

Thursday, 10 December 2020

(2.00 pm)

PROFESSOR GORDON LOWE, continued

SIR BRIAN LANGSTAFF: Good afternoon, Professor Lowe.

A. Good afternoon, Sir Brian.

SIR BRIAN LANGSTAFF: That means you can both hear me and see me.

So, Ms Richards.

A. I'm sorry, could I just make two quick comments arising from yesterday's session?

MS RICHARDS: Yes.

A. Right. Firstly, you asked me about freeze-dried cryoprecipitate and the reason that Scottish National Blood Transfusion did not progress its development, and I found last night the minutes of a meeting on 21 January 1983, which was a meeting of SNBTS and Scottish Haemophilia --

SIR BRIAN LANGSTAFF: Can you tell me, were you actually at the meeting yourself?

A. No, I wasn't, but it does answer the question that you asked.

SIR BRIAN LANGSTAFF: Right.

MS RICHARDS: We do have the minutes.

SIR BRIAN LANGSTAFF: We've got the minute, I think.

A. Right.

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research which were symposium highlighted, and arthritis; and they were starting a five-year study of arthritis and liver disease at the haemophilia review clinic. You may want to come back to that when you ask about research.

Further questioned by MS RICHARDS

MS RICHARDS: Thank you, professor.

Can I just pick up one document you referenced yesterday which we didn't have available to display but do now, just to check we're talking about the same document.

It's PRSE0004632, please, Soumik. You referred to attending a 1975 symposium, professor. Is this the symposium you were referring to?

A. That is it, yes.

Q. We can see for the four o'clock session, you referred to Dr Craske, and his presentation is entitled "Virus hepatitis complicating replacement therapy". We can see the date of the symposium is 19 September 1975. Would it be right to infer that his address, given what you said yesterday about your memory of it, included reference to the outbreak of non-A, non-B hepatitis in Bournemouth that he had published about in The Lancet in August of that year?

A. I think that was the focus of the talk, yes.

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SIR BRIAN LANGSTAFF: So what was the next point?

A. Okay. So it includes Drs Prentice, Forbes and MacDonald, who co-authored the paper on the trial. And Dr Cash, as you can see, thanked them for this and said that SNBTS decided to abandon the project for three reasons: closure of the West of Scotland Blood Transfusion Service freeze-drying plant at Law Hospital; secondly, cost of the meeting standards demanded by the medicines inspectorate, and then, as I mentioned yesterday, the most important was the prospective availability of a hepatitis risk-reduced Factor VIII concentrate. And that, of course, was very timely for the appearance of HIV in December 1984 so that they could proceed to immediately replace the old product.

SIR BRIAN LANGSTAFF: Thank you.

A. Second question: Ms Richards, you asked a very pertinent question about what patients were told about non-A, non-B hepatitis following the September 1980 symposium on unsolved clinical problems. I recall that within a few months, Dr Forbes and Dr Sturrock, the rheumatologist, presented at the monthly department unit research meeting their planned study which addressed two of the unsolved clinical problems: liver disease, including the unique opportunities for

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Q. Thank you. We can take that down, Soumik.

Professor Lowe, I am going to move on to ask you about HIV. I'll mostly be asking you about the process of HIV testing and informing patients of their diagnosis. But just before we come on to that, Professor Forbes told the Penrose Inquiry that he'd had some early contact with Dr Oscar Ratnoff in the States about an early case of this disease in a haemophiliac, possibly in late 1981. The evidence isn't entirely clear.

Did you have any knowledge at the time of any contact between Professor Forbes and Dr Ratnoff?

A. No, I didn't.

Q. You do say, however, in your witness statement to this Inquiry that you think you became aware of AIDS cases in haemophiliacs in late 1982 through being told about it by Professor Forbes who was initiating a study of immune abnormalities in patients with severe haemophilia; is that correct?

A. Yes. I think Dr Forbes, again at one of these monthly research meetings, was presenting the early data and saying that, from that point, he wanted to set up immunological studies. But I think I also in my own reading read about it I think perhaps in The Lancet which I subscribed to.

4

- 1 Q. I'll come back at a later stage to ask you about that
2 particular study in relation to immune abnormalities.
3 Do I also correctly understand from your
4 witness statement that as you had little, if any,
5 interaction with haemophilia patients in that crucial
6 period for HTLV-III purposes, '82 to '84, you had no
7 involvement in providing or communicating information
8 to patients about the risks of AIDS?
- 9 A. That's absolutely correct, and I think I have told you
10 what I did year by year. And at the start of 1983,
11 I had a talk with Professor Kennedy, my head of
12 department, and he said, "You really must take time
13 off and get your MD thesis written up." So he gave
14 me, I think, about six months off the ward completely.
15 And then he also told me that I had done enough
16 *haemophilia* and any other thing on his unit, and I was
17 to be rotated to Professor Lawson's unit to expand my
18 experience in other areas like diabetes and other
19 aspects of vascular diseases. So I had very little
20 contact with the haemophilia unit.
- 21 Q. So does this also follow -- it sounds like it probably
22 does -- but you didn't know, wouldn't know, from your
23 own knowledge, as opposed to anything you might have
24 read or thought about later, about whether any changes
25 were made to the centre's treatment policies at that

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- 1 Soumik, it's PRSE0004259. This is one of
2 Professor Forbes' written statements to the Penrose
3 Inquiry. If we go to the third page, please, Soumik,
4 and we look at the top two paragraphs, 4 and 4.1, you
5 will see a question about whether there was an early
6 testing of blood examples by Dr Melbye in his
7 laboratory in Denmark, and then subsequent testing by
8 Dr Follett. Professor Forbes' answer was:
9 "I do not remember in detail when the samples
10 were taken, but they must have been for some months
11 prior to the testing date, which was 1984, and these
12 initial samples were all tested by Dr Melbye in
13 Denmark. Subsequent to that, Dr Follett at Ruchill
14 was given samples for local testing, and that took
15 place for many months thereafter."
16 I am going to come on to Dr Follett in
17 a moment, in a few minutes.
18 Do you have any knowledge of whether samples
19 were tested by Dr Melbye in Denmark of Glasgow
20 patients?
- 21 A. I would have to check but I think that's a mistake
22 from Dr Forbes' memory which, as you understand, was
23 getting a bit more poor at the time of the Penrose
24 Inquiry. I think if you look at the statement of
25 Dr Karin Froebel, who was his colleague I think her --

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- 1 time?
- 2 A. The only thing I can think of was -- when you say "at
3 that time", do you mean 1983?
- 4 Q. '82, '83, '84.
- 5 A. Well, I think two things happened in 1983. First, as
6 you know, Scotland became almost -- well, pretty well
7 self-sufficient in Factor VIII concentrate, so there
8 was -- I don't think commercial Factor VIII
9 concentrate was used much, and we looked at that data
10 yesterday.
11 I'm trying to think. Was there also an early
12 UKHCDO suggestion about reverting to cryoprecipitate
13 for patients who received little treatment?
- 14 Q. There was a communication in the middle of 1983 from
15 UKHCDO, but we've looked at that on multiple
16 occasions. It's really whether you, from your own
17 knowledge at the time, are able to add to that at all?
- 18 A. No, I can't add to that.
- 19 Q. I want to move then to the question of testing for
20 HTLV-III in which I think you had some involvement,
21 even if potentially at a relatively late stage.
22 I want to look just first at what
23 Professor Forbes told the Penrose Inquiry in one of
24 his written statements on this issue to see whether
25 you can help us understand the position more widely.

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- 1 Q. That's the next document I was going to go to.
- 2 A. I beg your pardon.
- 3 Q. That's quite all right.
- 4 A. I think she corrected Dr Forbes' statement and said
5 that he was in touch with Dr Melbye, because she'd
6 read, I think, his paper in *The Lancet* or somewhere,
7 and they had a discussion and they agreed to combine
8 the samples from Denmark and from Glasgow and send to
9 Dr Froebel's laboratory and do the joint study to look
10 at the whole of the European samples if they were
11 related to American commercial concentrate.
- 12 Q. Let's look at Dr Froebel -- is it "freeble", the
13 pronunciation?
- 14 A. "Froebel", I think.
- 15 Q. PRSE0002026, please, Soumik.
16 So we can see this is a statement to the
17 Penrose Inquiry from Dr Karin Froebel, June 2011. She
18 talks about working in the Department of Medicine
19 Research Laboratory at the Glasgow Royal Infirmary.
20 If we just move to the second page, please, and
21 if we look at the third paragraph down, beginning
22 "Things were moving very quickly", if we just go to
23 the paragraph, please, Soumik.
24 So she refers to Montagnier and Gallo, and we
25 will leave aside the precise dates, and then says

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1 this:
 2 "We were interested to know as soon as possible
 3 whether the Glasgow haemophilic patients had antibody
 4 to the virus. In Glasgow there was a freezer-full of
 5 stored serum samples from an earlier study, which
 6 Dr Forbes suggested could be used. I wrote to both
 7 Montagnier and Gallo and had a reply from Dr Gallo
 8 directing me to send the samples to his research
 9 scientist. The samples (77) were located, I think by
 10 Dr Madhok, packed in dry ice, and Dr Forbes and I took
 11 them to Glasgow airport to be air-freighted to the
 12 laboratory in the US. At this point, I still thought
 13 the results would be negative; that we were dealing
 14 with something different in Scotland and I can still
 15 recall the shock when the news came back that 12 of
 16 our 77 samples, ie 16%, tested positive. Very soon
 17 after that, Mads Melbye appeared, and suggested
 18 writing a joint paper, pooling our results with his
 19 22 Danish samples, and this resulted in The Lancet
 20 paper in December 1984."

21 We will look at The Lancet paper in a moment,
 22 Professor Lowe, not least because it has your name as
 23 one of the contributors.

24 Is what is described here by Dr Froebel, the
 25 sending off of 77 frozen stored serum samples to

1 contributors, including Dr Karin Froebel,
 2 Professor Forbes, yourself, Dr Gallo, Dr Madhok
 3 Dr Melbye from Denmark.

4 Then if we just pick up the first few lines in
 5 the summary we can see that:

6 "77 Scottish haemophiliacs and 22 Danish
 7 haemophiliacs were serologically tested for antibodies
 8 to human T cell leukaemia virus III (HTLV-III)."

9 Then there's a description of the treatment
 10 which Scottish patients, it was said, had largely
 11 received and the treatment which the Danish patients
 12 had largely received.

13 If we go down to the bottom half of the page,
 14 please, Soumik. Zoom in under the heading
 15 "Introduction", so we can see the rest of the page.
 16 Thank you.

17 So the "Introduction":

18 "Haemophiliacs are at increased risk of ...
 19 (AIDS)."

20 And then it refers to it being 1 per cent of
 21 all diagnosed cases in the US and so on.

22 Picking it up towards the end of that
 23 paragraph:

24 "We have compared HTLV-III antibody prevalences
 25 in two populations of haemophiliacs -- Scottish

1 Dr Gallo in the States, your understanding of what
 2 happened?

3 A. Well, I wasn't involved. I wasn't working on the unit
 4 at the moment. I think the first I knew about this,
 5 and I think I said this at the Penrose Inquiry, was
 6 I first heard about this study from Dr Forbes and
 7 Dr Froebel maybe about late September, early October,
 8 because they had asked Dr Melbye to come to Glasgow
 9 and help draft this joint paper that's referred to
 10 there.

11 And I attended that meeting because Dr Forbes
 12 had asked if I could write as part of that (it was a
 13 bit separate) a brief account of a patient from
 14 England that Dr Forbes had -- who had come back to
 15 Glasgow. And -- well, you will see it in the paper.
 16 I wrote that description of this paper about a patient
 17 who developed AIDS.

18 Q. Let's go then to The Lancet article, which is
 19 PRSE0001630, please, Soumik.

20 So if we zoom in on the top half of the page to
 21 start with, we can read it more clearly. Thank you.

22 So we can see it's The Lancet, late December of
 23 1984, "HTLV-III sero-positivity in European
 24 haemophiliacs exposed to Factor VIII concentrate
 25 imported from the USA". Then we can see a number of

1 patients who mainly use ..."

2 Sorry, we have lost it, Soumik.

3 "... who mainly use Factor VIII concentrate of
 4 local origin, and Danish patients who use both
 5 imported and locally manufactured concentrates."

6 Then, in terms of materials and methods, it
 7 describes the taking of blood from Danish
 8 haemophiliacs during routine health evaluation in
 9 April of '84.

10 "Detailed information was available on the ..."

11 If we can go over the page, top of the next
 12 page, left-hand column:

13 "... amount and origin of Factor VIII or IX
 14 used by each patient ..."

15 Then it says this about the Glasgow patients:

16 "Similar data were obtained on Scottish
 17 haemophiliacs enrolled in the Regional Haemophilia
 18 Reference Centre, Glasgow. Blood was taken from these
 19 patients between December, 1983, and July, 1984."

20 And then we see description of the tests being
 21 done.

22 We'll just complete looking at this and then
 23 I am going to ask you some questions.

24 We can then see under the next heading,
 25 "RESULTS, Patient with AIDS", if we can go into that

1 paragraph, please, Soumik:
 2 "A 35-year old Scottish haemophilia A patient
 3 with no other AIDS risk factors had since 1979 been
 4 treated exclusively with US manufactured Factor VIII
 5 concentrate in high dosage. In his last 7 months, he
 6 had malaise, anorexia, weight loss, intermittent
 7 fever, lymphadenopathy and night sweats. There were
 8 persistent herpetic lesions of the lips and oral
 9 cavity, and also candidiasis of the mouth and anus.
 10 Latterly he complained of dysphagia and central
 11 sternal pain. He was HTLV-III seropositive,
 12 lymphopenic, and moderately thrombocytopenic, and had
 13 reduced responses to several mitogens. T helper cell
 14 numbers were reduced, as was the helper/suppressor
 15 ratio ... In September, 1984, he was admitted to
 16 hospital with streptococcal septicaemia and he died in
 17 late October with [PCP]."
 18 Just pausing there, professor, as I understand
 19 it from your evidence, you wrote that part of the
 20 article?
 21 **A.** That's correct.
 22 **Q.** Was this a patient who had been treated with
 23 concentrates at the Glasgow haemophilia centre?
 24 **A.** No. This was a patient from Glasgow who I think for
 25 several years -- well, several years before this,

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1 with the director of the English centre and explained
 2 what was happening. The patient went down but became
 3 more ill and decided he wanted to come home and be
 4 looked after by his parents and shortly after that he
 5 had his fatal septicaemia.
 6 I think the HTLV-III sero-positivity wasn't
 7 done in Glasgow because Dr Forbes didn't have the
 8 test. I think that was done at the English centre.
 9 **Q.** Okay. We've seen reference previously to a case in
 10 Cardiff, a case in Bristol and a case in Newcastle.
 11 Is this the same as the Newcastle case or a different
 12 case, do you know?
 13 **A.** Am I allowed to tell you that?
 14 **Q.** In relation to Newcastle it's published in the media
 15 that a patient died in Newcastle so, provided you
 16 don't give any more detailed information than that,
 17 then yes.
 18 **A.** I think if that was published in the newspapers it
 19 probably is, but I can't remember the newspaper.
 20 **Q.** That's fine.
 21 Can we then go, Soumik, to the right-hand
 22 column of this article, same page, and zoom in on the
 23 bottom half of the page. So we can see there the
 24 results in relation to Scotland:
 25 "In Scotland, 11 (18%) of 62 haemophilia A

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1 moved down to a haemophilia centre in England and
 2 attended there and had large quantities -- well,
 3 you've got the dates there. So he must have left
 4 Glasgow in the 1970s. I'd never seen the patient.
 5 And at the centre in England he received
 6 US manufactured concentrate in high doses.
 7 Dr Forbes admitted him to Glasgow Royal
 8 Infirmary maybe about May and July, because they are
 9 talking about some T helper cells -- round about that
 10 time.
 11 Basically his parents brought him up to the
 12 centre. They were concerned about his health, as you
 13 can see. And Dr Forbes said, "Oh, I think we need to
 14 admit you for a few days for investigation". So he
 15 was admitted to one of the investigation wards in
 16 Glasgow Royal Infirmary, and Dr Forbes assembled the
 17 colleagues in immunology and infectious diseases and
 18 they concluded that he may not have had the strict
 19 definition of AIDS that Professor Ludlam was talking
 20 about last week but it was perhaps more of a kind of
 21 AIDS-related complex, the pre-AIDS kind of syndrome.
 22 So that diagnosis was made and Dr Forbes
 23 informed the patient and his parents that that was the
 24 case, but the patient was very keen to go back to the
 25 centre in England. So Dr Forbes rang and communicated

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1 patients and 1 (7%) 15 haemophilia B patients were
 2 HTLV-III positive. All but 2 of the seropositive
 3 subjects were known to have received commercial factor
 4 concentrate in the period 1979-84: one had travelled
 5 yearly throughout Europe and could have received
 6 unrecorded treatment; the other was a citizen of
 7 Pakistan who often visited his home country.
 8 Seropositive haemophilia patients had received more
 9 commercial clotting factor concentrate than
 10 seronegative subjects ... whereas there was no
 11 statistical difference between the two groups in use
 12 of local products."
 13 Then there follows a discussion which I don't
 14 think I need to trouble you with.
 15 It would appear from this article that the
 16 tests that were undertaken on the 77 Scottish
 17 patients, Glasgow patients, were tests on blood taken
 18 from the patients between December 1983 and July 1984
 19 which had presumably then been stored. Is that your
 20 understanding?
 21 **A.** I wasn't directly involved in the study but I think
 22 these samples were taken by Dr Madhok at the
 23 haemophilia centre, because he and Dr Froebel and
 24 Dr Forbes were performing the study of immunological
 25 tests, that's the T cell subset stuff, that they had

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1 published I think the year before, in 1983. So at
 2 that time they were doing studies of such patients.
 3 And then I think the other potential source --
 4 because, I have to say, I don't know directly,
 5 I wasn't involved in the study -- was, in fact, the
 6 study I was mentioning right at the start of this
 7 session, the study that Dr Forbes and Dr Sturrock set
 8 up with -- to look at, in a larger population than the
 9 patients who had the immunological studies, this
 10 five-year study of arthritis and of liver disease, and
 11 as part of that study samples were stored in the
 12 rheumatology department of the Department of Medicine.
 13 And those, I recall, were used for immunological tests
 14 that they thought might be related to liver disease
 15 and/or to arthritis.

16 So those were studies done in the University
 17 Department of Medicine's rheumatology laboratory;
 18 things like rheumatoid factor complements, immune
 19 complexes, that kind of thing.

20 **Q.** So is this right, that the samples -- the 77 patient
 21 samples that were sent to Dr Gallo in the States to be
 22 tested using his tests for HTLV-III were taken from
 23 stored samples which were held at the Royal Infirmary
 24 which had been obtained for the purposes of research,
 25 you think, whether it was the Froebel-Madhok research

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1 of Medicine, my best guess, and it is only a guess
 2 because I wasn't involved, would be that that was the
 3 origin of the samples.

4 **Q.** Did the Glasgow haemophilia centre, to your knowledge
 5 at this time or from when you became more closely
 6 involved in 1985 onwards, did it have what we have
 7 seen referred to at Edinburgh and the Royal Free
 8 Hospital as a longitudinal sera store?

9 **A.** Not to my knowledge, no. All the routine blood tests
 10 that were done in patients at the haemophilia centre
 11 I recall were, you know, to the NHS Haematology
 12 Department for blood counts, Factor VIII levels,
 13 inhibitors, that kind of thing, biochemistry for liver
 14 function tests, and then the samples sent to the
 15 Regional Virus Laboratory for hepatitis B testing.
 16 I can't think of any other studies.

17 I was working on the thrombosis, as you know,
 18 for most of this time, and I was doing studies with
 19 Dr Forbes and Prentice on thrombosis patients, and
 20 some of those of their research studies would be
 21 studied in the coagulation part of the Department of
 22 Medicine. But the rheumatology part was quite
 23 separate from that, and I don't recall any haemophilia
 24 samples being stored by Dr Forbes and Prentice in the
 25 blood coagulation bit of the laboratory.

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1 or another piece of research held for research, and
 2 they were sent for HTLV-III testing. That's correct,
 3 is it?

4 **A.** Well, I can't confirm that. I'm just trying to think
 5 what samples would have been taken at the haemophilia
 6 centre and stored in the Department of Medicine,
 7 because reading Dr Froebel's account, it sounds as if
 8 those were the studies that the rheumatologists and
 9 Dr Forbes were studying in these other studies, which
 10 basically was studies of arthritis and immune
 11 abnormalities and liver disease in patients attending
 12 the haemophilia centre, but I wasn't involved in that.

13 I'm just trying to think. Those are the only
 14 studies I could think of in which samples from
 15 patients attending the haemophilia clinic would be
 16 stored in the Department of Medicine. The only other
 17 possible source could have been, I suppose, the
 18 samples that were routinely sent to Dr Philips at the
 19 Regional Virus Laboratory for hepatitis B testing
 20 because that was routine, as part of screening of
 21 patients with haemophilia for hepatitis B.

22 But the Regional Virus Laboratory was at the
 23 separate hospital, Ruchill Hospital, and they had
 24 stored samples, as was routine for hepatitis B
 25 testing. So if the samples came from the Department

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1 **Q.** The 77 patients whose samples were sent to the States
 2 for testing by Dr Gallo were not told, were they, that
 3 this was being undertaken and that their blood was
 4 being tested for HTLV-III?

5 **A.** Well, I think Dr Forbes was asked this question, and
 6 I can't quite remember what he said, to be honest.
 7 I have no direct knowledge. I think Dr Forbes at one
 8 point was asked at the Penrose Inquiry: these tests
 9 that were sent to Gallo, were patients informed of
 10 this, and I think he said no. Would that be right?

11 **Q.** That is right.

12 **A.** I don't want this misquoting. And that's the case --
 13 my best guess is that Dr Forbes -- well, I think the
 14 context at this time, as you know, was that the UKHCDO
 15 in general was suggesting that Dr Tedder had, I think,
 16 an HTLV test, an early one, in London and was happy if
 17 haemophilia centres in the UK wanted to send him
 18 samples. That's been published, as you know, in two
 19 publications in The Lancet, I think.

20 Dr Forbes -- I think, as far as I recall,
 21 Dr Tedder didn't have much capacity and said, you
 22 know, don't send me too many, but maybe you'd want to
 23 send me a dozen or so. I think Dr Ludlam and others
 24 have perhaps talked about this.

25 I think Dr Forbes and Dr Froebel thought -- to

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1 answer the question about the relationship between
2 commercial or European origin plasma from which
3 concentrates were prepared, you're going to need quite
4 a big number of samples. So I think their aim was to
5 try and get a reasonable number of studies, and that
6 was, I think, what was suggested to Dr Froebel by
7 Dr Melbye and Dr Gallo. I understand that that may
8 have been the arrangement.

9 **Q.** Okay. If we just go back to the first page of this,
10 please. You'll understand, professor, in part I'm
11 asking you these questions because this is a study
12 which bears your name.

13 You were involved with, to some extent at
14 least, the letters that were then sent out in
15 January 1985 to patients. I'm going to come on to
16 that. But at the point in time at which this was
17 published in December 1984, the results of these
18 tests, the 12 positive out of 77, had not been
19 communicated to patients, had they?

20 **A.** When the paper was published?

21 **Q.** When the paper was published.

22 **A.** I think that was what I was understanding. I'm sorry,
23 I'm just trying to go to my evidence on this question.
24 Sorry, could you remind which section of my witness
25 statement that's looked at?

21

1 onwards, but, as I say, I want to come on to that in
2 a minute.

3 **A.** So could I just address the critical review of it?

4 So, yes -- sorry, at some point, I do talk
5 about having a meeting in October with Dr Forbes,
6 Dr Madhok and Dr Melbye at which I tabled this account
7 of the patient. And my other contribution, the
8 critical review, as with the previous paper Dr Froebel
9 published on the immune studies, I think my
10 contribution there was as somebody who knew a bit
11 about statistical analysis and how many numbers you
12 needed of patients to get a significant result; in
13 other words, the statistical power of the study, and
14 that had been my critical review of the Froebel
15 manuscript on T cell subsets the year before. And
16 I think they asked me to look at the statistics and
17 check that their conclusions were correct on this one.
18 I think that was my other contribution.

19 **Q.** Would you accept that in December 1984, the issue of
20 AIDS, and in particular the issue of AIDS in
21 haemophiliacs, was an issue in which there was a lot
22 of press interest, was there not? We heard from
23 Dr Ludlam that that precipitated the meeting on
24 19 December '84 in the Edinburgh Royal Infirmary?

25 **A.** Yes, indeed.

23

1 **Q.** I'll have to just find it, professor. You deal with
2 the January letter from paragraph 41.1 onwards.

3 **A.** I'm sorry, could you repeat that number?

4 **Q.** You deal with the January letter from paragraph 41.1
5 onwards, and I'm going to come on to that. I just
6 want to take this in strict chronological order.

7 **A.** It's just I think I've heard it under the research
8 section, perhaps. I'm sorry, research, 77, 4112:
9 "My contribution as a co-author was critical
10 review of the manuscript and drafting the first
11 paragraph."

12 Not involved in anything else. Okay, I'm
13 trying to think. Perhaps it is back in that bit about
14 the letter then.

15 **Q.** Yes. You say in the paragraph of your statement you
16 just referred to that you weren't directly involved in
17 the study published in The Lancet, but your
18 contribution a co-author was: critical review of the
19 manuscript and then drafting the section that deals
20 with the specific Scottish patient who developed AIDS.

21 So you would have seen the manuscript at the
22 time --

23 **A.** Yes, indeed.

24 **Q.** -- and your letter is going to it. You then start to
25 talk about the January letter from paragraph 41

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1 **Q.** Did it not occur to you and your colleagues whether
2 you were -- when you were discussing this in October,
3 or at any point in the latter part of 1984, that
4 a publication like this might get picked up in the
5 mainstream media and that patients of the Glasgow
6 Royal Infirmary could have learnt about a cohort being
7 HTLV-III positive from the press in circumstances
8 where they had not yet themselves been told?

9 **A.** Yes, indeed. And I'm sorry, I'm still trying to find
10 where in my written evidence I address this issue
11 because I do describe this meeting in October with
12 Dr Melbye. And my recollection is that after this
13 meeting, there was a discussion -- and it may be back
14 in Dr Froebel's evidence as well -- Dr Melbye --
15 I think Dr Madhok drove Dr Melbye back to the airport,
16 and Dr Froebel and I sat with Dr Forbes and said,
17 well, before you publish a paper, do you want to think
18 about the validity of the test because, as a research
19 study which is looking at the association in a kind of
20 public health issue, if patients in Scotland are
21 infected, which is the product? Is it the commercial,
22 or the Scottish, or both, or whatever? But
23 Dr Froebel, I think, pointed out, and I think it's in
24 her statement, that the test that Dr Gallo had was
25 a research test which had not been validated as

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1 a clinical diagnostic test in America or anywhere
2 else, and that was a concern.
3 I think my memory of that was that Dr Forbes
4 was saying, well, yes, absolutely right. And he was
5 going to speak to Dr Follett at the Regional Virus
6 Laboratory to say, this is going to be very difficult
7 until you can get going with a validated clinical test
8 that would be suitable to confirm the diagnosis
9 because if you have research tests which could well be
10 false positives or false negatives -- and I think you
11 discussed that last week with Professor Ludlam with
12 respect to the Tedder tests which I recall were in the
13 same situation at the time.

14 So the conversation around that time, I think,
15 with Dr Forbes was: I need to really get a clinically
16 valid test as soon as possible. The other thing he
17 talked about was: I really need to get hold of
18 a counsellor who is going to help me in the
19 counselling of not just these patients but all
20 patients when routine testing for HIV comes about. So
21 he was thinking very carefully about how to handle the
22 situation.

23 **Q.** It's paragraphs 50.3, 50.4 and 50.5 of your statement,
24 professor, in which you refer to the October meeting
25 and discussions about the study and the finalisation

25

1 discovered, and the action taken to withdraw the
2 unheated SNBTS concentrate, et cetera.
3 And then 50.7 -- yes, so I think what Dr Forbes
4 had in mind when he drafted this letter of 8 January
5 was to write to patients being very open about
6 publishing the paper, talking about AIDS risk in
7 reproducing a form letter that had been drafted for
8 all the haemophilia centres in Scotland, and then
9 modifying it with regard to the Glasgow situation.
10 I think the critical thing about this letter drafted
11 on 8 January is: he enclosed an appointment to see you
12 to take a blood sample, perform skin tests, et cetera,
13 and then the standard information given about AIDS
14 risk.

15 My memory is that this letter was drafted,
16 given to myself and to the haemophilia sister, I think
17 I said to the Penrose Inquiry, and he said, "This is
18 what I've drafted. Can you have a look at it and let
19 me have your comments? And I want to take it to the
20 first meeting of the UKHCDO AIDS Working Party," which
21 he'd set up and was set chairing because they were
22 meeting in I think a couple of days' time.

23 So we had a very short time, Sister Campbell
24 and I, to look at it and give them our comments. And
25 we said "Okay, we can see what you're doing, but we

27

1 of the paper, if that assists?

2 **A.** 50.3.

3 **Q.** 50.3, 50.4 and 50.5.

4 Professor, if the tests were not thought to be
5 sufficiently reliable, wasn't the right course, rather
6 than publishing the material in The Lancet in terms
7 which, if picked up by the media, could have revealed
8 to some of the patients that they tested positive --
9 you will recall the article includes reference to
10 someone from Pakistan; it includes reference to
11 someone who travelled in Europe frequently -- patients
12 could have learnt from that article about their
13 positivity in circumstances where no effort had yet
14 been made to tell them by their clinicians.

15 Does it not occur to you that the right people
16 to be told first are patients?

17 **A.** Sorry, you're saying: would the right thing to do to
18 be to tell the patients first?

19 **Q.** Yes.

20 **A.** I think -- well, Dr Forbes, I think, was in a very
21 difficult situation. He had -- as I've said, he had
22 reservations about whether the tests were accurate or
23 not, and he did want authoritative tests. And then
24 I was asked at the Penrose Inquiry, as I say about
25 subsequent events, and the Edinburgh centre being

26

1 understand that you're going to discuss this with the
2 AIDS Advisory Group, and it does raise these
3 complicated issues." And he said, "Well, I've
4 appointed Dr Wilkie as a counsellor, and she will be
5 involved." And what we want to do is to see these
6 patients, in particular the ones who have tested
7 positive, inform them of the situation, and then offer
8 them what I suppose would be a mixture of
9 post-counselling about these research tests, stressing
10 that they are not all that reliable, and what they
11 want to do is to get their consent for a validated NHS
12 test as and when Dr Follett had set it up. So that
13 was my understanding of the situation.

14 **Q.** Before we look at the 8 January letter, which is sent
15 out in your name and Dr Forbes' name, can I just go
16 back to the question I asked about the December
17 publication.

18 **A.** Mmm.

19 **Q.** As a matter of principle, would you accept that the
20 proper course would be to tell patients, first of all,
21 about their results, if necessary undertaking
22 a process of confirmatory testing, before any
23 information about the test results is placed in the
24 public domain, as it was through the December article?

25 **A.** Yes, I think that is the case, and I think we're all

28

1 a bit unhappy. I think Dr Forbes was balancing the
2 need to publish the information in the public
3 interest. It was felt at that time that this showed
4 that it was largely the patients in Scotland who had
5 the commercial concentrates who were HIV positive, but
6 that, of course, within a very short time, was
7 balanced by Dr Ludlam's findings that, in fact, most
8 of his patients had received the NHS concentrate.

9 I think things were moving very fast, and
10 I think Dr Forbes was quite conflicted as to
11 publishing the information and his duties to the
12 patient.

13 **Q.** Let's look at the January letter. PRSE0000859 please,
14 Soumik. So we can see this is dated 8 January 1985.
15 If we just go to the third page briefly, please, we
16 can see it's co-authored by you and by Dr Forbes. If
17 we go back to the first page, we can see it says:

18 "Dear blank [presumably there for the patient's
19 name to be inserted], as you may know there, has been
20 recent publicity in the newspapers and television
21 concerning an increased risk of the disease known as
22 AIDS in haemophiliacs who have received treatment with
23 clotting factor concentrates."

24 Then it talks in the next paragraph about AIDS
25 being caused by a newly discovered virus:

29

1 rather than concentrate from the USA.

2 "We are writing to you now for three reasons.
3 Firstly, we enclose an appointment to see you. It is
4 important that we take a blood sample from you for the
5 virus tests so that we can monitor virus exposure in
6 all our patients who received Factor concentrates. We
7 would also like to perform some skin tests which
8 measure the body's defences against infections. At
9 the same time, we will very happy to give further
10 information and to answer any questions you may have
11 about the virus and the tests."

12 Then the second -- there's a recommendation
13 about precautions to take. I won't read those out;
14 they are set out there.

15 Thirdly, at the bottom of the page, it talks
16 about the position of why family members and sexual
17 partners. And the top of the next page says:

18 "We will be happy to talk with them about such
19 concerns. Please bring them along with you if you
20 would like us to do this."

21 So can you assist, professor, with enabling us
22 to understand better the process that was envisaged
23 with this letter?

24 **A.** Yes. So I've now found my written statement 41.1
25 where you asked me: what role did you play in drafting

31

1 "The risk of the disease, AIDS, in
2 haemophiliacs appears to be very small and less than
3 the risks of bleeding. We therefore recommend that
4 you should continue treatment with clotting factor
5 concentrates. Several steps have been taken to reduce
6 the risk of viruses in the clotting factor
7 concentrates."

8 And the two steps are there set out. Then it
9 says this:

10 "We do not yet have a blood test for the virus
11 particle but hope to have this within the next few
12 months. However, we and other haemophilia centres do
13 now have a blood test for antibody to the virus. If
14 this antibody test is positive, this means that the
15 person has been exposed at some time to virus
16 particles. A positive test does not mean that the
17 person will develop AIDS. Recent studies in England
18 have found that about half of regularly treated
19 haemophiliacs have positive antibody tests. We have
20 recently tested stored blood samples from many of our
21 patients, of whom about 10 per cent have positive
22 antibody tests. The reason why fewer Scottish
23 patients have positive tests compared to English
24 patients is probably due to the fact that we have
25 largely used Scottish concentrate in recent years,

30

1 the letter?

2 **Q.** Yes.

3 **A.** Okay. So I was asked about this at the Penrose
4 Inquiry, and at the Penrose Inquiry, I didn't
5 recognise the letter; I'd never had a copy of it. And
6 my recollection at the Penrose Inquiry was: I'd just
7 come back from a week's holiday, and that was the
8 busiest day of the year. I was working on another
9 unit. And the wards -- in January, the medical wards
10 are absolutely crammed full of casualties of Hogmanay,
11 and it was a very busy time.

12 So I really had only a very brief meeting with
13 Dr Forbes and the haemophilia sister, and he showed
14 the letter which I think was -- obviously hadn't
15 signed it by then. And at the Penrose Inquiry, I had
16 to read through it slowly and remember it because
17 I remember a further letter sent out in April, and
18 with the help of Mr Gardiner for the Inquiry who
19 showed me the form letter drafted by Dr Forbes with
20 other Centre Directors, he put that in as the advice
21 bit, and then he had customised it for the Glasgow
22 situation.

23 So I took it home from the Penrose Inquiry,
24 thought about it, and I recall that Dr Forbes drafted
25 the letter, discussed it, and asked if he could have

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1 my signature. And I said, "Why?" Because I'm not
2 a consultant; I'm not working on the unit. And
3 Dr Forbes wanted another doctor to sign it that in the
4 event that the patient wanted to discuss it and
5 Dr Forbes was not available, I could be the contact.
6 And I said, "Okay, that's fine."

7 I presumed that the letter would then be sent
8 out to patients with appointments by Sister Campbell.
9 And then when I looked at it, I saw that he was
10 wanting to take this draft and discuss it at the AIDS
11 Working Party which was addressing these kind of
12 issues.

13 I've only recently received the minutes of that
14 working party on 11 January, and it just says that
15 Dr Forbes issued a package of information which could
16 have included this letter for the discussion.

17 **Q.** As far as you know, first of all, was this letter, or
18 something very like it, sent out to the patients of
19 the haemophilia centre?

20 **A.** I don't know. Let me see. I had no role in sending
21 the letters, and I was asked what the purpose was
22 which I think we have discussed. Then he asked me
23 about: what's the evidence for the risk of the disease
24 being small? On what basis was it less than the risk
25 of bleeding, and asked about that. Why was the advice

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1 **A.** My recollection is that it took Dr Follett until about
2 April to set up a validated test that had been
3 approved for HIV testing in a format that could be
4 given to patients; in other words, a very low risk of
5 false positives and false negatives. And I think from
6 memory it was April, and I think listening to
7 Professor Ludlam's evidence last week, it took until
8 about that time for his colleagues in Edinburgh at the
9 regional virus laboratory there to set up
10 a confirmatory test. So I think it took a while to do
11 that.

12 I think that Dr Forbes wanted initially to see
13 the patients who were query positive on the basis of
14 the Gallo test with Dr Wilkie and counsel them
15 privately about the situation, about AIDS testing, and
16 about this results of the study, and indicating that
17 what they would want to do is to get their informed
18 consent to a validated test up to counselling about
19 AIDS, positive test, negative test, et cetera, and
20 then for Dr Follett to perform that, after which
21 Dr Forbes and Dr Wilkie -- and it's in their
22 evidence -- would inform the patients that they were
23 positive or negative by these tests.

24 I would assume that he would want to
25 concentrate on sending this letter first, as the

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1 given? Why was it given in those terms, and it's
2 consistent with the form letter:

3 "In your view, and given the terms in which
4 it's expressed, is that advice consistent with the
5 principles of patient consent that were in place at
6 the time."

7 **Q.** Professor, what I'm trying to understand is how and
8 when patients in Glasgow Royal Infirmary were tested
9 for HTLV-III and told of their results. We've looked
10 at the Gallo process, and as far as we can see and
11 certainly it seems to be the effect of
12 Professor Forbes' evidence at Penrose, that did not
13 lead to patients being told the results of the Gallo
14 testing.

15 You have referred to, and we'll pick it up in
16 later -- a minute of a meeting that you attended later
17 in '85, you referred in your evidence,
18 Professor Forbes in his, to there being then a further
19 process of testing undertaken by Dr Follett at
20 Ruchill.

21 Do you know whether patients -- whether that
22 testing was undertaken on stored samples, or whether
23 patients were asked to provide samples and had
24 explained to them what was going to be done with the
25 samples?

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1 Penrose Inquiry counsel suggested, and that seems
2 entirely reasonable. And though I recall that
3 Dr Wilkie's evidence, which I think I quote at some
4 point, was: she was asked about the evolution of the
5 events and said something about the first 20 patients
6 were sent letters, and Dr Wilkie I think said: yes,
7 that would be the positives, or words to that effect.

8 So I can see that the priority, in Dr Forbes'
9 mind, were probably to say: we should see these
10 patients as soon as possible, explain the situation,
11 and get their informed consent for a fresh sample to
12 be sent in the proper way to Dr Follett,
13 pre-counselled and then post-counselled according to
14 the result. That is my understanding.

15 But I should stress that during this time,
16 I wasn't working on the haemophilia unit; I was
17 working on another unit. Dr Forbes wanted very much
18 to do this himself with Dr Wilkie and Dr Follett.
19 I wasn't involved in any way, and I think it was only
20 in about April to May that Dr Forbes had a meeting
21 with myself and the haemophilia sister and said:
22 right, we've now seen the first -- we've now seen this
23 first group of patients, and we have validated tests
24 and the results. And at that time, Dr Forbes said:
25 right, you have just heard from the university that

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1 you're going to be promoted to a senior lecturer from
 2 October, and you'll then hopefully become a consultant
 3 or honorary consultant. And I'd like you at this
 4 stage to get involved on the assumption that, as and
 5 when you get to that stage, you can join me in
 6 returning to the haemophilia centre and help me in
 7 this situation of talking to patients about AIDS and
 8 the results because he thought that should be done at
 9 consultant level.

10 So he wanted me to be involved in the planning
 11 of that process, and he was then -- Dr Forbes setting
 12 up this Glasgow AIDS group. And I think you have the
 13 minutes of its first meeting, maybe 31 May, at which
 14 all these issues were discussed. And I don't know if
 15 you want to go on to that, but Dr Follett had
 16 confirmed that there were 12 patients seropositive by
 17 a validated test. And we were -- we had by that time
 18 met with Dr Kennedy from the infectious diseases unit
 19 and were setting up arrangements for general care of
 20 particularly seropositive patients.

21 That is what I recall as the version of events.
 22 Q. So you have got a recollection of a meeting you had in
 23 around April with Dr Forbes, along the lines you
 24 discussed.

25 Is this the position then: in terms of what

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1 the most number of years. The current haemophilia
 2 registrar has just been there for a year or so. And
 3 I think a lot of these patients will remember who you
 4 are and would be a contact at least to discuss with
 5 them if I'm not in the country." And I said, "Well,
 6 what use would that be?" So it is surprising.

7 Q. We'll look at the April letter then.

8 **SIR BRIAN LANGSTAFF:** What he could have done, had that
 9 been his purpose, would be to say: well, if I'm not
 10 available, contact Dr Lowe, but he didn't. Did you
 11 ever ask him why he didn't do that, rather than have
 12 your name put as a signatory to a letter you had not
 13 drafted and had no direct involvement in whatsoever?

14 A. Well, that's right. I mean, as I say, I only saw this
 15 letter very briefly for a brief discussion. I never
 16 had a copy of it. And I'm sorry, I think -- did
 17 I say -- sorry, it's just at the end of my written
 18 statement -- I'm sorry, so 41.5:

19 "I am surprised that my name appears first, and
 20 I wonder ..."

21 If it was a mistake.

22 Dr Forbes was doing all the work.

23 "I never saw any copy of this letter in Centre
 24 files or case records, and I wonder if it was in fact
 25 sent to patients in a different and more appropriate

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1 happened between December and the publication of the
 2 article in The Lancet and April, you've got no
 3 knowledge whatsoever of the process. And what you've
 4 told us your understanding is, is based primarily on
 5 evidence given by others to the Penrose Inquiry? Is
 6 that right?

7 A. Yes, indeed. So as I think I have said in my written
 8 statement -- well, I think I've covered it. Dr Forbes
 9 said he'd keep me informed, but he said this is my
 10 baby; I want to handle it. So I did send out with
 11 Dr Forbes a joint letter in April.

12 Q. We're just going to come to that.

13 A. Do you want me to go to that now?

14 Q. We're just going to come to that. PRSE0003567,
 15 please, Soumik.

16 Professor Lowe, can you just assist before we
 17 look at the detail of the April letter with this: it
 18 might be thought to be a little odd to be sending out
 19 in January such an important letter with the name on
 20 of a doctor who has been told nothing about the
 21 proposed process and is going to have no involvement
 22 in it. Do you have any observations to make on that?

23 A. Yes. Looking back on it, it does seem very strange.
 24 And I think I pointed out that, you know, why me?
 25 Dr Forbes' answer is, "Well, you've just been around

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1 format. I do not recall ever being contacted by any
 2 patient to discuss this letter. I do not recall any
 3 patient that I subsequently reviewed at the clinic
 4 mentioning it or producing it."

5 And then 41.6:

6 "Obviously, I could not discuss this with
 7 Professor Forbes during the Penrose Inquiry. After
 8 the ... Final Report was published in 2015, I visited
 9 him at his home for a social catch-up and to discuss
 10 the Report's conclusions and any matters arising,
 11 including this question. I recall that he told me
 12 that he thought he had modified the draft letter after
 13 discussion at the UKHCDO working party meeting on
 14 11 April, putting his name first."

15 Or something like that.

16 I don't know. But that's all I can really tell
 17 you.

18 **MS RICHARDS:** If we look at the April letter on screen,
 19 professor, and we can see it is dated April 1985, if
 20 we go to the third page, we can see Dr Lowe's name --
 21 your name is still first, Dr Forbes' is second.

22 Does it follow from what you have just told us
 23 and what you say in your witness statement at
 24 paragraph 41.6, that it's possible the January '85
 25 letter never went out at all and that the April '85

40

1 letter is effectively the redrafted version that may
2 have been sent to patients?

3 **A.** Yes, I remember paying more attention to this letter
4 because, by that time, as I say, I think we knew that
5 I had been informed of a promotion by the university
6 and I would be joining Dr Forbes in due course in this
7 work.

8 **Q.** Because we can see that this letter replicates quite
9 a lot of the information that we've seen in the
10 January version. It refers to a booklet "AIDS and the
11 blood", published by The Haemophilia Society, which is
12 being sent out to patients. It then says this in the
13 third paragraph:

14 "As you may know, we have a Haemophilia Clinic
15 on Ward 2 on Monday and Friday afternoons. We try to
16 see all our patients there at least once a year, and
17 we are always happy to see and advise you. We have
18 already seen and advised many of our patients about
19 AIDS. If we have not yet discussed AIDS with you, we
20 should be happy to do so at your next clinic
21 appointment this year, or sooner if you wish."

22 Then it invites the patient receiving it to
23 contact the sister if they want to see you before the
24 next appointment.

25 Then we've got similar advice on AIDS being set

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1 referred to which Dr Follett attends.
2 It's PRSE0001606, please, Soumik.
3 We can see it is "Minutes of AIDS Information
4 and Advisory Group, 31 May 85", chaired by Dr Forbes.
5 You are present, as indeed is Dr Follett.
6 We can see in paragraph 2, number 2 on that
7 page:

8 "HTLV-III Antibody testing.
9 "Dr Follett reported that the Regional
10 Reference Laboratory uses the Abbott kit at present,
11 confirmed by immuno-fluorescence testing. If
12 IF testing does not confirm, the sample is sent to
13 Dr Tedder in London. Of Glasgow patients tested to
14 date, haemophilic patients treated with commercial
15 Factor VIII concentrate have the largest number of
16 positive tests: all seroconverted between 1981 and
17 1983."

18 Just pausing there, professor, the statement in
19 the records that "all seroconverted between 1981 and
20 1983", which I think, as we will see when we look at
21 later material, doesn't turn out to be the ultimate
22 position, would that suggest that Dr Follett, as well
23 as testing possibly on fresh samples, must also have
24 been testing on stored samples to some extent?

25 **A.** It could be. I think there was a letter sent to

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1 out in the following pages. If we go to the top of
2 the next page, paragraph 3 at the very top of the page
3 it says:

4 "We do not yet have a blood test ... [we] hope
5 to have this within the next few months ... we ... do
6 now have a blood test which detects antibody ..."

7 And, again, it's similar text to the January
8 one. Refers again to having recently tested stored
9 blood samples, and the 10 per cent figure, and then
10 goes on to set out, in the bottom half of the page,
11 the general precautions.

12 It's quite difficult to make sense of who this
13 would be being sent to, professor, if the January
14 letter had been sent. Do you know who it was intended
15 this April letter would go to?

16 **A.** My understanding is that by April and -- sorry, it
17 doesn't have a date on April. Presumably that would
18 be put on in due course. As I say, Dr Forbes and
19 Dr Wilkie had seen and counselled and taken samples
20 from a test to be sent for Dr Follett, and I think the
21 understanding at this time is that we should now be
22 sending this letter to other patients with
23 haemophilia.

24 **Q.** Let's try to pick it up and see to what extent we can
25 make sense of it by reference to the meeting you've

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1 The Lancet in March 1985 in which Dr Madhok has been
2 looking back at presumably previous stored samples to
3 clarify the date of seroconversion. Is that correct?

4 **Q.** Rather than look at what Dr Madhok was writing, do you
5 have any recollection yourself of the process that was
6 being undertaken by Dr Follett at this time?

7 **A.** No, I don't, sorry. This was my first meeting
8 directly with Dr Follett as part of the group.

9 **Q.** If we go on to the third page, please, and we look at
10 the last paragraph it says:

11 "Dr Lowe reported that 16% of West of Scotland
12 haemophiliacs were HTLV-III antibody positive; the
13 lowest incidence amongst reported haemophilia centres.
14 None had clinical symptoms, although some lymphopenia
15 had been observed. These patients are being closely
16 followed."

17 What was the "close" following or "close"
18 monitoring that was being undertaken in relation to
19 the patients who had tested positive?

20 **A.** What Dr Forbes had arranged with Dr Kennedy from
21 Infectious Diseases is that these patients should be
22 seen at least every three months, as I think was
23 general advice at the time amongst HIV positive
24 patients, to monitor their condition and their T cell
25 results and that kind of thing. And that a flexible

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1 policy was developed, which I spoke about.
 2 So I'm reporting. I mean, I'd not seen any of
 3 these patients at all. I'm just confirming that
 4 Dr Follett has been testing these patients. And I'm
 5 reporting really on behalf of Dr Forbes, who was
 6 chairing the meeting, that he'd told me that:
 7 "None had [some] clinical symptoms, although
 8 some lymphopenia had been observed. These patients
 9 are being closely followed."
 10 And then we had had discussions about, should
 11 they require hospital treatment, what should the
 12 policies be about admission either to the
 13 Royal Infirmary if they needed treatment for bleeding
 14 or Ruchill Hospital if they needed treatment for
 15 infectious complications of HIV positivity. So I was
 16 talking really mostly about the policy.
 17 But I had no direct contact with these
 18 patients, I was just reporting what I had heard from
 19 draft and Dr Follett.
 20 **Q.** I want to look at one other document with you from
 21 earlier in 1985 -- well, actually undated, possibly
 22 earlier than 1985.
 23 PRSE0002785, please, Soumik.
 24 It's headed "Advice sheet for adult patients
 25 and families, Acquired Immune Deficiency (AIDS)", and

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1 Dr Forbes or indeed Dr Ludlam or anybody else about
 2 the terms in which an information sheet or information
 3 should be provided to patients and in particular about
 4 what they should be told about continuing with
 5 treatment?
 6 **A.** No. As I say, the two Glasgow letters were very much
 7 the work of Dr Forbes. I was very happy to add my
 8 name to the April one, for the reasons that I've been
 9 given -- and that the situation was now much clearer.
 10 I was hoping to become a consultant and was happy to
 11 help in due course. And that it was giving updated
 12 information, for example, that Factor IX concentrates
 13 were now heat-treated as well as Factor VIII,
 14 et cetera. And I felt that the Peter Jones booklet
 15 was actually very good. I think it was well received
 16 in the UK. It was written in a very helpful style and
 17 a very good book to send to people so they could read
 18 it and have a think before coming to the appointment.
 19 I thought that was very good.
 20 I had no discussions about what the strength of
 21 recommendations about treatment should be. I think
 22 Dr Forbes' term "should" rather than "must" -- well,
 23 you can argue about the degree of strength but I've
 24 nothing to do with that.
 25 **Q.** Okay. Can we move then to the end of '85 and look at

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1 if we look at the first paragraph, it looks as though
 2 it's been drafted with a view to being sent to Glasgow
 3 patients and Edinburgh patients, because it says:
 4 "... please do not hesitate to phone your
 5 Centre Director for a personal appointment ..."
 6 And it gives the numbers for Glasgow and
 7 Edinburgh.
 8 If we --
 9 **A.** Yes -- sorry.
 10 **Q.** If we zoom back out again, if we go to the third page
 11 please -- there are 3, I think there are -- we can see
 12 on the third page, at the very end, it says this:
 13 "Remember that you must continue to treat
 14 yourself with the concentrates as the risks are much
 15 greater of bleeding than of contracting the rare
 16 disease of AIDS."
 17 Professor, we understand from evidence given by
 18 Professor Ludlam that this is a sheet that was
 19 intended to, from his perspective, be -- and was sent
 20 to patients in Edinburgh. The recommendation we see
 21 there set out at the end, "you must continue to treat
 22 yourself", is not repeated in the January and April
 23 letters that we looked at from Glasgow, which says
 24 "you should continue" but not "you must".
 25 Were you party to any discussions with

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1 a letter which was copied to you. It's
 2 SBTS0000395_091.
 3 We can see it's a letter dated 4 December 1985
 4 addressed to Dr Cash. If we go to the third page, we
 5 can see it's from Dr Madhok, and we can see it's
 6 copied to you and to Dr Forbes at the Haemophilia
 7 Unit, as well as being copied to Dr Davidson also, at
 8 the Royal Infirmary.
 9 If we go back to the first page and I'm just
 10 going to see if you can help us understand what we
 11 might learn from this letter, professor.
 12 It's headed "Re: HTLV-III/LAV seroconversions
 13 since introduction of heat-treated concentrate":
 14 "We have had 3 seroconversions this year,
 15 details are as follows:
 16 "Patient 1.
 17 "Factor VIII deficient ..."
 18 So a haemophilia A patient. We can see from
 19 the dates that the first positive date there is
 20 25 October 1985, with a negative date from October of
 21 1984.
 22 It would seem from this, professor, please tell
 23 me if you think I'm wrong, that the process of testing
 24 is still ongoing in the autumn of 1985.
 25 **A.** Yes, it is.

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1 Q. If we go over the page then and look at patient 2, and
 2 we can see there it's a patient with Factor IX
 3 deficiency, and the test results there tell
 4 us: 29 January '85, negative; 8 November '85,
 5 positive.
 6 So, again, testing being undertaken, in this
 7 instance, in November or some time between November
 8 and early December 1985. And then if we look at
 9 patient 3, on the third page, it's another
 10 Factor VIII deficient patient. It said seroconverted
 11 in October/November. There's reference to the
 12 treatment that's been received in '84 and '85: FEIBA
 13 only. And then Dr Madhok says this:
 14 "Obviously, we cannot be entirely sure that
 15 heat-treated concentrate is implicated in patients: 1
 16 and 4 ..."
 17 Not quite sure what the reference to 4 is.
 18 "... but the weight of evidence in reviewing
 19 estimated dates of seroconversions strongly points to
 20 heat-treated material being the source."
 21 Then there is a discussion about literature for
 22 seroconversion intervals.
 23 Now this would tend to suggest that you are
 24 being told in December of 1985, or Dr Cash is being
 25 told and you no doubt are also being told, that you

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1 patients 1 and 3.
 2 Patient 3 has only been with FEIBA, which is
 3 a commercial activated Factor IX concentrate for
 4 a patient with a high titer inhibitor, and porcine
 5 Factor VIII, which obviously wouldn't transmit HTLV,
 6 being a human virus, for a dental extraction. These
 7 are both acceptable alternatives for treating
 8 inhibitor patients.
 9 So I don't think that patient has got anything
 10 to do with SNBTS but it's just good practice in
 11 keeping them informed in all the patients. But that
 12 would appear to be nothing to do with SNBTS
 13 concentrates and that presumably must be ascribable,
 14 that seroconversion, to FEIBA, which is a commercial
 15 factor concentrate.
 16 So working back to patient number 2, this is
 17 a Factor IX patient, treated only in 1983 and 1984,
 18 and no treatment in 1985. So this patient has always
 19 had, I presume, untreated SNBTS Factor IX concentrate,
 20 which was the routine treatment for all patients with
 21 Christmas disease unless they are very mild.
 22 So this patient doesn't ever appear to have
 23 received heat-treated concentrate because I think
 24 SNBTS only treated the Factor IX concentrate in about
 25 August 1985, and meantime Haemophilia Centre Directors

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1 have, in the autumn of '85, three seroconversions: two
 2 patients with haemophilia A, one with haemophilia B.
 3 What, if anything, can you recall about what
 4 was going on at this stage and the reaction to
 5 learning, as it seems from this, that patients were
 6 sero-converting on heat-treated concentrates?
 7 A. Right, the date is 4 December, and that was probably
 8 my first day as a consultant, which is probably why
 9 Dr Madhok is copying it to myself. I think it wasn't
 10 until early December that I was informed by the Health
 11 Board that: we are formalising that you are now
 12 a consultant. So that seems appropriate.
 13 Let me -- so I'm just trying to look at the
 14 data now.
 15 Q. Well, first of all, Dr Madhok was asked by Dr Forbes,
 16 just as he'd been doing in the kind of Melbye/Gallo
 17 paper, if he could liaise with Dr Follett and work
 18 back with all the information about the dates and
 19 collect data on the batches of different products, NHS
 20 or commercial. And that, of course, was routine
 21 practice, in informing SNBTS about any seroconversions
 22 which might or might not have been related to
 23 NHS concentrates.
 24 The easy one is patient 3, and I agree there's
 25 a misprint, that it's presumably patients 1 and 4, not

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1 in Scotland decided to use commercial heat-treated
 2 Factor IX concentrate. And I think somewhere in the
 3 files you should have a letter I was shown at the
 4 Penrose Inquiry, from Dr Davidson, said, "Just been to
 5 the reference directors' meeting and the decision is
 6 made that we'll stop using SNBTS unheated Factor IX
 7 concentrate and use heat-treated or virally
 8 inactivated Factor IX concentrate" and that's what was
 9 used.
 10 So it seems as if this Factor IX deficient
 11 patient only ever had un-heat-treated Factor IX in
 12 1984. The -- it sounds as if this would be obviously
 13 retrospective testing of stored serum samples,
 14 presumably by Dr Follett, because his first positive
 15 test was in November '85. Then I presume he attended
 16 the haemophilia clinic in January '85 and in
 17 August '84. There wouldn't have been routine testing
 18 at the time, because Dr Follett didn't have the HIV
 19 tests set up in Glasgow. So these would be studies of
 20 retrospective samples to try our best to make the date
 21 of seroconversion.
 22 So the patient seroconverted some time between
 23 January and November of 1985 and the batches -- it
 24 doesn't say when the batches were given, but it seemed
 25 most of his treatment was in 1983 and then a bit more

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1 in 1984.
2 Now, if that was in late-ish 1984, that could
3 well have been the infected batch because Dr Madhok
4 goes on in his last page -- oh, last page, third
5 paragraph:

6 "Obviously, we cannot be entirely sure that
7 heat-treated concentrate is implicated in patients 1
8 and 3."

9 But let me think. And Dr Madhok has reviewed
10 the literature for seroconversion intervals and this
11 is from the literature, I guess: medium duration 84
12 days, range 280 days.

13 So it is perfectly possible that if patient 2
14 had Factor IX concentrate late in 1984 --

15 **SIR BRIAN LANGSTAFF:** Could you just pause there for
16 a moment, please, professor, because those who are
17 watching online may wish to follow the document and
18 you've got it, but they haven't necessarily, and they
19 might want to see what is said about patient 2.

20 Could we go back please, Soumik.

21 **MS RICHARDS:** Thank you.

22 **SIR BRIAN LANGSTAFF:** Thank you very much. I'm sorry for
23 interrupting, but it is important that those who are
24 watching online have the chance to follow what you are
25 saying.

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1 antibody status."

2 In other words, to try and implicate
3 a particular batch, as, for example, was extensively
4 done in Professor Ludlam's patients in Edinburgh by
5 detailed studies.

6 Finally, patient 1.

7 **MS RICHARDS:** The first page, please, Soumik.

8 **A.** So this is a Factor VIII deficient, severe
9 haemophilic with no inhibitor, first positive test
10 25/10, date of last negative 5/10/84, and during 1984
11 had a lot of treatment and, again, we don't know the
12 dates in 1984 but same again as in patient 2: if that
13 last batch of 1984 concentrate had been given late in
14 1984, and then a year goes by before he has the first
15 positive HTLV test in October, at any time between --
16 well, any time between any date in 1984 and 10/85 he
17 could have seroconverted, which is well within the
18 literature for seroconversion intervals which
19 Dr Madhok states on page 3: medium duration 84 days,
20 range 21 to 280 days.

21 So you know, it's perfectly possible that these
22 are all patients who only received un-heat-treated
23 SNBTS concentrates and never received heat-treated
24 concentrates.

25 **MS RICHARDS:** Sir, I note the time. I may have a couple

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1 **A.** Okay. So what I was saying previously is Dr Madhok
2 has been reviewing the literature for seroconversion
3 intervals; in other words, how long can it take
4 between getting an infected batch of concentrate and
5 getting a positive result.

6 Then the page you're on now for patient 2, we
7 don't know when these batches were given in 1984 but
8 say the last batch was the infected one, so it's in
9 the later part of 1984 -- I don't know. The next test
10 done -- well, I'm sorry, the next sample taken for
11 retrospective testing is January, so that could have
12 been a relatively short time from being exposed to an
13 infected batch of concentrate and therefore it is
14 negative because the patient has been infected but has
15 not seroconverted until later in 1985, some time
16 between January and November. So I think what
17 Dr Madhok says is true.

18 In the absence of any other source of
19 infection, the suspect batch would have been given
20 some time in 1984 out of those two batches, and
21 I think that -- yes, at the very end of Dr Madhok's
22 letter, if you go back to page 3:

23 "Five Factor IX patients received either batch
24 695 or 714, which were the two batches this patient
25 received in 1984, and we shall be determining their

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1 more questions arising out of this document, but I can
2 do that after the break.

3 **SIR BRIAN LANGSTAFF:** Yes. We're continuing to talk about
4 testing, are we, after the break?

5 **MS RICHARDS:** For a little while longer -- not much more.

6 **SIR BRIAN LANGSTAFF:** All right. Thank you very much. We
7 will take a break now until 4.05. Will that give you
8 long enough, professor?

9 **A.** That would be fine.

10 **SIR BRIAN LANGSTAFF:** 4.05.

11 (3.27 pm)

(A short break)

12 (4.06 pm)

13 **MS RICHARDS:** Soumik, could we have back on screen the
14 document we were looking at before the break, so
15 SBTS0000395_091.

16 Professor Lowe, it must have come, one would
17 have thought, as something of a shock or cause for
18 concern in late 1985 for Dr Forbes, his co-director,
19 for you as the new consultant, to learn that patients
20 were still apparently sero-converting with a question
21 mark being raised about the involvement of
22 heat-treated concentrates.

23 Can you recall what, if any, enquiry or
24 investigation was undertaken into this and what its
25

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1 outcome was?

2 **A.** Well, first of all, I don't think it has been proven.

3 If we start with patient 3, the FEIBA, I'd no idea

4 that FEIBA was heat-treated. But no -- probably

5 wasn't. It was 1984 to 1985. I can't remember at

6 what stage FEIBA was heat-treated, and it wouldn't

7 have been the porcine --

8 **SIR BRIAN LANGSTAFF:** Can I just stop you there,

9 professor. I think the question is not whether the

10 report is accurate, but the way that counsel put the

11 question was: given that there was a question mark

12 about it, what investigations were undertaken to see

13 whether it was? So that's what I think you are being

14 asked about. I'm not sure you are answering the

15 question.

16 **A.** Right. This letter that I'm trying to think what

17 I would have thought when I got this letter from

18 Dr Madhok or been told by Dr Forbes on 4 September.

19 I would have been -- yes, the initial reaction would

20 be: this might mean that the heat-treatment is not

21 working. But then when I read it, and then going

22 through it today, I don't think there's any evidence

23 that this was a failure of heat-treatment because

24 I think all the patients that -- sorry, all the

25 batches that patient 1 and patient 2 had were

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1 for the Penrose Inquiry decades later. I'm asking

2 what the process was or the response was at the time

3 to this information and what, if any, steps were taken

4 to further investigate the matter or consider

5 a suspension of treatment or anything of that kind.

6 Was anything done at the centre, or was it just filed

7 and life went on?

8 **A.** No, it wouldn't have been filed. This was

9 a continuing process. I think that's what I'm trying

10 to say to you.

11 Dr Cash asked for regular reports -- I'm sure

12 you must have it in the correspondence -- from all the

13 Centre Directors saying, "Please keep testing, and

14 please keep me updated regularly." And this is one in

15 a series of reports that Dr Madhok and Dr Forbes' and

16 Dr Davidson's continued investigation would be.

17 I can't see evidence in this letter that any of

18 these patients got heat-treated product before their

19 positive test. So, in fact, this would be

20 a continuing process. And if you want to know if

21 further investigations were done, I'm pretty sure it's

22 all in the Penrose report. I cannot remember any

23 seroconversions following this day.

24 **Q.** Did your patients know, were they told, that they were

25 being tested for HTLV-III on a continuing and ongoing

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1 non-heat-treated. This is not a seroconversion. This

2 is probably a late seroconversion from

3 non-heat-treated concentrates.

4 Sorry, I can't recall what further studies were

5 done after this, but this would not have been too

6 shocking if you read it.

7 **MS RICHARDS:** Do you know whether any inquiry or

8 investigation was undertaken beyond the sending of the

9 letter by Dr Madhok to Dr Cash?

10 **A.** Oh, I think Dr Madhok's surveillance carried on for a

11 long time because, clearly, the first thing you do as

12 a manufacturer, SNBTS, is to say: for the next several

13 years, could you continue to test patients who are HIV

14 negative for HIV because that's the only way we're

15 going to find out.

16 Now, my recollection is that within two years,

17 from memory, there was no evidence of seroconversion

18 on heat-treated. I'm pretty sure you will find this

19 in the Penrose Inquiry, if you look at the Penrose

20 Inquiry reports about seroconversions because there's

21 a lot of work done between SNBTS and the haemophilia

22 centres on the other. I don't recall that ever coming

23 out in the Penrose report.

24 **Q.** Professor Lowe, I'm not asking what the ultimate

25 outcome might have been as a result of work undertaken

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1 basis?

2 **A.** Yes. So over the course of 1985, I think that all the

3 patients who had had treatment had been -- had got the

4 letters, got the appointments, and then been

5 pre-counselled about HIV testing. And all through

6 that year, patients were coming up and being tested.

7 I don't recall any of the patients saying, "I don't

8 want a test ever." I think that some wanted time to

9 think about it, which is entirely reasonable, and that

10 was part of the counselling that Dr Wilkie said,

11 "Well, that's fine. If you want to think about it and

12 discuss with people, that's fine. Let us know when

13 you're ready to have a test, and we'll have a test."

14 Of course, the other thing that was happening

15 then was that people were getting from life insurance

16 companies: oh, I see you've got haemophilia. We want

17 to know if you're HIV positive or negative so we know

18 if we need to load your premium more or not.

19 So I'm pretty sure everybody came up if not by

20 the end of '85 into '86, and we tested them and said:

21 we want to do this regularly. And explained why, he

22 said, "It's not only for your benefit. It's for the

23 good public health reason that if we ever find

24 a patient who's seroconverted, having been previously

25 negative on an SNBTS product, we want to know about

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- 1 it. We want to trace other recipients of that batch."
 2 So everybody knew that it was in the public interest
 3 as well as their own interest.
 4 Yes, they do, and yes, they approved.
- 5 **Q.** Were you involved in telling any patients this time
 6 about their HTLV-III diagnosis?
 7 **A.** I think only one patient in 1985, yes. I had to tell
 8 one patient who had been counselled and tested and
 9 they were now positive, and it was a very hard thing
 10 for both of us, obviously.
 11 **Q.** Is that the patient whose circumstances are described
 12 using a pseudonym in the Penrose report?
 13 **A.** Yes. The anonymised patient is discussed, and
 14 I discussed it in the Penrose report.
 15 **Q.** Whose evidence, as recorded Penrose report, is that he
 16 did not know he was being tested by you for HTLV-III.
 17 **A.** Well, I was giving him the result of a positive test,
 18 following another doctor seeing the patient and taking
 19 the sample and counselling the patient. There was
 20 a conflict between what the doctor who took the sample
 21 told Dr Forbes and what the patient said as to the
 22 amount of counselling.
 23 **Q.** Was it at this time the practice of the clinicians in
 24 the centre to record in medical records discussions
 25 about counselling and consent to testing?

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- 1 interviews, as I am told by Dr Forbes and Dr Wilkie,
 2 they were held in private, because it was [a] very
 3 complicated series of discussions to explain about the
 4 situation. And I think the records of Dr Forbes and
 5 Dr Wilkie's discussions with the patient and --
 6 I think probably what the patients agreed with is they
 7 did not want these put in the records at that time
 8 because of the fear of loss of confidentiality.
- 9 **Q.** Did Dr Forbes and Dr Wilkie then make records that
 10 were retained elsewhere of their discussions with
 11 patients, and if so where?
 12 **A.** Well, if you read Dr Wilkie's evidence, I understand
 13 it that they saw these patients outwith of the
 14 haemophilia centre, in a private room, and had
 15 confidential discussions, which were recorded. But
 16 I think Dr Wilkie also says that some patients were
 17 very concerned that these should not be in the case
 18 records, at least initially.
 19 By the time that I was seeing patients,
 20 patients with positive results, most of whom had been,
 21 you know, previously seen by Dr Forbes, I would say,
 22 "Are you happy that I fully record our conversation
 23 about the tests in the notes and I file your HIV
 24 positive result in the notes?"
 25 And this, I think, was a recurring theme across

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- 1 **A.** That should have been in the -- that should have been
 2 in the records, yes.
 3 **Q.** Should have been, but you don't know whether, as
 4 a matter of routine, it was recorded?
 5 **A.** I think that this test was done fairly quickly. And
 6 by the time the patient -- by the time Dr Forbes got
 7 the report -- and he asked me to see the patient
 8 because he couldn't fit in the appointment that week,
 9 so this is the first time I've had to break the news
 10 as a new consultant to a patient. I think that by
 11 that time, the doctor taking the sample was away, and
 12 the letter had not been -- letter to the general
 13 practitioner had not been sent, so it was difficult to
 14 know what degree of records there were.
 15 **Q.** Forgive me, I don't think that quite answers my
 16 question. My question is: at this time, was there
 17 a practice of recording in the patient records
 18 discussions that the clinician would have with the
 19 patient about the wish to undertake a HTLV-III test,
 20 so the pre-test counselling process, and the patient's
 21 response to that?
 22 You must have seen multiple records, professor,
 23 as the person who took over as director a few years
 24 later. Was that routinely recorded?
 25 **A.** I think it depends what stage, because the initial

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- 1 the UK, that some patients were very unhappy about
 2 that. But my policy was always to say, "I think it is
 3 in everybody's interest if we could show in the
 4 records that we have documented the discussions that
 5 we've had and that the result is there". And the
 6 other question I would always ask is, "It would
 7 normally be our practice to include this information
 8 in the letter to the general practitioner, but that
 9 would be marked 'Private and Confidential - Only to be
 10 opened by Dr Such and Such'", and I think that was the
 11 correct thing to do.
 12 I think -- so I think in the Penrose Inquiry,
 13 patient experiences, there was quite a lot of
 14 documentation about patient concern, and certainly
 15 I think in Dr Wilkie's evidence.
- 16 **Q.** Leaving aside Dr Wilkie's evidence, which we can read
 17 for ourselves, did you ever see, when you were taking
 18 over the care of these patients, records, as part of
 19 the materials available to you, which showed a proper
 20 pre-test counselling process being undertaken in 1985?
 21 **A.** I think it was variable. I think that that might have
 22 depended on the patients' views as to whether that
 23 should be included in the records or not. But all the
 24 patients that I was seeing from December 1985 onwards,
 25 I would be very clear and say it would be very good

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1 for all parties if everything is properly recorded and
 2 the results, and the letter to the GP marked "Private
 3 and Confidential", I think it is very important to
 4 have all this documented.

5 **Q.** Do you have any knowledge of how Dr Follett came to
 6 undertake testing of patients who had been treated at
 7 and, in a number of cases, were still patients at
 8 Yorkhill?

9 **A.** I've no knowledge of Yorkhill patients, no.

10 **MS RICHARDS:** Sir, I am going to move on to look at
 11 numbers of patients infected.

12 Was there anything in relation to testing --

13 **SIR BRIAN LANGSTAFF:** There is just something I want to
 14 ask you about, professor.

15 **A.** I'm sorry, Sir Brian, could you take the document off
 16 the screen so I can ...

17 **SIR BRIAN LANGSTAFF:** Yes.

18 **A.** So I can see everybody.

19 **SIR BRIAN LANGSTAFF:** Has it gone?

20 **A.** Yes, it has, thank you.

21 **SIR BRIAN LANGSTAFF:** Can I just be clear, from the last
 22 40 minutes or so of your testimony, what the
 23 chronology was. Let me just run through and see if my
 24 understanding is correct.

25 Sometime after July 1984, 77 stored samples of

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1 of the year, which must have been prepared some time
 2 before that for publication.

3 **A.** Yes.

4 **SIR BRIAN LANGSTAFF:** So what would that be? A month or
 5 two? Probably, roughly.

6 **A.** I would guess a month or two. I think we were asked
 7 about this during the Penrose Inquiry and I think it
 8 was pointed out that The Lancet was quite good at
 9 publishing relatively rapidly compared to other
 10 journals. They wanted to be first in the field, as it
 11 were. I would have thought that the draft would have
 12 been sent in maybe November.

13 **SIR BRIAN LANGSTAFF:** That on 8 January, a letter -- dated
 14 at any rate 8 January -- was prepared for possible
 15 sending by Dr Forbes and was plainly discussed with
 16 you or mentioned to you because your name appears on
 17 it, although there was a discussion about why that
 18 should be. So at that stage your understanding was
 19 that none of the patients involved had yet been told
 20 that they might be seropositive.

21 **A.** That was my understanding.

22 **SIR BRIAN LANGSTAFF:** That you later discovered, from what
 23 Dr Forbes told you in the margins of the Penrose
 24 Inquiry, that he had decided to revise the letter
 25 after discussion of it at the UKHCDO working party on

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1 sera from Glasgow Royal Infirmary were sent off to
 2 Gallo's laboratory in the States for testing.

3 **A.** Yes.

4 **SIR BRIAN LANGSTAFF:** That in October you had the results
 5 back, sometime in October?

6 **A.** Well, I was told about the results. I attended the
 7 meeting with Dr Melbye, Dr Forbes, Dr Madhok, and we
 8 went through discussion of the results and the
 9 drafting of the paper.

10 **SIR BRIAN LANGSTAFF:** So the results -- just on the
 11 chronology, the results came back in October and were
 12 discussed at that meeting?

13 **A.** Yes, there was a meeting in October and the results
 14 must have clearly come back in, what, September,
 15 I would guess. I don't know the details of that.

16 **SIR BRIAN LANGSTAFF:** So sometime before, at any rate,
 17 October, but probably September/October.

18 Those results showed that there were
 19 12 seropositive -- people testing seropositive on that
 20 test who had had their sera stored at Glasgow, Glasgow
 21 patients.

22 **A.** So I understand.

23 **SIR BRIAN LANGSTAFF:** There was an article written about
 24 that which was printed in The Lancet on December 22,
 25 so 29th -- it must be 29th -- of 1984, the last Lancet

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1 11 April.

2 **A.** I'm very clear that he said, "I'm not going to send
 3 the letter out this week", on the 8th or 9th or
 4 whatever, because there's a meeting of the AIDS Group
 5 on the 11th and we want to generally consider what
 6 kind of information should be sent to patients and
 7 I want to reflect upon that.

8 Then, as I think I said, I don't know if that
 9 letter was sent in that format. In my discussions
 10 many years later, in 2015-2016, when I saw Dr Forbes
 11 and I raised this point, he said, "Oh, yes, there was
 12 a lot of thinking back about what names, but I really
 13 can't remember". But he said, "Looking at the letter,
 14 it strikes me as surprising that you would be the
 15 first name". So I don't know.

16 **SIR BRIAN LANGSTAFF:** The note I have is that there was
 17 a meeting on 11 April of the working party. I thought
 18 that was the meeting you were talking about. Perhaps
 19 it was the 11th of some month earlier, was it, or not?
 20 Can you help?

21 **A.** I only recently found the minutes of the AIDS Group
 22 which Dr Forbes chaired, and item 2 in the first page
 23 it says:

24 "The Chairman presented an information package
 25 which he had produced containing publications and

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1 reports which he thought were useful and informative."
 2 **SIR BRIAN LANGSTAFF:** So that's 11 April 1985?
 3 **A.** Sorry, this is 11 January 1985.
 4 **SIR BRIAN LANGSTAFF:** In January, thank you.
 5 **A.** The meeting of AIDS Group of Haemophilia Centre
 6 Directors and -- sorry, what I was trying to say,
 7 Sir Brian, was Dr Forbes said, "I don't want to send
 8 this out until letters like this are discussed at this
 9 meeting".
 10 **SIR BRIAN LANGSTAFF:** At some time after that but you
 11 don't know when, a letter bearing your name telling
 12 the Glasgow patients of some of the risks of AIDS and
 13 saying, amongst other things, that about 10 per cent
 14 had positive antibody tests was sent out.
 15 **A.** Yes, I guess so.
 16 **SIR BRIAN LANGSTAFF:** Well, that's what the --
 17 **A.** *(Unclear: overspeaking)*
 18 **SIR BRIAN LANGSTAFF:** That's what the letter of
 19 8 January 1985 appears to say. Perhaps we should just
 20 have a look at that, shall we, Soumik. It's
 21 PRSE0000859:
 22 "A small point this; I just want your help on
 23 it. We've recently tested stored blood samples from
 24 many of our patients, of whom about 10 per cent have
 25 positive antibody tests."

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1 it may well be that the conclusion is that it was the
 2 same letter modified, not until after that.
 3 **A.** Oh, no. No. The April letter very much went out in
 4 April. I don't know what date in April, but it did go
 5 out. What I'm not sure about is -- and I'm pretty
 6 sure that this draft letter, if you like, of 8 January
 7 went out in January because Dr Forbes is very keen,
 8 having discussed it with his colleagues, that it
 9 should go out with early appointments to pick up,
 10 I would imagine, the patients who have tested positive
 11 and start counselling them and getting samples,
 12 because it was his obligation to try and find out with
 13 a reliable test if these were false positives or not.
 14 So he was very keen to get the process started. And
 15 the process started with, you know, information and
 16 then saying, "I enclose an appointment." I think that
 17 was good.
 18 I think Dr Forbes may have been unique in
 19 actually sending the patients most at risk (in other
 20 words, those who were provisionally positive but
 21 needing a definitive test), sending them an actual
 22 appointment, and, in fact, giving them a number to
 23 ring if they wanted to find out about it. Now,
 24 certainly, nobody rang me, but I think it was very
 25 clear that, having engaged Dr Wilkie, who was very

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1 Bear in mind the 10 per cent. Can we go back,
 2 please, to The Lancet letter, The Lancet publication.
 3 Do you have the reference for that, please?
 4 **MS RICHARDS:** Yes. It's PRSE0001630, Soumik.
 5 **SIR BRIAN LANGSTAFF:** Thank you. Just looking at the
 6 summary, can we highlight the summary, please? There
 7 it tells us in the text that the Scottish samples all
 8 came from the Glasgow Royal Infirmary. Do you know
 9 how 15.6 per cent became 10 per cent; went from 1 in 6
 10 to 1 in 10?
 11 **A.** No, I don't.
 12 **SIR BRIAN LANGSTAFF:** Thank you.
 13 Given the chronology, it would follow, would
 14 it -- it must follow that it was at least over three
 15 months, probably over four, between Dr Forbes knowing
 16 that there were positive -- seropositive tests for
 17 antibody in 15.6 per cent of his patients before the
 18 first of them could even have been told, before the
 19 letter was even sent out. That would be the
 20 inevitable conclusion from the chronology, would it
 21 not?
 22 **A.** Yes, it would.
 23 **SIR BRIAN LANGSTAFF:** If the letter was not sent and the
 24 letter was replaced by one later on, as we've seen
 25 some time in April 1985, very similar to the first, so

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1 keen to help him in January, they would start the
 2 counselling process and -- because that would take
 3 some time. The patients needed information, and they
 4 needed to think about it, and then they would give
 5 informed consent to a fresh sample being taken for
 6 Dr Follett to do the testing once he had a reliable
 7 test set up. That seems to me an entirely ethical
 8 process for Dr Forbes too.
 9 I think his letter was very open. I don't know
 10 what other letters were sent from other haemophilia
 11 centres in Britain, but I think Lord Penrose in his
 12 fine report said, you know, I think this was a good
 13 letter, and it was sent rapidly, offered them an
 14 appointment, and that was generally fine.
 15 **SIR BRIAN LANGSTAFF:** Well, two questions arise out of the
 16 chronology when it was known in September/October that
 17 15.6 per cent of the Scottish cohort were seropositive
 18 on one test and the fact that they weren't, any of
 19 them, told about that until after mid-January at the
 20 earliest, 1985.
 21 The first is in relation to something you said
 22 in evidence when you were asked about Dr Forbes, and
 23 you said you thought that he might have been very
 24 conflicted as between his duty in publishing his
 25 research and his duty to the patients concerned. Do

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1 you recall saying that?
 2 **A.** Yes. Could I also say, Sir Brian, my written
 3 statement, 41.10 --
 4 **SIR BRIAN LANGSTAFF:** I am going to come to that in a
 5 moment, but if you can just deal with this question
 6 first because you don't mention that there.
 7 As between his duty to his patients and his
 8 interest in publishing research, where do you suppose
 9 the ethical position lies? Might it not perhaps lie
 10 with the duty to the patient as trumping all?
 11 **A.** No, Sir Brian, I don't, with respect. I think the
 12 first duty of all the Haemophilia Centre Directors in
 13 Britain who sent samples, stored or unstored, usually
 14 without permission from the patient, was doing
 15 a time-tested emergency procedure in public health.
 16 You have the first test for a spreading pandemic of
 17 a virus, and the public health approach is to say: oh,
 18 there's a test for this baffling new, potentially
 19 fatal disease which at least gives us some measure of
 20 the exposure to this virus in the blood donor
 21 population, which has gone to the high risk group of
 22 patients who had had multiple exposure. I think that
 23 was the ethos of doing the study.
 24 If you read the minutes of the UKHCDO meetings
 25 which were going on in the summer, I think Dr Craske

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1 heat-treated product oven-ready perhaps, almost ready
 2 to go, and it could be done, and that was just a very
 3 appropriate thing to do.
 4 The data was published anonymously. I think
 5 Lord Penrose made that point. I'm sorry to keep going
 6 back to Penrose Inquiry, but, you know, all the
 7 details of the dates and things are in there, and
 8 appropriate action was taken. I think that was --
 9 **SIR BRIAN LANGSTAFF:** I should make it clear that this
 10 inquiry is its own inquiry, and we are looking at the
 11 facts. We are looking at a much wider terms of
 12 reference than Lord Penrose had. We have different
 13 evidence, much wider evidence because it's UK-wide.
 14 Whereas I'm very happy to note the facts upon which
 15 Lord Penrose based his conclusions, he may not have
 16 had all the facts that we have in a number of areas,
 17 and I must draw my own conclusions as to what happened
 18 or didn't happen and why. Now, that's for me.
 19 On the facts, then -- a lot of the facts, I'm
 20 very happy to take from what he has found as facts,
 21 but one has to distinguish between facts and opinions
 22 and also --
 23 **A.** Sir Brian, I apologise if I'm mixing up the two. What
 24 I am --
 25 **SIR BRIAN LANGSTAFF:** It's because you keep going back to

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1 is saying, well, Dr Tedder has a test, and we need to
 2 do this. I think the prime purpose there, it was like
 3 hepatitis B on its discovery in the 1970s. We need to
 4 know what is the risk. We need to test it. And it's
 5 important to publish the prevalence anonymously just
 6 to show what the extent of the situation is and take
 7 appropriate measures.

8 The most important thing that arose from the
 9 testing in Scotland, from Edinburgh and Glasgow, was:
 10 as soon as the data is clear that it is the SNBTS
 11 products and not just the commercial products that
 12 have been used in Glasgow for years before, these are
 13 the current products, and they must -- this
 14 transmission must be stopped. And, hence, the very
 15 urgent meeting of Scottish Haemophilia Centre
 16 Directors, SNBTS and Scottish Government Scottish
 17 health department saying, "Right. What's the action
 18 that we need to take? How soon can you get
 19 heat-treated virally inactivated concentrate to
 20 replace as soon as possible the stuff that patients
 21 keep and have in their homes? This is an emergency.
 22 This is a public health emergency. You have to stop
 23 further infections."

24 I think that this was addressed extremely
 25 rapidly in SNBTS. Fortunately, they had this

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1 the Penrose Inquiry. What you said about the Penrose
 2 Inquiry is what you have said. That's fine. What he
 3 said about matters, it may be right. I'm not saying
 4 it isn't, but it may not be, and I'm not saying it's
 5 that either, but I have to make my own mind up as
 6 a matter of conclusion because this is a different
 7 inquiry on its own evidence, its own terms of
 8 reference, looking at a wider timescale, looking at
 9 hepatitis B as well, and so on.

10 So if you can just park his conclusions for the
 11 moment, I would be grateful.

12 **A.** I will immediately withdraw any conclusions of
 13 Lord Penrose and only cite the Penrose Inquiry as
 14 a source of suitable material for you, Sir Brian, to
 15 examine independently and perhaps with much wider
 16 evidence. I accept that absolutely.

17 **SIR BRIAN LANGSTAFF:** Thank you very much.

18 **A.** So just to resume and try to make it as quick as
 19 possible, I think the first obligation of testing
 20 a sample of stored seam samples in patients with the
 21 haemophilia, or any other group that is an at-risk
 22 population, to establish the extent of a new infection
 23 and take appropriate action to turn off the tap, to
 24 stop any further patients being infected, is
 25 a priority.

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1 But the second obligation clearly is: what do
 2 you do now? This is the dilemma that not only
 3 Dr Forbes but other Haemophilia Centre Directors are
 4 confronted with because, particularly, and this is
 5 very evident to me, Sir Brian, if you look at the
 6 second meeting of Dr Forbes' AIDS Group where, having
 7 discussed with Haemophilia Centre Directors -- and
 8 I think it's a February meeting, I don't know if you
 9 want to put that up on the screen, but --

10 **SIR BRIAN LANGSTAFF:** Well, you are only being asked about
 11 the obligation of a doctor and what -- in summary what
 12 you are telling me is that you think that the doctor's
 13 obligation here is primarily, first, to public health,
 14 where there is a pandemic or an epidemic or some
 15 serious transmissible disease involved, rather than to
 16 the patient. And I was going to ask you when you
 17 finished what you have to say, and by all means go on,
 18 but I was going to ask you: do you know of anything --
 19 and it's a real question as to whether you know of
 20 anything -- that might have prevented Professor Forbes
 21 telling patients, even between the date that the
 22 manuscript was prepared for publication and the date
 23 it was published.

24 After all --

25 **A.** Yes --

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1 And he is giving -- the virologist's view is: this is
 2 a test for research. It gives you an idea. It gives
 3 you a direction. It is probably fine for public
 4 health control because you've got quite a large number
 5 of patients that you have reasonably reliable data to
 6 take a course of action, advice to Government,
 7 Department of Health, whatever. But your next
 8 obligation is you have a test that has not been
 9 clinically validated, there are false positives, there
 10 are false negatives, and you have to think: if you
 11 tell the patient about a research test that is not
 12 clinically approved by the National Health Service,
 13 what would be the consequence of giving a patient
 14 a false negative test and the patient says, "That's
 15 absolutely fine, I'll go on having sex or not
 16 modifying anything that could result in transmission
 17 to another person", and then months or years later it
 18 turns out to be positive. That's a catastrophe.

19 On the other hand, if you have a false positive
 20 test and the patient's life is ruined and they jump
 21 off a bridge or whatever, and then, you know, it turns
 22 out, when a reliable test comes along, it's actually
 23 truly negative. And that is the difficulty.

24 This is the position that Dr Follett made very
 25 clear to Dr Forbes. And the reference for this,

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1 **SIR BRIAN LANGSTAFF:** After all, they might have been
 2 regarded, might they not, as potential transmitters of
 3 a disease if, indeed, they did turn out to be
 4 infected, and thereby, by telling them, you might
 5 perhaps serve the interests of public health as well.
 6 But that may be a matter for argument at a later
 7 stage. It's not a matter of fact.

8 **A.** Could I address that now, Sir Brian?

9 **SIR BRIAN LANGSTAFF:** Certainly.

10 **A.** Number 1: public health. Because you can do that very
 11 quickly, and you don't need anybody's consent to do
 12 that. Turn off the tap, stop the flow.

13 The second obligation of the doctor, who's also
 14 a researcher, is to say: now, what do I do about
 15 telling the patient? And what I was going to say is
 16 that at this February meeting, consult it at leisure,
 17 Dr Tedder is there and he's talking about the tests,
 18 and he said, "Well, thanks for sending me all these
 19 samples but could I just say that my test is not very
 20 good. It's not been clinically validated, it's
 21 suitable for research, and I have reservations about
 22 its accuracy and I am not alone."

23 I think briefly he's saying, "The test that
 24 I have and, indeed, the test that Dr Gallo has, that
 25 the Glasgow results sent for, is a research test".

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1 Sir Brian, is the Scottish Medical Journal 1987 issue,
 2 which Dr Forbes, as editor of the Scottish Medical
 3 Journal, produced, and it has an article in virology
 4 testing for HIV by Dr Follett. And it makes very
 5 clear that the ELISA test, the first ones out, are not
 6 reliable and must always be confirmed by a reliable
 7 assay, which he eventually had. And that was the
 8 approach that Dr Follett took.

9 Yes, there's a screening test that's cheap and
 10 cheerful, but if you get a positive, you have to have
 11 it confirmed by a reliable, more expensive test. And
 12 Dr Follett, even in 1987, was sending results of two
 13 different tests, by two different methods in his
 14 laboratory, to Dr Tedder if he wasn't sure.

15 Now, that is the right way to do it, because
 16 then you are giving patients a correct diagnosis and
 17 correct advice. And that is why I think Dr Forbes was
 18 very professional in this, and he sent early
 19 appointments to the patients that were positive on the
 20 Gallo test, which was unreliable, explained the
 21 position and say: I want to tell you about this test
 22 but it's important that we want to repeat all the
 23 tests in all our patients with a reliable test so that
 24 we know what the true situation is, and that's
 25 important for you and your family and that's important

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1 for us. And that is the ethical action that he took.
 2 I think it would be the same in all the other
 3 haemophilia centres that used the Tedder test.
 4 I would have hoped that they would have thought in the
 5 same way.

6 **SIR BRIAN LANGSTAFF:** Well, I have your answer. Thank you
 7 for the comment which you made during the time as to
 8 where the doctor's primary duty lay.
 9 Can I ask you this, also in the light of the
 10 chronology which I've set out and you've agreed. It's
 11 paragraph 4.10 of your witness statement.
 12 Soumik, if we can go to the witness statement,
 13 it's 34960, and it's paragraph 41.10, which is
 14 page 92.
 15 You say there that you think that Dr Forbes'
 16 letter was "very prompt". How do you support that in
 17 the light of the chronology?

18 **A.** So it was -- it was prompt because, by this time, he
 19 had arranged a system in which he could tell the
 20 patients in an appropriate manner, and that system was
 21 first to get an experienced counsellor to join him in
 22 speaking to the patient, and their families if they
 23 wished, about what the situation was because, by this
 24 time, he was working with Dr Follett to say, "As soon
 25 as possible, can you get me a reliable test?"

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1 Dr Wilkie funding and agreement of Professor Kennedy
 2 to employ her. Her own evidence, I think, says:
 3 "I turned from seeing kidney patients four days a week
 4 to seeing haemophilia patients two days a week." It
 5 was very promptly arranged, and she was I think the
 6 most appropriate person to do it. She was an
 7 experienced counsellor, and she got ready to do it as
 8 well.
 9 So that -- those stages of the process I think
 10 were appropriate, but meantime, having done that,
 11 I think it was appropriate to publish the information
 12 in The Lancet. I think that's an important
 13 contribution to the epidemiology. It shows, using
 14 anonymous data of Danish and Scottish patients, that
 15 on aggregate there's no doubt that in European
 16 haemophilia centres it is the commercial concentrate
 17 that carries the highest risk.
 18 I think that is not too bad a sequence of
 19 events. And then he gets on with writing letters to
 20 the patients within two weeks of The Lancet paper
 21 coming out, explaining the situation and saying,
 22 "Right. We're now starting this process of giving you
 23 information and giving you the autonomy to hear about
 24 the whole situation and to think about and then
 25 hopefully give consent to a proper test that will

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1 So by sending out appointments in January, he's
 2 got that done. He couldn't have done that before,
 3 I don't think, because he hadn't got Dr Wilkie to
 4 agree to do the counselling with him, and Dr Follett
 5 said, "Right, I'm doing it, but it's going to take
 6 a while, but get on with starting the process of
 7 counselling and getting a sample, and then as soon as
 8 I can get a reliable test arranged, I will do that."
 9 I think that was prompt action.

10 **SIR BRIAN LANGSTAFF:** Very prompt?
 11 **A.** How prompt is prompt? I don't --
 12 **SIR BRIAN LANGSTAFF:** The words are yours.
 13 **A.** Right. I'm trying to think. Dr Forbes has the
 14 results by, what, October on these --
 15 **SIR BRIAN LANGSTAFF:** Well, you said September/October.
 16 **A.** Yes. So let's work out the chronology. So what's he
 17 going to do? He's going to think about how reliable
 18 are the tests, and he will speak, I assume, to
 19 Dr Follett and then at a later stage Dr Tedder when
 20 the AIDS group starts meeting in February to confirm.
 21 So how soon can I get a reliable test? But I think
 22 pretty immediately, according to his evidence and
 23 Dr Wilkie's test, he's thought, "Well, I know the
 24 ideal person that's working in the Department of
 25 Medicine on kidney disease." And he was getting

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1 clarify the situation for you and your family."
 2 I think that is not unreasonable.
 3 **SIR BRIAN LANGSTAFF:** Was there any record that you know
 4 of kept of when the 12 patients were actually
 5 informed?
 6 **A.** No, as I was -- well, I don't know.
 7 **SIR BRIAN LANGSTAFF:** Well, that's all that -- I don't
 8 think I can take your evidence any further than that.
 9 Thank you for that explanation, professor. It's been
 10 quite illuminating.
 11 **MS RICHARDS:** Sir, there are some further questions I have
 12 arising out of that.
 13 Professor Lowe, at the meeting in October 1984
 14 which you attended -- Dr Forbes was at, Dr Froebel was
 15 at -- at which the results and the publication were
 16 discussed, was there any discussion about the risks
 17 faced by the sexual partners or family members of the
 18 haemophiliac patients who had, on the testing so far,
 19 turned out to be HTLV-III positive?
 20 **A.** Well, it was, I think, a two-stage meeting. The first
 21 meeting was with Dr Melbye, and that was basically
 22 going through the data, putting together a paper.
 23 I can't remember if there was any discussion
 24 with Dr Melbye, who was an epidemiologist looking
 25 I think particularly at the gay population in Denmark

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1 and obviously would be addressing the issues that
2 you're addressing now about sexual transmission as
3 well as blood transmission.

4 I can't remember if -- if there was discussion
5 with Dr Melbye, I don't know. But what I do remember
6 is Dr Madhok then taking Dr Melbye to the airport, and
7 Dr Froebel and I having a long discussion with
8 Dr Forbes about: well, what do you do now? And
9 Dr Froebel pointed out the problems about false
10 positives, false negatives, needs for confirmation,
11 et cetera. Then, of course, it would be: well, what
12 are we going to do about the information to patients
13 about sexual partners?

14 I think what Dr Forbes -- my recollection is
15 that what Dr Forbes was thinking about is: right,
16 again, public health. The first priority is this kind
17 of core letter that goes out from all haemophilia
18 centres to their patients saying: right, here's the
19 problem because we have HIV infection in the blood
20 donor pool, and we're now trying to sort out what is
21 the situation for you by getting testing arranged. In
22 the meantime, the most important thing to do, having,
23 you know, got the non-heat-treated concentrate back,
24 is for you to think about sexual transmission, which
25 we know is a risk of this new virus, and to advise

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1 knows a lot more about AIDS than I do because he has
2 been working on it solidly for two years. He was
3 clearly thinking very hard about it. I don't think he
4 told Dr Froebel and I exactly what he was going to do.

5 **Q.** Was there any discussion at all about the issue at the
6 meeting that you can recall: yes or no?

7 **A.** I honestly can't remember. I think it was part of the
8 general conversation but I don't think it was a major
9 part of the meeting, which was focused on the paper.
10 And then Dr Froebel and I started to raise with
11 Dr Forbes: right, what are you going to do about
12 getting reliable tests and contacting the patients?

13 **Q.** As I understand your evidence from earlier this
14 afternoon, the more reliable tests were not available
15 for Dr Follett to use until around April 1985; is that
16 correct?

17 **A.** That's correct.

18 **Q.** So at the point at which if Dr Forbes did send out
19 a letter in January 1985, at that point there was
20 still no reliable test, but he was, if the letter was
21 sent, providing information and getting the ball
22 rolling. Why could that letter, that January '85
23 letter, not have been sent at the end of October 1984,
24 which would at least have put patients on notice that
25 some had tested positive and that further testing was

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1 everybody who's had blood products to wear condoms,
2 et cetera, you know, to protect sexual transmission.

3 And that is the clear message that I think is
4 going out from all the haemophilia centres in Britain.
5 And I think Dr Peter Jones' book, which was sent out
6 in April -- we would have sent it earlier, but it sold
7 out like hotcakes, you know. It had to be reprinted.
8 And by April, we had a copy to send in the second
9 letter. And that is very clear about that.

10 It's a clear message from The Haemophilia
11 Society bulletins and the Haemofact sheets, and it's a
12 clear message at this stage to anybody in Britain in
13 the general public --

14 **Q.** Professor Lowe, what is the answer to my question,
15 please? Was there any explicit discussion at the
16 meeting in October 1984 about the possible risks faced
17 by the sexual partners and family members of the
18 12 patients who, at that stage, were understood to be
19 HTLV-III positive? Was it actually considered at all
20 at the meeting?

21 **A.** Well, it was -- that was Dr Forbes' responsibility as
22 the consultant in charge of the patient to make. He
23 was clearly thinking long and hard about it. At the
24 time, I don't recall -- I mean, Dr Froebel was
25 a scientist. I'm a clinician, but, you know Dr Forbes

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1 required to confirm the position and that in the
2 meantime they should take all sensible precautions?

3 **A.** That's a good question and I don't know. I think that
4 Dr Forbes, like other Haemophilia Centre Directors,
5 would be giving information about the risk of AIDS,
6 and I cannot recall, because I was not involved at all
7 in 1984, about what information was being advised by
8 The Haemophilia Society or UKHCDO about, now that
9 there are cases of AIDS in Britain and blood is
10 a possibility, would that be a wise precaution to take
11 in all patients. I honestly don't know the extent of
12 that information.

13 **Q.** Can you think of any practical or other reason why
14 Dr Forbes could not have sent the 8 January letter at
15 the end of October 1984?

16 **A.** I can't at this moment really think about that, no.

17 **Q.** Do you know, from your own knowledge, and as someone
18 who took over the directorship of the haemophilia
19 centre in '88, whether any of the 12 Gallo tests were
20 found to be false positives on confirmatory testing?

21 **A.** I think what Dr Follett told us, and what I think is
22 perhaps at that 31 May meeting, I think they were
23 all -- no, I'm sorry, hang on a minute.

24 I think, from memory, there was one query
25 positive and they didn't know. And I think

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1 Dr Follett's test said it was definitely negative.

2 **Q.** Because your 16 per cent that you voiced at that

3 meeting of 31 May 1985 to Dr Follett and others is

4 very similar to the 15.6 per cent recorded in

5 The Lancet article. It doesn't appear that

6 confirmatory testing had revealed a significantly

7 different picture, does it?

8 **A.** Sorry, just run those figures past me again. What's

9 the difference?

10 **Q.** The Lancet Article recorded 15.6 per cent of the

11 patients tested being HTLV positive. You, in the

12 meeting of 31 May 1985 with Dr Follett, used the

13 figure 16 per cent. The confirmatory testing did not

14 reveal a significantly different picture from the

15 Gallo testing, did it?

16 **A.** No, I think that is just rounded up. I think 16 and

17 15.6 per cent are the same figure.

18 **Q.** The Lancet article, if we go back to it -- PRSE0001630

19 please, Soumik. And if we go to the second page,

20 please, right-hand column, bottom half of the page:

21 "In Scotland, 11 (18%) of 62 haemophilia A

22 and 1 ... of 15 haemophilia B patients were HTLV-III

23 positive ..."

24 It doesn't say there: it's a preliminary test,

25 there's a lot of doubt, we don't really know, we don't

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1 asked about the 10 per cent and it's not quite clear

2 precisely how the figures were calculated at that

3 point in time, I think. But there's nothing said

4 here, is there, about there being uncertainty about

5 the testing?

6 **A.** That is correct.

7 **Q.** If we go on to the top of the next page, and forgive

8 me, this is a question I meant to ask you when we were

9 looking at this previously and omitted to do. Top of

10 the page. It says:

11 "We would also like to perform some skin tests

12 which measure the body's defences against infections."

13 What were those skin tests and what was their

14 purpose?

15 **A.** So, at the time, skin tests were in vogue, if you

16 like, in terms of HIV positive patients, as being

17 a measure of susceptibility to develop clinical

18 complications of AIDS because, as it says, they

19 measure the body's defences against infection.

20 I think the more depressed the immunity, that was

21 a clinically relevant guide as to the patient who's

22 HIV positive has about risks of infection.

23 So it wasn't a research test, it would be --

24 well, was it? No, because there was a broader

25 question that I think you explored with

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1 know the significance of it.

2 It's stated in terms, to the world, that these

3 patients are HTLV-III positive, isn't it?

4 **A.** Yes.

5 **Q.** If we go then to the letter, please, of 8 January, and

6 leaving aside the uncertainty as to whether it was

7 sent or not. PRSE0000859. And if we look at the long

8 paragraph at the bottom half of the page, it says,

9 just over halfway down:

10 "We have recently tested stored blood samples

11 from many of our patients, of whom about 10 per cent

12 have positive antibody tests."

13 Then it goes on to say that -- compared the

14 Scottish and the English position.

15 Again, there's nothing there, is there, to say,

16 "But we doubt that they are correct" or "They are

17 uncertain"; it's being stated in terms: 10 per cent

18 have positive antibody tests.

19 **A.** Yes, it says "about 10 per cent", yes.

20 **SIR BRIAN LANGSTAFF:** Whereas it actually should mean

21 16 per cent, shouldn't it?

22 **MS RICHARDS:** If it is just Glasgow, yes, as opposed to

23 Scotland as a whole.

24 **SIR BRIAN LANGSTAFF:** Well, it was only -- I see.

25 **MS RICHARDS:** Yes. You will recall, sir, Dr Ludlam was

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1 Professor Ludlam last week in some detail. Was it

2 only HIV that was the one thing to consider in AIDS or

3 was it the body's defences against infections in

4 general that, perhaps through just general exposure to

5 blood products and foreign proteins, was an important

6 issue? So both as a prognostic issue for the patient

7 and -- I think that was the initial reason.

8 I don't think the skin test lasted very long

9 because, with the passage of time, it wasn't so much

10 an indication of risk of getting HIV. But as you may

11 come to later, Dr Madhok continued, as did

12 Professor Ludlam, in Edinburgh, to perform skin tests,

13 because it was apparent that some HIV negative

14 patients with haemophilia had these measures of

15 reduced defence even though they were HIV negative,

16 and that required investigation.

17 **Q.** We may need to come back to the skin tests when we

18 consider the question of research, probably tomorrow.

19 Can we then pick up the question of numbers

20 infected at the Glasgow Royal Infirmary, by reference

21 to the table in the Penrose Inquiry report.

22 PRSE0007002, please, Soumik. It's page 97 of the

23 numbered pages. I can't remember how many we need to

24 add on. Do you want to try 103 and see where we get

25 to? So five more pages further on.

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1 If we just look here at what's recorded in the
2 report about numbers, 3.281 tells us that:

3 "Dr Campbell Tait, director ... gave evidence
4 about the results of the exercise in Glasgow. In the
5 final count, 12 patients contracted HIV infection
6 while attending the GRI Haemophilia Centre."

7 And then we have the data in the table which
8 I will come back to in a moment.

9 Paragraph 3.282:

10 "Ten of the 12 patients had Haemophilia A
11 (eight severe and two moderate) and two had
12 Haemophilia B (patients G10 and G11). Most of the
13 patients received both commercial products and SNBTS
14 products and it is not always possible to be confident
15 of a robust allocation of imported or PFC products as
16 being the cause of HIV infection. The cause of
17 infection in three cases (G3, G6 and G12) appears
18 clearly to have been the use of imported Factor VIII.
19 Three patients received only PFC Factor VIII between
20 their last negative and first positive HIV test and it
21 appears that these three patients were very probably
22 infected by an SNBTS product. Retrospective testing
23 of stored data, where available, show that of the 12
24 patients infected with HIV ..."

25 And then we have the various states of

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1 So we continued to do this work. I cannot
2 remember any seroconversions after Dr Forbes left. We
3 did have -- I mean, there's always the possibility
4 that patients who had been treated at the
5 Royal Infirmary and gone somewhere else or just don't
6 come at all come back to us later and then you do the
7 tests, and -- but I can't remember acquiring any
8 patients who had been treated at the Royal Infirmary
9 who came back and were found to be a new case of
10 positivity.

11 **Q.** Do you know, again from your own knowledge in your
12 capacity as consultant and director at the centre for
13 many years, whether of the patients who were infected
14 through their treatment at the Royal Infirmary any of
15 them were the broader west of Scotland patients, or
16 whether they were all, as it were, full-time
17 Royal Infirmary patients?

18 **A.** I think these were all patients who attended Glasgow
19 Royal Infirmary. Obviously over the years we acquired
20 HIV positive patients from Yorkhill who were clearly
21 infected at Yorkhill.

22 We acquired patients from other adult hospitals
23 in Scotland. I can't name them, but I think there
24 were three who had received treatment at that hospital
25 and were then found to be HIV positive, and they

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1 seroconversion: so one in '81-'82; two, '82-'83; one
2 between '82-'84; one between '82-'86; one in '84-'85;
3 one in '85-'86; one during 1985. And for four
4 patients whose date of last negative HIV test is not
5 known, the first HIV positive tests were,
6 respectively, April '81, November '82, May '84 and
7 November '85.

8 If we can go back then to the table on the
9 previous page please, Soumik, I'm just going to ask if
10 you can assist at all with this, with understanding
11 this table.

12 First of all, this work obviously was
13 undertaken by Dr Campbell Tait for the Inquiry after
14 your retirement. What, if any, work was undertaken
15 whilst you were still director in the '80s or in the
16 '90s to try and establish the dates of seroconversion?

17 **A.** Well, we continued to do -- sorry, for these
18 individuals?

19 **Q.** Yes. Well, for the individuals that you had under
20 your care, yes.

21 **A.** Right. So these -- well, Dr Madhok under Dr Forbes
22 continued to analyse this in relationship to
23 treatments and report to SNBTS after Dr Forbes left
24 for Dundee and I succeeded him as co-director, middle
25 of/end of '87.

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1 agreed to transfer to Royal Infirmary because of the
2 services we set up about care of HIV infected patients
3 with haemophilia; Dr Wilkie infectious diseases,
4 et cetera.

5 **Q.** I just have a handful of questions about what we can
6 see from the table about some of the individual cases.
7 I'm not asking you in answering them to give any
8 information that might identify any individual.

9 G1 is last negative January '82; first positive
10 September '86. Now, that seems, looking at the table,
11 a fairly late stage at which to be performing an
12 HTLV-III test and identifying it as positive. Do you
13 know why it was that it was only in September of '86
14 that a positive test was found?

15 **A.** No, I don't know. I mean, patients move around.
16 Patients will go off and live somewhere else and then
17 come back. I find it difficult at this stage to work
18 out who these people are.

19 **Q.** In relation to the two patients who we are told in
20 this paragraph are haemophilia B patients, so that's
21 patients G10 and G11, in relation to the G11 we can
22 see last negative is said to be October '85; first
23 positive July '86. The treatment is said to be Defix.

24 Are you able to assist us with how a patient
25 during that period was sero-converting on Factor IX

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1 when, by then, heat-treated Factor IX should have been
2 available?

3 **A.** No, I don't recognise this patient or date at all.
4 Sorry, I'm just trying to recall the two Factor IX
5 patients. Right, I've identified one, but it is not
6 the 1985 to 1986 patient.

7 No, I don't. I would suggest if you want
8 further information on that, you'd have to ask Dr Tait
9 who did the -- who looked very exhaustively at all the
10 relevant data back in 2011.

11 **Q.** All right. Well, it doesn't look like I can take the
12 understanding of the table any further.

13 Can I then ask you next a little about how the
14 care and treatment of patients infected with HIV was
15 undertaken and organised at the Glasgow Royal
16 Infirmary, in particular what was the division of
17 responsibility between the Royal Infirmary and Ruchill
18 in terms of their care?

19 **A.** Well, this started very early. Dr Dermot Kennedy and
20 Dr Campbell Love were the two infectious disease
21 consultants who initially were the people who took on
22 the care of patients who were HIV positive, but it was
23 Dr Kennedy in particular who, as a neighbour -- and
24 friend, I should declare -- who was extremely helpful.
25 And, as you can see, he attended the AIDS group

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1 for the patient to go to Ruchill, like an acute
2 infection which might be HIV-related, probably the
3 best thing to do is to go to Ruchill and, while there,
4 if they are admitted there, if they need something
5 from us, like Factor or anything haematological, we
6 will come out and do that.

7 So we worked out these policies. They didn't
8 always work perfectly but we learned with experience.
9 And then the patient had these -- both resources
10 available.

11 Also the nursing staff spoke to each other. So
12 our haemophilia sister had a good relationship with
13 the infectious disease ward staff at Ruchill, and we
14 got to know each other, and I think that worked well.
15 And when it came to the treatments that were
16 appropriate, the first two of which were the AZT
17 drug -- well, Dr Kennedy would be very much in charge
18 of these anti-AIDS drugs and he would prescribe them
19 and monitor them and tell patients about the adverse
20 effects, et cetera.

21 The other drug we used initially was the
22 inhaled pentamidine which, before oral Septrin, was
23 the way to prevent the highly fatal condition of
24 pneumocystis pneumonia. We set up a room near the
25 haemophilia centre where they could be taught the

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1 meeting on 31 May, and Dr Forbes and I by this stage
2 had had discussions with him about how we're going to
3 do it. We thought the best thing to do is to arrange
4 particular timed appointments to see the HIV positive
5 patients where he would attend and we do the joint
6 clinic.

7 Depending on the patient, that would either be
8 the two of us or me just doing the haemophilia and
9 handing over to Dr Kennedy or vice versa. So we would
10 want to try and build up our individual relationships
11 as a haemophilia doctor and infectious diseases doctor
12 with the patient to say: we're both looking after you,
13 I'm expert in this, he's expert in that.

14 And I think we worked pretty well. We devoted
15 quite a lot of time, I think at least an hour, to
16 these sessions. And if we saw the patients
17 individually, we'd then have a combined chat and say:
18 well, what we recommend for your haemophilia is this
19 and what we recommend for you is that.

20 We had these policies worked out, as
21 I've briefly mentioned, that if it was
22 a straightforward bleeding problem, they would
23 continue to come straight to the haemophilia centre,
24 because stopping bleeding is still the priority. But
25 if there are particular circumstances that it's better

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1 inhaled pentamidine technique.

2 So I think we co-operated pretty well. And
3 when it came to the more -- additional therapies over
4 the years for HIV, we were in frequent contact with
5 the pharmacist at the Brownlee Centre about the
6 monitoring of drugs and blood tests and things and we
7 collaborated very closely upon that.

8 **Q.** Now, in the period from late December 1984, whenever
9 it was that heat-treated Factor VIII concentrates
10 became available and was supplied to patients at the
11 centre, to April 1987, the PFC product, Factor VIII
12 concentrate NY, was understood -- or believed and
13 hoped -- to inactivate HIV but not non-A, non-B
14 hepatitis. Is that right?

15 **A.** Well, at the start I think SNBTS were pretty confident
16 it would be protective against HIV because of data
17 from other manufacturers and sources, and that was
18 closely monitored. But there was certainly -- when
19 you say "doubt", it was not proven that it would
20 totally eradicate hepatitis C. And I think, as you
21 say, from about 1986, when I think the first case was
22 in Edinburgh, it was realised that it was less
23 effective.

24 That led to SNBTS, as you know, treating the
25 product with a higher degree of heat treatment. But

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1 there was this window period, which is well recorded,
2 where patients could get hepatitis C, particularly if
3 they hadn't been exposed before. The alternative was
4 to give them cryoprecipitate. That has been
5 extensively discussed. The risk then was could you
6 get HIV even despite the blood donor screening of HIV.
7 So it was a difficult time and that was discussed
8 a lot.

9 **Q.** I want to understand what the policy or protocol
10 system at the Glasgow Royal Infirmary was in this
11 period to address the position of the minimally
12 treated or previously untreated patient presenting
13 with a possible need for treatment.
14 As I understand your evidence to the Penrose
15 Inquiry -- please correct me if this is wrong -- the
16 Glasgow policy during this period was that
17 a moderately severe or moderate haemophilia A or
18 von Willebrand's sufferer who hadn't previously been
19 treated or had been minimally treated would be likely
20 to be treated with cryoprecipitate because of the
21 small pool size as opposed to the thousands. That was
22 what you told the Penrose Inquiry.

23 Is that correct?
24 **A.** That is correct. And the policy, as always, would be
25 made by discussion between Dr Forbes and Dr McDonald

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1 **A.** Yes. And certainly for the von Willebrand's, yes.
2 **Q.** You referred to a case in Edinburgh. I'm not asking
3 you about that case but were there any cases, to your
4 knowledge, of patients infected with non-A, non-B
5 hepatitis from factor concentrates in this period,
6 this window period, in Glasgow?
7 **A.** Yes, and I think you do have the report from the 2000
8 Scottish Executive inquiry which was set up to look at
9 this very issue. And we all, at the haemophilia
10 centres, looked very carefully through all the records
11 and recorded how many patients received treatment
12 during this time window with either cryoprecipitate or
13 with PFC Factor VIII or both, and we did that across
14 the country. And I think the report tells you that
15 there were less than ten patients affected. And
16 I don't know if you have a table of the results?
17 **Q.** We've got the report. I am wondering whether do you
18 have any recollection of what the position was in
19 relation to Glasgow Royal Infirmary. If you don't,
20 don't worry. We can look at the document ourselves.
21 **A.** I think we had two patients, from memory, at Glasgow
22 Royal Infirmary.
23 **Q.** What, if any, knowledge did you or, as far as you are
24 aware, the centre have at this time of what else SNBTS
25 was undertaking, or PFC was undertaking, to try and

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1 and Dr Davidson, because you had to prescribe
2 a product from blood transfusion.

3 Yes, and I think when push came to shove and
4 I was asked at the Penrose Inquiry: well, if it was
5 you and you have just been diagnosed, what would you
6 have? And after much persuasion at the
7 Penrose Inquiry, I said I'd probably go for the
8 cryoprecipitate.

9 **Q.** You also, I think, told the Penrose Inquiry -- again,
10 please correct me if this is not what the policy
11 was -- that in relation to mild patients that the
12 treatment of choice during this period for mild
13 patients would be DDAVP, and that would have been
14 sufficient to accommodate most situations?
15 **A.** Yes, we'd always try DDAVP if possible. As you know,
16 there's a variable response, but I think we
17 proactively gave all of these patients test doses of
18 DDAVP to see what we could get and then give that as
19 first choice always. And then if it didn't work we'd
20 have to go to a blood product.
21 **Q.** Presumably if your product of choice, first choice,
22 for the moderate or VW patient was cryoprecipitate,
23 for the mild patient, again, it would be
24 cryoprecipitate before concentrate at that point in
25 time?

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1 produce a factor concentrate that would effectively
2 eradicate non-A, non-B hepatitis?
3 **A.** I understood they were working hard on it. They will
4 give you the details, yes.
5 **Q.** Did you at the Royal Infirmary have access during this
6 period to it on a trial basis, to any SNBTS product
7 that was being worked on, in the way you described?
8 **A.** I'm sorry, I can't remember. You mean worked on --
9 you mean the trial of a more heat-treated product?
10 **Q.** Yes. Did you have access to their trial products?
11 **A.** I'm sorry, I can't remember.
12 **Q.** The BPL product 8Y during this period was being
13 evaluated, and a point in time came -- I'm not going
14 to ask you to consider documents as to when precisely
15 that point in time was -- when it was understood or
16 thought to be effective in relation to non-A, non-B
17 hepatitis.
18 Did it occur to you or any of your colleagues
19 at the centre to try and get hold of a stock of 8Y at
20 any point during the window period?
21 **A.** I didn't know it was available.
22 **Q.** You alluded yesterday I think to there being
23 a shortfall of Z8 in 1988. Without going into the
24 full background or detail of it, what was your
25 understanding of the reason for the shortfall?

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1 A. I think I've addressed this in my written statement
 2 that -- and the documentation is laid out in meetings
 3 between the Scottish haemophilia directors and SNBTS
 4 at this time, and I think it was multifactorial.
 5 SNBTS reported in 1988 that there had been reduction
 6 in material and there was going to be a shortfall in
 7 their production, and the factor at this time was that
 8 our demands had gone up, so there were two reasons for
 9 the imbalance.

10 We were catching up on a lot of knee
 11 replacement surgery, for example, where patients in
 12 a lot of pain had their operations delayed, and now
 13 that we're happy that we have a safe product, we're
 14 catching up on that.

15 So there were a variety of reasons, but there
 16 was a mismatch, and clearly we had to address it. And
 17 I think I've described to you the process that we
 18 underwent in Dr Davidson arranging for a licensed
 19 heat-treated commercial product -- I think it might
 20 have been Profilate -- that was used for a couple of
 21 years.

22 MS RICHARDS: Sir, I am going to move on to a topic next
 23 in relation to hepatitis C testing and the treatment.
 24 I note the time. I wonder whether it might be
 25 sensible to pick that up tomorrow at two o'clock?

1 SIR BRIAN LANGSTAFF: Yes, we will have adequate time
 2 I think tomorrow to deal with that, won't we?

3 MS RICHARDS: Yes.

4 SIR BRIAN LANGSTAFF: Professor, we'll have a slightly
 5 earlier finish than we did yesterday, you might be
 6 pleased to know, and we'll come back at two o'clock
 7 tomorrow. Same rules apply, of course, during this
 8 period as did throughout yesterday. So two o'clock
 9 tomorrow. Thank you very much.

10 A. Thank you.

11 (5.27 pm)

(Adjourned until 2.00 pm the following day)

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