

Tuesday, 20th October 2020

(10.00 am)

SIR BRIAN LANGSTAFF: This morning and tomorrow we have Professor Lee.

MS RICHARDS: That's right, sir.

PROFESSOR CHRISTINE ANNE LEE, affirmed

Questioned by MS RICHARDS

MS RICHARDS: Professor Lee, I'm going to start by asking a few questions about your career. You studied medicine at Oxford; is that right?

A. Yes.

Q. Then you held various house officer posts in the early 1970s?

A. Yes.

Q. You began your haematology training in September 1974; was that at St Mary's, London?

A. Yes, St Mary's, Harrow Road, London, yes.

Q. And you were a registrar there and the consultant was Dr Fielding; is that right?

A. Yes.

Q. And that was something that you did until 1976. You then moved to St George's as a senior registrar in November 1976?

A. Yes.

Q. You remained there until December 1982?

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A. It would have been the generality of the infections that were known at that time.

Q. Do you recall any particular impression of the centre at Tooting and how it was run?

A. No.

Q. Do you recall whether there were any shortages or supply issues? We've heard from Dr Winter that by the time he was dealing with the Tooting centre, there were difficulties because they were covering both the south east and south west regions; were you aware of that?

A. No.

Q. You then moved to the Royal Free Hospital at the end of 1982 and beginning of 1983; is that right?

A. Perhaps I should explain. I was given the appointment at the end of 1982. I actually took up the appointment at the end of January 1983.

Q. The post was entitled "Research Senior Registrar"; is that correct?

A. That's right.

Q. How did you come to apply for that job?

A. The job was advertised by being sent to all the haematologists in the London region. And Peter Flute, Professor Peter Flute, gave me the description of it, and that has been submitted in the papers.

3

A. Yes.

Q. You told the Lindsay Inquiry that it was at St George's you became particularly interested in haemophilia; is that right?

A. Yes.

Q. Now, you spent, during that time, I think, some ten months or so at the South London Transfusion Centre?

A. Yes, I was working part-time. So I was working two and a half days a week there for my training, for MRC Path.

Q. And that was the Tooting centre?

A. Sorry?

Q. Was that the centre in Tooting, the transfusion centre?

A. Sorry, yes.

Q. Can you recall who the director was of the transfusion centre?

A. No.

Q. You've said in your statement that you would have understood, at that time, the risks of transfusion acquired infection. I'll come on to knowledge of risks of infection in more detail later but can you recall what, if anything, was discussed or talked about that issue at the transfusion centre?

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Q. Yes, we'll look at that in a moment. Had you known or worked with Dr Kernoff or Dr Howard Thomas before?

A. Sorry, had I?

Q. Had you known or worked with either Dr Peter Kernoff or Dr Howard Thomas before?

A. When I did a neurology SHO post, in 1971, for six months, at the Churchill Hospital in Oxford. I was doing neurology and Dr Peter Kernoff at that time I think was doing his MD on inhibitors with Dr Rizza, and the Haemophilia Centre at the Churchill Hospital -- which incidentally is where I trained, in Oxford Medical School -- and the Haemophilia Centre was on the same site. And occasionally, I would see him because we had ward rounds to train us to take membership of the Royal College of Physicians. So that was how I knew him at that time.

Q. And had you known Dr Howard Thomas before you applied?

A. Dr Howard Thomas was a colleague of my husband in the Department of Medicine at the Royal Free, when Dame Sheila Sherlock headed up that department, and he was a professional colleague of my husband, and I did -- we did know him socially.

Q. We're just going to look at a couple of documents, the application Dr Kernoff made for a grant for the post that you took up, and the job description.

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1 Henry, could we have, please, WITN0644062, please.
 2 This is one of the exhibits to your witness
 3 statement, Professor Lee.
 4 If we see the whole page, please, Henry.
 5 This is:
 6 "A Grant Application to Action Research for the
 7 Crippled Child."
 8 Could you just explain what Action Research was?
 9 **A.** It was a charitable trust that awarded monies for
 10 research, and as you can see from the title there, at
 11 the time it was called Action Research for the
 12 Crippled Child, which is rather insensitive and that
 13 has now been dropped but, as I understand it, I think
 14 it still exists. And I imagine it was applied for
 15 because haemophilia before treating caused great
 16 disablement.
 17 **Q.** We can see that the application was -- this is
 18 November 1981, in fact. So obviously before you saw
 19 the post advertised and applied. It's called Aspects
 20 of the Natural History of Liver Disease and
 21 Haemophilia. I'm going to ask you to turn to a few
 22 pages. I want to get a sense of the work you were
 23 doing at the Royal Free under this post.
 24 If you go to page 4, please, Henry.
 25 We can see under the heading "Objectives" -- if

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1 **A.** No, I'm sure we're going to move on to this, but these
 2 were two ways in which progression of liver disease
 3 could be looked at by non-invasive methods, so
 4 avoiding liver biopsy, essentially. And there is
 5 a paper in my submission that records the results of
 6 this, but it was published much later, and it was
 7 effective to some extent.
 8 **Q.** Yes, we'll come on to look at that paper at a later
 9 stage of your evidence, Professor Lee. Just trying to
 10 get a sense of what the aim of the work was.
 11 2.3 was:
 12 "To make a detailed evaluation of patients treated
 13 with pooled immunoglobulin ..."
 14 And then:
 15 "To make a detailed evaluation of the response to
 16 steroid therapy and patients with severe chronic liver
 17 disease. If appropriate, to establish a multi-centre
 18 controlled trial to assess the possible benefits of
 19 steroid therapy."
 20 Was that part of the work which you undertook?
 21 **A.** No, I need to just take a little bit of time here.
 22 Most of the patients had been seen before I -- my
 23 post, essentially, was looking retrospectively at the
 24 data. The study that I analysed, obviously, was
 25 Dr Kernoff's supervision. The patients had been

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1 you want to zoom in on that paragraph, please, Henry.
 2 You can see the whole paragraph under the heading
 3 "Objectives".
 4 Sorry, can we see the whole of that section.
 5 Thank you.
 6 So there are three objectives there set out as the
 7 objectives of the post:
 8 "To use a newly-developed radioimmunoassay for
 9 immunological markers of non-A, non-B hepatitis to
 10 study (a) the natural history of acute and chronic
 11 [non-A, non-B] hepatitis in haemophiliacs; (b) the
 12 antigen/antibody content of different preparations of
 13 clotting factor concentrates; (c) the transmissibility
 14 of [non-A, non-B] infection to household contacts of
 15 haemophiliacs; (d) the antigen/antibody content of
 16 different preparations of pooled immunoglobulin."
 17 Just pausing there, is that an accurate
 18 description of part of what you were doing when you
 19 took up the post?
 20 **A.** This work I was not doing. This work was conducted in
 21 the Department of Medicine on samples, and it --
 22 I wasn't involved in that.
 23 **Q.** At 2.2, were you involved in what's set out there,
 24 which involves an ultrasound scanning, or was that,
 25 again, in the Department of Medicine?

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1 treated, and most of them had been treated actually
 2 before I even set foot in the centre, and I think this
 3 document you've got is the application.
 4 **Q.** Yes.
 5 **A.** And actually what was done was not necessarily in the
 6 application. I'm sure we're going to move on to
 7 discuss it, but the information in this significant
 8 paper that came out of the evaluation had largely been
 9 in the notes before I even started.
 10 **Q.** Yes. We will come on to the paper, but at the moment
 11 I'm just trying to get a sense of what the work was
 12 that you were asked to undertake?
 13 **A.** Yes, but I just want to emphasise again that this is
 14 the application for the grant, and actually what
 15 I ended up doing was not necessarily what's in this
 16 application.
 17 **Q.** Well, if we just look at a couple more passages in
 18 this and then we'll look at the job description, which
 19 was the job description that you answered.
 20 **A.** Yes, I think that's probably a better description,
 21 really.
 22 **Q.** If we look at the next page, please, Henry, before we
 23 leave this document, we can see -- if we have the
 24 first half of the page, please.
 25 We can see there there's a description of, at (c):

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1 "Patients to be studied are registered at the
2 Royal Free Hospital Haemophilia Centre."
3 You did some work at a later stage with Dr Rizza.
4 I'll come back to that. But for the purposes of this
5 study, and the work you were initially engaged to
6 carry out, it was all relating to patients at the
7 Royal Free, was it?

8 A. Yes.

9 Q. And we can see there it said:

10 "All age groups are represented. About 200
11 patients receive infusions of blood products in any
12 one year. All patients receiving infusion therapy are
13 reviewed at frequent intervals and detailed
14 information about types and amounts of blood products
15 given, and sequential changes in biochemical and
16 immunological tests, is available for a period of
17 several years in most patients, and a lifetime in
18 many."

19 If we skip down a few lines, it then says:

20 "A large bank of stored sera is maintained."

21 Is it correct that the stored sera had been
22 maintained since 1978?

23 A. Yes, the stored sera came into practice in 1978, when
24 Dr Kernoff took up his tenure as director of the
25 centre. And I think it's important to just expand on

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1 Q. Again, we'll come back to that in more detail at
2 a later stage.
3 If we just go on to the next page, please, Henry.
4 Go to the bottom of the page under the heading
5 "Reasons for support requested".

6 We can see, again this is the grant application,
7 but what is said there is that:

8 "The medical registrar will be involved in the
9 day-to-day supervision of patients included in the
10 clinical studies, and in the collection and analysis
11 of clinical and laboratory data."

12 So that's a description of what was intended for
13 the post that you then took up. So you were involved
14 not simply in the collection -- or the intention was
15 that you would be involved not simply in the
16 collection and analysis of data but also day-to-day
17 supervision of patients. Is that right?

18 A. No, that's not true. What I was involved in, the
19 patients had already been treated in the context of
20 a bleeding episode. And I was involved in analysing
21 the liver function tests, the treatment they'd had,
22 and their clinical symptoms from the notes and from
23 the results in the notes. I can't remember the detail
24 of it, but I think there was only about one or two
25 patients within that short frame. The study, if you

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1 this a little. It had become reported, and people
2 were aware, that there was a transaminitis, abnormal
3 transaminases, in people who were having concentrates.
4 And Dr Kernoff had come from Oxford. He had done
5 research through Dr Rizza. And the idea of storing
6 sera was in order to, in the future, if a test became
7 available, be able to see what was happening.

8 I think at this stage, it might also be important
9 to make a point about the first paper which was
10 published, in the year of my birth, in 1943, by
11 Paul Beeson, who was the Professor of Medicine when
12 I was a student there. He, at the end of that paper,
13 which reported seven cases of people who had got
14 jaundice and the common factor was a blood
15 transfusion -- this is 1943, no tests -- and he said
16 it's important that doctors begin to understand this,
17 and they should note down the details of the
18 transfusion, and they should store a specimen of it
19 for future use.

20 So the idea was really to understand what was
21 happening, and it became a regular part of the whole
22 practice of treating and caring for people with
23 haemophilia at that time. And this went on, and it
24 proved extremely helpful in understanding these
25 diseases.

10

1 look, finished -- it was '78 to '83.

2 And the actual patients who'd had treatment
3 that I followed, there are about two, out of the --
4 over 58. These patients had all been treated for
5 something that was bleeding associated. They weren't
6 chosen. And the significant thing about this study is
7 that these people had not been treated a lot before,
8 so they were first treatment patients. So it was
9 possible, at that time, the only way you could
10 diagnose non-A non-B hepatitis was you had to have an
11 increase in the liver function tests within one month
12 of twice the normal level, plus exclusion of other
13 causes of hepatitis. And the medical feature of non-A
14 non-B hepatitis is that it could be asymptomatic, and
15 transaminases were essentially what's called
16 a yo-yo response; they went up and down. So unless
17 these tests were taken about every two weeks for
18 three months, you would miss it.

19 This is what had already been done in these
20 patients under Peter Kernoff's direction, and I took
21 up the remaining ones that were put into this paper,
22 and I analysed what had gone before. The reason for
23 stopping in '83 is because there was a lot of
24 information that needed to be got out there for the
25 benefit of the patients and people treating them.

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1 Q. Again, we'll come back to the details of the study.
 2 I'm just trying to get a sense of the work that -- the
 3 day-to-day responsibilities you had, Professor Lee.
 4 So if we look at the job description.
 5 WITN0644061. So if we go to the heading "Duties of
 6 the post", bottom half of the page, please. It says
 7 there:
 8 "The main duty of the post-holder will be to take
 9 a primary responsibility, under the direction of
 10 Dr Kernoff and Dr Thomas, for the implementation,
 11 coordination, follow-through and completion of the
 12 research projects which are described in the attached
 13 protocols. He/she will be located in the Haemophilia
 14 Centre and will need to acquire a thorough knowledge
 15 of the principles of diagnosis and management of
 16 patients with congenital coagulation disorders by
 17 involvement in the service and academic work of the
 18 centre. There will be a strong clinical component to
 19 the job which will include frequent contact with
 20 patients with liver disease and their relatives,
 21 making appropriate arrangements for their
 22 investigation follow-up and collection of necessary
 23 samples and possibly establishing combined
 24 'haemophilia/hepatitis' clinics. He/she will be
 25 responsible for the collection, recording and analysis

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1 bit about liver biopsy.
 2 And before I took up this post, there had been
 3 a death from a liver biopsy. And that certainly was
 4 not part of what I took on. The only patient who, at
 5 that time, had a liver biopsy was the lady that is
 6 reported -- or who had fulminant hepatitis, and it
 7 was covered with cryoprecipitate. But I certainly was
 8 not trained to do liver biopsies. I never did liver
 9 biopsies.
 10 The detail of the extent to which I, in practice,
 11 got involved in all these things was quite -- was not
 12 quite as extensive as it would appear there, because
 13 I took over in the end of January in '83, and almost
 14 immediately we were consumed by the issue of HIV.
 15 Q. This document suggests that whilst the completion and
 16 analysis of the research project was an important part
 17 of -- a key part of the work that the person was being
 18 employed to undertake, it was also expected that there
 19 would be a clinical component, regular dealings with
 20 patients, and learning thoroughly the principles of
 21 the diagnosis and management of bleeding disorders.
 22 Was that part and parcel of what you did?
 23 A. I think -- I'm sure all the descriptions of the centre
 24 are there in my submissions, and almost by osmosis you
 25 had to get involved in this. It was a very big

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1 of data which will accrue as the studies progress and
 2 the final assembly of results for publication".
 3 If we just go to the next paragraph, please,
 4 Henry, it then continues:
 5 "An important component of the post will be to
 6 liaise between the Haemophilia Centre and the Liver
 7 Unit."
 8 Then various matters set out there, including:
 9 "It will be necessary for the post-holder to
 10 familiarise him/herself with aspects of liver disease
 11 and its management by participation in Department of
 12 Medicine meetings, seminars and ward rounds."
 13 Then if we just go over the page before I ask you
 14 a question. Sorry, if we can go to the next part of
 15 the document. Under the heading "Study and training":
 16 "The post-holder is expected to gain wide
 17 experience of clinical and laboratory aspects of
 18 bleeding disorders during the tenure of the post. And
 19 there will be many opportunities to participate in
 20 departmental activities which are not directly
 21 associated with the research projects."
 22 So is that an accurate description of the job that
 23 you took up, Professor Lee?
 24 A. Not entirely. I think the first thing that hits me
 25 that I would like just to make a comment about is the

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1 centre. So there were teaching sessions and meetings,
 2 planning, about what was happening and who was coming
 3 and things like that. But I would just emphasise that
 4 the main thing I was doing was analysing data, and
 5 I just got -- I know we're coming on to it, but it's
 6 relevant.
 7 The study was over a five-year period from
 8 April 1978 to March 1983. And this information was
 9 already in the patient notes, and the study was
 10 retrospective in the sense these people were not
 11 recruited to go into a study. They were people who
 12 came with a bleeding problem, and then they were
 13 retrospectively identified. And because there had
 14 been the collection of the samples and the results of
 15 the liver function tests, it was possible to
 16 retrospectively analyse that information.
 17 The five-year period went from April 1978, when
 18 Peter Kernoff was appointed, and it ended in
 19 March 1983 for the purposes of this study. I don't
 20 recall exactly the number of patients that I was
 21 taking two weekly specimens from, but clearly it
 22 wasn't very many because there's only a month that
 23 they had their treatments.
 24 Q. I understand your evidence, but for the purposes of
 25 that study, the time period of the patients being

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1 treated was coming to an end at the point in time at
 2 which you took up your post in January 1983.
 3 But following that, what clinical role did you
 4 have at the Royal Free, 1983, 1984? Did you, for
 5 example, sit in with Dr Kernoff when he saw patients
 6 with bleeding disorders?
 7 **A.** No. No. I think it also has to be understood that
 8 the care at the centre was a multi-disciplinary team.
 9 So there were the consultants, the clinical assistant,
 10 Dr Eleanor Goldman, who I know is making a submission;
 11 there were the family therapists; there was a
 12 physiotherapist, there were the laboratory staff. And
 13 the main day-to-day clinical work was conducted by the
 14 senior registrar or registrar who was rotating through
 15 the department from the department of haematology who
 16 was learning about haemophilia. New patients who came
 17 were seen by Dr Kernoff. I didn't see new patients.
 18 **Q.** Could we have on screen, please -- this is your
 19 evidence to the Lindsay Tribunal, Professor Lee --
 20 LIND0000326. Could we please go to page 3. You'll
 21 see you were being asked, as I am, about the various
 22 posts you'd held, and then you give an answer a few
 23 lines down:
 24 "Essentially, I cared clinically for this group of
 25 patients really since the beginning of 1983."

17

1 purpose of taking bloods, in the period 1983/1984?
 2 **A.** No, I don't have a recollection of the complete number
 3 of cases, but I can tell you that once HIV infection
 4 began to impact -- for example, I can remember
 5 a patient. He was the oldest patient who died of HIV
 6 infection, and I did look after him when he came up to
 7 the centre because we were totally confused about what
 8 he had. So we had to think of all the possible things
 9 to test. In retrospect, what he had was Pneumocystis
 10 carinii, but we didn't know that.
 11 So that was the kind of situation that I might be
 12 called upon to do clinical work. But the
 13 practicalities and organisation at that time was:
 14 Peter Kernoff was the director. He made the
 15 decisions. And there was a junior -- well, not so
 16 much junior, really; it would be a senior
 17 registrar/registrar -- in the department so that when
 18 the patients came up, as they could do at any time,
 19 that would be the first person who saw them and
 20 reviewed the problems, and they would probably discuss
 21 with Dr Kernoff what should be done.
 22 **Q.** So a new patient typically would be seen by
 23 Dr Kernoff. Existing patients who were returning for
 24 review appointments would be seen ...?
 25 **A.** It would depend on what the clinical problem was.

19

1 The evidence you gave to the Lindsay Inquiry
 2 suggests you had had a clinical role for patients with
 3 bleeding disorders from 1983 onwards.
 4 **A.** I think a clinical role of taking blood tests or
 5 discussing patients within a team is what I was
 6 talking about. But I was not the person who saw new
 7 patients. I was not the person who made the decision
 8 about what treatment should be given to a particular
 9 patient. Dr Kernoff was the director at that time,
 10 and I was doing research under him, under his
 11 direction. And clearly, I would help out if there was
 12 some -- somebody who needed to have blood taken or to
 13 be clerked, but I just emphasise that it was a team
 14 approach.
 15 I would also like to just put on record, when
 16 I gave information to the Lindsay Inquiry, it was
 17 20 years ago. I was working as the Director and
 18 Professor Of Haemophilia at that time. So I had
 19 access to documents. I was -- I knew my information.
 20 You are asking me about a period in 1983 which, on my
 21 account, is 37 years ago?
 22 **Q.** It is.
 23 **A.** And it's difficult to remember these things.
 24 **Q.** Do you have a sense or recollection of how often you
 25 had direct patient interaction, other than for the

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1 You also probably need to know that there was
 2 a very well-trained senior nurse. And at that time,
 3 I can't remember how many, exactly, nurses there were,
 4 but certainly one who very sadly died two years ago.
 5 But the nurses also would be very involved in the
 6 first -- seeing the patient as they came in.
 7 For serious situations which the patients, many of
 8 the patients -- all the patients who were treated in
 9 this paper, I'm quite certain Dr Kernoff will have
 10 seen them.
 11 I think it's also important that you know -- you
 12 know, I was working part-time. I wasn't on call.
 13 I didn't -- I was working four days a week then,
 14 I think.
 15 **Q.** And you --
 16 **A.** So I think it's very difficult for me to know what
 17 Dr Kernoff was doing 24 hours of the day.
 18 **Q.** Yes. I'll take you through some documents in due
 19 course and ask you about them which show some of
 20 Dr Kernoff's thinking at the time. But just going
 21 back to the question of how the care was organised and
 22 structured at the Royal Free in this 1983/1984 period.
 23 You've mentioned team discussions. Was that
 24 a regular occurrence, that there would be what would
 25 now be known probably as multi-disciplinary team

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1 meetings to discuss patient care?

2 A. Can I just refer to a document here --

3 Q. Yes, of course.

4 A. -- which you have. This is on record.

5 In order to just give you an idea of the sort of

6 team working we had --

7 Q. Sorry. Can I just stop you, Professor Lee, so others

8 can follow? Is that the document: "Haemophilia centre

9 haemostasis unit"?

10 A. That's right.

11 Q. Henry it's WITN0644069.

12 A. This was actually written in 1987 when I returned as

13 a consultant, but it gives a description of the

14 centre. Like, for example, by 1970, the centre had

15 180 patients, and this was housed in a prefabricated

16 extension and the end of a ward at the old Lawn Road

17 Hospital.

18 In 19 -- in 1972, they've got 220 patients. The

19 present director, Dr Kernoff, took up post in 1978.

20 And I think to give you an idea of the growth is

21 important, because that was also reflected in the team

22 that came together. So this is -- by 1987, you've got

23 981 patients in the period 1987-88. And this required

24 more staff, so you've got Dr Kernoff and now

25 Professor Tuddenham, who mainly was in the laboratory

21

1 I understand that most of the people that you've

2 mentioned would have been in post then -- so

3 Riva Miller, Dr Goldman, Dr Kernoff,

4 Professor Tuddenham.

5 In terms of the clinical decisions that were being

6 taken about, for example, what treatment a particular

7 patient should receive, was that something that was

8 discussed in team meetings, in some sense?

9 A. I don't recall that, no. I think those decisions were

10 made by Dr Kernoff.

11 Q. We'll come back to a number of these matters,

12 Professor Lee, but just completing the basic

13 chronology of your career, in November of 1984, you

14 worked -- went to work at the Charing Cross and

15 Westminster Medical School and Queen Mary University

16 Hospital; is that right?

17 A. I hope it's possible to put this into context.

18 I think it's important because you might wonder why

19 I left something that was very important to me, and I

20 really cared for those patients. I had two young

21 children. I lived in Richmond which, for those of you

22 who live in London may know, is very close to Queen

23 Mary's Hospital, Roehampton, which was then a district

24 general hospital that was a university hospital. And

25 there was a post of a senior lecturer in haematology

23

1 doing research, trying to purify Factor VIII. You had

2 an associate specialist, Dr Eleanor Goldman who tended

3 to see mostly the children, and she was a trained

4 family therapist. You have Riva -- she was 90 two

5 weeks ago, and I think is giving evidence to you. And

6 Riva Miller, who was called a social worker, but she

7 was a trained family therapist and went on to develop

8 the same-day testing clinic for HIV in the hospital,

9 and also to advise the Blood Transfusion Centre in

10 North London about HIV.

11 There was also a full nursing team. There was the

12 nurse manager, she was called -- there was Patricia

13 Lilley. There was a data processing officer, because

14 Peter had a computer put in in '79/'80. There was an

15 office manager. There were secretaries. There was a

16 reception coordinator, and there was a full laboratory

17 that did all the specialised tests for our patients

18 and also had to do the specialised haemostasis tests

19 for the whole hospital. We had a renal unit. We had

20 a big transplant unit, and we had a big emergency

21 department, so that was a big part of it.

22 In terms of the team -- would you like me to tell

23 you about the teamworking?

24 Q. I'm interested in particular in the years 1983 to 1984

25 for the purposes of my current questions.

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1 at Charing Cross medical school but essentially taking

2 up the single-handed haematology post at Queen Mary's

3 Roehampton. And the previous consultant in

4 haematology had been a laboratory-based haematologist,

5 and I was to change the service because this was

6 happening in haematology for it to be a clinical and

7 a laboratory service. It was a very attractive post

8 to me because there was no definite post at the

9 Royal Free. I was doing research. And it was

10 actually quite difficult for me to make this decision,

11 but I did it for family reasons and proximity reasons,

12 really.

13 So I applied for the post, and I became the

14 consultant. I was there for three years, and during

15 that time, because I was a senior lecturer, the head

16 of the department very kindly -- this is at Charing

17 Cross -- the professor at Charing Cross very kindly

18 let me go on secondment for one day a week back to the

19 Royal Free, essentially to try and write up

20 information that we had because it was very important

21 to get this into the public domain for the patients

22 and the people caring for these people.

23 So I think that was 1986, as I remember it, that I

24 started going a day off a day a week. And then,

25 during that time, the workload of HIV and non-A non-B

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1 hepatitis was becoming enormous, and Peter Kernoff
2 made the case within the Royal Free for a consultant
3 where the -- most responsibilities would be to manage
4 this group of patients. And he eventually succeeded
5 in getting the funding for that, and I applied for it
6 and took it up in November '87.

7 I think -- will you enable me now to just
8 sidetrack a little bit to what I was doing in this
9 post about HIV? Because it is relevant.

10 Q. Yes.

11 A. Or would you prefer me to keep that --

12 Q. No, I'll ask you about that in a moment. Can I just
13 ask two questions before you do that?

14 A. Yes, sure. Sure.

15 Q. The first is: in relation to the period 1984 to 1987
16 when you were at Queen Mary, my understanding from the
17 evidence you've given elsewhere is that you were
18 working initially one day a week at the Royal Free?

19 A. Yes.

20 Q. Then from 1986, you did two sessions per week at the
21 Royal Free; does that sound right?

22 A. One day I did. I used to drive over from Richmond to
23 Hampstead. And maybe that was called two sessions, I
24 don't know.

25 Q. It's simply the terminology --

25

1 specifically with haemophilia, but because I was the
2 consultant haematologist, if anybody bled in the
3 hospital, I was responsible for trying to diagnose it
4 and organise -- tell the laboratory what they should
5 test for. But again, the laboratory at Queen Mary's,
6 Roehampton, was nothing like the laboratory at the
7 Royal Free. So we were not doing -- we did very
8 simple screening tests for bleeding disorders.

9 Q. So you were a general haematologist --

10 A. Yes.

11 Q. -- in a district general hospital --

12 A. -- I looked after the whole of the haematology. And
13 as I say, it was quite a challenging post because
14 haematology was changing. You know, we're doubly
15 trained in haematology. We have what's called MRCP,
16 Membership of the Royal College of Physicians, so we
17 have to have done medicine, and we have to have done
18 a very full laboratory training which is medical --
19 MRC Path.

20 And at about that time -- previously, haematology
21 had been within pathology, had been a pathological
22 discipline, but now we were moving to a situation,
23 actually like Scotland had always had, where the
24 haematologist was a clinician and a laboratory person.
25 And I had to change that hospital laboratory to that.

27

1 A. I don't think I was paid. I wasn't paid for that. It
2 may be that -- because of the regulatory thing within
3 the hospital, Peter had to put in -- because I was
4 working there, he might have had to put some kind of
5 documentation into the hospital, because, you know,
6 hospitals don't let people just go and work in
7 a department without the authority. So I imagine
8 that's where the two sessions came. But I was not
9 paid. My salary was as a senior lecturer at Charing
10 Cross Hospital.

11 Q. And in terms of the work you were undertaking at
12 Charing Cross or Queen Mary University Hospital, did
13 you have any responsibility during that period for the
14 care of patients with bleeding disorders?

15 A. I think -- you know that -- well, I'm sure you'd
16 know -- haemophilia occurs in 1 in 10,000 people.
17 During the three years I was there, there was one
18 little boy who presented, and I actually referred him
19 to Peter. That was the only person. But, of course,
20 you know, haematologists, bleeding disorders aren't
21 just haemophilia. And, of course, also, that time --
22 we're talking about '84 -- our knowledge was perhaps
23 rather rudimentary about other inherited clotting
24 factor deficiencies.

25 But we -- at that time, I didn't have anybody

26

1 Q. You had wanted to make an observation about the work
2 you did in relation to HIV and AIDS?

3 A. Yes. We'll be talking about this, I'm sure, but
4 the -- as I remember it, the National Blood
5 Transfusion Service wanted to -- clearly wanted to
6 test blood for HIV, and this became possible in the
7 beginning of 1985. They were very concerned that
8 people would therefore go and give blood in order to
9 get a test. And in order for that not to happen, in
10 every -- I think every region or district general
11 hospital, I'm not quite sure of the size of the areas,
12 they appointed two AIDS counsellors, and they were to
13 provide a testing service for HIV, as it were, in the
14 community. And because, when I went to Queen Mary's,
15 they knew that I'd had some experience, I was
16 appointed one, and I had an HIV testing clinic that I
17 had to see people with.

18 The other quite extraordinary thing, and I think
19 this is important because it does set the scene of how
20 AIDS and HIV really overwhelmed not just haemophilia,
21 where it was quite tragic, but it overwhelmed the
22 whole country. And I was told to go and address every
23 secondary school in the borough of Richmond upon
24 Thames to educate them about AIDS.

25 Q. You returned to the Royal Free full-time at the end of

28

1 1987, November 1987 --
 2 A. Yes.
 3 Q. -- as a consultant?
 4 A. Yes.
 5 Q. And then you took over as acting director in around
 6 April of 1991 after Dr Kernoff was taken suddenly ill?
 7 A. That's right.
 8 Q. And you then became the director of the centre in
 9 April 1992 until your retirement at the end of 2005.
 10 A. Yes.
 11 Q. We'll come on to these in more detail, to some extent
 12 at, a later stage, but you were a member of the UKHCDO
 13 from 1991 to 2005?
 14 A. Yes.
 15 Q. Or before 1991?
 16 A. 1991 to 2005.
 17 Q. And you sat on various working parties and groups?
 18 We'll look at couple of those.
 19 A. Yes.
 20 Q. And you were on the medical advisory panel of the
 21 Haemophilia Society between 1993 and 2005.
 22 A. Yes. I think I was asked in my statement about this.
 23 I think what I remember is that David Watters used to
 24 phone me periodically, but I can't remember regularly
 25 going to meetings of that.

29

1 have anybody else that I can ask anything about
 2 St George's of. This is the 1983 return, so you'd
 3 still have been there in 1983 -- no, I'm sorry. You'd
 4 moved on at the beginning of 1983, but this may give
 5 us a flavour. You'd been there in 1982.
 6 We can see there 31 haemophilia A patients and 4
 7 von Willebrand patients, so a much smaller centre than
 8 the Royal Free.
 9 A. Mm.
 10 Q. If we look at the products that were used, we can see
 11 a small amount of cryoprecipitate, some NHS human
 12 Factor VIII concentrate used both in hospital and for
 13 home treatment, and then the predominant product used
 14 there was Armour Factor VIII. And we can see the
 15 quantities there: 270,755 per hospital treatment;
 16 309,680 per home treatment.
 17 Decisions as to what concentrates to use at
 18 St George's, were those taken by Professor Flute?
 19 A. I do not know.
 20 Q. Do you have any recollection of what the treatment
 21 policies were at St George's at that time?
 22 A. No. I could just comment on these figures.
 23 Q. Yes.
 24 A. I saw them for the first time, I think, last evening.
 25 You see that there's NHS Factor VIII and commercial

31

1 Q. I want to ask you a few questions about St George's,
 2 first of all, before we turn to look in more detail
 3 again at the Royal Free.
 4 So you were at St George's between 1976 and 1982,
 5 with the exception of the time you were on secondment
 6 for training purposes to the Regional Transfusion
 7 Centre. That's --
 8 A. Can I interject a little bit? And I'm sorry to get
 9 personal about this, but I was actually working
 10 part-time, so 6/10ths I was working, and it was under
 11 a scheme called the Married Women's Scheme. And I had
 12 two pregnancies during that time, so I was on
 13 maternity leave at two stages during that time.
 14 Q. St George's was a designated Haemophilia Centre, not
 15 a reference centre, but a small Haemophilia Centre at
 16 the time?
 17 A. I don't know about that because Peter Flute,
 18 Professor Peter Flute was the Professor then. I don't
 19 have knowledge of that.
 20 Q. I just want to get a sense of the number of patients
 21 and the kind treatments used there. And we can do
 22 that, I can prompt your memory, Professor Lee, by
 23 looking at the annual returns. It's HCDO0000143_003,
 24 please, Henry. If we go to the next page, please.
 25 This is just to get an idea, because we may not

30

1 here. It's roughly a third was NHS, and two-thirds
 2 was commercial, and the national figures were similar
 3 to that. But I have never seen that document before.
 4 I would have no part in any decisions that
 5 Professor Flute made, and of course --
 6 SIR BRIAN LANGSTAFF: If you look at the figures, it looks
 7 more like a fifth.
 8 A. Sorry?
 9 SIR BRIAN LANGSTAFF: If you look at the figures, the
 10 total there for NHS, as opposed Armour, it looks to me
 11 to be something more in the region of a quarter or
 12 a fifth.
 13 A. Yes, maybe. I mean, I think it's not really
 14 appropriate for me to comment on Peter --
 15 Professor Flute's figures, you know. I wouldn't have
 16 had anything to do with this.
 17 I mean, I suppose, to follow up on that comment,
 18 I mean, it just emphasises that much more commercial
 19 Factor VIII was being used than NHS Factor VIII.
 20 MS RICHARDS: As senior registrar and completing your
 21 training, effectively, under Professor Flute, you
 22 would presumably -- I appreciate what you said about
 23 periods of maternity leave and being part-time, but
 24 when you were there, you would presumably have been
 25 involved in the clinical care of patients?

32

1 **A.** Yes, but not an awful lot, actually. A lot of -- to
 2 do MRC Path training, you had to rotate through
 3 various specialities. So some of the time would be
 4 spent -- as we've seen from the transfusion centre,
 5 there was a whole big several months spent at the
 6 Royal Marsden to learn about leukaemia, and within
 7 St George's, I would occasionally have seen a patient.
 8 But my main clinical contact with patients was
 9 actually at a district general hospital that was part
 10 of the St George's network, St James', Balham, which
 11 was general haematology, and there I would see
 12 patients on the wards, and I ran an outpatient clinic,
 13 but I didn't do those things at St George's. And, of
 14 course, there was a large amount of microscope work to
 15 screen films.

16 I also, at St George's, was very involved in being
 17 trained in the laboratory to do Factor VIII assays and
 18 things that are relevant to haemophilia. But that
 19 wasn't in the context of doing work for patients; it
 20 was to actually learn how to do it, because when we
 21 did our MRC Path exam, we had a three-hour practical
 22 session doing such tests.

23 **Q.** And which year did you undertake the MRC Path exam?

24 **A.** I finally achieved the MRC Path exam in 1982, so then
 25 I was fully accredited as a haematologist, but before

33

1 I think I am right in saying that she made
 2 cryoprecipitate in the old hospital at Lawn Road in
 3 the labs there, and that the patients were actually
 4 started on home treatment with cryoprecipitate. In
 5 fact, if you go back and look through the notes of
 6 some of our older patients, the social work
 7 contribution was to raise the money to buy the deep
 8 freezers enabling them to have it at home."

9 Then if we just go to the top of the next page
 10 before I ask the question, you then --

11 **SIR BRIAN LANGSTAFF:** Just give Professor Lee a moment --

12 **MS RICHARDS:** I'm so sorry, Professor Lee.

13 **SIR BRIAN LANGSTAFF:** She's trying to follow it both in
 14 the document and on the screen.

15 **A.** Page 34 I've got ...

16 **MS RICHARDS:** I'm so sorry.

17 So you asked a question about cryoprecipitate
 18 being a thing that really --

19 **PROFESSOR LEE:** Which page is that, please?

20 **MS RICHARDS:** It's page 34, using the pagination at the
 21 bottom left-hand of the page. It is on the screen.

22 **PROFESSOR LEE:** Yeah, okay, sorry.

23 **MS RICHARDS:** You asked a question about
 24 cryoprecipitate --

25 **SIR BRIAN LANGSTAFF:** Just a moment.

35

1 that time I wasn't accredited.

2 **Q.** If we then move on to the Royal Free.

3 If we could have up on screen, please, Henry
 4 RLIT0000022.

5 Put this up as much as anything as an aid to
 6 memory, Professor Lee. This is a seminar you
 7 participated in, or helped organise, I think, in 1998.
 8 So that's when events would have been fresher in your
 9 mind.

10 **A.** I didn't just participate in it. I actually helped
 11 organise it.

12 **Q.** If we go to page 34, Henry -- oh, I'm sorry, I'm using
 13 the internal pagination, so can you go on 10 pages.
 14 Thank you.

15 I just want to get a sense of practices at the
 16 Royal Free in the 1970s. Obviously aware that you
 17 weren't there, Professor Lee, but you've talked about
 18 it in this seminar.

19 So we can see you ask a question:

20 "Was it right to think that cryoprecipitate was
 21 a thing that really pushed home treatment?"

22 And then you go on to say, after Dr Matthews'
 23 response:

24 "In our own Centre [Royal Free],
 25 Katharine Dormandy really made a major contribution.

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1 You may find it easier to look at the screen.

2 I don't know if it's easier -- you're working with.

3 **PROFESSOR LEE:** I think I will use this.

4 **SIR BRIAN LANGSTAFF:** Okay.

5 **PROFESSOR LEE:** As long as I have the page numbers, I'm
 6 fine.

7 **MS RICHARDS:** So you asked that question, Dr Matthews, who
 8 was at Oxford, responds about cryoprecipitate making
 9 a big difference because it was easily made, although
 10 he observes it wasn't the ideal material but many
 11 centres found it a very useful material for home
 12 treatment.

13 Then you made an observation about
 14 Katharine Dormandy, who had been the director at the
 15 Royal Free in the 1970s. And you observed that
 16 cryoprecipitate was made in the labs at the
 17 Royal Free, patients were started on home treatment
 18 with cryoprecipitate. And you refer to the notes of
 19 some of your older patients showing social work
 20 efforts to raise money to buy deep freezers.

21 Then if we go to the top of the next page, so it's
 22 the top of page 35, you then say that:

23 "In our Centre we were a bit slow to use large
 24 full clotting factor concentrate because it wasn't
 25 really until you [Professor Tuddenham] and

36

1 Peter Kernoff came that people were started on this
2 treatment, because Katherine had been so taken up with
3 the cryoprecipitate."

4 Now, I can obviously ask Professor Tuddenham about
5 this as well but your understanding was that
6 cryoprecipitate had been a significant part of the
7 treatment policies of the centre in the 1970s under
8 Dr Dormandy?

9 A. Yes, I think I would like you to refer to this paper.
10 I can give you the number if you like. Do you want
11 the number now?

12 Q. Yes, please.

13 A. It's the history paper that was written for the
14 50th anniversary of the KD Trust, and it's on the --
15 it's 644061.

16 Q. I'm not sure it is, I'm afraid.

17 A. All right, well, on my witness statement --

18 Q. Not your fault at all, Professor --

19 A. On my witness statement it's 0655067.

20 Q. Yes.

21 A. Okay.

22 Q. "Blood borne infections and haemophilia: the worst
23 of times."

24 A. Yes, and this --

25 Q. Professor Less, can I ask you just to pause for a

37

1 or bleeds or whatever, but they also came up,
2 eventually, when it went on to home treatment, to
3 collect cryoprecipitate.

4 If you read in some of these -- this paper of
5 hers, she describes how, in order to take the
6 cryoprecipitate home, it needed to be kept cool, and
7 she had card ice, you know? And that was given to the
8 patients and they'd have cardboard boxes to kind of
9 insulate this cryoprecipitate, because the problem
10 with cryoprecipitate is that, you know, Factor VIII
11 decays over 12 hours. So if you have cryoprecipitate,
12 the actual amount of Factor VIII in it depends on,
13 one, the speed with which you get the blood that's
14 taken out of the patient, to centrifuge it, to get off
15 the plasma, to freeze that plasma down to a low
16 temperature, and then warm it up to a slightly -- sort
17 of 4 degrees, and then decant that over to another
18 bag. This is a process. And she had this going in
19 this haematology ward at Lawn Road. And then those
20 bags have to be put in a deep freeze.

21 And all this time, every time that material is out
22 of freezing, the Factor VIII is decaying. And then
23 the patients who have driven -- often those patients
24 came from quite a distance to the Royal Free -- they
25 have to take this home to put in their own deep

39

1 moment so we can get it up on the screen so others can
2 follow?

3 A. Sure.

4 Q. Henry, it's WITN0644067.

5 Which page would you like to refer to?

6 A. I think the first page is talking about
7 Katharine Dormandy, and the references are very
8 relevant and you have these in my deposition.
9 Katharine Dormandy pioneered making
10 cryoprecipitate at the old Lawn Road Hospital. And
11 the paper that describes that is Bennett et al, in
12 1967, referenced in this paper. I was actually
13 working at the renal unit at the Royal Free when the
14 old Lawn Road Hospital was there, so -- and it was
15 a two-storey old Victorian hospital, and she
16 commandeered the whole of a haematology ward, the old
17 haematology ward, to make the cryoprecipitate on site.
18 And then eventually the North London Blood Transfusion
19 Service took it over. And she pioneered home
20 treatment with cryoprecipitate. And at that stage the
21 Haemophilia Centre was a caravan that had been paid
22 for by the Haemophilia Society in 1965, and she had
23 about six beds at the end of a ward bay on the ground
24 floor, and people -- the patients with haemophilia
25 would come up to that place if they needed treatment,

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1 freezers, if they've got a deep freeze.

2 And they had these boxes, the home-made boxes that
3 would be -- card ice put in and insulated to take them
4 home. And all the time the Factor VIII is decaying.
5 And I think that is very well described in the paper,
6 Bennett.

7 Q. Thank you.

8 So throughout the 1970s, Dr Dormandy essentially
9 establishing and operating a home treatment programme
10 using cryoprecipitate?

11 A. Actually, I'm sorry to -- you asked me another
12 question, didn't you, before that? About that she was
13 using cryoprecipitate, and Dr Kernoff and
14 Dr Tuddenham --

15 Q. I'm just going to come to that.

16 A. Oh, sorry. I'm sorry.

17 Q. Don't worry.

18 So Dr Dormandy's post was taken over by Dr Kernoff
19 and Dr Tuddenham in 1978. They were appointed
20 co-directors of the Royal Free at that point?

21 A. Well, that's not entirely true. Peter Kernoff was
22 initially appointed director, and I think he was
23 interviewed by Katharine Dormandy, and then he took up
24 a research -- he was doing research, I think, in
25 North America. And in the interim, Katharine Dormandy

40

1 was diagnosed [redacted] and she had a terminal
 2 illness, and they then managed to get a senior
 3 lecturer post to be her replacement, although she
 4 hadn't actually died yet.
 5 And Dr Tuddenham, you can ask him about this
 6 tomorrow, but it's my understanding, and this
 7 understanding comes from Peter Kernoff, Dr Tuddenham
 8 was appointed by the new Professor of Medicine,
 9 Professor Hoffbrand, and he was made co-director in
 10 Peter Kernoff's absence. He was actually appointed as
 11 a senior lecturer.

12 So I think, at that stage, Peter Kernoff's
 13 understanding was he was director, and when he came
 14 back from America he found out he was co-director.

15 Q. If we look at your evidence to the Lindsay Tribunal
 16 again, LIND0000362, please.

17 If we go to page 5 please, Henry.

18 Actually, we'll just pick it up -- to put it in
 19 context -- the bottom of the previous page, the second
 20 page.

21 So if we pick it up down there, Professor Lee, we
 22 can see, just about halfway down the page, you were
 23 talking about Dr Dormandy and the use of
 24 cryoprecipitate, and you referred to the notes and
 25 there being records of letters from social workers

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1 question tomorrow. I just need to just go back a bit
 2 about Katharine Dormandy. And why she was so
 3 enthusiastic about continuing cryoprecipitate was
 4 because she had made it, and she had pioneered home
 5 treatment. And also, she -- and this is listed in the
 6 blood-borne infections paper, she'd done a study with
 7 some American workers in North America, in Worcester
 8 in the United States, and they were treated
 9 exclusively with the new concentrates, whereas
 10 Katharine Dormandy was treating people with
 11 cryoprecipitate.

12 And what she found was that while both groups of
 13 patients, so that's the people on the concentrates in
 14 North America and the people just receiving
 15 cryoprecipitate at the Royal Free, while both groups
 16 of patients had raised transaminases, that's a liver
 17 function test, this was more common in those treated
 18 with concentrate. This was consequently shown to be
 19 due to be due to hepatitis C.

20 And in the comment at the end of this paper,
 21 published in 1977, Dormandy noted:

22 "The long-term significance of the various
 23 abnormalities recorded here is unknown. Aggressive
 24 therapy should continue."

25 And I don't know, I think you'd have to ask

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1 trying to get deep freezers and patients talking about
 2 having that treatment at home.

3 And then you were asked the question at the bottom
 4 of the page:

5 "For how long would the patients have continued to
 6 use cryoprecipitate for home treatment at the
 7 Royal Free?"

8 If we go to the next page, you say:

9 "... at the Royal Free, they went on using it
 10 probably for longer than other places."

11 And you've explained why: Dr Dormandy was very
 12 enthusiastic about cryoprecipitate. And then you say:

13 "[The] two co-directors were put in ... they were
 14 young doctors, and they came in in 1978 and very
 15 rapidly changed everybody to concentrate. There had
 16 been some people who had had concentrate before then,
 17 but I would think that up until 1978, the majority
 18 were still probably still on cryoprecipitate."

19 Then you're asked about this being a change of
 20 policy, and you answer yes.

21 What understanding did you have, from subsequent
 22 conversations or discussions or however you gained it,
 23 about the reasons for this change of policy? Why did
 24 they switch very rapidly to concentrates?

25 A. I think you should ask Professor Tuddenham that

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1 Professor Tuddenham, but I think it was probably the
 2 convenience and the efficiency. And so when you treat
 3 people with the concentrate -- I described this fall
 4 of the Factor VIII, making cryoprecipitate, let alone
 5 everything you needed to use this at home and also to
 6 draw it up in hospital. I'm sure that it was the much
 7 more effective treatment for bleeding. And that's
 8 probably what drove them to changing people. And it
 9 wasn't just them, it was the patients asking for it
 10 and the whole of the treatment community.

11 I am going to -- I think it's important to go
 12 through this again, if you will allow me. I just want
 13 to expand a bit about cryoprecipitate.

14 It comes in a plastic bag, and it's a very sticky
 15 solution. And when people treated themselves at home,
 16 if they, say, had a bleed, they would need probably
 17 ten bags of this. So the process of this was using
 18 two big syringes and having to draw this stuff into
 19 a syringe. And the volume that the patient had to
 20 then -- they were taught how to self-in fuse, and you
 21 imagine trying to -- it's not easy. The volume is
 22 enormous. Not only was the volume enormous but the
 23 efficiency, the amount of Factor VIII in it, you
 24 didn't know exactly how much Factor VIII was in it.
 25 It depended on how long that whole process I've

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1 described to you took.
 2 You know it also depended on the Factor VIII, the
 3 original donor, and some transfusion centres even got
 4 people running up stairs to raise the Factor VIII in
 5 the plasma.
 6 So when the concentrates came, you had two little
 7 bottles, and it was a very small -- much smaller
 8 volume, and you actually knew how much was being
 9 given. So you knew how much the patient would have in
 10 his bloodstream. It also meant that people could take
 11 the bottles to work, or they could go on holiday. You
 12 know, this had been virtually unheard of because you
 13 had to have a deep freeze full of cryoprecipitate.
 14 So I think that that was the reason that there was
 15 the complete change, and I don't think they could be
 16 criticised for that at that time.
 17 **MS RICHARDS:** Okay.
 18 I note the time, sir, is this a convenient point
 19 to take a break?
 20 **SIR BRIAN LANGSTAFF:** It is, yes.
 21 We take a break in the mornings. It will be
 22 45 minutes. That allows everyone to have a proper
 23 socially distanced refreshment. So we start again,
 24 shall we, at 12 o'clock.
 25 **MS RICHARDS:** Yes, and if you could give --

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1 **Q.** Was that the one in Edgware?
 2 **A.** Yes.
 3 **Q.** Okay.
 4 In your evidence to the Lindsay Tribunal, you
 5 described Dr Kernoff as a real stickler for detail.
 6 Could you just expand upon that?
 7 **A.** He -- well, I suppose he -- everything he did needed
 8 to be recorded. And I suppose it's really underscored
 9 with the fact that one of the very early things he did
 10 at the Royal Free in 1979/80 was that he recruited
 11 a computer person to get a computer that could record
 12 all the treatments that patients had, and the numbers
 13 of the batches of concentrate.
 14 And, you know, to set that in context, nowadays
 15 all of us computers in our hands, mobile phones.
 16 I didn't have a computer on my desk at the Royal Free
 17 until 1994. The idea that there was a computer in
 18 1980 is quite extraordinary.
 19 So that was one area, that he was a stickler for
 20 detail. The other thing which I was on the receiving
 21 end, and we're going to go on to talk about the way we
 22 disseminated the information that we were finding,
 23 I wrote a lot of that, and he would go through it with
 24 a fine-tooth comb, and make sure that the facts were
 25 right, the dates were right, and I suppose that's

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1 **SIR BRIAN LANGSTAFF:** Professor Lee, you're giving
 2 evidence. The rule is that in a break, you must not
 3 discuss your evidence, either the evidence you have
 4 given, or you suspect you may be asked to give, with
 5 anyone. That includes those near to you and it
 6 includes counsel, it includes family, but you can talk
 7 about anything else you like. I'll see you at 12.

8 (11.15 am)

(A short break)

10 (11.59 am)

11 **MS RICHARDS:** Professor Lee, I was asking you about
 12 arrangements at the Royal Free Centre. The Royal Free
 13 was part of the North East Thames region but also,
 14 I think, to some extent, part also of the
 15 North West Thames region; is that right?
 16 **A.** Yes. This was, of course, prior to us becoming
 17 a trust in 1991, but there were two regions and
 18 patients came from both areas.
 19 **Q.** We know that there were regular meetings of
 20 a haemophilia working party of the North East Thames
 21 region which were attended by Dr Colvin and
 22 Dr Kernoff. What regional transfusion centre or
 23 centres did the Royal Free predominantly deal with in
 24 the eighties?
 25 **A.** The North London.

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1 stickler for detail, really.
 2 He also -- it's quite extraordinary. I mean,
 3 these days we have clinical governance, everybody
 4 talks about governance. Dr Kernoff, as early,
 5 I think, as 1980, actually set up a management
 6 structure in the Haemophilia Centre and had regular
 7 management meetings of the key individuals who were
 8 leading each section, so the laboratories the nursing,
 9 the medical, the counselling. And I think that was
 10 also kind of reflection of his stickler for detail.
 11 The other thing that I think is also reflects it
 12 is that, you know, these days we can go online and get
 13 any kind of information, through PubMed or anything
 14 like that. In those days it was all paper bound. And
 15 in his office, he had a filing cabinet and he had file
 16 cards, and any publication that he was aware of, or
 17 that was important, it was put on this file card,
 18 and -- so that he had a kind of almost -- a very
 19 primitive kind of PubMed, if you like.
 20 So he was a stickler for detail.
 21 **Q.** Do you happen to know what became of that card file?
 22 **A.** No.
 23 **Q.** If we have up on screen, please, Henry, again the
 24 transcript of Professor Lee's evidence to the
 25 Lindsay Tribunal, LIND0000326.

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1 And if we could go to page 15, please, Henry.
2 Just picking it up halfway down the page you, were
3 asked questions -- and I'm going to ask you similar
4 questions in a few moments, Professor Lee -- about the
5 treating practice at the Royal Free, starting with
6 1983. And you explained that you were working very
7 closely with Peter Kernoff and you say this:

8 "... I was party to his thoughts. And we used to
9 discuss these things in that period.

10 "But it was his clinical decision ..."

11 And that's correct?

12 A. Yes.

13 Q. Before we look, then, in a little more detail at the
14 treating practices, just one further question about
15 Dr Kernoff.

16 You've mentioned that he worked in Oxford under
17 Dr Rizza or worked with Dr Rizza. What, if anything,
18 can you tell us about the relationships he had with
19 other reference centre directors, in particular
20 Dr Rizza and Professor Bloom?

21 A. Professor who?

22 Q. Bloom.

23 A. I know particularly about Dr Rizza, I don't know
24 that I know about his relationship with
25 Professor Bloom.

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1 Dr Rizza.

2 Oxford at that time was beginning to make
3 concentrates. MacFarlane had realised that if you
4 were going to provide enough blood to make
5 concentrates for the haemophilia population of the UK,
6 which then, I think, had been -- approximately 500 had
7 been identified, patients, you would need an enormous
8 amount of blood, and therefore they started making
9 concentrates from bovine concentrates, animal
10 concentrates.

11 And in fact, the very first tooth extractions for
12 haemophilia were actually done under bovine
13 concentrate. And, you know, for a patient with
14 haemophilia, your teeth -- if you had a tooth out, it
15 was terrible. And people could bleed to death with
16 that, so this was quite remarkable.

17 One of the problems about that early concentrate,
18 bovine concentrate, is that it developed inhibitors,
19 antibodies. So Peter, Dr Kernoff, had moved in
20 towards trying to look at what are these antibodies
21 about, because of that experience. And Dr Rizza had
22 clearly been the clinical person looking after such
23 patients and involved in the development of these
24 concentrates following on from MacFarlane and Biggs.

25 So I think the relationship was really like an

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1 And the relationship with Dr Rizza was that -- you
2 know, Oxford was the pioneering centre in the UK for
3 haemophilia, with Rosemary Biggs and MacFarlane, and
4 then the UKHCDO was set up, initially as group of
5 doctors in the country who knew about haemophilia.
6 Because it's so rare, she had recognised your average
7 GP or even hospital haematologist was unlikely to see
8 a person with haemophilia, and therefore it was
9 important to bring together people who had knowledge
10 in order to be able to know what was the best
11 treatment for people.

12 She was at Oxford with MacFarlane, and then
13 MacFarlane retired, and then she retired, and Dr Rizza
14 came down from Scotland to be the director. And
15 Dr Kernoff, as I understand it, was doing work towards
16 an MD at London -- for London University -- which is
17 where he trained, at the London. And I think
18 initially his topic was to look at why people with
19 haemophilia had haematuria, blood in their urine, but
20 actually he changed, because it became quite
21 a problem, an emerging problem, I suppose, in
22 haemophilia, and that was inhibitors. He did a thesis
23 on inhibitors.

24 And Dr Rizza was his supervisor, and I'm sure that
25 Peter, Dr Kernoff, learnt about haemophilia through

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1 apprentice, really. And, you know, I think in that
2 history document, Dr Rizza describes about sitting by
3 patients' bedsides transfusing cryoprecipitate. So
4 Peter, Dr Kernoff, would have learnt about haemophilia
5 from Rizza.

6 And, you know, clearly, certainly in my own
7 career, those of my teachers who are still alive, you
8 go on having a respect and a collaboration with them
9 in the sense of maybe asking them for advice or
10 whatever. So I think that explains their
11 relationship.

12 But I do not know the relationship between
13 Professor Bloom and Dr Kernoff.

14 Of course I knew Professor Bloom. Extraordinary
15 physician. And he -- I mean, his contribution to
16 people with bleeding -- inherited bleeding disorders,
17 was that he began to understand about von Willebrand
18 disease. I can remember in my training, and revision
19 for MRC Path, there was still an idea that
20 von Willebrand factor, they didn't -- the idea that it
21 was separate and was significant was ill understood,
22 and it was largely Arthur Bloom who understood that.
23 And he actually came and taught us on that training
24 course in London at that time.

25 But to go back to your first question, I don't

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1 know about Dr Kernoff and Professor Bloom.
 2 **Q.** I'm going to ask you about the treatment policies at
 3 the Royal Free, largely from around 1983 onwards. And
 4 similar question to those you were asked at the
 5 Lindsay Tribunal, but before we do that, I just wanted
 6 to look at one earlier document with you. It
 7 pre-dates your time at the Royal Free, Professor Lee.
 8 I just want to go through it with you.
 9 It's BART0000913, please.
 10 You'll see, Professor Lee, this is a letter from
 11 Dr Kernoff to the local Health Authority, Camden and
 12 Islington Health Authority, in June of 1980, and it
 13 gives -- it's a discussion about what are going to be
 14 the purchasing relations in terms of the commercial
 15 concentrate.
 16 So we see the first paragraph refers to:
 17 "... the views of the medical members of the
 18 adjudication panel -- [himself] and Dr Colvin -- on
 19 the tenders submitted for this contract."
 20 Now you've described how, when you became
 21 director, you didn't have a role in contractual
 22 relationships or choice between tenders, and we'll
 23 look at that later.
 24 Were you aware of this adjudication panel system?
 25 Was it a system still in operation when you took over

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1 decision-making, from the point that I was making the
 2 decisions, was that I would make a decision about
 3 which was the right type of concentrate. So the types
 4 of concentrate were: is it going to be plasma derived?
 5 Is it going to be high purity? Is it -- later is it
 6 going to be recombinant? And that, as far as I was
 7 able, was done through what was the guideline from the
 8 UKHCDO at that time. So it was a type. I didn't have
 9 anything to do with the decision as to which company
 10 to go with --
 11 **Q.** If we go back to --
 12 **A.** -- or the prices, which was -- I think I should
 13 just -- I think it's important, if you'll allow me, to
 14 just talk a little bit about what I know from 1991
 15 about buying.
 16 The Royal Free, when it became a trust, was very
 17 clear that managers looked after money, doctors look
 18 after patients, which is probably how it should be.
 19 So the contracts were not in the medical hands. And
 20 other institutions, other hospitals, who weren't
 21 actually trusts yet, but then they became trusts, some
 22 of the directors actually had the ability to choose
 23 which concentrate to have, which company to go with.
 24 And there was a deal of profit that could be made
 25 by the hospital, because the -- there's one particular

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1 as director?
 2 **A.** I don't know. This was 1980. I wasn't there. I don't
 3 know.
 4 **Q.** By the time you took over as director, was it a panel
 5 that you had to dismantle, or was it something that
 6 you knew nothing about?
 7 **A.** When I became -- I had nothing to do with the
 8 purchasing or the decision about which concentrate to
 9 make -- to have -- until 1991 when I became director.
 10 And when I became director, I -- it was the same time
 11 as the Royal Free became a trust, so there's no more
 12 North East Thames and North West Thames. There was a
 13 completely different -- the Royal Free had to get its
 14 own money in. And from that point onwards, the
 15 purchasing was actually done by the supplies
 16 department. And then it was changed to the chief
 17 pharmacist, but largely, actually very good advice
 18 I had from my husband, that I should never get
 19 involved in negotiations about which pharmaceutical
 20 company, or those kind of negotiations.
 21 There was a manager -- he was the chief
 22 scientist -- called Angus McGraw, and he --
 23 eventually, they changed from supplies to the
 24 pharmacist of the hospital, and together with Angus
 25 McGraw, they did all the negotiating. And the only

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1 trust that I know of that the purchasers would pay
 2 a price for the concentrate, and the director of that
 3 trust -- and I think it would be inappropriate of me
 4 to name names. I'm just explaining the system that
 5 could have gone on. The director of that trust had
 6 negotiated a price A. The purchaser was asked to pay
 7 a price A plus something or other, so that trust or
 8 that hospital made enormous profits out of
 9 haemophilia.
 10 **Q.** There maybe some --
 11 **A.** I have to say that, and that was not the case at the
 12 Royal Free, but the negotiation of contracts was very
 13 difficult because they had to negotiate with GPs
 14 sometimes, or small health authorities.
 15 And there was -- I remember we had a -- this is
 16 moving on a bit, but I think it's relevant. We had
 17 a little boy who sadly had an inhibitor, and the cost
 18 of his recombinant -- they were treated with a thing
 19 called recombinant 7A for inhibitors. I'm moving on
 20 a bit. But the cost of that child's care, which was
 21 totally appropriate and enabled that child to go to
 22 school and to do things which, you know, you hoped all
 23 children with haemophilia would be able to do,
 24 completely wiped out the whole budget of the authority
 25 that he lived in. And in my -- which maybe we're

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1 moving on to, but that was the reason I wrote probably
2 to the BMJ leader about the economics of haemophilia
3 care, that a single institution like the Royal Free,
4 that had a tenth of all the people with inherited
5 bleeding disorders in the country -- the Royal Free
6 was having to negotiate these concentrates in order to
7 get the money in to pay for the concentrate. It was
8 very, very difficult. And it was a poor management
9 system that had been brought in by the
10 purchaser-provider divide that happened in the '90s.
11 **Q.** I'm going to come on to that, but I'm going to take
12 you back to the first half of the 1980s,
13 Professor Lee.

14 We can see from this letter, and there are plenty
15 of other examples of it, that Dr Kernoff, in contrast
16 to what you've described of your own practice, and
17 Dr Colvin, were actively involved in decisions about
18 which concentrates to use. But I just want to explore
19 with you some of the points he makes about the
20 treatment policies at the trust in this letter.

21 So we can see in the second paragraph:

22 "The present buying policy of the Royal Free and
23 London hospitals" --

24 **A.** Can you --

25 **Q.** Yes, it's the second paragraph. It begins "In

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1 Professor Lee, on the page. It begins "In essence".
2 **A.** I hadn't got that. It's now come up.
3 **SIR BRIAN LANGSTAFF:** You may have if you go back -- have
4 you got the start of the --
5 **DR LEE:** Oh, I see. Sorry. I was looking at number --
6 it's got numbers 1 and 2. I'm sorry. "In essence."
7 Okay, sorry.

8 **MS RICHARDS:** So we can see there:

9 "The present buy-in policy at the Royal Free was
10 described as sharing purchased between Immuno and
11 Armour."

12 That's as at 1991. And then if we go back to the
13 full letter, please, Henry, the next paragraph says:

14 "We had taken account of several factors other
15 than the tender prices alone."

16 So we can see the price was a factor for
17 Dr Kernoff. But then he says this, and I wanted to
18 ask you about this:

19 "There is generally considered to be a medical
20 hazard in exposing patients to a brand of concentrate
21 which they have not previously received in that the
22 likelihood of contracting hepatitis seems to be
23 increased. Our policy has therefore been to attempt
24 to maintain individual patients on particular brands."

25 Now, were you aware, when you joined the

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1 essence". We can see that that --

2 **A.** No, it's not -- is this a letter to Mr Jones?

3 **Q.** Yes.

4 **A.** Well, I've only got the first line, is it?

5 **Q.** Ah. I'm sorry.

6 **A.** And the number 2:

7 "We feel rather strongly that the contract should
8 be shared."

9 **Q.** Is that the only thing you can see on your screen?

10 **A.** Yes. I've only got down to that.

11 **Q.** Ah, I think the other screens have the --

12 **A.** Okay, now I've got the full --

13 **SIR BRIAN LANGSTAFF:** Mine doesn't. Mine has exactly what
14 Professor Lee has.

15 **MS RICHARDS:** Mine has the whole second half of the
16 document. Are you able to read it in that form?

17 **A.** No. It's just -- the letter only has page 1.

18 **Q.** Yes, we'll start with page 1 and move on.

19 **SIR BRIAN LANGSTAFF:** I now have the whole.

20 **MS RICHARDS:** If we pick it up in the second paragraph, we
21 can see there that the present buy-in policy --

22 **A.** No, I still haven't got it. It just says:

23 "We feel rather strongly that the contract should
24 be shared between two companies" --

25 **SIR BRIAN LANGSTAFF:** No, I think the second paragraph,

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1 Royal Free, that that was the policy at the
2 Royal Free?

3 **A.** Yes, that certainly was the policy, and the idea
4 behind that policy was that maybe you could limit
5 exposure. And throughout, we always had a policy that
6 patients were kept on the same batch, the same number
7 of concentrate, until that batch ran out.

8 **Q.** And then if we could go on to the third page of the
9 letter, please, Henry. We can see in the paragraph
10 that's numbered 6, so towards the top of the page,
11 Dr Kernoff says this:

12 "In common with the directors of most other large
13 Haemophilia Centres in the UK, I have in the past both
14 sought and accepted financial support for research and
15 educational purposes from all the companies now making
16 tenders. We're currently receiving support from
17 Immuno, who paid the publication costs of the
18 Royal Free 'Haemophilia Centre Handbook' which we're
19 now selling to augment our research funds. The
20 maintenance of our academic programme has always
21 depended to some extent on assistance from commercial
22 companies, and it is my intention to continue to seek
23 such support and, if funds are offered, to accept
24 them."

25 Again, dealing with the period in the first half

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1 of the 1980s, so in terms of your work there -- it
 2 would have been 1983 and 1984 predominantly -- are you
 3 aware what funding was received from pharmaceutical
 4 companies by the centre or by Dr Kernoff in that
 5 period?
 6 **A.** No. I think the description in this letter I am sure
 7 is true, but I didn't know the detail of it. This is
 8 1980, isn't it?
 9 **Q.** It is. I'm just seeking to --
 10 **A.** I wasn't there.
 11 **Q.** I understand that, Professor Lee. I'm just seeking to
 12 establish from this what the position was in 1980 --
 13 **A.** I think it's highly likely, and again, I said that
 14 Dr Kernoff was pretty much, as we said, a stickler for
 15 detail, and I'm sure he provided the information which
 16 this document is based.
 17 **Q.** Then if we go to the next paragraph, please, Henry.
 18 Just have the whole of the next paragraph. If we pick
 19 it up about halfway down, he says this:
 20 "I do not view Factor VIII simply as a commodity
 21 which forms part of a general hospital supplies list.
 22 It is an essential human blood component whose use is
 23 accompanied by serious risks to patients and whose
 24 methods of production by commercial companies are the
 25 subject of intense medical, ethical, and political

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1 interactions with Dr Kernoff from 1983 onwards when
 2 you were working with him?
 3 **A.** I don't know that we would have had discussions about
 4 purchasing products. It was, as you like, below my
 5 pay grade. I wasn't a consultant; I was a senior
 6 registrar, so I don't think I would have had any
 7 discussions with him.
 8 **SIR BRIAN LANGSTAFF:** I don't think the question is really
 9 about purchasing; it's about the nature of the
 10 commercial product. So the issue, I think, is whether
 11 you may or may not have discussed at any stage with --
 12 **A.** You mean whether it's Immuno or Armour or what --
 13 **SIR BRIAN LANGSTAFF:** Whatever. Just call it "pharma", if
 14 you like. Pharmaceutical. Commercial companies.
 15 **A.** No, I wouldn't have had those discussions in 1983.
 16 **MS RICHARDS:** Did you ever have discussions with
 17 Dr Kernoff, whether in 1983 or later on during the
 18 1980s, about what he talks there of the intense
 19 medical, ethical and political controversy? Methods
 20 of commercial production of concentrates?
 21 **A.** I don't think so. I don't recall anything.
 22 **Q.** When you arrived in 1983 -- I'm just going to ask you
 23 for your assistance on, in broad terms, the treatment
 24 policies --
 25 **A.** Sorry. In broad terms?

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1 controversy."
 2 Are those issues about medical, ethical, and
 3 political controversy, are those matters which you and
 4 Dr Kernoff ever discussed?
 5 **A.** I don't know that I specifically discussed with him,
 6 but I can understand from this letter, and I think
 7 what's also happening here, is that we're in
 8 a transition period. The reason that initially the
 9 contracting was done through suppliers, you know, who
 10 did everything from toilet papers to, I don't know,
 11 soap or whatever, was because it was blood, cryo. And
 12 all the blood went -- it was suppliers that did it.
 13 I mean, actually, I don't know when you had to start
 14 paying for blood. I'm sure you had to start paying
 15 for it by the time you became a trust.
 16 But what's happening is that you're transitioning
 17 into a drug, a therapeutic product, from blood. And
 18 I think the managerial and financial implications of
 19 that changed. That's why gradually, and by the time
 20 I got there, it changed from supplies to a pharmacy
 21 because you've got a drug.
 22 So I think what is written in this letter is true,
 23 but what you're asking me is: was I aware of that in
 24 1980? No.
 25 **Q.** Really more, were you aware of it from your

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1 **SIR BRIAN LANGSTAFF:** You're moving away from the
 2 microphone.
 3 **MS RICHARDS:** I'm so sorry. My apologies, Professor Lee.
 4 I'm going to ask you in broad terms about the
 5 treatment policies of the Royal Free in 1983/1984. So
 6 the matters that you were able to assist the
 7 Lindsay Tribunal on I'm going to ask you about.
 8 **A.** Could we have that -- the Lindsay Tribunal statement
 9 that I made --
 10 **Q.** Absolutely.
 11 **A.** -- because that was made 20 years ago, and at the time
 12 that I made that, I also had access to information
 13 within the centre, and I -- you know, it's very
 14 difficult for me to recall that now, so I'd be
 15 grateful if you would put up what I said to the
 16 Lindsay Tribunal.
 17 **Q.** Yes. I should say, we don't have the written
 18 statement you provided to the Lindsay Tribunal, but we
 19 do have the transcript of your oral evidence, and we
 20 can have that on screen. It's LIND0000326. If we go
 21 to page 15. I'm not going to ask you at the moment
 22 about specific parts of the transcript, but if we need
 23 to look at it, or you need to look at it to refresh
 24 your memory, we can find any useful sections.
 25 Do you have any recollection of, broadly speaking,

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1 the proportion of patients in 1983 who would have been
 2 on home treatment at the Royal Free Centre?
 3 **A.** No.
 4 **Q.** Do you know whether home treatment at the Royal Free
 5 Centre by '83/'84, was that for adults and children or
 6 just adults?
 7 **A.** Both, I think.
 8 **Q.** Do you know whether it was -- a home treatment was
 9 only used for patients with severe haemophilia A?
 10 **A.** Yes. I know that because it's mostly the practice
 11 still today. You have to train somebody to treat
 12 themselves, and as many people in this room will
 13 attest, it's not easy, and if you're not doing it
 14 regularly -- so somebody with mild haemophilia would,
 15 you know, maybe not have a bleed or a problem; they'd
 16 have it very infrequently. So they would lose their
 17 practice. So you trained up the patients, and of
 18 course the parents, which was not so easy.
 19 So the question you're asking me, whether it was
 20 the same for all patients, I think it was the severe
 21 patients who were on home treatment.
 22 **Q.** And then dealing first with adults with severe
 23 haemophilia as a cohort, what products -- I don't mean
 24 the specific pharmaceutical companies, unless you can
 25 remember those. What products were used for the

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1 Lindsay Tribunal evidence --
 2 **A.** Yes.
 3 **Q.** -- so that's one of the reasons why I'm asking you.
 4 **A.** I would just remind you that at the time I gave the
 5 Lindsay Tribunal evidence, I actually was able to have
 6 access by telephone to the people within the centre to
 7 review the treatment records. And that information
 8 was not information that I remembered or information
 9 that -- in that time period, or information that had
 10 been because of my decision, but I was able to get the
 11 evidence from records. And so that's -- I hope I'm
 12 not appearing to be difficult, but I would really
 13 prefer for the -- what I said then to be taken as what
 14 was happening because, you know, I can't remember
 15 after 20 years.
 16 **Q.** Yes. You'll appreciate not everyone will have had the
 17 opportunity of looking at the Lindsay transcript --
 18 **A.** Yeah, sorry.
 19 **Q.** -- which is one of the reasons for asking you in this
 20 forum.
 21 So children, NHS Factor VIII; adults with severe
 22 haemophilia, commercial concentrates, or NHS
 23 concentrates or both.
 24 **A.** Yes.
 25 **Q.** In terms of adults with moderate or mild haemophilia

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1 treatment predominantly of adults with severe
 2 haemophilia A? Was it commercial concentrate, or NHS
 3 concentrate, or something else?
 4 **A.** It's very difficult for me to be precise about this,
 5 but the generality of my memory, and I think what's
 6 recorded here, we were very fortunate to be able to
 7 have all our children on NHS concentrate, and that was
 8 really, I suppose, for two reasons. One is they're
 9 small, so there was not a supply problem. And the
 10 other is that, although at that time there wasn't any
 11 evidence that NHS product was to be preferred, we
 12 didn't have any evidence that commercial concentrate
 13 transmitted more than NHS concentrate, but many
 14 parents had an instinct that they would prefer NHS
 15 concentrate for their children. And that was done,
 16 and we were able to maintain that.
 17 And, you know, in retrospect, it was fortunate,
 18 because I think the only child we had to care for with
 19 HIV actually acquired his infection, I think, abroad
 20 somewhere when he was given commercial concentrate.
 21 As far as the adults were concerned, I believe it
 22 was a mixture. But again, it's very difficult for me
 23 because I -- you know, I didn't make the decisions,
 24 and that wasn't my day-to-day work.
 25 **Q.** Again, this is territory you largely covered in your

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1 -- you said in your Lindsay evidence it was difficult
 2 to distinguish between the two, not diagnostically but
 3 in terms of your recollection of treatments --
 4 **A.** Yes. I think just to clarify that, I mean, severe
 5 haemophilia is less -- it's defined as less than
 6 2 per cent, but basically it's nothing, and non-severe
 7 haemophilia is above 2 per cent.
 8 **Q.** So for adults with non-severe or mild or moderate
 9 haemophilia, what was the general approach to
 10 treatment for those adults?
 11 **A.** I think we're talking about 83, so by then, we did
 12 have access to DDAVP, I think.
 13 **Q.** Yes.
 14 **A.** Professor Mannucci's paper was published in '77, and
 15 I was actually quizzed on it during my MRC Path exams,
 16 so -- in the early 80s, so I think we had DDAVP by
 17 then.
 18 And DDAVP you can give to people who have
 19 non-severe Factor VIII deficiency. You can't, of
 20 course, use it for anybody with Factor IX deficiency.
 21 It acts by raising the Factor VIII. You can also use
 22 it for people with von Willebrand's disease, but at
 23 that time we hadn't worked out what it was all about,
 24 von Willebrand's disease. And some people didn't
 25 respond and some people did respond, and it was only

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1 later that the different types emerged because we had
2 molecular diagnosis.

3 So DDAVP was beginning to be used where it was
4 possible, but if -- particularly in the context of
5 von Willebrand's disease, I would say, if a patient
6 had an enormous bleed, like, you know, some of the
7 nosebleeds that people had, which are called epistaxis
8 in the papers, it could be torrential. So to use
9 DDAVP was just totally inappropriate. And there were
10 also people who just didn't respond to it.

11 **Q.** So for the patient who is a non-severe haemophiliac,
12 and for whom you've judged that DDAVP would not be
13 appropriate in those particular circumstances, what
14 would be the next line treatment in 1983/84?

15 **A.** Factor VIII.

16 **Q.** Concentrates?

17 **A.** Yes.

18 **Q.** Not cryoprecipitate?

19 **A.** No.

20 **Q.** You told the Lindsay Tribunal, and we can look at this
21 if we go to the next page, we pick it up at out of the
22 third of the way down, you were asked the question --
23 this here was about children, but you were asked the
24 question:

25 "... were any of your children receiving

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1 **A.** Yes, I really -- I do remember when I was giving the
2 Lindsay Tribunal evidence actually phoning back to the
3 Royal Free for them to check, I think probably either
4 the treatment records, the Oxford returns, you know,
5 or to find out that fact, because I was being asked
6 that fact, and that was the information I got at the
7 time, I think.

8 **MS RICHARDS:** So that was the use of cryoprecipitate for
9 a single severe haemophiliac. You were then asked:
10 "Whether for children or for adults, the choice
11 was if somebody was a person with mild haemophilia and
12 who could be treated with DDAVP, that was done [which
13 is the answer you gave me a few moments ago] if not,
14 they were treated with concentrate, either NHS or
15 commercial --"

16 And you answered "Yes".

17 Do you know why cryoprecipitate was not used as
18 the second line treatment for a mild haemophiliac if
19 DDAVP was not an option?

20 **A.** Well, I think I partly have rehearsed the answer to
21 this question in that the practicalities were very
22 difficult. But more than that is the issue of
23 exposure, that to treat a bleed you need ten -- what
24 are we talking about? We're talking about --

25 **Q.** Mild haemophilia.

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1 cryoprecipitate as distinct from concentrate?"

2 You said:

3 "No ... I have carefully checked on that issue,
4 and the only person with severe Haemophilia A who
5 received cryoprecipitate during that period was, if
6 you like, a kind of conscientious objector who didn't
7 want to have concentrate."

8 Pausing there, what did you mean by "conscientious
9 objector"?

10 **A.** It was somebody who didn't want to have blood
11 products. I don't think -- is "conscientious
12 objector" the right word, actually? The parents
13 didn't want any blood product.

14 **Q.** You describe it there as a patient who received
15 cryoprecipitate. So someone who didn't want
16 concentrates.

17 **A.** Yeah, I -- quite honestly, I think it's very difficult
18 for me to remember precisely what that means.

19 **SIR BRIAN LANGSTAFF:** Let me tell you how I read it.

20 Somebody who on principle -- I think is the words
21 I would replace "conscientious objector" by, but on
22 principle didn't want to have concentrate. It doesn't
23 say what the principle is but that's the sense of it
24 that it conveys to me at the moment.

25 Is that about right, do you think?

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1 **A.** Mild haemophilia ... no, I think it's more about the
2 risk of not getting the right level and not having
3 effective treatment, I think, is probably the
4 decision-making process here.

5 And, you know, it relates to the fact that the
6 Factor VIII in the cryoprecipitate was not known, in
7 that you couldn't measure it, and it would probably
8 have had a fall-off by the time you got it into the
9 person. And also, it may also have been the issue of
10 the bleed they got, you know. The treatment just
11 wouldn't be so effective.

12 But, you know, again, the decision-making process
13 is Dr Kernoff's. It's very difficult for me to know
14 exactly how he came to that decision. And I --
15 I think it would have been very difficult, in some
16 situations -- in many situations -- to use
17 cryoprecipitate effectively and to stop the bleeding,
18 and to prevent the problem.

19 **Q.** Was prophylaxis a feature of treatment at all at the
20 Royal Free in the first half of the 1980s or was that
21 something that only came later?

22 **A.** No, prophylaxis, we started prophylaxis at the
23 Royal Free in 1994. It depends, in a way, what you
24 call prophylaxis. You know, regular prophylaxis for
25 children was begun in 1994, where you gave three

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1 treatments a week to keep the level up to a certain
 2 level, to stop bleeds, but sometimes there was
 3 a certain kind of prophylaxis used if people had
 4 a particularly important day, you know, that was -- in
 5 their life, that they needed cover. I'm trying to
 6 think of an example.
 7 I mean, for example, I suppose if you had a job
 8 interview or something like that. But it wasn't used
 9 widespread in the sense that we now know about
 10 prophylaxis.
 11 Q. Haemophilia B was the predominant treatment NHS
 12 Factor IX concentrate?
 13 A. Yes. And the reason for that is that it's sixth less
 14 common than haemophilia A, and there was not a supply
 15 problem.
 16 Q. And then you've touched on this already, but
 17 von Willebrand's disease, what was the predominant
 18 mode of treatment in 1983/84?
 19 A. Well, it depended what the bleed was, but if it was
 20 a severe bleed it would be concentrate. And you'd try
 21 and use DDAVP if you felt that that was going to be
 22 effective.
 23 Q. Just look at the 1983 returns for the Royal Free which
 24 would have been completed by Dr Kernoff and/or
 25 Dr Tuddenham.

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1 hospital treatment and 1.2 million for home treatment.
 2 And then Koate, 1.2 million for home treatment.
 3 If we go further down that, we can see "Porcine
 4 Factor VIII". I'll ask you a little more about
 5 porcine later, but what, at that time, was porcine
 6 Factor VIII predominantly used for?
 7 A. Inhibitor treatment. And it's important, I talked
 8 a bit about -- or do you want to leave this for later,
 9 about porcine?
 10 Q. We'll come back later to porcine and one of the papers
 11 you wrote about it later, if we may, Professor Lee.
 12 Then we can see reference to some other products,
 13 including DDAVP.
 14 And then von Willebrand's disease we can see
 15 cryoprecipitate was still being used for
 16 von Willebrand's disease, it would appear, in
 17 hospital, and then smaller amounts of NHS treatment
 18 used, hospital and home.
 19 If we can then go to HCDO0000184_051, please.
 20 I won't go through the details of the inhibitor
 21 treatments, Professor Lee, but we'll just look at
 22 haemophilia B.
 23 So this is the annual return for 1983 in relation
 24 to haemophilia B treatment. Thirty-one patients
 25 treated throughout the year, one carrier treated, and

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1 Henry, it's HCDO0000184_006, first of all, please.
 2 We can see here it's the annual return for 1983,
 3 the directors are identified as Drs Kernoff and
 4 Tuddenham. Total number of haemophilia A patients
 5 treated during the year, 128; carriers of haemophilia
 6 A treated during the year, 4; total number of
 7 von Willebrand's disease patients treated during the
 8 year, 24.
 9 Then if we look for the haemophilia A patients, we
 10 can see for hospital treatment, there's an amount
 11 1,443 bags of cryoprecipitate which someone has
 12 translated into units.
 13 Then we can see NHS Factor VIII concentrate at
 14 193,965 units for the hospital treatment.
 15 And then the total use for home treatment that's
 16 given there, would that have been predominantly
 17 children, in all likelihood?
 18 A. No, I don't think it would necessarily be all used for
 19 children. That seems quite a lot. I think there
 20 would have been adults who were on home treatment with
 21 NHS, not necessarily all of them. I don't know.
 22 Q. Then we can see the figures for use of commercial
 23 products, so in that year, Factorate, Koate, Hemofil
 24 and Kryobulin were all used, and the concentrate used
 25 most was Factorate, just over a million units of

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1 we can see there that the bulk of the material used
 2 there is NHS Factor IX concentrate.
 3 Are you aware of 1983 representing any particular
 4 change in approach to treatment or, as far as you
 5 know, was this broadly consistent with what had been
 6 the treating practices at the Royal Free?
 7 A. No, I -- you know, I just say again that I was
 8 a senior registrar in the department. These decisions
 9 and what was going on with the treatment was managed
 10 by the directors. So I think what is here is here,
 11 and I'm sure it's true.
 12 Q. If we just look at WITN0644070, please, Henry.
 13 This is a document from much later, it's
 14 a 1995 document that you prepared.
 15 If you could just go to page 20, which is the last
 16 page of this document, please.
 17 You provide there a table showing "Clotting factor
 18 concentrate obtained 'free' in the context of
 19 therapeutic trials", and that gives figures from 1988
 20 onwards to 1995, which was the date of the document,
 21 with a total value attributed to it of £1,572,000.
 22 Do you know what the position was at all pre-1988?
 23 Were clotting factor concentrates provided free to the
 24 Royal Free for therapeutic trials?
 25 A. No, this is -- covers the time period that I was in

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1 charge. I was a consultant. I became a consultant
2 in 1987. So prior to that, I didn't -- I don't know
3 what was obtained.

4 **Q.** Do you know at all -- and again, I'm asking you now,
5 again, about 1983/'84, what the arrangements were at
6 all for obtaining NHS concentrates?

7 **A.** No.

8 **Q.** You don't? You don't know whether that was from the
9 Regional Transfusion Centre or directly from BPL?

10 **A.** No, I don't know.

11 **Q.** You've alluded to the fact that there were possibly
12 supply issues in relation to NHS concentrate because
13 you focused the supplies you had on children and then
14 some for adults. Do you recall any more detail about
15 what those supply issues were? Was it something you
16 discussed with Dr Kernoff or he discussed with you?

17 **A.** No. I do have memory that he tried to save up
18 concentrate if he knew somebody had got to have an
19 operation. That's the vague memory I have.

20 **Q.** NHS concentrate?

21 **A.** I don't know which particular one it was. I just know
22 that he would do that, because I think there was
23 a supply problem in general sometimes. But I think
24 it's probably not appropriate that I make statements
25 about this period because I would say again that I

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1 you discussed, that you were to some extent privy to
2 Dr Kernoff's thinking, and you did give evidence to
3 the Lindsay Tribunal about what the treatment policies
4 were, in broad terms, in 1983 and 1984.

5 **A.** Yes, but what I would also say is that we are now in
6 2020, so this was 20 years ago. And I think the
7 information that I provided for the Lindsay Tribunal
8 at that time was what I remembered 20 years ago from
9 17 years before that. We're now 37 years, and I'm
10 sorry, I think that what I said in the
11 Lindsay Tribunal was as true as I knew at that time,
12 and from my standpoint now, I stand by what I said.
13 But I don't think it's fair for me to speculate, in
14 a way, because trying to remember back 37 years, when
15 I've been retired 15, is quite difficult for me. But
16 what I said to the Lindsay Tribunal was true at that
17 time.

18 **SIR BRIAN LANGSTAFF:** Not only at that time, so far as you
19 know, you've just said that you think it's -- that you
20 have no reason to think that anything said there was
21 inaccurate?

22 **A.** No.

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

24 **MS RICHARDS:** You've said Dr Kernoff was a stickler for
25 detail and for records. What, if any, policy or

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1 wasn't responsible for making any of these decisions,
2 I wasn't looking after the patients that needed to
3 have an operation. It wasn't my job, you know. So
4 I think what we have to do is rely upon what's in the
5 returns and things --

6 **Q.** And your evidence to the Lindsay Tribunal, which
7 you've said --

8 **A.** -- yes, yes -- (overspeaking) -- what is said in the
9 Lindsay Tribunal, which, as I say, I said it 20 years
10 ago, at the time that I said that, I cross checked
11 with people who were then alive, like the chief nurse
12 in the unit, who -- and she -- I phoned up and
13 cross-referenced, and she checked out things. But
14 I think it's very difficult for me now to give
15 reliable information about that period. I'm quite
16 happy to give you the detail for when I was in charge,
17 in 1991, and how it was done. But I think it's
18 unfair, it's probably unfair for Dr Peter Kernoff, to
19 say why the decisions were making what he was doing,
20 you know, because I don't know.

21 **Q.** Professor Lee, to make it clear, I'm not asking you to
22 speculate.

23 **A.** Yes, well, that's why -- I don't want to speculate.

24 **Q.** The reason I'm asking these questions is because you
25 told the Lindsay Tribunal that these were matters that

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1 practice was in operation at the Royal Free during the
2 1980s for recording what particular products patients
3 received and what particular batches patients
4 received?

5 **A.** This is the 1990s?

6 **Q.** 1980s. You returned as a --

7 **A.** 1980s, okay. Well, I have explained to you that there
8 were the beginnings of a computer in '79/'80, but
9 every patient had a treatment record which was in
10 addition to the medical record, and all the notes and
11 all the treatment records were all kept in the
12 Haemophilia Centre. And in those treatment records,
13 which the patients had at home, and we had access to
14 them in the centre, they had to record the date, the
15 type of bleed, the number on the concentrate bottle,
16 and how much used.

17 They had those forms at home. Initially, they
18 would post them back, and within the centre, they were
19 filed in this treatment file. And of course, if we
20 were administering treatment in the centre, because
21 sometimes a patient might come up with a problem and
22 they needed treatment in the centre, we would record
23 in those treatment files. And gradually, from 1980
24 onwards, that treatment was put on a -- on the
25 computer, which was a pretty primitive computer to

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1 start off with.
 2 And you showed us the records that were sent to
 3 Oxford. We called them the Oxford returns. And there
 4 are a large number of patients we looked after and
 5 a large amount of treatments. So that detail
 6 eventually was -- we were able to put the numbers down
 7 because we had a computer. But it was still there in
 8 the records, and the data manager within the centre,
 9 Francoise Kendall, one of her big jobs was to go
 10 through these records and, you know, add it all up.
 11 Gradually, we were able to appoint additional
 12 people in the centre. I think we had two people
 13 eventually. We had a -- we were so lucky because we
 14 -- the patients were so lucky. We had a big cold room
 15 where all the concentrate was kept, and eventually we
 16 had a good stock control, so there was a record of
 17 what's here, what numbers are here, what's gone. So
 18 I think that answers your question, does it?
 19 **Q.** Yes. The treatment records from the 1980s that you've
 20 described --
 21 **A.** Yes.
 22 **Q.** -- so the physical treatment records, and leaving
 23 aside whatever there might have been transposed to the
 24 computer --
 25 **A.** Yes, yes.

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1 treatment records enabled us to have an enormous
 2 information about haemophilia, which wasn't just so
 3 that you would get publications; it was so that you
 4 could inform your care and understand what was
 5 happening. It was there on paper. Sadly, I think
 6 the -- certainly, the hospital record has now been
 7 computerised because I know my rule nine request,
 8 we've had to, you know, get them. I don't know what's
 9 happened to the treatment records. And I tell you, it
 10 is a real tragedy. I mean, maybe they've been
 11 digitised. I don't know.
 12 **Q.** Well, we can no doubt ask that question of the
 13 Royal Free.
 14 Sir, I'm about to move on to a topic that won't be
 15 capable of being resolved within the next two to three
 16 minutes, so shall we break for lunch now?
 17 **SIR BRIAN LANGSTAFF:** Yes, let's break for lunch until
 18 two o'clock. So an hour for lunch. Back at
 19 two o'clock. The same rules apply as they do at any
 20 break.
 21 **(12.59 pm)**
 22 **(Luncheon Adjournment)**
 23 **(1.58 pm)**
 24 **Q.** Professor Lee, I'm going to ask you about the
 25 developing knowledge of risk of non-A non-B hepatitis

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1 **Q.** -- were they part of the patient's medical records, or
 2 were they kept separate?
 3 **A.** No. They were -- the medical record was, you know,
 4 like we all remember medical records, was a big file.
 5 And then there was a separate folder which had these
 6 sheets of paper in. And within the centre, initially
 7 when I went there in '83, when there were less
 8 patients, we actually had a whole bank of filing
 9 cabinets, alphabetical filing cabinets, where these
 10 records were kept together.
 11 When we were able to have the new extension opened
 12 in 1994 by the Duchess of Kent -- and, in fact, just
 13 to add in, that was the last decision Peter was able
 14 to get out of the Trust before he was ill. It wasn't
 15 a Trust then, but the hospital was to go forward with
 16 this extension. We were able to put in that
 17 extension, a huge area -- it was about the size of
 18 this platform here -- where the notes were put in
 19 filing cabinets, hanging in filing cabinets, but the
 20 notes were with the treatment folder. So if you saw
 21 a patient, anybody saw a patient within the centre,
 22 they had those notes.
 23 **Q.** And when you retired in 2005, did those hard copy
 24 treatment recordings still exist?
 25 **A.** Yes, I think -- it's a tragedy, actually. Those

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1 as the next topic.
 2 First of all, as part of your general medical
 3 training and then your haematology training, what do
 4 you recall you learnt about the risks of viral
 5 transmission from blood and blood products?
 6 **A.** Sorry, the risk of?
 7 **Q.** The risks of transmission of virus through blood and
 8 blood products, to what extent did that feature in
 9 your medical training?
 10 **A.** Well, going back to when I was a house officer --
 11 sorry, a medical student at the Radcliffe, at Oxford,
 12 Professor Paul Beeson was the Professor of Medicine.
 13 And I remember very distinctly going on ward rounds,
 14 almost the first ward round we went with him as
 15 a student, he would -- he asked us what the risks of
 16 blood transfusion are. And we very quickly learnt to
 17 say hepatitis.
 18 And of course the reason he focused on that was
 19 because he was -- I said earlier, he was the man who
 20 in 1943, as probably a very junior doctor, had noticed
 21 that seven patients he wrote up who had become
 22 jaundiced, there seemed to be a common feature that it
 23 was due to transfusion.
 24 And he was the person at the end of that report
 25 that said that it was very important that doctors

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1 recognised this problem, and recorded details of what
2 they'd had transfused. I think scientifically
3 speaking, looking at it, you could argue, you know,
4 maybe it was hep B. But it was probably more likely
5 that it was non-A non-B hepatitis. And of course, you
6 know, there were no tests, at that time. I suppose
7 that was my first knowledge.

8 Then, of course, the Australia antigen, as it was
9 called, was identified in 1965, and I remember this
10 was the measure of hepatitis B, it was called
11 Australia antigen because it was first identified in
12 Aboriginal people. I can remember as a medical
13 student, we had -- he's died now -- we had
14 a professor -- no, he wasn't a professor, he was
15 a gastroenterologist/hepatologist, Ralph Wright, and
16 I can remember going with a bottle to get a patient's
17 blood who had come in, when I was a house physician,
18 for access to this Australian antigen which he had in
19 his laboratory.

20 I think my knowledge -- I think, if I remember
21 rightly, and maybe I don't need to remember the
22 details of this, and we can refer to it, but the test
23 for hepatitis B came in 1973, so by the time I did my
24 blood transfusion training, which is 1979, I think
25 I would have certainly been aware of hepatitis B. But

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1 I -- had a life subscription to New England Journal,
2 so that would have been in the house. British Medical
3 Journal was also in the house, I would that have read.
4 Lancet also. We took Lancet at home, I think. And in
5 terms of other relevant journals for haematology, I
6 would have read the British Journal of Haematology.
7 That would have been in the library at St George's
8 Hospital.

9 Again, I think what's really changed so much over
10 this time is the -- you had to go to paper journals.
11 I mean, now you go straight into the Internet and can
12 find anything. And the other thing, I suppose, is
13 really the delay in publication. So sometimes you
14 would rely on hearing things at meetings, and
15 sometimes there would be departmental meetings, but it
16 wasn't really very focused, really. When I did blood
17 transfusion I think hepatitis B I would have really
18 known about, and hepatitis A to a certain extent, but
19 that was it.

20 I think the other thing to say just about blood
21 transfusion, when we did our training in blood
22 transfusion a lot of it was on the basis of looking --
23 doing the laboratory things of looking at antibodies
24 and antigens. You know, you had to identify whether
25 somebody had an antibody to a certain blood antigen,

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1 of course by then, we had a blood test for it, so ...

2 In terms of -- of course I knew about hepatitis A,
3 because it's orally -- you know, it's a problem not
4 necessarily from blood transfusion, although later it
5 transpired that one of the concentrates transmitted
6 it. I think non-A non-B hepatitis, to be perfectly
7 honest, I don't think I was particularly aware of it
8 until I was aware of this research post. I think
9 that's probably true.

10 **Q.** I'm going to ask you in a moment to look at a small
11 number of papers from the 1970s.

12 **A.** Yes.

13 **Q.** You may not have seen them at the time but they're
14 a set of articles that we've asked other clinical
15 witnesses to look at so far.

16 **A.** Yes.

17 **Q.** Before I do that, generally speaking, in the 1970s and
18 1980s, what journals or periodicals, magazines, would
19 you read in order to keep yourself up to date with
20 medical developments?

21 **A.** I think for the most part, in that time, I would more
22 read textbooks. You know, there was a particular
23 volume for haematology called Postgraduate Haematology
24 that was the sort of bible, if you like, for MRC Path.

25 In terms of journals, I mean, we -- my husband and

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1 so it was quite complicated and we spent a lot of time
2 doing that. So, I think --

3 **Q.** Okay.

4 You've already indicated, I think in the responses
5 you gave this morning and just now, that it had
6 generally been known, certainly from the 1940s
7 onwards, that hepatitis was a major risk of blood
8 transfusion. I'm going to ask you to look at -- it's
9 four or five short articles.

10 If we could first of all, please, have, Henry,
11 PRSE0001431.

12 I'm going to show these to you or extracts from
13 them, they're all fairly short, Professor Lee, then
14 ask you some questions about them.

15 The first is a Lancet article from August of 1974,
16 it's:

17 "Long-incubation post-transfusion hepatitis
18 without serological evidence of exposure to
19 hepatitis B virus."

20 There are just two passages, I think that will
21 suffice for current purposes.

22 The summary explains that:

23 "An agent other than hepatitis B virus seems to be
24 the cause of 36 (71%) of 51 cases of post-transfusion
25 hepatitis identified during prospective biweekly

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serological follow-up of 204 cardiovascular-surgery patients. The sera of the 36 cases showed no evidence of the antigen or antibody response expected to accompany response by HB virus and to be detectable by the assays used. Incubation periods and clinical and epidemiological features were inconsistent with hepatitis A. Cytomegalovirus-associated seroconversion was no more common among the HB-negative cases than amongst HB-positive cases or amongst patients who did not develop hepatitis. The data suggest that a large proportion of long-incubation post-transfusion hepatitis is unrelated to hepatitis B and that control of post-transfusion hepatitis will require identification of a hepatitis virus(es) type C."

Then if we go to the last page, please, Henry, left-hand column, towards the top of the page, the first main paragraph beginning, "The fact that":

"The fact that non-B hepatitis cases are less frequently associated with serious acute illness does not imply that such cases are of lesser importance. Long-term complications of acute hepatitis B infection, such as chronic hepatitis, cirrhosis, and hepatoma, have been reported to follow mild anicteric infections more frequently than severe icteric cases;

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I realised that general practice wasn't for me. I'm very privileged to have had that experience because I think it helped me understand people and patients and other concerns. I went back into my first love, really, which was haematology, because before I went to university, I'd worked for eight months in the post-graduate medical school in the haematology laboratory.

So I went into haematology, and that was when I started at Harrow Road, so St Mary's Hospital, Harrow Road, with Dr Jack Fielding. And that was a district general hospital, September 1974. I don't think we had any patients with haemophilia. And I certainly would not have been aware of that article then. But I know the article and I probably, I think, became aware of it when I took up the research post in 1983.

I think it's also important to -- for me to remember and to let people know what the knowledge was and -- around about that time.

I was a Senior Registrar, part-time Senior Registrar at St George's, and then I said I'm going to take this post to look at non-A non-B hepatitis. And amongst my colleagues, there was almost a universal thing: what is that? Why are you doing that?

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consideration must thus also be given to the possibility that non-B hepatitis may play a role in the aetiology of some forms of chronic liver disease."

Pausing there, Professor Lee, first of all, I'm not expecting you necessarily to remember if you read this at the time, but would you have been reading the Lancet at the time? Is this the kind of material you're likely to have come across in 1974?

A. I think no is the answer, because I was just reviewing my CV and trying to -- in 1972 to '73, I was a research registrar in renal medicine to now Sir Keith Peters, and then, for domestic reasons, really, I left that post, I had an MRC training fellowship but I left that post to work as a general practitioner, because I thought that would fit in with my domestic responsibilities.

I think it's very important -- and this is in the College of Physicians recordings that I made, which were essentially to look at how women went into medicine in that period, early sixties, early seventies. There was no opportunity, really, to have children in creches or nurseries and things, and so my husband and I felt that it might be a better career path for me. And I actually trained in general practice for a year, until September 1974. And then

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So, to answer your question, I probably became first aware of this paper when I took up the research, because it's a very significant paper, but up until then, I would not have seen it, and probably very few of my colleagues would have been aware of it.

Q. Well, I understand the basis for the first part of your answer, Professor Lee, that you wouldn't have seen it at the time. What's the basis for your suggestion that your colleagues, in haematology, would not have seen it at the time?

A. The basis is my personal memory of when I said I was leaving to go and do this research. So I'm talking about the group of doctors that I worked with --

Q. At St George's?

A. -- at a very significant department of haematology, headed by somebody who worked -- who specialised in haemostasis.

Q. You rightly said that this was a significant piece of work, something which you realised later. It's significant because it's one of the first articles which identifies the existence of what then, over the next few years, became referred to as non-A non-B hepatitis, isn't it? So that's its key significance: that this is the emergence of non-A non-B hepatitis, and an understanding that there was some other form of

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1 post-transfusion hepatitis. Would you agree?

2 A. Yes.

3 Q. And the second part of its significance is that

4 observational warning on the last page, that -- I'm

5 going to paraphrase and put it in perhaps more

6 colloquial terms: that clinicians shouldn't assume

7 that non-A non-B hepatitis is going to be something

8 mild or insignificant. Would you agree?

9 A. Well, I agree what's written there, yes.

10 Q. If we could then have up on screen, please, Henry,

11 PRSE0001794.

12 This is an article by Craske, Dilling and Stern in

13 August of 1975 in The Lancet:

14 "An outbreak of hepatitis associated with

15 intravenous injection of Factor VIII concentrate."

16 We can just, again, look at two passages. I think

17 this is one, again, that you're familiar with,

18 Professor Lee.

19 So the summary tells us there was:

20 "An outbreak of jaundice associated with three out

21 of four batches of a commercial brand of freeze-dried

22 Factor VIII concentrate ... at the Bournemouth

23 Haemophilia Centre between April and June, 1974.

24 Seven cases of non-B hepatitis and four of hepatitis B

25 occurred within 6 months of the first use of this

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1 I was also pregnant with our first son, and I don't

2 think I would have been aware of this article then.

3 I certainly, of course, became aware of it as soon as

4 I started looking at this problem, and again, I would

5 remind you, in 1975, I think that was when

6 Katharine Dormandy was in charge of haemophilia.

7 Q. Yes.

8 A. And of course, if you read -- subsequently I read her

9 articles, and it was quite clear that she must have

10 been aware of that and she must also -- because she

11 wrote that paper where she compared the rate of

12 transaminitis in her patients treated with

13 cryoprecipitate, and the American, but I don't --

14 I certainly wasn't aware of this paper in 1975.

15 Q. I absolutely understand that, Professor Lee. I'm

16 trying to explore these papers to some extent

17 generally with you but drawing on the fact that you

18 consequently specialised in haemophilia. Would you

19 agree that this is a report that ought to have been

20 given serious consideration by those caring for

21 patients with bleeding disorders in 1975?

22 A. I don't know, really, I don't think I can comment --

23 I think what it says I agree with.

24 The question you're asking me is if everybody

25 caring for people with bleeding disorders would have

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1 product. Two patients contracted both types of

2 hepatitis ... nine ... became ill out of a total of

3 twenty regularly seen at the centre, eighteen of whom

4 received commercial Factor VIII concentrate."

5 So here we have a report of non-B hepatitis in

6 haemophiliacs published in The Lancet.

7 And if we go on, please, Henry to page 3, and look

8 towards -- in the left-hand column, second half of the

9 page, towards the bottom of the page, please, Henry,

10 the paragraphs numbered (1), (2) and (3), we can see

11 that Dr Craske and his colleagues say this:

12 "In the meantime, some or all of the following

13 measures might help to lessen the frequency of

14 jaundice.

15 "(1) Commercial Factor VIII concentrates should be

16 reserved for the treatment of life-threatening bleeds

17 in all haemophiliacs and for covering major

18 operations."

19 And then it goes on to make two other

20 observations.

21 Is this is an article that you think came to your

22 attention at the time?

23 A. In 1975, I think, did you -- wasn't it?

24 Q. Yes, it's August of 1975.

25 A. In 1975 I was working for Jack Fielding, I think, and

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1 known this. I don't know. You know, I wasn't

2 involved in that at that time.

3 Q. Yes. My question is not whether they would have known

4 it as a matter of fact, because obviously you can't

5 speak to that, but whether you would accept that they

6 should have known it. This was a significant

7 publication in terms of haemophilia and non-A non-B

8 hepatitis.

9 A. I think that's probably right. But, you know, I think

10 it's very difficult for me to comment on those people

11 at that time because, you know, knowledge moves, and I

12 don't know how long -- I mean, this kind of

13 information might have been presented at meetings. I

14 don't know. I wasn't -- you know, I wasn't at those

15 meetings.

16 Q. No, and we have access to meetings such as those of

17 UKHCDO.

18 Do you recall whether -- later, once this became

19 an issue that you were going to be researching with

20 Dr Kernoff, do you recall ever discussing with him the

21 recommendation that we see here from Dr Craske and

22 others that commercial Factor VIII concentrate should

23 be reserved for the treatment of life-threatening

24 bleeds and for covering major operations?

25 A. I don't remember specifically discussing it with him

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1 because, as I said, you know, my responsibilities were
2 not in deciding what should happen; it was trying to
3 find out what was happening at that time.

4 **Q.** If we could then have, please, PRSE0000381. This is
5 a publication in the Yale Journal of Biology and
6 Medicine in 1976 by Purcell, Alter and Dienstag. If
7 we just have, please, Henry -- to page 246. So it's
8 the fourth page.

9 There's just one passage I wanted to invite your
10 attention to, Professor Lee. And we see, by this
11 time, the terminology of non-A non-B hepatitis is
12 being used. Third paragraph down:

13 "Although type non-A non-B hepatitis is associated
14 with less severe acute illness than type B disease,
15 the long-term prognosis for the two diseases may be
16 similar."

17 And then the passage goes on to discuss
18 transaminase elevations. I just invite you perhaps to
19 read that to yourself, Professor Lee, and then I'm
20 going to pick it up in the last sentence of that
21 paragraph:

22 "Chronic non-A non-B hepatitis is not necessarily
23 a benign infection and may be the cause of
24 a significant proportion of chronic hepatitis" --

25 **A.** I haven't got there.

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1 Biology and Medicine. 1976, I think, was the year you
2 moved to St George's. You've described the broad
3 nature of the work you undertook there.

4 Do you think you would have come across this
5 article at the time?

6 **A.** 1976 is a very significant time in my life because our
7 elder son was born on [redacted] 1976, and I was on
8 maternity leave, and I spent the time trying to
9 negotiate a part-time post. I had no job, and in
10 those days it was quite difficult if you wanted to
11 have a part-time post. And I think I eventually
12 started at St George's Hospital on October 14, 1976.
13 So I certainly was not aware of this paper then, but
14 I did become aware of it, of course, because it's a
15 very significant paper and, you know, I knew
16 Harvey Alter, eventually, and I think this last
17 sentence is very important. It says, you know:

18 "Thus, chronic non-A non-B hepatitis is not
19 necessarily a benign infection and may be the cause of
20 a significant proportion of chronic hepatitis not
21 identifiable as type B disease."

22 The significant word is "may". May. And the
23 whole point of studying this -- there was no test --
24 was to find out more about it. I mean, the whole --
25 all people at that time, and this was knowledge that I

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1 **Q.** I'm so sorry, I'm going too fast.

2 So that others can follow, I'll read the whole
3 passage:

4 "Thus elevation of transaminase values persisting
5 for six or more months has been observed more
6 frequently following non-A, non-B hepatitis than
7 following type B hepatitis. Others have reported
8 similar results. Transaminase elevations have been
9 documented for several years in some patients. Three
10 such patients at the NIH underwent liver biopsy. Two
11 had histopathologic changes in the liver compatible
12 with chronic active hepatitis, and the other was
13 diagnosed as having chronic persistent hepatitis.
14 Thus, chronic non-A non-B hepatitis is not necessarily
15 a benign infection and may be the cause of
16 a significant proportion of chronic hepatitis not
17 identifiable as type B disease."

18 This a publication 1976. I'm afraid I don't know
19 the month without --

20 **SIR BRIAN LANGSTAFF:** It's a bit of a publication in
21 February.

22 **MS RICHARDS:** Yes.

23 **SIR BRIAN LANGSTAFF:** And that's the best we can do.

24 **MS RICHARDS:** I'm sure we can find the precise date, but
25 in any event, it's published in the Yale Journal of

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1 would have, you know, become aware of as I started
2 doing the -- putting the data together. People were
3 aware of these transaminitis. There was an idea
4 that it might be some kind of metallic thing in the
5 concentrates. But they were aware of the
6 transaminitis, but the knowledge of what was going to
7 happen was just not there. Indeed, even the acute
8 infection, until we published our very detailed
9 follow-up, the -- what happened when you have an
10 infection was not so clearly defined.

11 You know, a lot of people who have their first
12 attack, it was asymptomatic, and as I think I said
13 earlier, the only way, at the time that we were doing
14 this, to prove as best you could that somebody had had
15 it was to do sequential transaminases. And to have
16 a baseline, you needed to know what the level was
17 before somebody had the treatment. And, of course, we
18 didn't know the long-term consequences really until --
19 I would suggest the knowledge didn't really become
20 defined as to long-term consequences until the 1990s.
21 And perhaps our long-term study in 2000 actually was
22 very significant because what it showed was that for
23 people who didn't have HIV co-infection, the
24 progression rate was very slow.

25 So I hope that answers your question.

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1 Q. Yes. Would you agree that, whilst you're right to
2 point out the use of "may" and to observe that there
3 was still much that was unknown --
4 A. Yes.
5 Q. Would you agree that, again, for clinicians practising
6 in the field by 1976, this, from a very authoritative
7 source, should have been, at the very least, a warning
8 against any assumption that non-A non-B hepatitis was
9 somehow mild or insignificant?
10 A. No.
11 Q. Why?
12 A. Because I don't think they would have read this
13 journal. Sorry, this is the Lancet one?
14 Q. No. This is the Yale Journal of Biology and Medicine.
15 A. Yes. I mean, I doubt whether anybody in this country
16 reads the Yale journal. I don't think they would have
17 been aware of this.
18 Q. How would important research such as this from the
19 States have been disseminated in the United Kingdom,
20 then, in the late 1970s?
21 A. I would think that somebody like Dame Sheila Sherlock
22 would have probably attended the American association
23 meetings of hepatology. That's probably how it would
24 have got disseminated. But I don't think this would
25 necessarily have been disseminated amongst haemophilia

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1 Q. Would you expect haematologists to be broadly familiar
2 with research or --
3 A. In 1977?
4 Q. -- advice of this kind?
5 A. I doubt whether -- not every haematologist would have
6 read Vox Sang. I think it might be quite helpful, if
7 I am allowed, for us to -- am I allowed to do this --
8 to help answer these questions about what people were
9 thinking and what they knew around this time because,
10 you know, it was 1977. I wasn't moving in these
11 circles.
12 Q. No, but I'm very keen to keep this chronological,
13 Professor Lee --
14 A. Yes, but can I --
15 Q. Materials from the 1970s, absolutely.
16 A. I just -- you've had this article, and I just feel
17 it's important for people to get a feel for what
18 people knew and didn't know. Haematologists, I'm
19 talking about, and haemophilia physicians. In fact,
20 the most -- the person who has contributed the most to
21 haemophilia care in the whole world, I would say, and
22 that's Professor Pierre Mannucci, who is now 80. And
23 you have this.
24 Q. Yes. What's the reference, please?
25 A. The reference is witness 755071, and --

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1 physicians, this particular paper.
2 Q. Let's look at one more from Harvey Alter which is now
3 the following year, 1977. Henry, this is NHBT0000092_
4 002, please. This is headed "International forum".
5 It's published in Vox Sang 32 in 1977, and it appears
6 to be an address by Harvey Alter. I'm just going to
7 ask you to go to the end of it, to the second page,
8 please, Henry. Last paragraph of the paper, so the
9 bottom right-hand column:
10 "Although non-A non-B hepatitis is, on the
11 average, less acutely severe than type B hepatitis, it
12 can cause severe acute disease, and, more disturbing,
13 it appears to have considerable propensity to progress
14 to chronic hepatitis."
15 Then he says:
16 "The main thrust of post-transfusion hepatitis
17 research must now be directed at developing detection
18 methods for the non-A, non-B agent or developing some
19 reliable method of viral inactivation or removal which
20 would be independent of testing."
21 Were you familiar, first of all, with this
22 journal?
23 A. Sorry, what was the journal?
24 Q. If you go to the first page, it's Vox Sang.
25 A. No, I didn't read Vox Sang.

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1 Q. So that reference -- could you give me the title
2 of it?
3 A. It's "AIDS, hepatitis and haemophilia in the 1980s:
4 memoirs from an insider".
5 Q. If you give me a moment, Professor, I. Know we have
6 it, but it's not necessarily --
7 A. I may be able to give you a different reference
8 that is -- your references are all different.
9 Q. It's WITN0644071, please, Henry.
10 A. This is wonderful. Thank you very much.
11 To answer your question, really, you were asking
12 about what would you expect people to know? And
13 I think what Mannucci's writing here really
14 encompasses it, really, that through the 1970s it was
15 recognised that the use of concentrates -- coagulation
16 factors made from plasma pools -- were associated with
17 hepatitis. And then it goes on to talk about the
18 first tests of liver function tests, and I think it
19 quotes the Alter paper. And then I would just point
20 you to the second page, the next page, and I think
21 it's important that -- that sentence that he writes:
22 "It was only in the mid-1970s it became clear that
23 hepatitis was frequent in haemophiliacs and it was only
24 in mid-'80s that it was shown to be progressive and
25 severe in one-sixth of patients."

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1 Q. If we look at the -- it's right to note this was an
 2 article written by Professor Mannucci, I think, in
 3 2003, or published in 2003. I'm going to ask you some
 4 more about this later.

5 A. You've got the wrong one. That's why, is it?

6 Q. The top of the first page, to cite this article, and
 7 then we see the date --

8 A. Okay.

9 Q. -- 2003. But if we go to the second page which you
 10 were referring to, Professor Lee, you'll see in the
 11 paragraph above there, he talks about:

12 "A relatively benign picture of non-A non-B
 13 hepatitis initially emerging from studies being
 14 questioned by three subsequent studies published in
 15 1985 and 1986."

16 A. Yes.

17 Q. The issue I'm exploring with you, or seeking to
 18 explore with you, Professor Lee, is whether it's right
 19 to characterise the understanding of non-A non-B
 20 hepatitis in the second half of the 1970s as being
 21 a relatively benign condition.

22 A. I think, for some people, it was a benign condition.
 23 It probably was, and it was probably right to
 24 characterise it. I think the whole problem was that
 25 it was very difficult to sort out who was going to

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1 That's the first point. Second:

2 "Non-A non-B hepatitis appears to be spread
 3 predominantly by the parenteral route. Most cases
 4 have been described in association with transfusion,
 5 intravenous drug use or serum inoculation."

6 Then we can skip to the third point:

7 "Third, non-A non-B hepatitis appears to be
 8 associated with a chronic carrier state and chronic
 9 liver disease."

10 Then it goes on to talk about the particular
 11 study.

12 "These 'implicated' blood donors were, for the
 13 most part, asymptomatic, although liver function tests
 14 and liver biopsy examinations frequently showed
 15 evidence of underlying chronic hepatitis."

16 Then:

17 "Finally, non-A, non-B hepatitis appears to be
 18 common. Three of the five infectious donors studied
 19 here transmitted this non-A, non-B hepatitis."

20 Then it goes on to talk about the screening of
 21 blood donations.

22 If we can just go a little further down, Henry.
 23 Then goes on to say:

24 "... at the present time, more than 90% of
 25 post-transfusion hepatitis is due to non-A non-B

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1 have a benign prognosis and who was going to progress
 2 quickly to liver disease. And that only really
 3 evolved later.

4 Q. We'll look at some of your later studies in due
 5 course, Professor Lee, but if I can return you to the
 6 second half of the 1970s, there are just two further
 7 documents I'm going to ask you to look at.

8 RLIT0000228, please, Henry. This a publication by
 9 Hoofnagle and others called "Transmission of non-A
 10 non-B hepatitis", and the date is 1977. This from the
 11 Annals of Internal Medicine. If we could go, please,
 12 Henry, to page 6. It's the long paragraph in the
 13 right-hand column, beginning "Several clinical and
 14 epidemiologic features of non-A non-B hepatitis".
 15 Thank you. I'm just going to read certain parts of
 16 this, Professor Lee, and then ask you about it.

17 "Several clinical and epidemiologic features of
 18 non-A non-B hepatitis have become clear from studies
 19 such as the present one. First, non-A non-B hepatitis
 20 closely resembles type B hepatitis. The incubation
 21 period, the clinical symptoms and signs, and the
 22 potential for chronicity appear to be similar to type
 23 B hepatitis. Undoubtedly, what was once referred to
 24 as serum hepatitis included both type B and non-A
 25 non-B hepatitis."

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1 hepatitis."

2 Professor Lee, this doesn't appear to be
 3 consistent with Professor Mannucci's description of
 4 a benign picture in the 1970s of non-A non-B
 5 hepatitis, does it?

6 A. Well, I would just comment, and I think we need to
 7 perhaps talk about the work that I did for -- with
 8 Dr Kernoff and Dr Thomas, and that is that certainly
 9 the acute attack in some of those patients was totally
 10 asymptomatic.

11 And I would also like to fast forward to tell you
 12 that come the year 2000, so we're talking 30 years
 13 after, there was a very low number of people who had
 14 progression of their hepatitis in those who were not
 15 infected with HIV. HIV was a terrible co-infection
 16 that speeded up the progression of this condition.

17 I think it's also quite difficult, in 1977, to
 18 talk about progression when there is not a test, and
 19 in certain -- I think it's very difficult. And, you
 20 know, I think it's very important to understand that
 21 part of the rationale, if you like, of trying to
 22 understand what happened following concentrate
 23 treatment -- which had been given because it was
 24 necessary because the patient had some kind of
 25 life-threatening bleed or needed an operation or

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1 whatever, acute operation -- it's important to
2 understand that we needed to know what was happening,
3 you know.

4 And I don't -- I've got a bit lost with your
5 question, actually. I'm getting tired.

6 **SIR BRIAN LANGSTAFF:** Would you like a break?

7 **PROFESSOR LEE:** I think I probably would like a bit of
8 a break, if that's possible. Just five minutes or
9 something.

10 **MS RICHARDS:** Or we could take the half hour break now,
11 sir.

12 **SIR BRIAN LANGSTAFF:** That would be a good idea, I think.
13 It's not an endurance course; it's evidence. So by
14 all means, if you feel tired, you just let us know,
15 and you've done that.

16 So take a break now for half an hour. Allow
17 everyone to get a cup of tea. A bit earlier than
18 usual, but that's what we'll do. So be back, please,
19 at 20 past 3.

20 (2.42 pm)

(A short break)

22 (3.16 pm)

23 **MS RICHARDS:** Professor Lee, there's one further article
24 from the 1970s I want to ask you to look at.
25 It's PRSC00003622. And this is The Lancet,

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1 We can see it starts by saying that:
2 "77% of our treated haemophiliacs had abnormal
3 liver function tests and a history of a hepatitis-like
4 illness was listed in 50%."

5 And then this contrasted with earlier reports.

6 Then if we go to the next paragraph, please,
7 Henry, we can see it talks about biopsies, and then
8 halfway down the paragraph it says:

9 "We also found a wide spectrum of chronic liver
10 disease including benign self-limiting chronic
11 hepatitis, potentially treatable aggressive hepatitis,
12 and established cirrhosis. All our patients were
13 symptom-free at biopsy and it was impossible to
14 differentiate between the different forms of liver
15 disease on the grounds of biochemical abnormalities.
16 Since the patients undergoing biopsy had been
17 arbitrarily selected it is reasonable to conclude that
18 in a large proportion of haemophiliacs receiving
19 treatment with Factor VIII have important chronic
20 liver disease."

21 Then one final paragraph.

22 Next column, please, Henry. Go up a bit.

23 Picking it up six lines down into the first main
24 paragraph, Professor Lee:

25 "In addition, non-A non-B hepatitis may well be an

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1 September 1978. It's a report by a Professor Preston
2 and others, "Percutaneous liver biopsy and chronic
3 liver disease in haemophiliacs".

4 If we look at the summary, and this should come up
5 on the screen in front of you, Professor Lee, the
6 summary says:

7 "Systematic screening of forty-seven haemophiliacs
8 in Sheffield revealed abnormal liver function tests in
9 thirty-six (77%), with a tendency for these
10 abnormalities to persist. To assess the importance of
11 these abnormalities, percutaneous liver biopsy was
12 carried out on eight symptom-free patients under
13 Factor VIII cover. A wide spectrum of chronic liver
14 disease was demonstrated, including chronic aggressive
15 hepatitis and cirrhosis. The liver pathology bore no
16 relation to clinical history or to biochemical
17 findings. Hepatitis B virus markers were common, but
18 evidence suggests that this is not the only factor
19 contributing to the development of liver disease. The
20 high incidence of chronic liver disease seems to be
21 a recent development and is probably related to
22 factor-concentrate replacement therapy."

23 Then if we go to the third page, please, Henry,
24 under the heading "Discussion", we see -- a little
25 closer.

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1 important factor and observations in four of our eight
2 patients support this possibility."

3 And then that is developed in the rest of that
4 paragraph. And then we have the conclusion that
5 histological liver disease is common in haemophiliac
6 patients, and then again it goes on to talk about
7 assessment by use of biopsy.

8 Now I'm not at the moment asking you about the
9 practicalities or, indeed, the risks of liver
10 biopsies, which you've already alluded to and we may
11 come back to, but just in terms of the importance here
12 of the findings of evidence of chronic liver disease,
13 would you agree that this was a significant paper?

14 **A.** This was a significant paper, but I think it's
15 important that it's realised that there were other
16 studies.

17 I think the other thing I've had time to reflect
18 on when I was -- had the break, is I don't think this
19 is a memory test, and I am a great believer in looking
20 at documentation. And if I'm allowed, could we look
21 at what Mannucci writes on this matter.

22 **Q.** Is that the same document we were looking at before?

23 **A.** Yes, it's --

24 **Q.** Yes. So Henry, it is WITN0644071.

25 **A.** I would -- the next page, please. I'd point you to

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the second paragraph. As we've discussed, it talks about, you know, unequivocal evidence of the existence of structural liver disease in people with haemophilia and elevated transaminases, we've talked about that.

But I think what's important is the bottom of that paragraph where he talks about:

"A prospective biopsy study was undertaken by me with hepatologists Colombo and Rizzetto in 10 haemophiliacs with non-A, non-B chronic hepatitis followed up for more than 6 years. The study, published in 1982, demonstrated no case ..."

No case.

"... of progression towards cirrhosis or hepatocellular carcinoma."

So that was that his experience. I'm not saying this is universal; what I'm trying to show is that different patients were showing different progression rates and not everybody was showing every kind of abnormality.

And then I think the other significant thing that he states here is:

"The relatively benign picture of non-A non-B hepatitis initially emerging from these studies was questioned by three subsequent studies published in 1985 and 1986."

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liver biopsies were very often done on more severe patients. So it wasn't at all clear as to how many of the patients were progressing. There was no doubt there was some kind of problem. And some of the experience at this time -- and, you know, Mannucci's study was showing that.

What these people were looking at is, you know, when you treat a patient with clotting factor concentrate, you're doing it for a reason. You're doing it to stop severe bleeding. And what they were weighing up is how severe is this transaminitis, or non-A non-B hepatitis? We don't know. And is the risk of not treating them, of them not receiving concentrate, is that risk worth taking? That was the debate.

And I think the other important thing in this paper that he writes is on two pages, 2068, it's on the paper.

Q. It's two pages further on, Henry.

A. And this called "The fallacy: a retrospective knowledge". And he sets out in the table --

SIR BRIAN LANGSTAFF: Just a moment. I think it's at the bottom of the --

DR LEE: Yes, but I think we need --

SIR BRIAN LANGSTAFF: You're looking at your paper --

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So.

"A large retrospective study of liver biopsies collected by Aledort ... provided histologic [change] ... in 15% of cases."

So 15 per cent of the total. And it's worth noting that within that worldwide collection of liver biopsies, one of his patients had died of the liver biopsy.

Then I think this is the study you're talking about, isn't it? I think?

Q. No --

A. Well, this is from the same group:

"In an 8-year prospective study conducted in Sheffield, histological signs of cirrhosis were found in nine of 79 haemophiliacs (12%) ..."

I mean, what I'm trying to show you is that there was a realisation this was a problem, but there was debate at that time as to how severe this problem was, and what was happening. And some of the papers published, who had done biopsies, showed abnormalities. Some of the studies did not show abnormalities.

And of course the other issue, which I think I took up with Professor Preston in the debate over doing liver biopsies, because it is relevant, is that

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(overspeaking) --

DR LEE: No, no, no. There's a table at the top.

SIR BRIAN LANGSTAFF: I see.

DR LEE: Can we just see the table at the top first? He sets out in this table a very good chronological order of how knowledge developed, both for hepatitis and AIDS. Now can we go back to the bottom which you -- and it's talking about:

"The fallacy of retrospective knowledge. Table 1 summarises the chronology of the development of knowledge about hepatitis and AIDS in haemophiliacs. To sum up, even though the problem of hepatitis was known since the 1970s, there was no reason to believe that this adverse effect of haemophilia care was heralding the much more ominous AIDS. On the whole, everybody was muddled in the period between the early 1980s and the first cases of people with haemophilia and AIDS were reported."

Now, I know you're talking here -- you've separated off hepatitis, but there is absolutely no doubt at that time that there was a debate going on about how severe these changes were. Was everybody going to get this? Was it vastly progressive? And that was being weighed about -- it's all a balance of risk. It was being weighed up about whether treating

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1 the patient -- it was important to treat the patient,
 2 to give effective treatment.
 3 I mean, some of the reasons -- people would have
 4 died of bleeding if they hadn't had these
 5 concentrates. So it's a balance of risks.
 6 **MS RICHARDS:** I'll come back to balance of risks,
 7 Professor Lee, but first of all, Professor Mannucci
 8 entitles this "The fallacy of retrospective
 9 knowledge". He is, of course, writing retrospectively
 10 at this point.
 11 **A.** Sorry. He's writing what?
 12 **Q.** He's writing retrospectively in this article. If we
 13 look at his table at the top of this page and we just
 14 look at hepatitis, because we're going to come on to
 15 AIDS separately, we can see, for example, none of the
 16 materials which I've just referred you to are there
 17 set out in his chronology of the main events in
 18 hepatitis. He refers to some early reports, '70 to
 19 '72. 1975, he cites his own piece of work. 1977, he
 20 cites liver biopsy. And the reasons you've explained,
 21 liver biopsies were not something that could be
 22 frequently undertaken. And then he goes on to
 23 desmopressin, DDAVP, and then to the 1980s. So it's
 24 not, by any stretch of the imagination,
 25 a comprehensive chronology of the development of

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1 that in this time there was debate about the
 2 seriousness of the transaminitis. I don't think
 3 anybody doubted it was there, but there was debate
 4 about the progression and the seriousness. And
 5 I would say again, Preston's paper where he
 6 biopsies -- he worked alongside a very able
 7 hepatologist called Dr David Trigger -- it's more
 8 likely they were biopsying the patients who looked as
 9 if they were more badly affected.
 10 **Q.** Yes.
 11 **A.** So you have a skewed vision.
 12 **Q.** You and Professor Preston I think have crossed swords,
 13 if I may put it that way, in relation to that issue in
 14 the past --
 15 **A.** I don't think it's a question of crossing swords.
 16 **Q.** I disagree --
 17 **A.** I'm sorry, I don't like that. I am a physician.
 18 I cared desperately about my patients. They're not my
 19 patients; it's the patients. And throughout my
 20 career, I have wanted to do the best for those
 21 patients. And for me, the best I can do for patients
 22 is based on evidence and also safety and efficacy.
 23 And I do not -- and the reason you're using this term
 24 "cross swords", which I don't really like because it
 25 was just showing our experience and questioning

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1 knowledge of non-A non-B hepatitis, is it?
 2 **A.** I really find that very difficult, what you've just
 3 said. This man lived through treating his patients
 4 through all of that period. And there is absolutely
 5 no doubt around this time that there was a debate as
 6 to what transaminitis meant. There is no doubt that
 7 it was clearly stated in some of these papers that
 8 this hepatitis occurred, but the debate was also about
 9 how serious the transaminitis was. Was it worth
 10 stopping the treatment because it was terrible, or was
 11 it more important to go on using the treatment?
 12 And, you know, as things transpired, the later
 13 information we had showed that, actually, for many
 14 patients, it was a very, very slow progression. And,
 15 indeed, for some patients -- quite a few, actually --
 16 they lived through an era where we had treatment for
 17 hepatitis, so it could be cleared. So are you saying
 18 that in this period, that treatment should have been
 19 stopped because they get hepatitis and maybe they have
 20 the problem of bleeding?
 21 **Q.** Professor --
 22 **A.** And these people -- can I just finish? I'm sorry.
 23 **Q.** Of course.
 24 **A.** But these people benefited from the clearing of their
 25 hepatitis in the end. And I just will emphasise again

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1 whether it was right to risk death from a liver biopsy
 2 and provide cover to cover the biopsy. I don't think
 3 that's crossing swords. It's trying to fight for care
 4 and investigation of patients to be relevant.
 5 **Q.** Would you accept that you and Professor Preston
 6 disagreed about whether his was effectively
 7 a selection of the most serious cases?
 8 **A.** I think what I would say is that I put into the public
 9 domain the experience we had had. And as a physician,
 10 the way I have approached looking after and caring for
 11 patients has been that I need to know what is going
 12 on, but I need to know in a way that is not risky for
 13 them. And what I have -- we're going to perhaps talk
 14 about it, I don't know, but what I wrote up in that
 15 letter was an experience -- it wasn't when I was there
 16 that the person died of the liver biopsy. It was
 17 during the time that Dame Sheila Sherlock was
 18 investigating these patients with liver biopsy.
 19 But having had that experience, there was no way
 20 we were going to expose patients to the risk of death
 21 from bleeding. And I do not like the idea that you
 22 are suggesting that I crossed swords with somebody.
 23 You know, I'm a doctor, and we're all in the thing
 24 together. We're all trying to find out knowledge, to
 25 find out what is best for our patients. We're not

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1 fighting.

2 **Q.** Professor Lee, let's leave aside the term I used.

3 **A.** Sorry?

4 **Q.** Leave aside the term I used.

5 **A.** Thank you.

6 **Q.** The question I was simply putting to you is: are you

7 aware and do you accept that Professor Preston

8 disagreed with your characterisation of his research?

9 That's all.

10 **A.** I think -- I didn't disagree with the results he got.

11 Not at all. Not at all. In fact, they were very

12 helpful. What I did disagree with was the approach of

13 doing unnecessary liver biopsies. And for the reasons

14 I've said. You know, there was a patient that died.

15 But what I would also say is that, as we went

16 through the '90s, and then we had CT scans and

17 imaging, the consultant hepatologists that I worked

18 alongside were able to do what's called transjugular

19 liver biopsies where the needle went down through the

20 vessel into the liver, and they could do that under an

21 image. They can see where the needle goes. When you

22 do a liver -- I've never done a liver biopsy. When

23 you do a liver biopsy, in the days that these were

24 being done, the needle goes into the liver. The liver

25 is an incredibly vascular organ, so you could hit

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1 **SIR BRIAN LANGSTAFF:** Before you do that, can I just ask

2 a couple of questions about this paper by Mannucci in

3 the 1990s? Can we go down to the bottom of the page,

4 please, Henry? Under "The fallacy of retrospective

5 knowledge", the second sentence:

6 "To sum up ..."

7 So what he appears to be saying, this sums up the

8 fallacy of retrospective knowledge:

9 "Even though the problem of hepatitis was known

10 since the 1970s, there was no reason to believe that

11 this adverse effect of haemophilia care was heralding

12 the much more ominous AIDS. On the whole, everybody

13 was muddled in the period between the early 1980s ..."

14 That muddling, as I read this -- and please tell

15 me if I'm reading it wrong. I read the muddling to be

16 about AIDS and the link between hepatitis and AIDS.

17 Because I think he's saying that hepatitis is one

18 thing. Put that on one side. AIDS is another.

19 That's the way it seemed. Have I got it wrong?

20 **A.** Well, not really wrong, but what he's trying to say is

21 that ... one of the big problems was that mostly --

22 and this was knowledge that was gained later. The

23 people who, mostly, who had big problems with liver

24 disease actually had co-infection with HIV. And we

25 now know that HIV was coming in, in '79. So I'm not

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1 a vessel. It's quite dangerous. And also, each one

2 of those liver biopsies had to be covered with a large

3 amount of concentrate, so that's another issue.

4 That's probably a minor issue because, I think, you

5 know, that shouldn't be an issue, but it's the safety

6 issue.

7 And I think it's terribly important that we're

8 pursuing science here, as applied to haemophilia care,

9 which then makes the care of those patients good and

10 safe, but you can't do anything unless you know what's

11 going on.

12 **Q.** Professor Lee, we may be slightly at cross-purposes.

13 I'm not seeking to challenge your view that liver

14 biopsies could be dangerous, or your view that they

15 are not something that should generally be undertaken.

16 That's not the purpose of my questions. I'm looking

17 simply at the question of what was known in the second

18 half of the 1970s and what was not known; the emerging

19 picture in relation to non-A non-B hepatitis.

20 Professor Preston's work was a part of that

21 picture. An important part of the picture. I'm not

22 suggesting it was a complete part of the picture, and

23 you pointed to some of the other studies here.

24 Can I ask you to look at two descriptions of non-A

25 non-B hepatitis --

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1 saying all these studies, but some of these studies

2 overlapped that period. So what he's saying is that

3 we had no reason to know that then. I don't know if

4 that explains it or not.

5 **SIR BRIAN LANGSTAFF:** I'm not sure it does because it's

6 really a question of how one reads the words.

7 But the second question I want to ask you -- can

8 we go back to the very first page of this article,

9 please, Henry. Just something that caught my eye at

10 the bottom of the page. It's the very bottom

11 right-hand side:

12 "Hepatitis. Emergence of the hepatitis problem."

13 This is what Mannucci says throughout the 19 --

14 through the 1970s:

15 "Recognised the use of concentrates of coagulation

16 factors made from plasma pooled from several thousands

17 of blood donations was often associated with

18 hepatitis. However, the first large study of liver

19 function tests was published in 1975."

20 Now, that's Mannucci's own study, I think, because

21 that's the reference. And:

22 "Our survey of 91 multi-transfused Italian

23 haemophiliacs found that 45% of them had elevated

24 serum transaminases. Although non-A non-B

25 hepatitis ..."

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1 Can we turn over the page?
 2 "... was expected to be responsible for
 3 transaminase abnormalities, a definite distinction
 4 between transfusion associated hepatitis and
 5 transaminitis could not be made at that time."
 6 The last sentence:
 7 "Our findings were subsequently confirmed and
 8 extended by a joint American/English study that
 9 demonstrated that transaminase abnormalities
 10 persisted, supporting the views that they were a
 11 hallmark of chronic viral hepatitis."
 12 Now, what he appears to be saying is that his own
 13 work in 1975 demonstrated that there was a condition
 14 which was associated with factor concentrates made
 15 from large pools and the development of chronic viral
 16 hepatitis. It doesn't say how serious the chronic
 17 viral hepatitis was, but that's what he appears to be
 18 saying. And then what does it go on to say after
 19 that, Henry?
 20 **A.** I think --
 21 **SIR BRIAN LANGSTAFF:** "Unequivocal evidence."
 22 So he's saying that what he had suspected in '75
 23 was unequivocally confirmed in 1977, and on it goes.
 24 Have I got that right? Is that the way it would
 25 read?

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1 look at this, Henry. BART0002487. Go to the second
 2 page, please, Henry. You'll see there it's a letter
 3 to Dr Colvin, 27 April 1979. We go to the paragraph
 4 numbered 2 under the heading "Types of therapeutic
 5 material available", and we'll go halfway down the
 6 paragraph. He's talking about commercial versus NHS
 7 concentrates. I don't need to ask you about that, at
 8 least not at this stage. Then he says:
 9 "The clinical reason [referring to the NHS] is the
 10 growing awareness that the probability that commercial
 11 concentrates are the higher risk of transmitting non-A
 12 non-B hepatitis than NHS material."
 13 Then this the sentence, Professor Lee:
 14 "This is a serious disease with long-term
 15 consequences."
 16 I can take you to a reference the following month
 17 by Dr Kernoff and Dr Colvin which talked about it
 18 being serious with long-term sequelae and that the
 19 acute disease may sometimes be fatal.
 20 Would you agree with that characterisation, as at
 21 1979, recognising there's still much to learn, it was
 22 known that this was a serious disease with long-term
 23 consequences?
 24 **SIR BRIAN LANGSTAFF:** Shall we use the word "believed"?
 25 **MS RICHARDS:** It was believed.

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1 **A.** Yes, but I think the other important thing in that
 2 paragraph is what I said earlier: the thing about the
 3 joint American/English study -- this was
 4 Katharine Dormandy's study with Levine in Boston. And
 5 I said earlier about this, that she had shown -- she
 6 had been worried about transaminitis, and she compared
 7 her patients who were treated with cryoprecipitate
 8 with the American patients who had been treated with
 9 concentrate. And transaminitis was in both, but there
 10 was more transaminitis in the American patients. So
 11 this was a piece of information that was in
 12 circulation.
 13 The other thing that's not actually written here,
 14 but I can tell you that there was a view held by some
 15 people that transaminitis may be accentuated by
 16 metallic things in the fractionation process. So what
 17 I'm trying to do -- you know, it's quite clear that
 18 there was -- they're descriptions of non-A non-B
 19 hepatitis. They're not really defined as non-A non-B,
 20 but going on -- but the extent of this problem and the
 21 rate of progression and the seriousness of it was not
 22 clear. There was evidences in both directions, and it
 23 was that kind of information that was informing the
 24 way people or haemophilia treaters were treating.
 25 **MS RICHARDS:** Dr Kernoff, in April 1979 -- perhaps we'll

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1 **A.** Yeah. Can we begin at the beginning of that
 2 paragraph? The paragraph you just had, it's
 3 disappeared, has it?
 4 **Q.** That's the paragraph:
 5 "Types of therapeutic material available."
 6 **A.** Saying that he wrote:
 7 "The clinical reason is the growing awareness that
 8 the probability that commercial concentrates have a
 9 higher risk of transmitting non-A non-B hepatitis than
 10 NHS material."
 11 Dr Kernoff wrote that. It later transpired
 12 that is not true, and we're going to go and discuss
 13 that paper. That came after that. So what I'm saying
 14 here -- this is 1979 -- that even Dr Kernoff clearly
 15 moved his view.
 16 **Q.** That wasn't, with respect, the question I was putting,
 17 Professor Lee, which is: do you agree with
 18 Dr Kernoff's characterisation, as at 1979, that non-A
 19 non-B hepatitis is a serious disease with long-term
 20 consequences? Is that a fair way of describing non-A,
 21 non-B in 1979?
 22 **A.** I think all I would say about that sentence, and this
 23 is written in 1979 by Dr Kernoff, okay, is that he
 24 writes: "As far as is known." And I think that is the
 25 qualification: as far as is known. And, as we know,

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1 subsequent work shows --

2 **SIR BRIAN LANGSTAFF:** I think the "as far as it's
3 known" is dealing with its prevalence, rather than the
4 long-term consequences -- (overspeaking) -- if you
5 just read it through:

6 "As far as is known is, at present, much less
7 common in the UK than in the USA, et cetera."

8 **A.** Yes, okay. As far as is known: what I'd say to
9 that is it is a qualification. This is written in
10 1979. And if Peter had been -- Dr Kernoff had been
11 alive in 2000 or 1994, he would have realised that,
12 actually, there were some patients where the
13 progression was very slow. Sadly, it was mostly the
14 patients who had co-infection with HIV who progressed
15 very rapidly. And, you know, we cared for those
16 patients, and because all the clotting factors are
17 made in the liver, it was very difficult.

18 So I think -- I suppose what I'm trying to say is
19 this is written in 1979, and Dr Kernoff is aware of
20 all these publications that you've shown. And he's
21 balancing those publications up, and he's saying that
22 it's a disease with long-term consequences. Of
23 course, that's '79. You know, the long-term
24 consequences for many patients didn't come until 2000.
25 That's what I'm trying to explain. Is that helpful?

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1 was going on. I mean that was why the study was being
2 done: to understand it.

3 So I think the idea that everything was understood
4 by the end of the 1970s is wrong. There were all
5 sorts of emerging knowledge coming out. And in
6 parallel with that, there was treatment, remarkable
7 treatment. And that's what people were weighing up.
8 And they were -- you know, one of the reasons for this
9 study, this retrospective study that Dr Kernoff wanted
10 to be looked into, for the information to be assembled
11 and published, was to find out more about what is
12 happening, what is going on.

13 And of course, the -- we're going to talk about
14 it, I know, but the most important thing that that
15 study showed, and the knowledge up to that date had
16 been completely wrong on it, was that whether the
17 concentrate was made from blood donors in America or
18 anywhere, or the UK, everybody got non-A non-B
19 hepatitis on their first exposure.

20 And, you know, none of that knowledge was
21 available in the late 1970s. That emerged and began
22 to be presented at clinical meetings, I suppose, from
23 1983 onwards. But what was known -- you've shown
24 it -- was the Craske paper, and, you know, the
25 knowledge was building up.

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1 **SIR BRIAN LANGSTAFF:** Yes, thank you very much.

2 **MS RICHARDS:** Would you accept, in light of the material
3 that we've looked at and any other material that
4 you're aware of from the second half of the 1970s,
5 that it should have been appreciated by
6 haematologists, by the end of the 1970s at least, that
7 non-A non-B hepatitis was a clinically significant
8 condition which carried a significant risk of causing
9 liver disease?

10 **A.** No.

11 **Q.** Why?

12 **A.** Because they weren't aware of that.

13 **Q.** Well, Dr Kernoff is saying it in terms. It is
14 a serious disease with long-term consequences.

15 **A.** Yes, you asked me about all haematologists, didn't
16 you? What was your question?

17 **Q.** I'm asking you whether you would accept that, in
18 general, haematologists should have known by the end
19 of the 1970s that non-A non-B hepatitis was
20 a clinically significant condition which carried
21 a significant risk of causing liver disease?

22 **A.** I think, I suppose what I would say in answer to
23 that is, in an ideal world, they should have known,
24 but what I would say is that they did not know.
25 I don't think any of us really knew for certain what

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1 **Q.** Professor Lee, you used the term "for certain", things
2 weren't known for certain.

3 **A.** Yes.

4 **Q.** Professor Mannucci used the term "unequivocal" in the
5 paper you've referred us to. Finding certainty,
6 finding unequivocal evidence, may be something that
7 might take many years of research and study.
8 Clinicians will rarely have evidence of certain
9 outcomes. They have to look at the risks. Would you
10 agree?

11 **A.** Yeah, and I think -- yes. And I think what is
12 important when you're considering risk, the only risk
13 that you are considering or you're throwing at me, is
14 the risk of this emerging picture of transaminitis,
15 non-A non-B hepatitis.

16 Haemophilia treaters at that time, and indeed now,
17 also have the risk to think about: what happens --
18 what happens -- if I don't give this patient
19 treatment? What happens if this patient isn't having
20 regular home treatment at home so that when he
21 develops a knee bleed at home he can treat himself
22 immediately so that that knee in future is not going
23 to be a target joint and he becomes -- "crippled" is
24 a word that I don't like using -- disabled.

25 And I think always in this risk -- and, you know,

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1 it goes for the whole of medicine. You're balancing
2 risk. You know, what were haemophilia physicians
3 trying to do? They were treating people who had an
4 inherited bleeding disorder, and they had to balance
5 up what is the greater risk: that I risk this person
6 being at home and getting a cerebral haemorrhage?
7 Or -- you know, I'm sorry to labour this point but it
8 really is important. And I just -- I think it's
9 important.

10 You've got this document somewhere, I've got
11 a number. It's to try and convey what haemophilia is
12 like untreated. And it is relevant.

13 We're now in 2020, and what I want you to put up
14 on the screen, if I'm allowed, is -- it's witness
15 number 644002.

16 **Q.** Sorry, could you tell me what the --

17 **A.** The title of it is the -- it's from the textbook of
18 haemophilia, it's a historical introduction
19 that I wrote.

20 Can you find it?

21 **Q.** Unless it's exhibited to the long statement that you
22 prepared for today, then it's not something
23 that I can --

24 **A.** All right, well, am I allowed to read from it and
25 provide this to you afterwards? I think it is

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1 prophylaxis, and indeed now there's even gene therapy,
2 so nobody ever sees a bleed. And of course cerebral
3 bleeding was the most devastating thing of all. So
4 that's what I'm trying to convey.

5 **MS RICHARDS:** 1937 was not 1979, and the choice was not
6 necessarily one of, in every case, treatment with
7 concentrates or no treatment. Amongst other things,
8 cryoprecipitate was available, and for non-severe
9 haemophiliacs, DDAVP.

10 **A.** Yes, let's go back to cryoprecipitate.

11 We know, then, that the incidence of hepatitis in
12 blood transfusions was one in 300. This was done from
13 post-transfusion studies. If you treat somebody with
14 cryoprecipitate, you very quickly accrue a large
15 number of treatments. And indeed, the paper that you
16 have here from the lady who was a carrier of
17 haemophilia, you know, people -- women who are
18 carriers of haemophilia, sometimes they have quite
19 a low level of Factor VIII. And she had an operation
20 on her knee, and was given cryoprecipitate. I'd need
21 to get the paper, but I think in the end she had about
22 300 units of cryoprecipitate. She developed fulminant
23 hepatitis C. She was in intensive care and nearly
24 died. That was from cryoprecipitate.

25 And that lady went on with long-term hepatitis C,

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1 probably in one of my Rule 9s.

2 **Q.** It's fine for you to read from it. We will have it
3 but we don't have it electronically to display.

4 **A.** Will you forgive me if I -- I won't read too much.
5 What I was going to say was, this is 2020, and this is
6 a publication that came in 1937 from America. And it
7 was --

8 **SIR BRIAN LANGSTAFF:** Is it the Birch paper?

9 **A.** Sorry?

10 **SIR BRIAN LANGSTAFF:** Is it the Birch paper?

11 **A.** Yes, yes.

12 So it was 113 people with haemophilia in 1937.

13 And she -- actually, it's a he, with a strange
14 spelling -- reviewed the causes of death from
15 bleeding.

16 Just to give you an example, 15 out of these
17 people died from circumcision, six died from
18 epistaxis, seven from central nervous bleeding.

19 And what's even more awful was that most of these
20 people died before the age of 15 years. I think only
21 eight survived beyond 40. And what you're balancing
22 is always risk of bleeding. I think we must not
23 forget that people bleed. And it's often forgotten
24 now because fortunately we now have recombinant
25 products and our little boys can be treated with

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1 and indeed in the end she and her son both had
2 type 1 hepatitis -- of course her son had severe
3 haemophilia -- and they both cleared it with
4 treatment, with interferon, later on.

5 So the idea that you could go and treat everybody
6 with cryoprecipitate, and it was safe and effective,
7 because people had a transaminitis or a non-A non-B
8 hepatitis for which we did not know the progression of
9 the seriousness, was really not a correct idea.
10 Furthermore, I followed your questioning of
11 Dr Brian Colvin, and following that question, I went
12 back to Katharine Dormandy's original papers, and
13 I think it was the one in 1974 which shows in great
14 detail what was needed to train people and to make
15 cryoprecipitate.

16 You're suggesting, I think, that in the late
17 1970s, that this concentrate is stopped being used,
18 and we start going back to cryoprecipitate.

19 Well, for a start off, if people are treating at
20 home, they haven't got deep freezers anymore. In the
21 hospital, the Blood Transfusion Service is not geared
22 up to making this anymore. That's just a provision
23 thing. But the most important thing, probably -- and,
24 you know, there are many people in this room who were
25 in receipt of concentrates, the convenience for the

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1 patients of these concentrates was extraordinary,
2 because it was, you know, injecting -- I don't know,
3 20mls into your arm, having a little bottle that you
4 shake up, that you can take when you go in your car
5 somewhere, or you can go abroad or you go to work, the
6 patients wanted it. You know, it ...

7 And the other thing that we haven't talked about
8 at all -- I mean, we have kind of talked about it,
9 I discussed with you how bovine Factor VIII was
10 developed and how in Oxford they were therefore able
11 to take people's teeth out.

12 As things moved on, operations could be done for
13 these patients. You know, people with haemophilia are
14 no different to any of us. They can get appendicitis.
15 They can get things that you need to do an acute
16 operation on. And having these concentrates
17 absolutely transformed things because you could do
18 that now.

19 So I hope that explains things, and why it would
20 not be sensible or even practical to go on back --
21 back -- to using cryoprecipitate. It was not a safe
22 product.

23 **Q.** It was a safer product than factor concentrates,
24 whether NHS or commercial, was it not?

25 **A.** Well, it depends how you define "safer".

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1 can precisely dose it. It's just a whole safer
2 procedure.

3 And I think from the quality of life perspective,
4 it would also be an issue for the individuals with
5 haemophilia.

6 **Q.** Do you agree or accept that patients with haemophilia
7 or other bleeding disorders who are going to be
8 treated potentially with concentrates should be told
9 that non-A non-B hepatitis was a risk of their
10 treatment and that it was a serious disease with
11 long-term consequences? To quote Dr Kernoff.

12 **A.** I think at the time that you're talking about this,
13 I -- fortunately, maybe, for me, I wasn't in the
14 position of talking people through their treatment.
15 I've explained that what I was doing was following up
16 information that had been acquired from that
17 treatment.

18 What I do know is that patients -- when the
19 knowledge evolved, was that patients would be told
20 there was a possibility of this transaminitis or
21 hepatitis, but the treater, or Peter I suppose, at
22 that stage, would have said, "We don't know what the
23 long-term consequence of this was."

24 And I think I would just go back also to the point
25 that, for most people, it was an asymptomatic

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1 **Q.** In terms of risks of transmitting hepatitis to start
2 with.

3 **A.** In terms of transmitting hepatitis, if -- once you've
4 got over 300 units, it's almost inevitable you're
5 going to get it. But, you know, if you're treating
6 a patient who has bleeding, what is the greater risk?
7 Do you want somebody with, say, a cerebral haemorrhage
8 to die because, you know, they've been treated with
9 ineffective cryoprecipitate that hasn't brought the
10 level up?

11 And, you know, if you're operating on somebody,
12 it's very difficult to plan how many units of
13 cryoprecipitate you want when you can't even know
14 what's in the bag. It's just -- it's an extraordinary
15 idea. And I think you have to balance the risks. And
16 all you -- and -- sorry, I don't want to be
17 aggressive -- but all that is being seemingly
18 considered at the moment is the risk of non-A non-B
19 hepatitis, which at the time there was very limited
20 information. We didn't have -- the virus wasn't
21 identified until 1989 so we didn't have a test. You
22 are suggesting that it was important to avoid that
23 risk, and then you expose the patient with the
24 haemophilia to a much bigger risk. Because if you use
25 the concentrate, you know what's in the bottle, you

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1 disorder. So it wasn't an issue, you know. Their
2 priority was to be treated.

3 But I think it probably -- I don't know, because
4 I wasn't Dr Peter Kernoff in that period. I was, at
5 that time, or certainly in the 1980s when I was doing
6 this research, I was looking at data. I wasn't the
7 person who was administering the treatment.

8 **Q.** The question I asked, Professor Lee, and I'm not sure
9 that you've quite answered it, is not what as a matter
10 of fact patients were told at the Royal Free, do you
11 accept -- you're free to disagree -- do you accept
12 that by the late 1970s or early 1980s, patients had
13 a right to know, should have been told, that the
14 treatment they were being offered carried a risk of
15 non-A non-B hepatitis and that, whilst much was still
16 unknown, non-A non-B hepatitis was a serious condition
17 with long-term consequences?

18 **A.** I don't agree with that. And, you know, I'm trying to
19 remember back 37 years, basically. You know, you've
20 quoted the papers, and what you've quoted is certainly
21 true. But there was also a great, great unknown. So
22 I don't agree with the totality of what you said
23 there.

24 **Q.** Do you disagree with my characterisation of the
25 condition, or are you disagreeing with the suggestion

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1 that patients should have been given that information?

2 **A.** I don't disagree with patients being given

3 information. I think all patients should be given

4 information, and that's all -- the way certainly I've

5 practiced. But it's very difficult giving information

6 when the information itself is being debated, and it

7 is not entirely clear what is happening.

8 **Q.** So this is a hypothetical question because

9 I understand that you were not at the Royal Free at

10 this time. But bearing in mind Dr Kernoff's own

11 characterisation of the condition as a "serious

12 disease with long-term consequences", is that a piece

13 of information which, in your view, should have been

14 given to patients at that time?

15 **A.** Well, I go back to what I said earlier. It was the

16 knowledge at the time. He qualified it. So I don't

17 know. I wasn't in the position of giving the

18 information at that time, to the patient. I don't

19 know what he told the patient. But when he qualified

20 that, as far as is known, I'm sure he probably would

21 have told the patient, "This is a problem". That was

22 his way. He told patients things. So I don't -- but

23 I -- again, I think it is inappropriate to ask me what

24 Dr Peter Kernoff would have told patients.

25 **Q.** That's not the question, Professor Lee.

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1 I wasn't in that position -- of giving people

2 untreated concentrate before 1985, and I'm sure that

3 what I would have said is that there may be a problem,

4 but we don't know what it means.

5 **MS RICHARDS:** Is this your evidence in relation to what is

6 a matter of fact the position was at the Royal Free,

7 1983, and --

8 **A.** No, it's not a matter of fact because I don't know

9 what Dr Kernoff said to patients, and I wasn't in the

10 position to actually give treatment then.

11 **Q.** Professor Lee, if you'll let me ask the question,

12 you'll understand I wasn't suggesting what you think

13 I may have been suggesting.

14 As I understand your evidence so far, you're

15 saying: as a matter of fact, you don't know what was

16 or wasn't said to patients about non-A non-B

17 hepatitis.

18 **A.** Yes, that's right.

19 **Q.** Is that not something that you ever discussed with

20 Dr Kernoff, given that you were researching the

21 incidence of liver abnormalities in these patients?

22 **A.** Can I remind you again that the study I was looking

23 at, the information, the retrospective information

24 I was looking at, I started looking at the end of

25 January 1983, by which time most -- all the patients

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1 **A.** What is the question?

2 **Q.** The question, I'll say it again. The question is: do

3 you consider, as at 1979, or 1980, that patients

4 should have been told that their treatment carried

5 with it a risk of developing non-A non-B hepatitis

6 which was believed to be a serious condition with

7 long-term consequences?

8 **A.** Can I answer that question. It's very difficult for

9 me to say what people -- what consultants delivering

10 care at that time should have said. Maybe I can

11 say -- I never treated one of those patients first

12 time. Ever. Then.

13 **Q.** In 1979?

14 **A.** No. I wasn't there.

15 **Q.** Yes. I know. I'm trying to understand the point

16 you're making, Professor Lee.

17 **A.** I didn't. I -- I didn't treat any patient there

18 until 1987. Okay?

19 So I've forgotten what the question is. I'm

20 terribly sorry.

21 **SIR BRIAN LANGSTAFF:** It's the hypothetical question.

22 **A.** Yes, well, what I think I would say is that I can't

23 project what I would have said then, but what I can

24 project is what I would have said when I was in the

25 position that -- if I was in that position -- in fact,

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1 had been treated. What -- there was still patients

2 who were being followed up.

3 **Q.** So is the answer to my question that you didn't have

4 any discussions with Dr Kernoff about the information

5 that was provided to patients at that time?

6 **A.** No. My job was to try to find out more information.

7 **Q.** As far as you know from your time at the Royal Free in

8 1983 and 1984, or indeed anything that you may have

9 learnt subsequently about that time when you took up

10 your consultant post there, were any changes made to

11 treatment policies or practices in response to the

12 risk of non-A non-B hepatitis?

13 **A.** Which period are you talking about?

14 **Q.** The first half of the eighties, but in particular '83

15 and '84.

16 **A.** No, I wasn't -- I wasn't in the position to -- that

17 wasn't my role and it wasn't in my knowledge. And by

18 the time I was in the position that I was

19 a consultant, in 1987, the concentrates were all

20 heated. So the practices were never part of my job.

21 **Q.** If we could just look at your evidence to the

22 Lindsay Inquiry, LIND0000326.

23 If we could turn, please, to page 15, so the very

24 bottom of that page, you can see you were asked about

25 what the practice was in 1983 and you talked there

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1 about a very strict policy about using DDAVP for those
2 with mild disease. And then if we go over the page,
3 you say at the top of the page:
4 "For those who had severe Haemophilia A, there was
5 not any positive stopping of treatment and people went
6 on having both National Health Service and commercial
7 concentrate."
8 Now the context of that question may have been the
9 response to the developing knowledge of AIDS, but is
10 it right to read that as being practices in relation
11 to the treatment of patients at the Royal Free didn't
12 change in 1983 and '84? That's --
13 **A.** I don't know about change, what I -- this evidence
14 that I gave to the Lindsay Inquiry 20 years ago was
15 cross-checked with the people who were still -- who
16 had been working at the Royal Free at that time, and
17 the records.
18 **Q.** So, as you previously indicated, this is the most
19 reliable evidence you've given on those questions of
20 fact?
21 **A.** This is very reliable evidence, what I've said here,
22 and, you know, I would remind you again that you're
23 asking me questions in my memory about things that
24 happened in 1983, which is 37 years ago. And what
25 I would say about this evidence is that it is much

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1 overnight as they do at any break.
2 **PROFESSOR LEE:** So I can't talk to my husband tonight.
3 **SIR BRIAN LANGSTAFF:** Well, you can talk to him.
4 I wouldn't ever want to stop that, but not about your
5 evidence, either what you have said or what you may
6 yet say.
7 **(4.20 pm)**
8 **(The hearing adjourned until 10.00 am the following day)**
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1 more reliable. I'm then the Director and Professor of
2 Haemophilia at the Royal Free, and more importantly,
3 I have the experience and I'm able to find or
4 cross-check the record of what was happening. But at
5 the time that I was doing the research, or looking at
6 the information from the patient notes and trying to
7 work out what had happened when these people had their
8 first treatment with concentrate, these decisions and
9 if there were changes, they weren't my remit. All
10 I can do is provide the evidence that was available.
11 And I think it's very difficult for me -- you know,
12 Peter's dead and ceased working in 1991. It's quite
13 difficult for me to know what rules and changes and
14 things he made. I don't know.
15 **MS RICHARDS:** Sir, I note the time. I'm going to move on
16 to the next topic of questioning to HIV and AIDS.
17 **SIR BRIAN LANGSTAFF:** Well, let's give the Professor the
18 opportunity to break now until tomorrow, if you'd
19 rather.
20 **PROFESSOR LEE:** I would prefer that. I'm exhausted.
21 **SIR BRIAN LANGSTAFF:** I thought you might say that.
22 **PROFESSOR LEE:** Thank you very much.
23 **SIR BRIAN LANGSTAFF:** It is one of those days, I think.
24 Shall we meet together then, at ten o'clock tomorrow
25 morning. The rules that I've mentioned to you apply

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I N D E X	
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2	PROFESSOR CHRISTINE ANNE LEE, 1
3	affirmed
4	Questioned by MS RICHARDS 1
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