Service.

23 In your statement you have said that you feel  
24 that the North London centre was sometimes held back  
25 by slower centres. Can you help us with what you were

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1 **A.** Yes.

2 **Q.** Why was that? Why did you feel it was a drift rather  
3 than a shift?

4 **A.** Well, if you use those words in relation to the  
5 evolution of flu variants, year-by-year you get slight  
6 changes, and that's a drift. Every now and again you  
7 get a massive change, and that's a shift. So I don't  
8 think there was an immediate massive change. I think  
9 that as a growing awareness of the relevance of  
10 transfusion-transmitted infections that came about,  
11 for example, with the development of SHOT and the  
12 better reporting of hospital -- from hospitals of  
13 transfusion infections, I think people became aware  
14 that one needed to do as much as one reasonably could  
15 to prevent or reduce the risk from transfusion  
16 infections.

17 With the advent of variant CJD and the  
18 precautionary principle as espoused by  
19 Mr Frank Dobson, who was secretary for health, when he  
20 came to talk to us at a British Blood Transfusion  
21 Society annual meeting, he basically was saying that  
22 the precautionary principle ruled, and with the  
23 interventions for variant CJD you will be able to see  
24 that if anything was thought that it might help, it  
25 was introduced.

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1 referring to there?

2 **A.** I think sometimes we had developed initiatives and  
3 ideas, like, for example, the AIDS questionnaire or  
4 the self-exclusion questionnaire, which we thought  
5 were very relevant and significant, and I think other  
6 centres felt we were being over the top and being too  
7 intrusive. And there were issues like this where we  
8 might have wanted to introduce concepts, set up  
9 national registers, which sometimes we got some  
10 resistance about.

11 **Q.** Was your perception that that slowness changed, either  
12 for better or worse, when the National Directorate was  
13 set up?

14 **A.** I think all I can say there is when the National  
15 Directorate was set up, we had at least got a unified  
16 service that, if you like, was all singing to the same  
17 hymn sheet. So I think that, provided that we had the  
18 platform to put our ideas forward, they could be  
19 considered nationally, and if it was felt there was  
20 something relevant, then, that could then be  
21 initiated. So I think it probably helped.

22 **Q.** You have also said in your statement that you think  
23 there was a gradual drift in attitude and direction  
24 towards a more precautionary approach, and you used  
25 the word "drift" rather than "shift".

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1 **Q.** Given the enormity of the AIDS crisis, why did a shift  
2 in attitude not take place at an earlier date, from  
3 your perspective?

4 **A.** In relation to HIV --

5 **Q.** Why did that --

6 **A.** -- did you say?

7 **Q.** Yes. In relation to HIV, why did that not mark  
8 a point when a shift in attitude and direction took  
9 place?

10 **A.** I think in large part because it took us quite a while  
11 to perceive just how uniformly devastating an HIV  
12 infection was. Because, as I said before, it could  
13 take years before immune deficiency developed and  
14 before that showed itself as opportunistic infections  
15 in often very horrible, very aggressive Kaposi's  
16 sarcoma, Cytomegalovirus, otherwise very mild, that  
17 would prove very fatal, toxoplasmosis.

18 I think it took quite a while to understand that  
19 HIV was not just horrible in certain cases but it was  
20 uniformly devastating.

21 **MS FRASER BUTLIN:** Sir, those are the questions I have for  
22 Professor Barbara. I have had some questions already  
23 from recognised legal representative but I recognise  
24 that we should take a break to allow them to send in  
25 any further questions.

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1 **SIR BRIAN LANGSTAFF:** Do you have any sense of how long  
 2 you might need?  
 3 **MS FRASER BUTLIN:** I think only ten minutes, sir.  
 4 **SIR BRIAN LANGSTAFF:** Let's take quarter of an hour and  
 5 come back at 2.45.  
 6 Professor, what happens -- forgive me for  
 7 talking with my mask -- now is that Core Participants,  
 8 whose representatives have been listening to what you  
 9 have said so far, may have questions which they want  
 10 to put to you, and they put those through counsel.  
 11 She must first of all, obviously, be told what those  
 12 questions are, and that's what this next period will  
 13 give a chance to happen.  
 14 So we will come back at 2.45 pm. I can't tell  
 15 you quite how long we will be, it could be very short,  
 16 it could be quite a long time, it all depends how many  
 17 questions there are, of course. But 2.45 pm.  
 18 **A.** Could I just interrupt, Sir Brian?  
 19 **SIR BRIAN LANGSTAFF:** Yes, certainly.  
 20 **A.** You had asked -- you raised the interesting question  
 21 which I've sort of paraphrased as: if we had  
 22 introduced first generation anti-HCV ELISAs, would we  
 23 have lost any more blood or donors and caused  
 24 ourselves any more problem than if we had introduced  
 25 surrogate testing?

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1 (2.31 pm)

2 (A short break)

3 (2.45 pm)

4 **MS FRASER BUTLIN:** Thank you, sir.  
 5 Dr Barbara, I just have a few questions that  
 6 others have raised for me to ask you about.  
 7 First of all, you suggested that Dr Cleghorn was  
 8 a visionary because he recognised that rather than  
 9 being a nuisance that you had to get round, he was  
 10 aware that transfusion-transmitted infections would  
 11 become an increasing problem. To what extent did  
 12 other directors of Regional Transfusion Centres feel  
 13 that dealing with transfusion-transmitted infections  
 14 was a nuisance to get around?  
 15 **A.** Well, I think that the obvious expertise in blood  
 16 transfusion was a haematological one. And I'm not  
 17 sure that all the other directors, at least in the  
 18 early days, recognised the potential significance and  
 19 risk to patient safety that blood-borne agents might  
 20 pose.  
 21 Again, I'm probably being somewhat flippant in  
 22 my comments and I apologise for that, but I think that  
 23 there wasn't the recognition of the significance and  
 24 the impact that things might have and then one thinks  
 25 about HIV and the concerns of variant CJD and, yes,

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1 Looking back at my very brief notes, depending  
 2 on where you set cut-offs for raised ALT and anti-HBc,  
 3 and if we were to use both those markers, I think we  
 4 would have probably had less of a problem with first  
 5 generation anti-HCV. But that wasn't a question that  
 6 had arisen before. So it certainly is an interesting  
 7 point.

8 And the other thing I remembered was that,  
 9 actually, if you had taken appropriate cut-offs for  
 10 ALT and anti-core and excluded donors who were both --  
 11 only excluded donors who were both anti-HCV pos and  
 12 ALT raised, you were approaching the predictive value  
 13 of real infectivity as you did with the first  
 14 generation anti-HCV ELISAs.

15 So in retrospect, and with the benefits of  
 16 hindsight, these are quite -- do prove indeed very  
 17 interesting. So yes, thank you for bringing those up.

18 **SIR BRIAN LANGSTAFF:** Thank you for that answer. It  
 19 confirms what I suspected may be the case but I'm not  
 20 qualified to know, this is why I asked you. So thank  
 21 you for that. That's fascinating. I shall have to  
 22 work out what I make of the implications of that  
 23 answer but thank you for it.

24 2.45 pm.

25 **MS FRASER BUTLIN:** Thank you.

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1 I would stick to my choice of words as visionary.  
 2 I think that, over time, all transfusion directors did  
 3 recognise the importance and I wouldn't want to dilute  
 4 that but, for me, Tom Cleghorn could see it very  
 5 clearly and of course that was, in part, because of  
 6 his close association with Dr David Dane.

7 **Q.** Could we have CBLA0000043\_040, please.

8 Professor Barbara, this isn't a document that  
 9 was specifically flagged to you in advance but I'm not  
 10 going to ask you about the detail in it. Given the  
 11 significant contact you had with PHLS and CDSC were  
 12 you aware of this letter, sent by Spence Galbraith, on  
 13 9 May 1983 to the Department of Health and Social  
 14 Security?

15 Let me read to you just the core section of it.

16 It indicates that Spence Galbraith had:

17 "... a case of the Acquired Immune Deficiency  
 18 Syndrome in a haemophiliac in Cardiff who had received  
 19 USA factor VIII concentrate was reported."

20 He then identifies that he's reviewed the  
 21 literature, and this is the part I want to highlight  
 22 to you:

23 "I have reviewed the literature and come to the  
 24 conclusion that all blood products made from blood  
 25 donated in the USA after 1978 should be withdrawn from

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1 use until the risk of AIDS transmission by these  
2 products has been clarified."  
3 I just want to ask you, Professor Barbara,  
4 whether you were aware of this letter at that time?  
5 **A.** No, I wasn't aware of it.  
6 **Q.** Moving on then to non-A, non-B hepatitis, I'm asked to  
7 explore with you whether you ever tested your views on  
8 the clinical severity of non-A, non-B against the  
9 views of hepatology colleagues who were dealing with  
10 the effects of it from a clinical perspective?  
11 **A.** Yes, I understand the relevance of that.  
12 I suppose we tended to live in slightly  
13 different worlds and we were aware, and became  
14 increasingly aware at symposia and seminars, of the  
15 concerns of clinical colleagues. I think to some  
16 extent myself and others in the Blood Service would  
17 have taken a view that if you spend your working day  
18 dealing with a particular condition, then you tend to  
19 think that that condition is prevalent everywhere. So  
20 I think I'd have to say that we didn't really test  
21 those views against our clinical colleagues. We did  
22 have in mind what they said and became increasingly  
23 aware of the actual relevance of a -- I believe small,  
24 but real proportion of cases of infection.  
25 **Q.** Do you agree with Professor Contreras' evidence that

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1 the Plasma Fractionation Centres had also to check their  
2 bulk source material in whatever respects were  
3 possible."  
4 In relation to the suggestion that there was  
5 a need for a central authority, et cetera, to collect  
6 and coordinate information, including on reactions and  
7 diseases that were developing, can you confirm that  
8 there was no body or group that carried out that  
9 function centrally at that time?  
10 **A.** I believe there was not.  
11 **Q.** What can you recall about North London's practice, if  
12 any, of informing the CDSC about post-transfusion  
13 hepatitis cases?  
14 **A.** From when I started, again, because of the clear  
15 advice from Dr Dane, I would provide an annual report  
16 of our investigations, in conjunction with the  
17 Middlesex, on -- investigations into post-transfusion  
18 infection. And I would send a copy of this report to  
19 I believe then it was Dr Sheila Polakoff at CDSC. So  
20 this would be a regular and recognised exchange of  
21 information.  
22 **Q.** What then would have been the benefits, do you think,  
23 of having a central body or group collecting and  
24 coordinating that information?  
25 **A.** I suppose that procedure could have been rolled out on

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1 if there had been some sort of central advice from the  
2 Chief Medical Officer, this may have assisted you in  
3 having earlier understanding of the significance of  
4 the risk of non-A, non-B hepatitis?  
5 **A.** Yes, I could see the benefit of that. Yes.  
6 **Q.** Can we turn then to NHBT0007639, please.  
7 These are minutes of the Working Group on  
8 Microbiology held on 15 January 1988. If we go over  
9 to the second page, please, we have paragraph 2.3.  
10 The minutes record:  
11 "There is also a need for a central  
12 authority/body/institution to collect and coordinate  
13 information on, and give guidance on, quality control  
14 matters.  
15 "Such a centre could record and provide  
16 information on data on supplies and quality of products  
17 in various RTCs; on reactions and diseases (eg malaria)  
18 developing in recipients of blood, blood components or  
19 plasma fraction products.  
20 "Advice on special matters such as how to take  
21 blood from infected persons could be provided. It is  
22 not clear at present where the responsibility for  
23 checking the quality of blood packs, or for the quality  
24 of bulk plasma lies. In charge measure this must be at  
25 the Transfusion Centres where plasma is collected, but

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1 a national basis, with a consistent approach across  
2 all blood centres.  
3 **Q.** And with the benefit of hindsight, do you think such  
4 a national body, centralised body, would have led to  
5 improved data and understanding on a national basis of  
6 the incidence of post-transfusion hepatitis?  
7 **A.** I think, with hindsight, it might well have done.  
8 I notice it covers quality control matters, and I must  
9 mention that NIBSC, the National Institute for  
10 Biological Standards and Control, also provided  
11 analyses of our routine QC test results on our tests  
12 for all agents, and we would get monthly reports on  
13 this, and again there would be seminars that were  
14 organised by NIBSC. Dr Ferguson -- Dr Morag Ferguson  
15 and myself used to arrange these jointly. So there  
16 was the developed and improved national quality  
17 control coordination.  
18 **Q.** We looked at a letter earlier that you co-wrote with  
19 Professor Contreras to The Lancet in August 1989, in  
20 which you referred to the UK donor population as being  
21 a low prevalence population in relation to non-A,  
22 non-B hepatitis. It is a point we have discussed  
23 a few times, Professor Barbara, but I have been asked  
24 to clarify whether your reference to a low prevalence  
25 population was simply based on the low rate of

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1 post-transfusion hepatitis reports that you received?  
 2 **A.** Yes, I suppose it must have been mainly due to that.  
 3 And probably because of a feeling that there was  
 4 a low incidence of reported cases of non-A, non-B in  
 5 the general population.

6 **Q.** And finally, in relation to the hepatitis C assays,  
 7 following your assessment in 1989 that the tests of  
 8 the assays constituted a welcome advance over  
 9 surrogate markers, was any thought given to using the  
 10 first generation of assays in conjunction with  
 11 surrogate testing?

12 **A.** I don't believe there was.

13 **MS FRASER BUTLIN:** Thank you.

14 Sir, there are no further questions that I have  
 15 been asked to put to Professor Barbara. Is there  
 16 anything, sir, that you want to raise?

#### 17 Questions from SIR BRIAN LANGSTAFF

18 **SIR BRIAN LANGSTAFF:** Yes. Really two ends almost of the  
 19 time spectrum, but the first in relation to  
 20 hepatitis B and, given your interest in microbiology  
 21 and virology and your knowledge of Dr Dane, you may be  
 22 able to help with this.

23 When the screening test for hepatitis B was  
 24 introduced in 1972, the first generation anyway of the  
 25 tests had, as I understand it, a reputation of not

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1 iodine-125.

2 **SIR BRIAN LANGSTAFF:** At what stage did it manage to reach  
 3 the level of universal or pretty universal  
 4 detectability, the improved sensitivity of the test?

5 **A.** Again, from memory, the haemagglutination test --  
 6 actually, especially the enhanced haemagglutination  
 7 test that I developed and that most centres in the  
 8 country took up, would have detected between 90 and,  
 9 say, 93 per cent of positives. Then the  
 10 radioimmunoassay would have detected from 93 to 97,  
 11 98 per cent. So it was a very sensitive test and the  
 12 ELISAs similarly, but then, of course, with PCR you  
 13 were able to detect practically everything unless it  
 14 was very early in the window period and with any viral  
 15 infection there is a phase called the eclipse, where  
 16 no test is going to be positive but given a donation  
 17 given by the pint, as it were, such a large volume of  
 18 inoculant, there may have been some residual  
 19 infectivity.

20 It was a gradual and steadily improving process  
 21 and it was lovely to see how the sensitivity could  
 22 increase and of course when we had the availability of  
 23 seroconversion panels, we could measure, very  
 24 accurately, the sensitivity of the different tests and  
 25 the tests from different manufacturers and, again,

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1 being particularly accurate, is that fair or not?

2 **A.** The immunodiffusion assay, Sir Brian, were accurate in  
 3 as much as they provided a built-in confirmation by  
 4 looking at the way the immunoprecipitant lines formed  
 5 and whether you got lines of identity with new  
 6 reactive samples. But it wasn't particularly  
 7 sensitive. So I think I would say it was accurate but  
 8 not sensitive.

9 **SIR BRIAN LANGSTAFF:** So it missed a number of cases?

10 **A.** Yes.

11 **SIR BRIAN LANGSTAFF:** That went on through the -- did  
 12 it -- in 1975 the -- was it the RIA test or -- came in  
 13 or maybe the -- (overspeaking) --

14 **A.** Or the haemagglutination test.

15 **SIR BRIAN LANGSTAFF:** Yes.

16 **A.** If I may say, the sequence was: initially it was  
 17 immunodiffusion, and then an electric current was  
 18 passed across the gel and you got what was called end  
 19 osmo-immunophoresis, which was like immunodiffusion  
 20 but made it faster, which of course helped in the very  
 21 manual testing, the routine screening for release of  
 22 blood within a half day. And I think it was slightly  
 23 more sensitive. Then haemagglutination tests came in.  
 24 Then radioimmunoassay came in. Then the ELISAs came  
 25 in because of the concerns of using radioactivity,

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1 that was so gratifying because it just made you sleep  
 2 easier when you knew that your day's testing was going  
 3 to be really much more reliable.

4 **SIR BRIAN LANGSTAFF:** The second end of the spectrum, as  
 5 it were, which I want to ask you about is in respect  
 6 of hepatitis C. My understanding is that the cloning  
 7 of the -- the sequencing of the genome of the virus  
 8 was first told to the world in a press release in  
 9 1988, 10 May 1988.

10 Now you won't remember the date, I'm quite sure,  
 11 but you might remember the event. It was some time  
 12 after that before the details, I think, were  
 13 published, at the same time as it was suggested there  
 14 was an assay which the Chiron corporation had  
 15 available for use to detect the virus.

16 What was the reaction -- your reaction first and  
 17 secondly the reaction of those around you -- to the  
 18 announcement that there was a claim, at any rate, that  
 19 whatever it was that was causing the large proportion  
 20 of non-A, non-B hepatitis had been found and  
 21 identified?

22 **A.** So virologists' equivalent of joy, Sir Brian, and  
 23 a relief as well that, at last, this elusive and  
 24 nebulous agent -- I don't normally like American  
 25 phrases because they are clumsy but non-A, non-B

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1 absolutely described what it was. It wasn't A, it  
2 wasn't B, we didn't know what it was. And here was  
3 clear evidence from Harvey Alter's very testing panel  
4 of samples, that when the Chiron assay, or the  
5 partners also who produced the ELISA, when they ran  
6 this there was such a predictive value in the assay  
7 for those samples, which were going to be -- a high  
8 proportion were going to be really, HCV positive.

9 And it was great relief that from this sort of  
10 side-field approach of cloning there had come an assay  
11 that was going to really get a handle on this  
12 condition, non-A, non-B hepatitis.

13 **SIR BRIAN LANGSTAFF:** What do you recollect happening in  
14 the period between the press announcement that it had  
15 been discovered -- and it was very nearly a year later  
16 I think that the actual details were published. What  
17 was happening in that period of time? What was the  
18 community doing?

19 **A.** I think that Chiron Corporation would have been  
20 confirming those findings. Of course, companies like  
21 to do a press release to generate interest. But for  
22 scientists, they would have wanted to be rock solidly  
23 sure that that was real. Then they would have been  
24 trying to formulate assays that were going to be  
25 robust, reliable, as sensitive as possible, as

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1 in effect blocked anyone from doing any research that  
2 wasn't based on their clone.

3 So one of the concerns we had was that there  
4 could be other -- other variants -- and we know about  
5 viral variants these days -- but the whole assay was  
6 based on this one particular variant, if you like, and  
7 we were concerned that the patent was so solid that it  
8 would block further progress.

9 If I may just add, when myself, Peter  
10 Glazebrook, Richard Tedder patented the, if you like,  
11 British HCV assay that Wellcome Diagnostics produced,  
12 we had hoped that there would be leeway for that to be  
13 used because it -- that clone contained a structural  
14 antigen and that assay, although it was the first  
15 generation of that assay, was actually more specific  
16 than the first generation Ortho assay, which didn't  
17 have any structural antigens. But in the end the  
18 patent court found against us. Which, I suppose, with  
19 the nature of the patent, was almost inevitable.

20 **SIR BRIAN LANGSTAFF:** Yes. So the market, in effect, was  
21 cornered, was it?

22 **A.** Absolutely, sir. Absolutely topped up.

23 **SIR BRIAN LANGSTAFF:** And having been cornered, I suppose  
24 that Ortho, whose test by then it was, would have  
25 expected to sell it around the world, I suppose?

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1 specific as possible. And of course there would have  
2 been trials of any reagents produced. So this would  
3 have been what was going on in that time. And, you  
4 know, the scientific and medical community would have  
5 just said: well, we will have to wait because we know  
6 these things do take time.

7 **SIR BRIAN LANGSTAFF:** You would have known it was coming  
8 at some point?

9 **A.** We would have known that a test -- once you clone  
10 an antigen, we would have known that that would  
11 eventually form the basis of some sort of assay.

12 **SIR BRIAN LANGSTAFF:** You would think it was probably  
13 a credible press release because it had -- amongst  
14 other things, I think it mentioned the name of Harvey  
15 Alter?

16 **A.** Yes. Yes, yes. Harvey, of course, his panel, was  
17 instrumental in validating the validity of that. So  
18 that was a press release I could have believed in,  
19 yes.

20 **SIR BRIAN LANGSTAFF:** To what extent do you think part of  
21 the delay may have been the patenting of Chiron  
22 Corporation of an assay that could then be sold around  
23 the world?

24 **A.** I think that could have been a considerable part,  
25 because the patent was absolutely rock solid, and it

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1 **A.** Yes. And they only -- if I may digress, they only  
2 licensed other companies to produce HCV antibody assay  
3 based on the Chiron clone -- if those other  
4 manufacturers had some hold on Ortho, so if they had  
5 licensed something to Ortho, they would expect to have  
6 the HCV licence cross-licensed to them. So you had  
7 UBI and you had Sanofi Pasteur, but Wellcome didn't  
8 have any such thing, so there was no bargaining power  
9 in that aspect.

10 It also meant that they could charge a price  
11 that was at least four times greater than any of the  
12 other routine screening assays that we were able to  
13 negotiate in the UK.

14 Sorry, you have triggered emotions, Sir Brian.

15 **SIR BRIAN LANGSTAFF:** Yes, I can see that. But I suppose  
16 it leads to the next question, which was: if that was  
17 the case, and if I think it was April 1989 that the  
18 test and the assay was announced in -- or published in  
19 science, and therefore known to be available, and the  
20 methodology was understood, there was a test which  
21 could have been used?

22 **A.** Yes.

23 **SIR BRIAN LANGSTAFF:** It wasn't a question of someone  
24 saying, "Look, we have just found" -- as it was with  
25 HIV -- "We have found the virus, now we are going to

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1 find a test for it"? The test was, as it were,  
2 readymade.  
3 **A.** When that was announced, yes, '89 -- and I know a lot  
4 of countries started it in 1990, but as I have laid  
5 out and my colleagues have laid out, our concerns were  
6 the prediction which was borne out of the poor  
7 specificity because of the cell line used and the  
8 anti-globulin format which lent itself to false  
9 positives and the lack of the confirmatory test. But  
10 yes, there was a test.  
11 **SIR BRIAN LANGSTAFF:** Thank you. That is all that I have  
12 to ask.  
13 It may be some questions arise out of that,  
14 Ms Fraser Butlin, I don't know?  
15 **MS FRASER BUTLIN:** I don't think we have had anything.  
16 No, sir.  
17 Professor Barbara, is there anything else you  
18 would like to add before we finish?  
19 **A.** Oh, in relation to the whole session?  
20 **Q.** Indeed.  
21 **SIR BRIAN LANGSTAFF:** Or anything that you want to say.  
22 We always give -- every witness has an opportunity to  
23 say whatever they may feel moved to say at the end of  
24 the evidence which they have given.  
25 **A.** If I may then, if you will forgive me from reading out

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1 path to completing its crucially important work.  
2 **SIR BRIAN LANGSTAFF:** It has most certainly helped. It  
3 helps us enormously to have different perspectives  
4 because there are different perspectives on what took  
5 place and yours is, if it isn't unique it is very  
6 close to being unique as being the only microbiologist  
7 in a Regional Transfusion Centre, employed as such for  
8 many years. And the insight which you have given from  
9 that particular point of view, it is absolutely plain  
10 that you are devoted to your subject and to the  
11 science of it and it is very good of you to be  
12 prepared to give us the benefit of that and I'm very  
13 grateful. Thank you.  
14 **A.** Pleasure, sir.  
15 **SIR BRIAN LANGSTAFF:** And I hope that it hasn't been too  
16 painful an experience and that your neck is, as it  
17 were, warming up a bit.  
18 **A.** Thank you for that.  
19 **MS FRASER BUTLIN:** Tomorrow, sir, we hear from  
20 Dr McClelland.  
21 **SIR BRIAN LANGSTAFF:** Yes, and that is which  
22 Dr McClelland?  
23 **MS FRASER BUTLIN:** Brian McClelland, the Scottish Dr Brian  
24 McClelland.  
25 **SIR BRIAN LANGSTAFF:** So Dr Brian McClelland tomorrow,

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1 a statement.  
2 **SIR BRIAN LANGSTAFF:** Go ahead.  
3 **A.** So I would like to finish by saying that I have tried  
4 to the best of my ability to assist the Inquiry on  
5 behalf of infected blood recipients and those who have  
6 been adversely affected. The only goal of myself and  
7 my colleagues was to help patients who might require  
8 blood as best we could. As a life-long blood donor,  
9 accredited with more than 250 donations of blood and  
10 platelets, this too reflects my goal (unclear).  
11 Naturally I completely sympathise with any  
12 recipients of blood who have been harmed by  
13 transfusion of blood components or products. I deeply  
14 regret the suffering or harm caused to patients and  
15 their families by any inadequacies in the provision of  
16 what was intended to be life saving or life enhancing  
17 transfusions. I would have wished that this Inquiry  
18 could have happened sooner. This would have enabled  
19 the inadvertently but tragically harmed patients to  
20 have some redress and justice for what happened to  
21 them. During the course of the Inquiry, the injury  
22 they have suffered has been made so movingly clear.  
23 I wish it could have been possible for me to  
24 attend the Inquiry in person and I very much hope that  
25 my evidence will have helped the Inquiry along the

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1 10 o'clock. Thank you.  
2 (3.18 pm)  
3 (Adjourned until 10.00 am on Thursday, 27 January 2022)

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1983</b> [1] 38/4</p> <p><b>12.25</b> [1] 77/17</p> <p><b>125</b> [1] 103/1</p> <p><b>12x8</b> [1] 10/19</p> <p><b>13</b> [2] 9/1 19/22</p> <p><b>15</b> [2] 19/20 80/18</p> <p><b>15 January 1988</b> [1] 98/8</p> <p><b>150</b> [1] 54/22</p> <p><b>153</b> [1] 82/19</p> <p><b>15th February</b> [1] 68/2</p> <p><b>16</b> [2] 16/8 16/9</p> <p><b>16 July 1982</b> [1] 31/19</p> <p><b>16 September 1978</b> [1] 23/18</p> <p><b>1970s</b> [1] 11/22</p> <p><b>1972</b> [1] 101/24</p> <p><b>1974</b> [2] 2/17 7/18</p> <p><b>1975</b> [1] 102/12</p> <p><b>1976</b> [1] 19/5</p> <p><b>1977</b> [1] 19/5</p> <p><b>1977-80</b> [1] 19/21</p> <p><b>1978</b> [3] 19/5 23/18 96/25</p> <p><b>1979</b> [1] 19/5</p> <p><b>1980</b> [1] 19/5</p> <p><b>1980s</b> [1] 44/16</p> <p><b>1981</b> [6] 15/25 16/5 16/8 16/17 17/6 18/9</p> <p><b>1982</b> [3] 15/23 31/19 31/24</p> <p><b>1983</b> [7] 25/9 31/13 31/25 32/14 38/4 38/19 96/13</p>	<p><b>1984</b> [1] 3/2</p> <p><b>1985</b> [3] 43/18 46/8 46/13</p> <p><b>1987</b> [3] 49/23 50/2 51/19</p> <p><b>1988</b> [3] 98/8 104/9 104/9</p> <p><b>1989</b> [9] 53/24 54/1 55/8 59/10 60/1 61/17 100/19 101/7 108/17</p> <p><b>1990</b> [1] 109/4</p> <p><b>1990s</b> [1] 82/10</p> <p><b>1991</b> [9] 67/4 67/23 68/2 68/14 68/17 69/1 70/9 71/14 76/16</p> <p><b>1992</b> [1] 87/16</p> <p><b>1993</b> [1] 82/24</p> <p><b>1994</b> [1] 3/13</p> <p><b>1999</b> [1] 77/16</p> <p><b>1ml</b> [1] 11/8</p> <p><b>1st</b> [3] 68/2 68/14 68/17</p> <p><b>2</b></p> <p><b>2 million</b> [1] 62/9</p> <p><b>2 per cent</b> [1] 47/5</p> <p><b>2 years</b> [1] 20/18</p> <p><b>2.05 pm</b> [3] 80/23 81/12 81/16</p> <p><b>2.2</b> [1] 54/23</p> <p><b>2.3</b> [1] 98/9</p> <p><b>2.30</b> [1] 80/25</p> <p><b>2.31 pm</b> [1] 95/1</p> <p><b>2.45</b> [1] 93/5</p> <p><b>2.45 pm</b> [4] 93/14 93/17 94/24 95/3</p> <p><b>2.5 million</b> [1] 61/6</p> <p><b>20</b> [1] 80/18</p> <p><b>20 milli-IU</b> [1] 84/12</p> <p><b>2001</b> [1] 3/16</p> <p><b>2005</b> [1] 3/21</p> <p><b>2006</b> [1] 3/22</p> <p><b>2022</b> [2] 1/1 112/3</p> <p><b>23</b> [1] 55/5</p> <p><b>23.6.89</b> [1] 58/16</p> <p><b>250</b> [1] 110/9</p> <p><b>26 January 2022</b> [1] 1/1</p> <p><b>27 January 2022</b> [1] 112/3</p> <p><b>3</b></p> <p><b>3 April 1991</b> [2] 67/23 69/1</p> <p><b>3-4 years</b> [1] 50/13</p> <p><b>3.18 pm</b> [1] 112/2</p> <p><b>3.7.4</b> [1] 55/18</p> <p><b>32</b> [1] 44/7</p> <p><b>4</b></p> <p><b>4,000</b> [1] 5/4</p> <p><b>4.30</b> [1] 77/17</p>	<p><b>4.4</b> [1] 55/3</p> <p><b>400,000</b> [1] 52/12</p> <p><b>47</b> [1] 23/21</p> <p><b>5</b></p> <p><b>5,000</b> [1] 5/4</p> <p><b>50</b> [1] 48/22</p> <p><b>50 pence</b> [1] 62/11</p> <p><b>6</b></p> <p><b>6 weeks</b> [1] 25/25</p> <p><b>64</b> [1] 44/8</p> <p><b>64 NLBTC</b> [1] 54/23</p> <p><b>7</b></p> <p><b>7 October 1993</b> [1] 82/24</p> <p><b>7 September 1992</b> [1] 87/16</p> <p><b>70s</b> [2] 7/18 8/4</p> <p><b>8</b></p> <p><b>8 August 1989</b> [1] 60/1</p> <p><b>80</b> [1] 19/21</p> <p><b>80s</b> [1] 36/3</p> <p><b>9</b></p> <p><b>9 June 1989</b> [1] 54/1</p> <p><b>9 May 1983</b> [1] 96/13</p> <p><b>90</b> [1] 103/8</p> <p><b>93</b> [1] 103/10</p> <p><b>93 per cent</b> [1] 103/9</p> <p><b>97</b> [1] 103/10</p> <p><b>98 per cent</b> [1] 103/11</p> <p><b>A</b></p> <p><b>Abbott</b> [1] 68/6</p> <p><b>ability</b> [3] 63/10 70/16 110/4</p> <p><b>ablating</b> [1] 12/15</p> <p><b>able</b> [16] 4/15 6/4 6/6 14/6 15/10 23/8 24/22 34/25 49/7 57/4 58/5 86/11 91/23 101/22 103/13 108/12</p> <p><b>about</b> [72] 2/20 3/21 3/22 3/23 4/5 6/18 7/21 9/4 9/25 10/12 14/16 14/18 17/3 17/15 17/17 17/20 19/16 23/1 25/17 31/13 32/23 35/15 36/18 37/8 37/15 37/17 37/18 40/1 40/6 40/7 40/11 40/20 44/23 46/8 46/14 46/20 47/6 47/15 48/6 48/13 49/9 52/3 57/10 58/7 62/2 63/25 64/6 65/9 70/18 72/7 74/20 76/8 76/25 78/4 78/9</p>	<p>78/19 80/11 81/6 82/4 82/24 83/14 86/10 89/18 90/10 91/10 95/6 95/25 96/10 99/11 99/12 104/5 107/4</p> <p><b>above</b> [1] 88/15</p> <p><b>absence</b> [5] 25/18 42/19 72/12 74/2 77/5</p> <p><b>absolutely</b> [13] 13/24 19/11 27/9 31/14 35/25 46/11 54/15 85/22 105/1 106/25 107/22 107/22 111/9</p> <p><b>accept</b> [2] 47/17 47/22</p> <p><b>accepted</b> [1] 65/13</p> <p><b>access</b> [2] 14/5 84/1</p> <p><b>accord</b> [1] 59/9</p> <p><b>account</b> [1] 53/22</p> <p><b>accredited</b> [1] 110/9</p> <p><b>accurate</b> [4] 37/3 102/1 102/2 102/7</p> <p><b>accurately</b> [1] 103/24</p> <p><b>acellular</b> [2] 31/11 31/12</p> <p><b>Acquired</b> [2] 38/21 96/17</p> <p><b>across</b> [7] 9/19 9/20 19/5 29/4 89/21 100/1 102/18</p> <p><b>acting</b> [1] 54/4</p> <p><b>action</b> [2] 51/1 60/12</p> <p><b>active</b> [1] 30/14</p> <p><b>actual</b> [5] 4/14 74/25 75/3 97/23 105/16</p> <p><b>actually</b> [11] 6/10 19/17 35/19 40/15 62/12 69/5 79/4 89/8 94/9 103/6 107/15</p> <p><b>acute</b> [5] 12/19 50/14 73/25 75/15 75/23</p> <p><b>add</b> [9] 17/20 19/14 27/4 45/23 71/5 74/17 87/4 107/9 109/18</p> <p><b>added</b> [5] 86/22 86/23 87/2 87/5 87/6</p> <p><b>addict</b> [1] 35/1</p> <p><b>addicts</b> [2] 33/6 34/18</p> <p><b>adding</b> [2] 81/3 86/25</p> <p><b>additional</b> [2] 54/25 68/8</p> <p><b>address</b> [4] 29/13 71/11 72/20 80/13</p> <p><b>addresses</b> [1] 82/25</p> <p><b>addressing</b> [1] 81/20</p> <p><b>Adjourned</b> [1] 112/3</p> <p><b>adjournment</b> [1] 81/15</p> <p><b>adjunct</b> [1] 44/14</p> <p><b>Administration</b> [1] 67/8</p>	<p><b>advance</b> [7] 60/10 64/17 64/20 64/21 66/5 96/9 101/8</p> <p><b>advantage</b> [1] 85/13</p> <p><b>advent</b> [2] 61/13 91/17</p> <p><b>adversely</b> [1] 110/6</p> <p><b>advice</b> [7] 4/15 7/14 49/10 88/7 98/1 98/20 99/15</p> <p><b>advise</b> [1] 88/11</p> <p><b>aetiological</b> [1] 72/22</p> <p><b>affect</b> [2] 75/22 87/4</p> <p><b>affected</b> [2] 24/23 110/6</p> <p><b>affirmation</b> [1] 1/9</p> <p><b>affirmed</b> [2] 2/5 113/3</p> <p><b>afflicted</b> [1] 5/8</p> <p><b>afraid</b> [2] 18/22 54/9</p> <p><b>after</b> [19] 1/9 25/25 26/4 31/21 43/2 44/13 44/18 44/20 50/23 50/25 51/2 56/9 66/16 74/4 80/25 83/4 88/18 96/25 104/12</p> 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<b>A</b>	<b>amongst</b> [2] 33/16 106/13 <b>amount</b> [1] 53/19 <b>amounts</b> [2] 10/21 30/13 <b>amplify</b> [1] 17/9 <b>an acute</b> [2] 12/19 75/15 <b>an adjunct</b> [1] 44/14 <b>an advance</b> [2] 64/20 64/21 <b>an aetiological</b> [1] 72/22 <b>an agent</b> [1] 41/1 <b>an annual</b> [1] 99/15 <b>an anomaly</b> [1] 8/13 <b>an answer</b> [1] 50/13 <b>an anti-core</b> [1] 84/24 <b>an anti-HBc</b> [1] 84/11 <b>an antibody</b> [2] 71/16 75/16 <b>an antigen</b> [1] 106/10 <b>an appropriate</b> [1] 68/3 <b>an archive</b> [1] 10/14 <b>an argument</b> [1] 50/11 <b>an article</b> [1] 15/22 <b>an aside</b> [1] 33/18 <b>an assay</b> [5] 63/1 63/12 63/12 104/14 105/10 <b>an association</b> [2] 76/14 76/17 <b>an attendance</b> [2] 77/15 78/14 <b>an average</b> [1] 52/14 <b>an earlier</b> [1] 92/2 <b>an early</b> [1] 42/3 <b>an electric</b> [1] 102/17 <b>an ELISA</b> [4] 69/6 69/10 69/17 87/8 <b>an email</b> [1] 83/18 <b>an emeritus</b> [1] 3/18 <b>an enormous</b> [1] 24/10 <b>an error</b> [3] 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