

1 Thursday, 19 November 2020

2 (10.02 am)

3 **SIR BRIAN LANGSTAFF:** Good morning, Dr Giangrande. Can

4 you hear me?

5 **A.** I can hear you perfectly, Sir Brian.

6 **SIR BRIAN LANGSTAFF:** And you can see me?

7 **A.** I can indeed, and good morning to you, sir.

8 **SIR BRIAN LANGSTAFF:** That's quite a good start. The

9 reason I say that is for your benefit and for the

10 benefit of those who are watching remotely -- I'll

11 describe the scene to you in a moment -- there have

12 been one or two gremlins, I'm afraid, with the

13 transmission online generally. They may affect us

14 this morning. It's not here at the Inquiry but

15 between the Inquiry and the general world, maybe you

16 as well. We have server problems, and if they cause

17 us problems, I just hope that you and everyone else

18 will bear with us. I hope -- that's the best I can

19 say -- I hope -- that they don't come back to be real

20 problems and that what I'm saying now will simply be

21 forgotten by the end of the day.

22 But let me tell you what you are facing as you

23 look at your screen. In this room there are a handful

24 of lawyers. There are three lawyers from the Inquiry,

25 there is your own counsel, Mr Thomas. Then there are

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1 three members of the Inquiry staff and Mary, who will

2 swear you, administer the oath, in a moment or two,

3 together with a technician whose job it is to show the

4 various documents that we will be referring to.

5 But it's not just us you're talking to, it is

6 a very large number, probably round about 200, of

7 those who are interested in the Inquiry from different

8 perspectives and they are watching remotely. Many

9 would have wished to be here, you may well have wished

10 to be here yourself, and it will have been my wish

11 that that could have been the case. But it isn't

12 because of the virus, the coronavirus this time, and

13 as a result we are where we are and I'm afraid that we

14 have no option, if we are to continue, but to screen

15 your evidence remotely. So you will be seen by lots

16 of people, you will be heard by lots of people. There

17 will be a running transcript which will be corrected

18 at the end of the day to make sure it is faithful to

19 what you actually said, and that's where we are.

20 So you now understand what the position is, Mary

21 will now ask you to take the oath.

22 **DR GIANGRANDE, sworn**

23 **Questioned by MS RICHARDS**

24 **SIR BRIAN LANGSTAFF:** Dr Giangrande, I should have asked,

25 you are, I think, at home in your own with your wife?

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1 **A.** I am indeed, yes.

2 **MS RICHARDS:** Dr Giangrande, can you see and hear me?

3 **A.** I can hear you perfectly and see you perfectly.

4 I have no problems with internet connection myself.

5 **Q.** Good. Well, I hope ours holds up as well.

6 You qualified as a doctor in Manchester in 1979?

7 **A.** Yes.

8 **Q.** And your statement tells us that from 1979 to

9 July 1981 you held various house officer and senior

10 house officer posts in Manchester?

11 **A.** Yes.

12 **Q.** Can you assist us with the extent to which you

13 undertook any haematology work during that time?

14 **A.** After I got full registration, that is after my house

15 jobs, I then undertook a rotation at the University

16 Hospital of South Manchester, colloquially known as

17 Withington Hospital, and that involved rotating round

18 the four sections of pathology, because I knew I was

19 likely to head in that direction career-wise, and that

20 involved spending three months in each of

21 microbiology, chemical pathology, histopathology and

22 haematology.

23 The haematology I did was largely

24 laboratory-based. Most of the clinical haematology

25 was at Manchester Royal Infirmary.

3

1 **Q.** Did you work at all with Dr Craske at that time?

2 **A.** I did. He was the microbiologist -- the virologist,

3 I'm sorry, in the microbiology department. And I met

4 him -- of course I had no idea at that stage that he

5 had any interest in the haemophilia world, and

6 I didn't know I was going to be moving to that world

7 either at that stage, but that's where I got to know

8 him first.

9 **Q.** You then moved to London in August of 1981. You were

10 an SHO in renal medicine at the Hammersmith?

11 **A.** Yes.

12 **Q.** Then you moved to St Mary's in an SHO position in

13 metabolic medicine?

14 **A.** That's right.

15 **Q.** Just dealing first with the time spent in renal

16 medicine, did you come across any dialysis patients

17 who had been infected with blood-borne viruses at that

18 time?

19 **A.** No, it was very much an area of -- where they took

20 a lot of precautions, and it was something that was

21 greatly feared, so, you know, great precautions were

22 taken, absolutely, because if a machine got

23 contaminated, the potential consequences were

24 enormous.

25 **Q.** Then I understand it was during the time at St Mary's

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1 that you first came across reference to AIDS.
 2 **A.** That's right. I mean, the first death from AIDS in
 3 the United Kingdom was reported in December
 4 of 1981: a patient died in the Brompton Hospital. And
 5 of course, others were -- patients, sadly, were
 6 falling ill at the time. And it was the subject,
 7 particularly based in West London, of educational
 8 materials and talks.
 9 In fact, I remember one talk particularly well
 10 because Dr Pinching, who had previously been at the
 11 renal unit at Hammersmith Hospital, had moved at
 12 roughly the same time as me, and I remember very well
 13 a talk he gave on AIDS when the cause was completely
 14 unknown, and indeed I remember him telling us about
 15 a paper published in The Lancet which was implicating,
 16 of all things, amyl nitrate/poppers, but it was
 17 a respectable paper, published in The Lancet, from
 18 a very reputable group in the US. So it was taken
 19 seriously at the time.
 20 **Q.** So that would have been late 1981 or the first part of
 21 1982?
 22 **A.** 1981 was when I was there. I did look up -- the
 23 publication on amyl nitrite was published in
 24 The Lancet on February 20th. So because these
 25 educational talks tend to be given quite soon after

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1 the publication, I would guess that lecture was
 2 probably March, perhaps April of -- of '82. I'm sorry
 3 if I said '81. But '82.
 4 **Q.** And then you completed your MRCPath qualification
 5 I think at this time?
 6 **A.** No, I think -- it was the MRCP qualification in --
 7 I think I got it in June. The MRCPath came later, it
 8 was '86.
 9 **Q.** We will get to that in a moment, then.
 10 You then, I understand from your statement,
 11 moved to Switzerland, where you worked from
 12 August 1982 to July 1983, including six months of
 13 haematology work. What can you tell us about that?
 14 **A.** Yes. I mean, the background -- first of all, it was
 15 a European exchange scheme that I applied for. The
 16 Hammersmith Hospital at the time was part of what was
 17 called the Royal Postgraduate Medical School and there
 18 was an opportunity to spend a year abroad, so
 19 I applied for that.
 20 And when I moved to Switzerland originally, they
 21 let me do six months in internal medicine, then they
 22 said: what would you like to do for the rest of your
 23 time here? And thinking of my future career,
 24 I decided to do haematology.
 25 It was a very exciting time when I was there in

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1 Switzerland, there was a lot going on in haematology,
 2 and that's what made me determined to move into
 3 haematology.
 4 **Q.** Do you recall whether there was any consideration or
 5 discussion at that time, '82 through to July 1983,
 6 about the risks of AIDS that could be associated with
 7 the use of blood and blood products?
 8 **A.** Not when I was in Switzerland. Not at all. In fact,
 9 at the haematology department where I worked we did
 10 a lot of bone marrow transplantation, and they
 11 specialised also in treatment of patients with
 12 aplastic anaemia. So very intensive use of blood
 13 products. And at that stage there was no concern at
 14 all about HIV.
 15 Indeed, actually, in I think September or
 16 October of that year, I was offered a plasma-derived
 17 hepatitis B vaccine, and that was new to Switzerland,
 18 it had been produced in the United States, it wasn't
 19 yet available in the UK, and it's produced from plasma
 20 of American donors, and the whole point is it contains
 21 hepatitis B from plasma of these donors, it's not
 22 a recombinant vaccine, and it was offered to me by the
 23 hospital, and they wouldn't have offered it to me had
 24 there been any concern, and equally I took it without
 25 any concern.

7

1 **Q.** So --
 2 **A.** I should add, by the way, I am aware in retrospect,
 3 from one of the papers that you sent me, that in
 4 a report dated April 24, 1983, there were -- and
 5 I didn't know this at the time -- four cases of AIDS
 6 that had been reported in Switzerland.
 7 Actually, one of those was a resident from the
 8 US who had come back for treatment of his final
 9 illness.
 10 **Q.** So no discussion at all in the period that you were
 11 undertaking haematology work of AIDS?
 12 **A.** No, none at all.
 13 Actually, the story in Switzerland is quite an
 14 interesting one, because the head of the Swiss Blood
 15 Transfusion Service was a man called
 16 Professor Alfred Hässig, and after a very stellar
 17 career as head of the Swiss Transfusion Service based
 18 in Berne, when AIDS came along, he was actually a bit
 19 of an AIDS denier, if you look up some of his work,
 20 and felt that HIV was related to stress and nutrition,
 21 and Switzerland didn't introduce HIV screening of
 22 blood donors until May of 1986. Indeed, there was
 23 no -- so there was no screening of donors, there was
 24 no heat treatment of the local cryoprecipitate --
 25 lyophilised cryoprecipitate they used to treat

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1 haemophilia. And, in due course, Professor Hässig was
 2 actually prosecuted and got a year's suspended prison
 3 sentence in 1998 for criminal negligence.
 4 **Q.** That is information you have gleaned subsequently, as
 5 I understand it?
 6 **A.** Yes. Of course, yes.
 7 **Q.** Your next position was at the Westminster Hospital
 8 from August of 1983 to November of 1984, where you
 9 were a registrar in haematology under
 10 Professor Barrett?
 11 **A.** Yes, that's right.
 12 **Q.** What did that work entail?
 13 **A.** Well, the interest of the Westminster Hospital was
 14 very much bone marrow transplantation, and indeed
 15 Professor Barrett, who is still active actually,
 16 clinically, I understand, is -- that was what the
 17 Westminster was known for. So it was a general
 18 haematology hospital as well but the main interest was
 19 the treatment of the malignant disease.
 20 **Q.** Westminster was or did operate as a haemophilia
 21 centre, and this was the first time, as I understand
 22 it from your statement, that you had any involvement
 23 with patients with bleeding disorders, but that
 24 involvement was limited to one patient; is that
 25 correct?

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1 **A.** Well, that's the only one that I remember. We have to
 2 remember that the Westminster Hospital was just
 3 across -- and by the way, the Westminster Hospital
 4 we're talking about just to clarify is not to be
 5 confused with the Chelsea and Westminster Hospital,
 6 which many people will know. The Westminster
 7 Hospital, which closed in 1992, was literally a few
 8 hundred yards from the Houses of Parliament and just
 9 north of Lambeth Bridge.
 10 That's important because literally ten minutes
 11 away was St Thomas' Hospital, which of course was
 12 a reference centre, with dedicated haemophilia
 13 treatment, experts and facilities.
 14 The Westminster Hospital didn't have any of
 15 that. So, you're right, it was technically classified
 16 as a haemophilia centre. I only recall one very --
 17 and I have to say -- inspirational patient, I very
 18 much enjoyed talking to him, who had haemophilia B,
 19 and he used to come in for periodic self-infusion.
 20 Like many adult patients at the time, he wouldn't
 21 trust a junior doctor with his veins, of course.
 22 Now, there may have been other patients, and I'm
 23 sure you are going to show me some treatment records
 24 from the UKHCDO database, but I only recall one
 25 patient with haemophilia B.

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1 **Q.** In fact, I am not going to show you any records
 2 relating to Westminster. Such records as we have do
 3 suggest a very small number of patients indeed.
 4 Can you recall, in relation to that one patient
 5 with whose treatment you were involved, what the
 6 product was or the treatment was that he was treated
 7 with?
 8 **A.** I'm afraid I can't remember offhand. I know that he
 9 died a couple of years ago, when he must have been in
 10 his 70s, perhaps even beyond that. But he was a very
 11 inspirational guy. And it's no exaggeration to say,
 12 I think, you know, he helped me develop an interest in
 13 haemophilia actually.
 14 **Q.** You attended the AGM of the UKHCDO in October 1983,
 15 and we'll just have a look --
 16 **A.** Yes, I mean, as background, I have to say it was
 17 a slightly extraordinary situation, because I must
 18 have been by far the most junior person there, and
 19 quite why -- I say this after a career as a boss in
 20 a haematology department myself -- someone who's been
 21 in the job for two months suddenly gets asked to go to
 22 a meeting, I really don't know and understand.
 23 I would guess Professor Barrett realised the meeting
 24 was potentially important at this time, received
 25 a letter with an agenda, and I happened to be the

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1 first doctor that walked past his door.
 2 Again, it was a decision that -- one of these
 3 fortuitous things in life that really lays the part
 4 out for future career paths, because, again,
 5 I developed an interest. But I was surprised to be
 6 sent.
 7 **Q.** We'll just have a quick look at it. As much as
 8 anything for the benefit of those who are following
 9 your evidence, doctor.
 10 It's PRSE0004440, please Soumik.
 11 We can see from this, this is the meeting on
 12 17 October 1983 chaired by Professor Bloom. And if we
 13 go down the list -- and there's a large list of
 14 attendees. If we just keep going down the page, we
 15 can see your name appears there representing the
 16 Westminster Hospital:
 17 "Dr PLF Giangrande, Westminster Hospital,
 18 London."
 19 **A.** Yes.
 20 **Q.** If we just go over the page, again, we can see a very
 21 long list of actual attendees.
 22 Then if we go to the third page, if we go
 23 towards the top of the page, please, Soumik, we can
 24 see there Dr Barrett, Westminster Hospital, has given
 25 his apologies and represented by you. So you were

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1 there in Professor Barrett's stead?

2 **A.** Yes, he was then -- they call him doctor, but he was

3 Professor Barrett.

4 **Q.** Can we go to page 10, please, Soumik.

5 You'll see here, Dr Giangrande, a reference

6 under "Any Other Business" to AIDS and an issue being

7 raised by Dr Chisholm, who was a director of the

8 haemophilia centre in Southampton, and a discussion

9 about reversion to cryoprecipitate. And then a view

10 expressed by Professor Bloom, a discussion ensuing,

11 and then at the end of the page an agreement being

12 recorded.

13 If we just go to the next page, you'll see,

14 under paragraph 10, "Current situation regarding

15 AIDS", a presentation of a paper by Dr Craske?

16 **A.** Yes.

17 **Q.** First of all, do you have any recollection of that

18 meeting?

19 **A.** I do, and in fact what I remember from that meeting,

20 and I have a striking visual memory of it, is indeed

21 Dr Scott giving details of the case of a patient that

22 had died -- the first death. It was a case that was

23 reported subsequently in The Lancet in November, and

24 I have to say that made a big impression. I can still

25 see him in front of me, to my left, two rows along,

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1 and I remember that presentation vividly. It was

2 a shock to me, to be honest.

3 **Q.** Dr Scott, again, for the benefit of those who are

4 following your evidence, was a Haemophilia Centre

5 Director in Bristol --

6 **A.** Bristol.

7 **Q.** -- and that was the patient who was the first

8 haemophiliac patient to die in the UK in August of

9 1983.

10 **A.** Yes.

11 **Q.** Your statement suggests, I think, that this was the

12 first time you knew of the association between blood

13 products and AIDS; is that correct?

14 **A.** Yes. Yes, this made a big impact on me.

15 **Q.** Do you recall anything of the discussion that we've

16 seen recorded in the minutes about cryoprecipitate and

17 Professor Bloom's views about there being no proof?

18 **A.** No, I'm afraid I don't recall anything about that

19 discussion. It wouldn't have meant much to me at all,

20 I'm afraid, at such a junior role.

21 **Q.** We can see that you then attended the AGM the

22 following year in 1984, and again we'll just put that

23 up on the screen. It's PRSE0003659.

24 **A.** Yes. While that's coming up, I mean, that was in

25 Cardiff, and I remember it well. One of the good

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1 things about that meeting was after this meeting in

2 Oxford, it was decided to have an educational day

3 before the annual general meeting, and so it was ideal

4 for someone like myself in training. And, indeed,

5 I remember Professor Mannucci actually attended this

6 meeting in Cardiff and gave a lecture during the

7 educational day.

8 But I attended the AGM on behalf of Westminster

9 in '84 and '85 and, I believe, '86 as well.

10 **Q.** Other than the educational day, I think we've also

11 heard it referred to as a scientific day --

12 **A.** Well, scientific.

13 **Q.** -- and the attendance of Professor Mannucci. Do you

14 have any other recollection of the discussions at that

15 meeting?

16 **A.** I'm afraid I don't.

17 **Q.** In terms of the work that you were still undertaking

18 in Westminster at that time, was AIDS an active issue

19 for the Haematology Department at Westminster?

20 **A.** Not particularly. Although, I do remember in '84 in

21 September that Cheingsong-Popov paper was published in

22 The Lancet in September. It was 1 September. And,

23 actually, one of the authors was then Dr Brian Gazzard

24 and, although he gives his affiliation as St Stephens

25 in that paper, which is part of the Westminster group,

15

1 he was a consultant gastroenterologist at Westminster

2 Hospital. So, clearly, it was -- you know, something

3 that was talked about, and we knew about it. So

4 I certainly remember that particular publication.

5 **Q.** Sticking with 1984, a little earlier in 1984, there's

6 an Armour document that refers to you, Dr Giangrande.

7 Could we, Soumik, please have ARMO0000148.

8 **A.** Yes.

9 **Q.** We can see this is a letter dated 29 May 1984 from

10 Armour Pharmaceutical Company. It's described as, in

11 terms of the subject, being "Heat-treated

12 factorate/CTX: additional investigators." And it's

13 addressed to -- can we just go up to the top of the

14 page again, Soumik -- we can see it's addressed to the

15 Medicines Division of the Department of Health and

16 Social Security. Then the letter says this:

17 "We wish to include the following additional

18 investigators on the above CTX ..."

19 And then there are three names listed. The

20 second is Dr Oscier at Bournemouth. A third is

21 Dr Winter from whom the Inquiry has already heard.

22 But the first name is yours, Dr Giangrande,

23 Westminster Hospital.

24 What, if anything, can you tell us about this

25 and any involvement in the investigation in relation

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1 to heat-treated Factor VIII?
 2 **A.** Thank you, by the way, for sharing this document with
 3 me some time ago. I regret that I can't remember any
 4 detail about it, but it's certainly an interesting
 5 document which I find very curious. Clearly, we must
 6 have had discussions in the hospital about putting the
 7 very few patients we must have had with haemophilia A
 8 on a heat-treated product. I note, by the way, that
 9 my name is misspelt in this document.

10 It's a CTX, and a CTX, of course, allows
 11 a company to carry out a clinical trial using an
 12 unlicensed product. What I find odd about it is the
 13 fact that my name is on there because normally a CTX
 14 is issued in the name of the consultant or the person
 15 in charge of the department. And it's a bit strange
 16 for a first-year registrar to be put as the named
 17 person on a list with much more distinguished and
 18 senior people, such a consultant like Mark Winter or,
 19 for that matter, Dr -- later Professor -- Oscier. So,
 20 clearly, it reflects that there must have been
 21 discussions in the department about using
 22 a heat-treated product before they were supplied by
 23 the NHS. But sadly, I really don't recall any
 24 discussions. Clearly, the UKHCDO database records
 25 will be able to tell you whether or not we used

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1 Factor VIII.

2 **Q.** So you have no recollection of actually being involved
 3 as an investigator in the use of the product?

4 **A.** I'm sorry to say I have no recollection. I say thank
 5 you for showing it to me so far in advance, but,
 6 despite that, I have no recollection of it.

7 **Q.** Now, in 1985, I think, you've already referred to your
 8 attendance at the AGM of UKHCDO in Oxford. By this
 9 time, your statement tells us, you were a lecturer and
 10 honorary senior registrar in haematology at
 11 Westminster and Charing Cross Medical School.

12 **A.** Yes. So what happened -- by the way, my position as
 13 lecturer was basically the same as a senior registrar,
 14 so it wasn't a purely academic *position*. My career
 15 was a little bit unusual because, in those days, most
 16 people moved to a different hospital to be a senior
 17 registrar and often undertook a period of research
 18 in-between being a registrar and senior registrar.
 19 I did the reverse. I did my research after I got my
 20 MRCPPath. Equally, I stayed within the same hospital
 21 group.

22 So when a position became available as senior
 23 registrar, I applied for that position in the
 24 knowledge that I wouldn't just be staying in the
 25 Westminster where I think I'd learnt enough about bone

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1 marrow transplantation, and I needed greater exposure
 2 to general haematology. And I knew that if I got that
 3 position, I would be moved to Charing Cross Hospital
 4 and a district general hospital for rotation, and a
 5 Blood Transfusion Service as well. So I went for the
 6 job, and I got it, and I moved virtually straight
 7 away, I think, to Charing Cross Hospital at the end of
 8 1984.

9 **Q.** And your statement says that you rotated between three
 10 hospitals: Charing Cross, Westminster and Roehampton.

11 **A.** That's right. And, indeed, in Roehampton, that's
 12 where she then was, Dr Christine Lee was, and I met
 13 her there, and she was doing a great job actually
 14 turning a -- what was basically a laboratory
 15 haematology service into a clinical haematology
 16 service, and I learnt a lot there. That's where
 17 I first got to know the now Professor Christine Lee.

18 **Q.** To what extent did your work during that period at any
 19 of those three hospitals involve the care of patients
 20 with bleeding disorders?

21 **A.** Well, it didn't include haemophilia specifically
 22 because Charing Cross, and certainly Queen Mary's
 23 Roehampton, they were not designated haemophilia
 24 centres. But it would be fair to say that my interest
 25 in coagulation as a field developed while I was at

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1 Charing Cross. And, you know, there'd be
 2 anticoagulant patients, investigation of clotting
 3 problems, but I wasn't specifically dealing with any
 4 patients with congenital bleeding disorders.

5 **Q.** You then, I think, took your MRCPPath qualification in
 6 1986?

7 **A.** I did, yes. In the summer -- I think about June of
 8 1986 I passed it.

9 **Q.** Then at the end of 1987, you moved to the Royal Free
 10 Hospital as a clinical research fellow under
 11 Dr Kernoff and remained in that post for two years.
 12 What can you tell us about that work?

13 **A.** Yes. Well, basically, after I got my MRCPPath -- the
 14 MRCPPath is a qualification which is regarded as an
 15 exit qualification, so with that you can then apply,
 16 technically, for consultant positions. I felt a bit
 17 young and inexperienced despite that, and more than
 18 that, I wanted to develop a research interest and
 19 indeed go on and get a research -- higher research
 20 degree.

21 The Royal Free Hospital was the place to go,
 22 certainly in London at the time, and Peter Kernoff
 23 himself, I think who is sadly missed, was a great
 24 leader in that field. So it's somewhere I wanted to
 25 go to, and so I wrote to him in, I think, July that

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1 year and asked in '87 whether I could possibly come
 2 and work in a research capacity there. He accepted me
 3 using their own research funds.
 4 **Q.** I'm going to ask you in a moment about involvement in
 5 a recombinant trial, but before we get to that, what
 6 was the primary focus of the research that you
 7 undertook at the Royal Free?
 8 **A.** It was related to immune function in people with
 9 haemophilia and addressing the question about whether
 10 treatment could influence the progression of HIV. So
 11 it was related to that important question of whether
 12 high purity products could affect the progression of
 13 HIV in people with haemophilia.
 14 **Q.** Was that work purely research and laboratory-based, or
 15 did you undertake clinical work in relation to
 16 patients for the purposes of the research?
 17 **A.** For that research, it was purely laboratory work. So
 18 I produced my own monoclonal antibodies, we did flow
 19 cytometry, we analysed blood samples, and I wasn't
 20 involved specifically with patients for that aspect.
 21 But as you rightly say, after I got to the Royal Free
 22 Hospital, Peter Kernoff took on a clinical trial
 23 involving recombinant Factor VIII. And he asked me to
 24 take charge of the care of two patients enrolled in
 25 that study, which was of the first brand of

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1 recombinant Factor VIII to be licensed in this
 2 country, which came to be known as Kogenate. So I
 3 looked after them, and actually that formed a chapter
 4 of my subsequent MDA thesis.
 5 **Q.** What practical clinical involvement did you then have
 6 with those patients?
 7 **A.** Well, I had to follow them closely. So, as with all
 8 clinical trials, there was a very strict protocol, and
 9 I had to arrange the follow-up, the blood tests, and
 10 arrange the treatment; the supplies. So it was
 11 important that we followed the menu, if you like,
 12 because that's what a protocol is. It's a very
 13 complex menu. Blood samples have to be taken on
 14 schedule. So I looked after them for that clinical
 15 trial period.
 16 **Q.** Did you, whilst you were at the Royal Free, have any
 17 involvement in the care and treatment of patients with
 18 HIV in relation to their HIV, other than in relation
 19 to the recombinant trial that you've described?
 20 **A.** Clearly, as with any, you know, research centre,
 21 I was -- although not looking after the patients,
 22 I was closely following and involved in all the
 23 clinical meetings about patients and listening to
 24 lectures. So, absolutely, I would have been involved,
 25 and as -- I know you've spoken to Professor Lee, and

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1 she's told you about the research she was doing, so of
 2 course I followed that closely.
 3 **Q.** We know from other evidence, documentary and indeed
 4 Professor Lee's evidence, that the Royal Free Hospital
 5 had stored sera samples; essentially, a bank of
 6 samples that had been built up over a number of years.
 7 Did your research or any aspect of it involve
 8 the use of stored samples?
 9 **A.** No, I don't believe it did because my work focused
 10 very much on looking at the cellular material. So, in
 11 other words, we were looking at the lymphocytes of
 12 patients, and the sort of stored samples which the
 13 Royal Free had would not have contained lymphocytes.
 14 So I can give a categorical "no" to that.
 15 **Q.** And then there's one document from your time there I'm
 16 going to invite you to look at. Soumik, it's
 17 BAYP0000016_011, please. If we can go to the second
 18 page, please.
 19 So we can see this is an internal Cutter
 20 document. It's dated 28 July 1989. The subject is
 21 "Trip report to the UK, 26 and 27 July 1989." Then it
 22 describes a visit to the Royal Free Hospital. And if
 23 we could go down the page, please, Soumik, we can see
 24 there it refers to a meeting with Dr Kernoff,
 25 Dr Giangrande and a sister, and it refers to concerns

23

1 Dr Kernoff was expressing about a patient's liver
 2 status. It goes on to say this:
 3 "In fact, this problem represents a true matter
 4 of conscience for him in an extend which may be
 5 considered surprising from a pure medical point of
 6 view, considering the medical past history of this
 7 patient. But perhaps understandable from his point of
 8 view is he's involved in several civil lawsuits
 9 investigating responsibilities for the contamination
 10 of haemophiliacs with HIV. This was a confidential
 11 remark made by Dr Giangrande after this meeting and
 12 previous one in May."
 13 Then the next paragraph refers to Dr Kernoff
 14 having consulted other hepatologists and:
 15 "... debated this question in detail with
 16 Professor Bloom, whose first reaction when he heard
 17 about the patient's problems for the first time had
 18 been to suspect Koate HS of being a possible HBV
 19 contaminant."
 20 And the discussion continues.
 21 Can I ask you, first of all, and without giving
 22 any details of the particular patient, for reasons you
 23 will understand, what was the issue here about -- that
 24 was giving rise to particular concern on Dr Kernoff's
 25 part?

1 A. Again, thank you for sharing the document with me some
2 time ago because originally I had no recollection.
3 But I did find reference to it in my thesis, and
4 that's exactly right.

5 So without giving details of the patient away,
6 what I can say is that before he embarked on
7 a clinical trial with recombinant Factor VIII, he had
8 separately in a separate clinical trial focusing on
9 Factor VIII kinetics -- that is looking at the level,
10 how it decreases over time -- been given a batch of
11 Koate HS. Please stop me if I'm giving any details
12 I should not be giving out about the patient.

13 A different batch of that product had
14 subsequently been reported as transmitting hepatitis B
15 to a patient in Japan. And this particular patient
16 that I was looking after developed quite marked
17 abnormalities of liver function tests about three
18 months after receiving the first dose of recombinant
19 Factor VIII. At the time, of course, there was no
20 test available for hepatitis C serology. We're
21 talking about the end of 1988, the very beginning of
22 '89.

23 So the concern was that this patient, who was
24 immuno-suppressed, might have been susceptible to get
25 hepatitis B, and the serological evidence for that was

25

1 that he was shown, as is underlined in the bottom
2 right of this document, to be anti-HBs negative. That
3 is the antibody that confers protection against
4 hepatitis B if it's infused.

5 So the issue was, has this person been infected
6 with hepatitis B or with the related agent, the delta
7 agent? Now, to cut a long story short, in retrospect,
8 I can tell you -- and, again, tell me if I am -- stop
9 me straight away if I'm saying things I shouldn't be
10 saying, but it was attributed to hepatitis C. And the
11 patient was known to be infected with hepatitis C at
12 the beginning of the trial of recombinant. It was not
13 really appreciated at the time that people with
14 hepatitis C can have fluctuating abnormal liver
15 function tests. And, to cut a long story short, this
16 patient had not been reinfected with hepatitis B. The
17 abnormal liver function tests were attributed to prior
18 hepatitis C infection, and this was just a flare up.

19 Having said that, the patient was withdrawn from
20 the clinical trial of recombinant Factor VIII and put
21 back on to his usual brand of Factor VIII which I've
22 forgotten what it is. I hope that answers your
23 question. It was a bit long.

24 Q. It does. Do you have any recollection of the remark
25 that you are recorded to have made about Dr Kernoff's

26

1 involvement --

2 A. I'm afraid I don't, but I would infer from what is
3 written that perhaps he was worried that there may be
4 potential medical legal consequences if the patient
5 had been infected with hepatitis B from a product
6 which had been prescribed by himself.

7 Q. Did you have any involvement with the HIV litigation
8 yourself?

9 A. Are you talking about in general, or are you talking
10 about in --

11 Q. First of all, in relation to the period of your
12 employment at the Royal Free.

13 A. No.

14 Q. More generally, did you have involvement in the HIV
15 litigation?

16 A. Not in the big -- you know, the action that was taken.
17 Clearly, there were one or two letters that I was
18 asked to comment on by my Trusts when I subsequently
19 moved to Oxford solicitors, but I wasn't involved
20 formally in any HIV litigation.

21 Q. Now, following the completion of your work at the
22 Royal Free you moved in January of 1990 to Milan where
23 you worked until March 1991, and you were working
24 there with Professor Mannucci, or under
25 Professor Mannucci.

27

1 What was the nature of your work there, and to
2 what extent was it research-based or clinical?

3 A. Before answering that question, just to set the scene,
4 I had been working for Dr Kernoff for two years, which
5 is what he had promised me, and we had not been
6 successful in finding a further source of income, in
7 terms of either we apply to both the Medical Research
8 Council and Action Research. And I needed time to
9 complete my thesis. That's what I was keen to do.
10 And so between us we came up with the idea of going to
11 work in Milan for two reasons.

12 Firstly, I speak Italian. My father was
13 Italian. Secondly, because the Milan Haemophilia
14 Centre was and still is one of the most important in
15 the world. So I went to Italy to do more research
16 work, and I was not registered with the Italian
17 General Medical Council equivalent. So I could have
18 been, but I did not. So my work was essentially
19 laboratory, working in two particular areas, but
20 obviously I was very closely engaged with the clinical
21 team there, and, indeed, two of them in particular
22 became life-long colleagues, and, indeed, I would call
23 them friends.

24 Q. What were the two main areas of research upon which
25 you were engaged?

28

1 A. Well, there were two areas. I started out doing some
2 work on platelets, but the area I got most involved in
3 was actually looking at the porcine Factor VIII,
4 actually, and a particular aspect of it, and that is:
5 porcine Factor VIII used to treat patients with
6 haemophilia A and inhibitors contains small amounts of
7 pig porcine von Willebrand factor, and the pig porcine
8 von Willebrand factor, in contrast to human
9 von Willebrand factor, is capable of directly
10 aggregating and glutenating human platelets.

11 I was involved in looking at that in some
12 detail, or what was the receptor it bound to. It was
13 slightly different from the binding site for human
14 von Willebrand factor (how could you block it, that
15 sort of thing) and it led to an abstract which
16 I presented in an Italian research meeting. It led to
17 a publication in 1992 as well as in the British
18 Journal of Haematology. And also, I was involved in
19 analysing some data on adverse reactions to porcine
20 Factor VIII which was published in, again, I think
21 1992.

22 Q. We've heard Professor Mannucci's name mentioned not
23 least in relation to DDAVP and his publication from
24 the second half of the 1970s. Do you recall any
25 particular work or discussions about the use of DDAVP?

29

1 A. DDAVP was clearly very widely used in Milan, and
2 I learnt a lot about it there. And, actually, it was
3 also used in other bleeding conditions, so in --
4 people with, say, renal failure, for instance, were
5 receiving it prior to renal biopsies; a practice
6 I introduced in my own hospital when I moved to Oxford
7 subsequently.

8 But, certainly, I learnt a lot about DDAVP. It
9 was quite widely used, and I became very much
10 a convert to the use of DDAVP in people with bleeding
11 disorders.

12 Q. There's one document, a somewhat curious letter from
13 Professor Mannucci, that I just want to ask you about.
14 Again, Dr Giangrande, you have seen it and addressed
15 it in your statement, but it's BPLL0005814_004.

16 This is a letter from Professor Mannucci to
17 Dr James Smith at the Plasma Fractionation Lab in
18 Oxford. We can see the date is 3 October 1990. And
19 he is referring to a discussion in Sheffield that he'd
20 had with Dr Smith and intention to treat patients with
21 severe von Willebrand's disease with 8Y concentrate.
22 And he says he needs:

23 "... as soon as possible approximately 50,000
24 units of the concentrate from the same batch."

25 Then he goes on to say this:

30

1 "As I told you in Sheffield, 'smuggling' is the
2 simplest way to avoid the emotional reactions of the
3 Customs when they see the word 'plasma'. Perhaps the
4 material could be fetched to Italy in two different
5 occasions to avoid bulky bags. One possible smuggler
6 is Dr Paul Giangrande who commutes to and from London
7 relatively frequently. The other is my associate,
8 Dr A Gringeri who will visit London on November 7-8
9 for a meeting in London. My proposal is that you ask
10 on my behalf Peter Kernoff to store the material in
11 his cold room and that Gringeri and/or Giangrande or
12 anybody else pick it up from the Royal Free at the
13 time of their visits to London. In this way, all the
14 material should hopefully reach us within Christmas.
15 I also realise I shall see you soon in Groningen.
16 Could we start the smuggling with an amount that is
17 feasible both for and for me?"

18 Did you see this letter at the time, or were you
19 aware of the request being made?

20 A. No, I wasn't. Again, thank you for giving me an
21 opportunity to see this letter some time ago. I have
22 subsequently supplied you with an email which
23 Professor Mannucci, with whom I stay in close
24 contact -- and he confirms what I said in my statement
25 that I was never asked to do this.

31

1 I think it's also important, just from a patient
2 perspective, to point out that the product we're
3 talking about is 8Y. It is common practice for people
4 with haemophilia going on holiday or abroad for work
5 to take product with them, and I would hate anyone
6 reading this correspondence to be left with the
7 impression that they may be committing an offence by
8 taking their product abroad.

9 But coming back to what you asked me, I was
10 never asked to take any Factor VIII from -- he never
11 asked me to do it, I can assure you of that.

12 Q. For the sake of completeness, I will also put on
13 screen Professor Mannucci's recent correspondence with
14 you on this issue. It's WITN3311011.

15 A. Thank you for showing Mannucci's reply.

16 Q. If we zoom closer, we can see it's October 2020. Am
17 I right to understand that you've contacted him
18 because as part of the process of asking you to make
19 a statement, the Inquiry had sent you the document
20 we've just looked at?

21 A. Yes. In fact, the date is somewhat later because you
22 sent me very kindly the document well in advance, but
23 he is now in his 80s, and I had difficulty tracking
24 down his up-to-date email address. That's why it's
25 only dated as recently as October 5. I had tried to

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1 contact him before that.

2 **Q.** It tells us in the second paragraph:

3 "I confirm I've never received from you or other

4 people any amount of 8Y, even though, of course, the

5 letter of request that I wrote is a fact indeed that

6 cannot be denied. I do not remember more details

7 about the matter. I may only grasp that at the time I

8 was interested in the comparison of various

9 plasma-derived VWF Factor VIII concentrates in the

10 correction of the laboratory abnormalities in patients

11 with type 3VWD, but I know for sure I never managed to

12 use 8Y for this purpose. It is very unfortunate that

13 I did use the word "smuggling". Yet, I am sure that

14 you grasp that in the Italian language, inverted

15 commas are often used to emphasise something, rather

16 than to cite literally actual words. In other words,

17 the term was used as a sort of joke without any

18 relationship on the literal significance of the word.

19 I'm sorry if I caused any trouble to you, but I

20 reiterate once again that you did never fetch any

21 plasma derivative from the UK to Milan when you were

22 with us."

23 **SIR BRIAN LANGSTAFF:** On the face of it, it looks as

24 though this proposal never came to pass, but it was

25 a proposal not for someone to take their own treatment

33

1 on holiday, but for product which was NHS product

2 given to a hospital for NHS patients to be taken to

3 treat other patients in Italy; Italian patients. That

4 was the proposal.

5 **MS RICHARDS:** Yes.

6 **SIR BRIAN LANGSTAFF:** I don't think it helps us in the

7 Inquiry one way or the other, but it's a curious

8 letter.

9 **MS RICHARDS:** Yes, and we don't, I think, know what, if

10 any, response Dr Smith made to it.

11 **SIR BRIAN LANGSTAFF:** It's a very strange -- on one level,

12 it's a very strange request for a clinician to make of

13 another.

14 Does it perhaps indicate that the relationships

15 between those people practising in the field of

16 haematology throughout the world may have become quite

17 familiar with time?

18 **A.** Is that a question for me, Sir Brian?

19 **SIR BRIAN LANGSTAFF:** It is, I think.

20 **A.** I'm sorry. I'm sorry, I didn't quite understand the

21 question. Would you --

22 **SIR BRIAN LANGSTAFF:** One has to ask why he would be

23 asking or expecting, at least on the basis of the

24 first letter, that others would take product from

25 their own health system in order to supply a fellow

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1 haematologist in another system.

2 **A.** I think he -- again, it's difficult for me to be

3 certain, but I think it's not entirely proven that he

4 is asking for product to be taken out of stock free of

5 charge from the Oxford Haemophilia Centre's own

6 personal stock.

7 We have to remember that Dr Smith was working

8 for the PFL, the Plasma Fractionation Laboratory.

9 They were actually making -- they were manufacturing

10 this product, and, indeed, Dr Smith was very much one

11 of the people involved in the development of 8Y. So

12 my interpretation is, he was basically asking for free

13 samples of a product directly from the producer of

14 that product, and, in other words, in order to

15 expedite delivery, to ask somebody who visited the UK

16 fairly frequently or was going over for a meeting

17 basically to exact a courier. That's how I understand

18 it. I don't believe he's asking for Oxford

19 Haemophilia Centre stock. It's very important to

20 distinguish, and I know we haven't talked about Oxford

21 yet, that at the time the Oxford Haemophilia Centre

22 was sharply divided. There was the clinical centre

23 and NHS unit, and there was a production and

24 development laboratory.

25 **SIR BRIAN LANGSTAFF:** So this is addressed to PFL and says

35

1 nothing about cost. He's looking for a free sample,

2 perhaps?

3 **A.** Yes --

4 **SIR BRIAN LANGSTAFF:** I take your point, and I am very

5 grateful that you made it. Thank you.

6 **MS RICHARDS:** Before we turn to your appointment in

7 Oxford, Dr Giangrande, can you just assist us with how

8 and when your knowledge of the risks of transmission

9 of hepatitis, and in particular non-A, non-B

10 hepatitis, how had that developed in the course of

11 your medical training and the various research and

12 clinical placements you've told us about?

13 **A.** Well, to begin at the beginning, when I was a medical

14 student, one of the medical students I was sharing

15 a house with developed overt hepatitis B with

16 jaundice, and that would have been about 1976. So,

17 clearly, you know, I did a lot of reading on the topic

18 at the time and was aware of the distinction between

19 hepatitis A and B, and I was aware at the time that

20 those did not account for all the cases of known

21 hepatitis.

22 When I was working in Manchester as a Senior

23 House Officer in that rotation where I met Dr Craske,

24 it was very much a laboratory-orientated work that

25 I was doing, and one of my roles was, indeed, to

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1 investigate reactions to blood transfusion. There was
 2 a form and lots of samples that had to be collected.
 3 So, you know, a common reason -- "common" is perhaps
 4 an exaggeration, but is a delayed blood transfusion
 5 reaction. So if somebody has a low level of antibody
 6 against one of the red cell antigens such as Kell or
 7 Duffy which hasn't been picked up before the
 8 transfusion, a few days later they will turn slightly
 9 pale yellow, and, you know, blood tests will be able
 10 to be done which shows that that is a problem.

11 Equally, I was well aware that people could
 12 develop hepatitis as well after blood transfusion.
 13 And there was a standard panel of tests that was done
 14 in any suspected blood transfusion like that, and that
 15 would include liver function tests.

16 Having said that, I'm sure that many cases of
 17 transfusion -- hepatitis after blood transfusion were
 18 not picked up simply because the incubation period
 19 meant that most patients had left hospital. And if
 20 they fell ill, people would say, "Oh, it's because
 21 they've had this big operation." And many of the
 22 patients, of course, with non-A, non-B infected by
 23 blood transfusion don't turn yellow and become overtly
 24 jaundiced. So I was certainly well aware of that.

25 I have followed in the transcripts and the

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1 evidence that has gone before me of all the work from
 2 the 1970s, and I must confess that I was not aware of
 3 that. In the era in which I first became exposed to
 4 haemophilia in the 1980s, actually that was the time,
 5 by chance I guess, when many of the publications about
 6 non-A, non-B in haemophilia showed that it was, you
 7 know, relatively benign.

8 I remember the publication in the British
 9 Journal of Haematology -- and by the way, it's
 10 incorrect in a previous transcript, I believe with
 11 Charles Hay, the Manchester publication of the British
 12 Journal of Haematology saying "Liver disease in
 13 [haemophilia]: an overstated problem?" was not 1981,
 14 it was December 1983. And I certainly remember
 15 reading that because I was back in practice, it was in
 16 the British Journal of Haematology, Dr Craske was one
 17 of the authors as well, of course, as the
 18 haematologist in Manchester that I knew.

19 So, to cut a long story short, I was well aware
 20 of the concept of non-A, non-B hepatitis by the time
 21 I graduated, but I did not, in my early haematology
 22 career, appreciate the potential gravity of it. And
 23 for me what transformed the picture was The Lancet
 24 publication from Charles Hay and Eric Preston in 1985.

25 Q. Now you took up your post in Oxford in April of 1991

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1 as consultant haematologist at the Oxford Haemophilia
 2 Centre.

3 A. Yes.

4 Q. Dr Rizza was still there and was the director.

5 A. Yes.

6 Q. You replaced Dr James Matthews?

7 A. Yes.

8 Q. When Dr Rizza retired in October of 1993, you then
 9 took over his role as director of the centre?

10 A. Yes.

11 Q. You were the sole consultant there until 1995 when you
 12 were joined by Dr David Keeling?

13 A. Yes, we had a locum that joined in between.

14 Q. You remained in post until your retirement in May of
 15 2015?

16 A. Yes.

17 Q. Now, please don't take this next question the wrong
 18 way, Dr Giangrande, but when you took up the post as
 19 consultant at what was then either the largest or one
 20 of the largest haemophilia centres in the country, is
 21 it fair to say that you had had comparatively little
 22 experience in the treatment and clinical management of
 23 patients with bleeding disorder?

24 A. Yes. And I think it's a very perceptive question you
 25 ask because, I'll be absolutely frank, when the

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1 position came up -- actually I first heard about it
 2 from Christine Lee. She phoned me up in Milan and
 3 said, "There is this position". She said, "Look,
 4 it's" -- because -- I'm going to answer your question
 5 in a moment, but just to set the scene.

6 If you had asked me what I was going to do, my
 7 career plan, I thought I would end up -- what I wanted
 8 was a teaching hospital position, to do general
 9 haematology. I'd kept my general haematology very
 10 active, I'd done a lot of locum positions, even while
 11 doing my research at the Royal Free and before, and
 12 I didn't see myself working exclusively in
 13 haemophilia. I thought I would be a haematologist in
 14 a teaching hospital with an interest in clotting.

15 But -- and you've asked a very perceptive
 16 question, and the important point to make is, I went
 17 for it not really expecting to get it, but
 18 a persistent problem around this time, and many others
 19 found it, is that people didn't want to go into
 20 haemophilia. They found it a rather, I guess, toxic
 21 field to go into. Recruitment into the field was
 22 simply not easy and papers have been written about
 23 that ever since actually.

24 Q. Would we correctly infer that the reason for that is
 25 the events of the 1980s that we have been examining?

40

1 A. There's absolutely no doubt about that. Publications
 2 have been written about it. I mean, it is -- as
 3 I say, when I applied for that job, and I wasn't the
 4 only person to apply, but it is astonishing that, for
 5 instance, there wasn't anybody, an internal
 6 candidate -- I mean, it commonly happened -- these job
 7 applications, of course, are put out but we all know
 8 often there are local favoured people. This is not
 9 something just particular to Oxford. Other hospitals
 10 around the country and other haematologists who are
 11 listening to me now will know exactly what I'm talking
 12 about, papers have been published, not just in the UK,
 13 the United States as well, it was a big problem
 14 getting people into haemophilia.

15 So you asked a very perceptive question. And
 16 I think that in many ways Dr Rizza wanted to stay
 17 on -- I mean, he was older when I started in Oxford
 18 than I was when I retired. And I think he felt he had
 19 to stay on, firstly, because I do genuinely believe --
 20 he was a very honourable man -- he wanted to sort out
 21 the final issue of hepatitis C, and also just to make
 22 sure that I was capable of flying solo, to put it that
 23 way.

24 Q. Now, I want to ask you a little about Oxford now. You
 25 told the Lindsay Tribunal in your evidence in 2001

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1 that Oxford, the Oxford Haemophilia Centre, had
 2 a wider responsibility than Oxford and Oxfordshire
 3 alone. It had responsibility for an area that
 4 encompassed Oxfordshire, Berkshire, Buckinghamshire,
 5 Gloucestershire and Northamptonshire; is that right?

6 A. That -- right, that was the original co -- then
 7 Wiltshire joined what became the consortium. Then we
 8 had quite a few patients that also came from beyond
 9 there. But those five counties were the core, very
 10 much, of our patients. We provided very much
 11 a regional service, not just Oxfordshire.

12 By the way, if I may say, it's interesting
 13 looking at the demographics of people with haemophilia
 14 around the country because, you know, Oxford as
 15 a county, and so does Northampton, has far more people
 16 with haemophilia than you would imagine. And it is
 17 true to say people actually moved house to be near the
 18 first haemophilia treatment centre.

19 Q. Could you give us a description of the facilities of
 20 the Oxford Haemophilia Centre in 1991 when you
 21 arrived.

22 A. It was a very different from the hospitals I'd worked
 23 in before. So the Royal Free and Milan haemophilia
 24 centres were part of very busy, bustling hospitals.
 25 The Churchill Hospital was part of the Oxford

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1 University Hospitals group, but the haemophilia centre
 2 was an isolated building at the periphery of the
 3 Churchill Hospital. It was just one floor, which was
 4 great for patients -- and they loved the easy parking
 5 incidentally as well. It was a -- purely
 6 a haemophilia service. For both adults and children,
 7 which was quite unusual.

8 The building at the time was divided into two.
 9 We had the clinical facilities, which were out-patient
 10 facilities only. So there were no beds in the
 11 haemophilia centre; we had a laboratory and we had
 12 three clinic rooms in which to see the patients.

13 We stored the Factor VIII there. So it was
 14 a base to see the out-patients and a base from which
 15 we sallied forth to treat patients in the other
 16 hospitals in the Oxford group. So that would include
 17 the orthopaedic hospital, the old Radcliffe Infirmary
 18 in the centre of town, and the John Radcliffe
 19 Hospital.

20 But the building was split in two, and the
 21 plasma fractionation laboratory occupied the other
 22 half. We were completely separate. I must have gone
 23 in that building probably only twice. We had to get
 24 changed to go in there. It was the original
 25 production facility that made Factor VIII and

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1 Factor IX used in -- and sent out to other cities as
 2 well.

3 By the time I got there, it was mainly involved
 4 in research and development. So they did make some
 5 products for clinical use. There was a Factor VII
 6 concentrate they made there, which was for use in
 7 a small number of patients, and that was used
 8 elsewhere in the country. But most of the work there
 9 was research and development.

10 It was quite a ramshackle old building, and
 11 after the plasma fractionation laboratory closed down
 12 in 1992, we got funds to refurbish -- in fact,
 13 demolish part of the old haemophilia centre, and after
 14 1993 we got some spanking brand new premises, which
 15 were much better. But it was an out-patient facility,
 16 purely for the treatment of haemophilia, adults and
 17 children, with its own laboratory.

18 Q. So, broadly speaking, what were the regular
 19 out-patient clinics that were held there? How often
 20 did they take place and how regularly, routinely,
 21 would you expect to see patients?

22 A. The typical patient with severe haemophilia would be
 23 invited for review every six months, and at the time
 24 we used to invite -- people could choose when to come.
 25 So there were no fixed clinics, as you would say.

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1 People came when they wanted to throughout the week.
 2 But the most important element of the work, as
 3 far as I'm concerned, was seeing the cases that needed
 4 to come in for treatment, because when I started there
 5 prophylaxis was not used. We did have home treatment.
 6 So the number of patients seen with bleeds was much
 7 higher than the current staff would experience now,
 8 for instance.

9 So it was a mix of -- I guess the important part
 10 of the work, there were three elements to it: it was
 11 the regular six-monthly reviews; it was going out to
 12 treat in-patients, mainly in the orthopaedic hospital
 13 but elsewhere; and then dealing with the urgent cases,
 14 and people could come whenever they wanted, we had
 15 open access.

16 Six months was the rule for adults and for
 17 children it was more frequently, typically about every
 18 three months. Then, in addition, and this had been
 19 a long-standing arrangement, and a very important one,
 20 there was a regular liver clinic with Dr Joan Trowell.
 21 That was always on a Tuesday morning. And so patients
 22 were followed-up by Joan Trowell. They would come for
 23 their follow-ups on the Tuesday so that we could do it
 24 at the same time. But that was the only other clinic
 25 which we held, at that time, in the haemophilia centre

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1 itself.

2 **Q.** How was the relationship with the other counties for
 3 whom Oxford had a responsibility? How was that
 4 managed? What, in practical terms, did responsibility
 5 for Buckinghamshire or Gloucestershire entail?

6 **A.** It worked extremely well. Firstly, let's look at it
 7 from a professional point of view and then I'll look
 8 at it from the financial point of view.

9 The way things worked then was we had a very
 10 good network of doctors, many of whom had trained in
 11 Oxford as senior -- not necessarily students but they
 12 had done senior registrar or other -- and then they
 13 moved to the region. And that helped foster long-term
 14 bonds.

15 We also had a regular what was called a blood
 16 club, and this would also help bond those professional
 17 links. So we would meet every, you know, six months
 18 or so to discuss cases and that sort of thing.

19 I have to say, in later years -- the way, well,
 20 the NHS develops -- those bonds were unfortunately
 21 ripped apart because the way the system developed,
 22 instead of letting those natural bonds develop, for
 23 instance, we were told that Northampton and Kettering
 24 should really develop links with Leicester because of
 25 the way the funding flowed, and similarly there was

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1 a pull from Gloucestershire towards Bristol. And
 2 equally we were expected to develop links with
 3 Southampton, which we hadn't previously got links
 4 with.

5 From a financial point of view, it worked
 6 extremely well, and we were very fortunate -- and
 7 I would like to pay tribute to the late Kendall Bird,
 8 who really helped us; he helped develop what was
 9 called the Oxford consortium. Because when fund
 10 holding became a reality in the NHS in 1993,
 11 individual GP practices were taking on a huge risk if
 12 they were looking after patients with haemophilia
 13 because the expenditure could go up and down in
 14 a shocking way for an individual patient. Therefore,
 15 the concept was formed of having a consortium pooling
 16 the risk, so that people funding haemophilia care in,
 17 say, the whole of Gloucestershire would know, very
 18 much on -- you know, they have a very good idea of
 19 what they were going to spend on haemophilia in
 20 a given year. So, from a financial point of view,
 21 developing the consortium allowed the sharing of risk
 22 and making sure that there wouldn't be unexpected
 23 calls for large sums of money for people with
 24 haemophilia.

25 So I have to say the relationship worked

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1 extremely well on both planes.

2 **Q.** Just going back to what you told us about the blood
 3 club, Dr Giangrande, as I understand it that's doctors
 4 meeting from not just from Oxford but from these other
 5 areas?

6 **A.** Absolutely. I'm sorry if I didn't make that clear.
 7 So what would happen is someone would host it in their
 8 hospital. So each centre -- each hospital, rather,
 9 would have an education building or something. So you
 10 would go to Milton Keynes and they'd put on a buffet
 11 there and we'd have our -- hear about cases. It was
 12 a social event as well as an academic event.

13 **Q.** Was that something which had, as far as you know,
 14 existed for a number of years when you arrived
 15 in 1991?

16 **A.** Oh, yes. That had been, yes.

17 **Q.** In terms of other staffing at the Oxford Haemophilia
 18 Centre, obviously Dr Rizza was still in charge when
 19 you arrived and until his retirement, what other staff
 20 were available to you at the centre?

21 **A.** Okay. So when I started the arrangement was that we
 22 had two junior doctors, they were called senior house
 23 officers, and they were actually very good. They
 24 worked -- they spent six months with us. So they were
 25 the junior doctors. It was a single -- their only job

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1 was a six-month job working in the haemophilia centre.
 2 Then we had three nurses, one of whom was the
 3 conventional unit nurse, if you like, dressed in
 4 a nurse's uniform, who ran a very tight ship and ran
 5 all the aspects of the internal workings of the
 6 haemophilia centre from a nursing perspective. And
 7 she also ran the home treatment programme. That is,
 8 she would box up products to be sent off to patients
 9 by courier because we did that from an early day.

10 We had then two other nurses who would do
 11 home visits. In fact, in those days, remarkably, we
 12 even had a unit car. There was some, you know, Crown
 13 allowances. So we had a car, and the nurses would do
 14 home visits.

15 Then of course we had our own laboratory. We
 16 had a manager. And then we had other people we had
 17 close links with. They weren't employees -- I'm sure
 18 we're going to come on to it but, for instance,
 19 a social worker funded specifically for HIV, but in
 20 terms of employees, the ones I would highlight would
 21 be the two junior doctors, the three nurses, who had
 22 differing roles, and the laboratory staff, as well as
 23 a manager of course.

24 **Q.** What was the position in relation to the social work
 25 support?

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1 **A.** We had a lady whose name I can tell you if you want
 2 it, but she was funded specifically by Oxfordshire
 3 County Council to deal with patients and support
 4 patients with HIV. She was in post when I arrived and
 5 had been there for some years and she remained with us
 6 until the late 1990s. After she left, that position
 7 was not filled again.

8 **Q.** When you say "dealing with patients with HIV", was
 9 that patients with HIV across the board, whatever the
 10 cause of the HIV, or just haemophilia patients?

11 **A.** Well, in practice -- that's a very good question, and
 12 I think the answer's going to be, in effect, it was
 13 just the people with haemophilia. Because one of the
 14 strange things about Oxford (and we'll talk about it
 15 later, I'm sure, when we come to talk about HIV among
 16 our patients) is that we had the luxury of being able
 17 to set up a dedicated clinic for patients with
 18 haemophilia and HIV, because the other at-risk
 19 categories didn't really feature high on the agenda,
 20 if you like, in terms of numbers within Oxford. The
 21 number of patients unfortunately exposed to HIV with
 22 haemophilia was much higher than other risk groups.
 23 So, to my knowledge, at that time, this particular
 24 social worker really devoted her time to people with
 25 haemophilia.

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1 **Q.** In terms of psychological support, there was no
 2 psychologist or specialist counsellor attached to the
 3 centre?

4 **A.** That's correct. There was a doctor (I never met him),
 5 a Dr Catalan, who had done a number of MRC-funded
 6 research projects which led to publications, but he
 7 had left Oxford by the time I left.

8 I did try on two occasions to explore avenues of
 9 getting psychologists involved. The problem was -- in
 10 fact, I met up with, as I say, two psychiatrists. The
 11 problem was that they had very specific provision of
 12 psychological services. So, for instance, near us
 13 there was a unit that dealt with children, the
 14 assessment of children with developmental problems, or
 15 there would be a clinical psychologist to look after
 16 people with addiction problems, for instance. But,
 17 unfortunately, I was never able to secure specific
 18 psychological input for our patients.

19 And even the psychiatrists, when I approached
 20 them -- you know, sometimes some of our patients,
 21 quite unrelated to haemophilia, had, you know, overt
 22 psychiatric problems, and they were helpful there but
 23 not for the general cases.

24 But I would have to say that our nurses were
 25 really brilliant and rose to the challenge, and it's

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1 very important to emphasise that our nurses (and one
 2 of them in particular, who was a trained
 3 psychotherapist) provided fantastic support for our
 4 patients, and I believe any of my former patients
 5 watching now -- I hope they would agree with me. They
 6 went beyond the usual role of nurses. They became
 7 close friends and confidantes of many of the patients.

8 **Q.** What, if any, discussions did you have with Dr Rizza
 9 about the position of the cohort of patients, the
 10 large cohort of patients, who had been infected with
 11 HIV as a result of their treatment at Oxford? Was
 12 there any discussion with Dr Rizza about those events
 13 and those years?

14 **A.** Not really, if I'm honest. It was -- no, it's not
 15 something that he and I discussed in any detail. I --
 16 no.

17 **Q.** Sorry, carry on.

18 **A.** I was going to say, you know, one of the things I did
 19 when I went to Oxford is I did feel that we could do
 20 more for the patients with HIV in terms of setting up
 21 a clinical follow-up. I mean, in hepatology that had
 22 certainly been -- a dedicated service had been set up
 23 some years before. Actually, not just some years, it
 24 had been a long stint because Dr Trowell, who was
 25 deeply embedded in the haemophilia world, knew a lot

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1 about haemophilia, knew all the patients well.
 2 But with HIV, I rather felt that the -- there
 3 was no formal link with the infectious diseases team,
 4 which actually was based right next door to us. So
 5 one of the first things I did when I started in Oxford
 6 was to set up a dedicated follow-up clinic. Initially
 7 that was with Dr Peto or through Dr Peto. In reality,
 8 the clinics were run by a senior registrar called
 9 Dr Luzzi -- that's L-U-Z-Z-I -- and then
 10 Dr Chris Conlon was appointed, I think, in about 1995.

11 But what we did was to hold these clinics on
 12 a Wednesday morning and I would sit in with Dr Luzzi
 13 or Dr Conlon, and we would see the patients together.
 14 But I did not really discuss the events of the early
 15 1980s with Dr Rizza. It's not something he did with
 16 me.

17 **MS RICHARDS:** Sir, I note the time. I am going to look at
 18 some of Dr Giangrande's evidence to the
 19 Lindsay Tribunal with him next, so this might be
 20 a convenient point at which to take the morning break.

21 **SIR BRIAN LANGSTAFF:** Yes, indeed.

22 So we'll take a mid-morning break. I'm sure you
 23 can probably do with one but certainly there will be
 24 those who are watching who would appreciate a break.
 25 It's normally half-an-hour, so we will come back, if

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1 we can please, at 11.45. So 11.45.

2 **MS RICHARDS:** Sir, could you give Dr Giangrande the normal
 3 warning.

4 **SIR BRIAN LANGSTAFF:** Yes.

5 I tell everyone at this stage -- you may have
 6 heard me do it if you have been watching at all
 7 online -- you are in the middle of evidence, what you
 8 must not do is discuss anything that you have said in
 9 evidence or anything you think you may yet be asked to
 10 say in evidence with anyone, whoever they are, but you
 11 can talk about anything else you like. I'll see you
 12 at 11.45. That, by the way, applies at every break.

13 (11.14 am)

(A short break)

15 (11.45 am)

16 **MS RICHARDS:** Dr Giangrande, I'm going to ask you to look,
 17 first of all, at a passage in your statement with me.

18 Soumik, it's WITN3311003. If we could go to
 19 page 85. No, that's ... page 85? I'm so sorry, try
 20 page 35, Soumik. My apologies.

21 **SIR BRIAN LANGSTAFF:** What's the paragraph number?

22 **MS RICHARDS:** It's paragraph 83.

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

24 **MS RICHARDS:** If we go to the next page, please, Soumik --
 25 sorry I have an unpaginated copy. That's it, thank

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1 you. If we go to the bottom half of the page, please.
 2 Dr Giangrande, you will see you were asked about
 3 how the care and treatment of patients with HIV and
 4 AIDS was managed at the Westminster Hospital and the
 5 Oxford Centre, and in 83.1 you have said in relation
 6 to the Westminster Hospital you have no information.
 7 Is this correct, that you were not involved in the
 8 care of any patients with HIV or AIDS at Westminster?

9 **A.** Absolutely right. That's correct.

10 **Q.** Then, in relation to Oxford, you say:

11 "Patients ... would have been referred for
 12 specialist advice and follow up ..."

13 We'll come back to hepatology and hepatitis
 14 separately.

15 Follow up to an infectious diseases expert.

16 And then you were asked about what treatment
 17 options were offered over the years to those infected
 18 with HIV, and you said the care would have been
 19 provided by the infectious diseases team.

20 Then if we go to the top of the next page, you
 21 were asked what information was provided about risks
 22 and benefits of specific treatments and side effects,
 23 and you said that these treatments were only provided
 24 by the infectious diseases team. And the same answer
 25 in relation to follow-up and ongoing monitoring.

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1 Now, Dr Giangrande, would you accept those
 2 answers give the impression that you didn't have any
 3 involvement yourself with the care and treatment of
 4 the patients with HIV at Oxford?

5 **A.** I'm sorry if that's the impression that's given.
 6 Indeed, I thought I had made clear in the earlier
 7 session, before coffee, that I indeed set up the
 8 collaboration between the infectious diseases team and
 9 the haemophilia centre, and we were, of course,
 10 neighbours. So I'm sorry if that's the impression
 11 that's been given.

12 What I'm trying to say is, although I was
 13 closely involved, and indeed attended joint clinics at
 14 least for the first few years that the system -- that
 15 the combined clinics operated, the decisions about
 16 treatment were very much in the hands of the
 17 infectious diseases team. And indeed, I'd go as far
 18 as to say -- I can remember one or two occasions,
 19 actually, when we've tried to, you know, modify things
 20 that the infectious diseases team has -- had -- when
 21 they were not happy.

22 So let's be clear, I was involved in the
 23 follow-up, having set it up, but the decisions about
 24 treatment, in other words, was I involved in any
 25 decisions about which anti-retroviral agent to use,

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1 clinical trials to participate in, did a patient need
 2 admission and certain treatment, that was not my link.
 3 We've got to be clear about that. That was not my
 4 role. That was the prime role of the infectious
 5 diseases team, who were right next door to us, and
 6 with whom we had very good and close collaboration.
 7 I hope that's clarified that?
 8 **MS RICHARDS:** I just want to look at --
 9 **SIR BRIAN LANGSTAFF:** Just pause for a moment.
 10 We are asking about the top of the page, are we?
 11 "c. What information was provided to patients
 12 about the risks and benefits ..."
 13 **A.** Yes. So --
 14 **SIR BRIAN LANGSTAFF:** You were present at the
 15 consultations, as I understand it, when you first
 16 started, because you set up the joint consultations?
 17 **A.** Yes, I would have been involved in those
 18 consultations. Yes, that's certainly true.
 19 **SIR BRIAN LANGSTAFF:** So you would have heard the
 20 information that was provided then to those patients.
 21 **A.** Yes. I'm sorry if I --
 22 **SIR BRIAN LANGSTAFF:** And that -- insofar as information
 23 was given to the patient about risks and benefits of
 24 treatment, that isn't a treatment decision because the
 25 treatment decision presumably is reached jointly by

1 patient and doctor. The patient is a participant.
 2 **A.** I see your point and I fully accept your point.
 3 **SIR BRIAN LANGSTAFF:** Was there a reason why you said you
 4 weren't able to answer that question?
 5 **A.** I think what I was -- in other words, I was certainly
 6 involved in the clinics at the very early stage. So,
 7 in other words, I set the clinics up as soon as
 8 I arrived in Oxford in around -- sorry, in April '91.
 9 And then I remained running the combined clinics with
 10 the infectious diseases people until, if I had to
 11 guess, probably '95, that sort of period.
 12 At that stage, the combined clinics, I was not
 13 attending them, for the simple reason that then the
 14 patients with haemophilia were -- there were patients
 15 with other HIV -- you know, triggered by other things,
 16 and therefore I did not attend the clinics, because
 17 the patients with haemophilia only formed a minority.
 18 So I guess what I'm trying to say is, looking
 19 back at a period, you know, lasting until 2015, it's
 20 true to say I was in the clinics in the very early
 21 years but when the more complicated treatments became
 22 available (for instance HAART, which became available
 23 in around '96, going from memory) I was not involved
 24 in that stage. But I quite accept that at the
 25 beginning I was present and I would have discussed

1 some of the then basic and initial treatments for HIV.
 2 But I was not for most of the time that I was working
 3 in Oxford. Most of the time the patients were
 4 followed up just by the infectious diseases team.
 5 **SIR BRIAN LANGSTAFF:** Thank you.
 6 **MS RICHARDS:** I just want to look at one document. It's
 7 from patient records but I'm not going to be asking
 8 you about the specific patient, it's just to see how,
 9 in practice, the clinics operated.
 10 Could we have JEVA0000013, please, Soumik.
 11 So it's slightly faint. We can see it's
 12 a letter from you, May 1991, so not long after you had
 13 arrived in Oxford, about a particular patient. And if
 14 we go further down the page, second main paragraph, it
 15 says:
 16 "We have taken the opportunity to review this
 17 patient's general condition."
 18 **SIR BRIAN LANGSTAFF:** Could I just raise -- the name of
 19 the patient appears to be there.
 20 **MS RICHARDS:** Yes, that's with the consent of the
 21 patient's relative.
 22 **SIR BRIAN LANGSTAFF:** Thank you.
 23 **MS RICHARDS:** It's not intended to be anonymous. But I am
 24 not going to ask you about the specific care of the
 25 individual.

1 So we can see that in the main paragraph, second
 2 main paragraph, there's a reference to reviewing the
 3 condition -- to CD4 counts. And then a decision:
 4 "We have decided to start treatment with co" --
 5 That is Septrin, isn't it, I think we can see
 6 there?
 7 **A.** It is, yes.
 8 **Q.** It's said it will be permanent treatment.
 9 Then if we go on to the second page, so this is
 10 picking up in 1993, so this is approximately two years
 11 later, and this is a letter to Dr Conlon -- so this is
 12 now the infectious disease specialist, is it?
 13 **A.** Yes.
 14 **Q.** Then we can see reference to a combined clinic,
 15 reference to the full blood count, a decrease in white
 16 cell count likely to be due to the Septrin therapy and
 17 a suggestion that the patient stop taking Septrin.
 18 So I don't know whether those documents assist
 19 generally in trying to give a clearer indication of
 20 the timeline here. In May of 1991, the first document
 21 we looked at, there's no reference there to a joint
 22 clinic, and it looks like the letter you're writing is
 23 to the GP. So is it fair to infer that -- it's only
 24 a month or so after you have arrived -- there was at
 25 that point no joint clinic?

1 **A.** I think that is probably the case, but equally, again,
 2 it's very difficult for me to see these and give
 3 a definitive answer in the absence of seeing any
 4 clinical notes. But I think looking at the previous
 5 letter, how I would respond is to say that an
 6 agreement had already been reached on a general
 7 principle of treatment, and that is, as prophylaxis
 8 against pneumocystis pneumonia, it was general
 9 practice to start the treatment with Septrin once the
 10 CD4 count had fallen below 0.2 times 10 to the 9 per
 11 litre.

12 That would have been, like, general advice from
 13 the infectious diseases team, and I would make that
 14 decision without having to consult, specifically, an
 15 infectious diseases colleague about that. That's
 16 a general decision -- a policy that's been made.

17 As you rightly point out, that letter was
 18 written -- that will have been the first time that
 19 I had met Mr Evans, whom I remember very well, and his
 20 wife actually. It would have been the first time
 21 I had seen him. And what the letter shows is that he
 22 had come in, I think, to -- he was on an orthopaedic
 23 ward, for whatever reason, and I had picked up and
 24 acted on the fact that the CD4 count was low.
 25 Presumably the last count had been done probably

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1 six months before then, because that was the fairly
 2 standard thing. We therefore started the treatment at
 3 an early opportunity.

4 Chris Conlon was indeed the consultant that was
 5 taken on -- I hadn't realised it was as early as 1993,
 6 actually, but anyway, he took over the running of the
 7 combined clinics from Dr Luzzi. And, looking at this,
 8 I can see that we'd obviously recently reviewed him on
 9 our combined clinic. I had received the full blood
 10 count and, indeed, the white count is low, and we had
 11 attributed this to the Septrin, which is a known side
 12 effect of the drug, and clearly he was going to be
 13 reviewed in our next combined clinic, and if
 14 Chris Conlon wanted to make any alternative
 15 suggestions for treatment in the meantime, this was
 16 giving him an opportunity to let me know about
 17 alternative therapies he may wish to offer.

18 **Q.** So we can infer, I think, from this that between
 19 May 1991 and July 1993 the joint clinics were set up?
 20 **A.** Yes, I can't -- it was -- it started fairly soon, that
 21 I can say, but I can't remember when -- certainly they
 22 will have been set up sometime in 1991.

23 **Q.** Was Septrin, as a treatment, already in use in Oxford
 24 by the time you arrived?
 25 **A.** I think it was because the previous treatment, which

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1 I had come across -- I think they had at the
 2 Royal Free at the time -- was inhaled -- pentamidine
 3 was used, by inhalation, as a preventative measure,
 4 but Septrin had become a standard therapy. So I think
 5 the answer to that must be yes.

6 **Q.** And the reference to the "combined clinic" in this
 7 letter is to the joint clinics with Dr Conlon and, as
 8 I understand your earlier answers, you think that
 9 those -- the joint clinics came to an end sometime in
 10 the mid-1990s?
 11 **A.** Yes. And I say -- why they came to -- it's a bit like
 12 our orthopaedic clinic, actually, but that's
 13 a separate story, where -- but as regards the HIV
 14 clinic, what happened was the people seen in the
 15 clinic that I set up originally were exclusively
 16 people with haemophilia. And in contrast to other
 17 cities, certainly London, people from other risk
 18 categories were never seen in this combined clinic.
 19 There wasn't the demand. There was a genito-urinary
 20 department down at the Radcliffe Infirmary that saw
 21 a few patients, but the decision was then taken to
 22 unify everything up on the Churchill site. And that
 23 was certainly, I would guess -- certainly by '96,
 24 probably 1995. This was when the more complex
 25 therapies came into being.

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1 So just to clarify, those were the decisions
 2 that I was not involved in. I was in on the combined
 3 clinics in the relatively early days. And I think,
 4 having set it up, you know, it worked very well under
 5 the auspices of the infectious diseases team alone.

6 **Q.** So just in terms of how patients would receive their
 7 care once the joint clinics had ceased to operate,
 8 whenever precisely that was, a patient would then have
 9 an appointment with the haemophilia centre, at least
 10 if they were a severe patient requiring their regular
 11 out-patient reviews, but would have a separate
 12 appointment with the infectious diseases unit that
 13 would be managed by the infectious diseases unit, is
 14 that correct?
 15 **A.** It is correct, but I want to expand on that and to say
 16 there was extremely close collaboration between the
 17 two. I emphasise they were neighbours of ours and we
 18 had very good working links with them. So it's not
 19 that we corresponded simply by letter as one might
 20 infer from these two letters you are showing here. We
 21 had regular meetings between the two teams to discuss
 22 the patients. And, furthermore, there was the social
 23 worker that I told you who stayed until the end of the
 24 1990s, she was much a link between the two.
 25 What we tried to do, just as happened for the

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1 hepatology clinics, is if a patient came to see the
 2 infectious diseases team, we would try to set up the
 3 follow-up, if it was needed, in the haemophilia centre
 4 right next door, and then we would actually take all
 5 the bloods. So what would happen is they would come
 6 to us from John Warin Ward and they'd have filled-in
 7 forms, we would do the follow-up and the bloods would
 8 be taken. But it's important to emphasise there was
 9 very good collaboration between the two departments.
 10 We discussed the patients at regular meetings. So we
 11 both knew what was going on.

12 **Q.** I want to move next to hepatitis C testing at the
 13 haemophilia centre, and I'm going to ask for your
 14 statement to go back on screen because I think there's
 15 one part of your statement you want to correct.

16 **A.** Yes.

17 **Q.** So could we have WITN3311003.

18 Could we go, please, Soumik -- it's probably
 19 page 30 or thereabouts, paragraph 68. Go on one more
 20 page.

21 Am I right in understanding it's paragraph 68
 22 that you want to correct?

23 **A.** Oh, that was the one that was -- that is the one
 24 that's been corrected. But the two I highlighted when
 25 we had our previous exchange were paragraphs 73.1

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1 and 77.1, and this was entirely an error of mine in
 2 copying and pasting, I'm afraid, which I noted only
 3 after this had gone in.

4 **Q.** Sorry, I'll just stop you there, Dr Giangrande, just
 5 so we can follow. We'll go on to the relevant
 6 paragraph.

7 If you can go on two pages, please, Soumik. So
 8 we've got 73.1.

9 **A.** Okay. So the mistake is there in line 3, and I had
 10 done that -- I had inadvertently -- it clashes with
 11 what was said before. I said -- HIV, obviously, by
 12 the time I have arrived, people had been informed of
 13 the diagnosis as well as being tested. The incorrect
 14 statement is in line 3, where I said that patients
 15 "infected with HCV had been informed of the
 16 diagnosis"; that is not correct. The same error
 17 appears, because it was cut and pasted, in 77. So
 18 people had been tested but they had not been informed
 19 of the diagnosis.

20 **Q.** We'll look in a moment at your evidence to the
 21 Lindsay Tribunal, which obviously was given closer in
 22 time to the events than now, but before we do that,
 23 what can you recall about the arrangements for the
 24 testing of patients for hepatitis C in Oxford from
 25 your arrival in April 1991 onwards?

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1 **A.** Okay. Again, I must preface this by saying clearly
 2 I have no reference to notes now and I've not seen any
 3 statements that have been produced that may have been
 4 produced by, for instance, Dr Rizza or Dr Trowell, so
 5 I'm going to from memory.

6 I think it's fair to say when I arrived from
 7 Milan, all the patients in Milan had been tested and
 8 informed of their diagnosis. In fact,
 9 Professor Mannucci published the results of the Milan
 10 cohort in the Annals of Internal Medicine on
 11 1 March 1990, and he found that 82 per cent of the
 12 236 patients had tested positive for HCV.

13 Furthermore, the Italian Blood Transfusion Service had
 14 introduced screening of blood donors sometime in 1990.

15 When I came to Oxford in 1991, I was aware
 16 that -- and after an absence of, professionally,
 17 15 months in the UK, I was a little bit surprised to
 18 see that screening of blood donors had not started
 19 here.

20 I was aware that patients at the Oxford
 21 Haemophilia Centre had been tested for HCV because
 22 I could see in the back of the clinical notes there
 23 were flow charts -- this was the day before
 24 computerised records -- and I took over from
 25 Dr Matthews the role of completing those flow charts,

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1 so I saw that patients had been tested before
 2 I arrived. I note in the Lindsay Tribunal I stated
 3 a start date of October of 1990. That's what I said
 4 then and I don't know -- you know, I can't add to
 5 that.

6 My belief is that that was done -- I say this
 7 now, in retrospect -- I think on tested samples.
 8 I did follow the presentation you gave on October 9
 9 about the Oxford Haemophilia Centre, and I have to say
 10 I was surprised at the number of patients that appear
 11 to have been tested. If you had asked me to guess
 12 beforehand, I would have thought it was less than that
 13 but it seems, from the presentation you gave, that
 14 around 400 patients were tested.

15 Now, my recollection is that patients were not
 16 informed of the diagnosis then. I believe there were
 17 two issues. The first is that the Blood Transfusion
 18 Service and, therefore, presumably, the virologists
 19 were wanting to set up the second generation assays,
 20 which were undoubtedly more reliable.

21 The second issue was also -- I think Dr Rizza
 22 was not clear about what the implications of
 23 a positive result were. So what I remember is that
 24 the patients started to be tested again (using,
 25 I believe, fresh samples) some months after I arrived

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1 in Oxford, and I would see results come back saying
2 "HCV study". Informing patients of those results
3 began in probably the second half of 1991.

4 There was also another important component to
5 this, and that is, very specifically, a study of the
6 risk of sexual transmission of hepatitis C. And for
7 this a study was set up analysing 104 men with --
8 actually not all men, I think there were one or two
9 women with von Willebrand's disease, but 104 patients
10 with bleeding disorders, the vast majority of whom
11 were people with haemophilia, and their partners,
12 their long-term partners.

13 The results of that study were published in
14 1993, well into 1993. Now I was not involved in that
15 study, I was not involved in any discussions relating
16 to that study either, and absolutely appropriately,
17 therefore, I was not included as a co-author. The
18 named co-authors from the Oxford Haemophilia Centre
19 were Charles Rizza, Mary Fletcher, and then there was
20 another nurse who was acknowledged as having helped
21 collect the blood samples.

22 Now the point about that is -- and it will
23 relate to the question of, you know, consent -- were
24 patients -- I have always -- or, I had always assumed
25 that consent had been forthcoming, particularly for

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1 have definitely got chronic infection. In fact,
2 Dr Rizza was more cautious, and I think he was proved
3 right, in that the PCR results showed that the
4 majority but not all people with HCV antibody positive
5 results were chronically infected.

6 Of course, the second major contribution of that
7 study was it showed the risk of sexual transmission to
8 long-term partners was low.

9 Again, if I may just carry on, I think that the
10 majority of the patients were informed of their
11 results by the end of 1993. One of the things I did
12 after Dr Rizza announced his retirement -- he gave me
13 about three months' notice, so he just said, "Paul,
14 I'll be going" -- is I introduced a checklist for
15 hepatitis C, because many of the patients had been
16 told their results by, you know, other people. So
17 either Dr Rizza, who I think, because he was a long
18 association with the patients, wanted to tell people,
19 and certainly Dr Trowell was involved.

20 So I, faced with the prospect of taking over
21 this cohort, large cohort of infected patients,
22 devised a checklist. And the checklist went in the
23 notes, and it was a record for us all, and the
24 checklist was as follows. It said: name of the
25 patient, date, and then it would say what -- I've

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1 the study of sexual transmission, because I made the
2 assumption, which I don't think was unreasonable, that
3 to carry out a survey of 104 people, I mean -- and
4 their partners, how do you tell them, "Next time you
5 come to the clinic, bring your wife", or go to their
6 home to take a blood sample -- I mean, if my wife
7 accompanied me to a hospital appointment and someone
8 said, "Oh, could you please -- could we have a blood
9 sample from you?", I can tell you she would not just
10 proffer her arm and ask for blood to be taken.

11 So, just continuing the story, so I know, having
12 reviewed that paper again recently, that although it
13 was published in 1993, it was accepted in November.
14 So if we go back from then, probably the blood
15 collection stopped, was complete, by the summer
16 of '92. And we know from the paper that most of the
17 bloods were taken in 1991 and 1992. It says that very
18 clearly.

19 That study was helpful in two ways, because it
20 included PCR results and it provided evidence that not
21 everybody with a positive anti-HCV result had, indeed,
22 got chronic infection. I contrast that with the Milan
23 situation because I remember well from discussions
24 there -- and Mannucci implies it very strongly in his
25 1990 article -- that a positive HCV result means you

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1 discussed the following with the patient, the current
2 HCV results, current liver function tests, follow-up
3 arrangements, the synergistic effect of alcohol (in
4 other words, cut down on alcohol), risk of sexual
5 transmission and the treatment options.

6 Then at the bottom it said patient was or was
7 not aware of this result.

8 Now I know that quite a few of the patients that
9 I saw towards the end of 1993 had still not -- well,
10 apparently -- they told me they had not got their
11 result. But I think the vast majority had been told
12 their results by the end of 1993. I know it's a very
13 long story but I think I will have to revisit the
14 question of consent, because I had assumed that
15 consent had been forthcoming. But I am not going to
16 contradict anyone. And I have read the witness
17 statements not only of Oxford patients, whom I am
18 pleased to say are few in number, on the IBI website,
19 but others as well, and I'm by no means confident that
20 consent was obtained in all cases.

21 I'm sorry, it's a very long answer.

22 **Q.** That's fine, Dr Giangrande. Can I just break it down
23 to check I've correctly understood.

24 So your understanding is that by the time you
25 arrived in April 1991, there had been testing of

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1 patients for hepatitis C but it had been done on the
 2 basis you think of stored samples?
 3 **A.** I have no doubt about that. That's my clear
 4 impression. And that would be the first generation
 5 assay.
 6 **Q.** Then in the period of time that followed from your
 7 arrival to around the end of 1993, there was a second
 8 round of testing. Would it have been a first round
 9 for some patients, do you think?
 10 **A.** Well, as I say, it was very helpful for me to read the
 11 transcript and indeed some of the letters that you had
 12 included in the presentation on the Oxford Haemophilia
 13 Centre because those are letters, as I'm sure you saw,
 14 I was not copied in to, and I was not present at some
 15 of the meetings that clearly took place with the
 16 virologists.
 17 But it was a large number of patients. I was
 18 surprised at the number. I've got it written down.
 19 It was about 400 patients who had been tested. So
 20 mainly haemophilia and a small number with
 21 von Willebrand's disease. So I think people were
 22 retested or tested for the first time on fresh
 23 samples. And not all of those -- I mean, the PCR
 24 testing really came in towards the bottom end of
 25 the -- I think probably 1992 I began to see results of

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1 that.
 2 **Q.** In relation to the testing on fresh samples, what is
 3 your best understanding of the information that was
 4 given to patients about the purpose for taking the
 5 samples?
 6 **A.** Well, that is where I now have my doubts because very
 7 clearly there was a formal HCV study. I saw that on
 8 the results that came back, and I had seen it in notes
 9 as well. So one of the nurses that would go out, they
 10 put HCV study, and there was nothing about -- you
 11 know, more detailed than that.
 12 As I say, I had assumed that consent was sought,
 13 and I've explained that I thought it would be
 14 difficult, particularly when partners are involved, to
 15 take samples. But I must be honest and say I have my
 16 doubts about that now. But without actual notes, it's
 17 difficult to say.
 18 **Q.** If the purpose of taking the samples was explained to
 19 a patient and consent sought, would that have been --
 20 and I'm talking now the period '91 through to --
 21 onwards, so when you are there. Would that have been
 22 done by a nurse or by a doctor, typically?
 23 **A.** The vast majority of cases, undoubtedly the nurse.
 24 And, indeed, the nurses -- because there were a lot of
 25 patients to get through, as I told you, they went out

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1 to people's homes as well. But, you know, the nurses
 2 had the role of collecting the blood samples. I'm not
 3 saying doctors didn't collect blood samples on people
 4 that turned up to clinic, but my clear recollection
 5 and impression is that the nurses were responsible for
 6 collecting the blood samples.
 7 **Q.** Do you recall any discussions you had with patients
 8 during this period in which you told patients you were
 9 going to be testing them for hepatitis C?
 10 **A.** Certainly, when I have tested people for hepatitis C,
 11 I have always sought consent, and it's never been with
 12 pre-counselling, as I've said in my statement to the
 13 Lindsay Tribunal, and I wouldn't have written it down
 14 if I'm really honest. I would have told -- just put
 15 it in the notes that I was doing it. But I wasn't
 16 really involved in that initial round of the HCV, the
 17 formal study. I was not involved in that.
 18 My work -- when I came -- I mean, following on
 19 from the point you made earlier, I think most of my
 20 work when I arrived was actually -- I was the one
 21 dealing with the wards which were much busier. I was
 22 doing the clinical stuff. Dr Rizza tended to stay in
 23 the haemophilia centre and deal with more of the admin
 24 and that sort of thing.
 25 **Q.** And then in terms of when the test result came back,

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1 the telling the patients that they had tested
 2 hepatitis C positive, what is your best recollection
 3 of how that was done?
 4 **A.** That tended to be done when patients came for their
 5 follow-up. So -- or if somebody popped into the
 6 department. Now, I definitely was involved in telling
 7 some of the patients their results. Absolutely, I was
 8 involved in that. But my impression is and my
 9 recollection is that Dr Rizza and Dr Trowell had much
 10 closer links with the patients at that time and were
 11 dealing with patients. After all, Dr Trowell, she was
 12 having weekly clinics and reviewing patients every six
 13 months or every year. So you can imagine a large
 14 number of patients are coming through to her.
 15 **Q.** So a severe haemophiliac or another patient who had
 16 regular scheduled six-monthly appointments would
 17 typically be told the hepatitis C result, as far as
 18 you understand, at their next scheduled appointment?
 19 **A.** That's correct. So people were not told by letter,
 20 and there was no meeting that was convened to tell
 21 people about the infection. I think the view was it
 22 was a slightly different scenario than, say, the HIV
 23 scenario. Many of these patients had, after all, been
 24 infected. They were infected probably in the 1970s.
 25 **Q.** Then in relation to those patients who were not

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1 regular attenders, so did not have their six-monthly
 2 appointments because they were mild haemophiliacs or
 3 infrequent bleeders, whether that was haemophilia,
 4 von Willebrand's, what to the best of your knowledge
 5 were the arrangements for testing them and telling
 6 them the test result?

7 **A.** That really happened as a second wave, and I think
 8 I said this in the Lindsay Tribunal. The focus was
 9 undoubtedly, in the period 1991 through to the end of
 10 1993, to deal with a large cohort which was, you know,
 11 well over 200 people that had to be counselled. But
 12 we did then try to track down as many people as
 13 possible to test them, and that I will accept went on
 14 until certainly 1995, 1996.

15 I even remember, actually, because we kept our
 16 eye out, there was one patient -- I was thinking about
 17 this this morning -- that we picked up years later. I
 18 remember the Skipton Fund had been set up, so we're
 19 talking 2003. And after many years, he made contact
 20 with us because I remember telling him the results and
 21 talking to him about the Skipton Fund.

22 So I fully accept that there was a delay in
 23 arranging for the testing and informing the milder
 24 patients and, indeed, some of the patients with
 25 von Willebrand's disease. But we had a large number

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1 of regular patients that were informed first.

2 **Q.** When a patient was told of their result, I think you
 3 told the Lindsay Tribunal that at the time there
 4 wasn't any written material that was given to
 5 a patient with information about hepatitis C.

6 What kind of information do you recall was given
 7 to patients, at least those patients whom you were
 8 seeing and breaking the news to them that they were
 9 hepatitis C positive?

10 **A.** So there were two issues. Some of the patients, of
 11 course, already knew that they had some form of liver
 12 infection, and they were under Dr Trowell, so it
 13 really wasn't, shall we say, a surprise.

14 I think the difficulty we faced right at the
 15 beginning was not having the PCR test result, because
 16 that was crucial. So in '91 and certainly
 17 a significant chunk of '92, we didn't have the PCR
 18 result which enabled us to distinguish between those
 19 with persistent infection and those who had been
 20 exposed to hepatitis C but eliminated it
 21 spontaneously. So the advice would have been along
 22 the lines of -- and some guidance, of course, would be
 23 provided by the liver function tests. If they'd been
 24 persistently normal, you might take a different view
 25 than someone who's got clearly, or had intermittent at

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1 least, abnormal liver function tests. But they would
 2 be told they'd been exposed to hepatitis C, which
 3 perhaps they'd heard of as non-A, non-B hepatitis, and
 4 we would make it clear that we were, you know,
 5 following up or going to be doing regular liver
 6 function tests. And if the question of sexual
 7 transmission came up, by certainly the end of '92, it
 8 was clear from three published studies that the risk
 9 of transmission was low.

10 **Q.** In terms of the stored samples, other than being used
 11 for the purpose of testing for hepatitis C, were they
 12 used after your arrival for any other purposes?

13 **A.** Okay. So the question of stored plasma, just to be
 14 clear, just to set that out, I mean, it certainly was
 15 the custom and practice before I started and when
 16 I left to collect stored samples. And before I answer
 17 your question specifically, let me just say a little
 18 bit about that.

19 There wasn't a systematic collection. It's not
 20 that we said -- you will find no memo from me to the
 21 lab staff saying, "I'm going to send you a separate
 22 tube. Please collect this and put it to one side."

23 It was really what was left over from clotting
 24 tests that we had done in our laboratory, and quite an
 25 archive was built up.

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1 Now, why was it started in the first place?
 2 I think, clearly, because there was some research
 3 interest, and I think I heard you allude to
 4 a Professor Zuckerman some time ago who'd recommended
 5 doing this. I think also in a haemophilia centre, we
 6 have to remember that Factor VIII deficient plasma was
 7 a precious resource because you need it for
 8 Factor VIII assays and inhibitor assays. And in later
 9 years, we had to move -- for health and safety
 10 reasons, we had to buy it commercially because it had
 11 been screened for Hep C and HIV.

12 So it was custom and practice not only in the
 13 haemophilia centre, other departments within the
 14 Trust, also other haemophilia centres. There are
 15 guidelines that are published on the storage of serum
 16 and plasma by the Royal College of Pathologists, and
 17 they recommend keeping plasma for as long as
 18 practical, actually. "Practicable" is the wording
 19 they use in the guidelines on storage and retention of
 20 plasma for two reasons. Firstly, for future research,
 21 and, secondly, it says for disease surveillance.

22 Of course, the Royal College of Pathologists
 23 made clear in its guidelines that, very specifically,
 24 serum and plasma are excluded under the human tissue
 25 act from the requirement to obtain consent for

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1 storage.
2 But to answer your original question, did we use
3 it for anything else? Yes. The samples were useful
4 sometimes. We would pull them out if a patient came
5 up for review and they had an equivocal inhibitor
6 screen, for instance, yes -- to give an example --
7 we'd go back to a previous sample, or even previous
8 samples, to see if there had also been a similar
9 problem. So did this patient have a fluctuating low
10 titre inhibitor, just to give you one example.

11 What I can say categorically is that although we
12 stored plasma -- and this was done, I fully accept,
13 without the consent and indeed knowledge of the
14 patients -- we didn't do any serological testing for
15 other pathogens, be it parvovirus or research other
16 projects. And I can give an assurance that if we'd
17 wanted to do -- if a new test had come available for,
18 let's say, variant CJD, I fully accept that patients
19 would have to have their consent sought for such
20 a test. It's a long answer, I'm sorry.

21 Q. Is this correct, then, that the plasma that was
22 stored -- and I'm talking now about your knowledge of
23 matters from April 1991 onwards, rather than what may
24 or may not have happened before -- if it was used, it
25 was used for purposes relating to the patient's

1 treatment and management, albeit without them knowing
2 that. Are you able to be categorical that it wasn't
3 used for purposes unrelated to the patient's own care
4 and treatment?

5 A. I'm not aware -- I must say this to you -- that's the
6 wording I would use. I've certainly never initiated
7 serological surveillance at all. You know, if someone
8 comes up with a hepatitis X, you know, we've done
9 nothing like that, no.

10 Q. And they weren't used for purposes of research?

11 A. No, not that I'm aware of at all.

12 Q. Just going to back to the checklist that you referred
13 to, and indeed you told the Lindsay Tribunal about,
14 you referred in your earlier answer to the point in
15 time at which Dr Rizza was retiring. Was it around
16 then, 1993, that you introduced the checklist, as far
17 you can recall?

18 A. Yes. I started before he -- so if I -- you would find
19 the first ones in the notes from probably
20 July/August 1993. And just to be clear -- sorry.

21 Q. Carry on.

22 A. I was just going to explain the purpose of the
23 checklist was -- and the only people who went through
24 the checklist, they had to be doctors. So we talked
25 about the nurses taking blood samples. It didn't have

1 to be me. It could be either the other locum
2 consultant who joined us afterwards, or the junior
3 doctors. It was -- you know, we went through the
4 story. I told them what to say, and it was a record
5 that was put to the notes. It wasn't signed by the
6 patient. It wasn't hidden from the patient, but it
7 was primarily to be a record for the clinical staff of
8 the haemophilia centre not just to understand whether
9 patients had been told about hepatitis -- actually,
10 you know, their HCV result -- what they had actually
11 been told by people.

12 Q. You say it wasn't hidden from the patient. As
13 I understand your evidence to Lindsay, it wasn't, as a
14 matter of fact, shown to the patient or shared with
15 the patient either?

16 A. That's correct. It would have been on the desk when
17 I'm writing -- and the patient will be opposite or
18 next to me, and they will have seen it. But I would
19 fully accept I never said, "By the way, here's
20 a hepatitis C checklist." But it was not hidden from
21 them, but it was equally true to say they were not
22 shown the checklist.

23 Q. Then there's one further document on hepatitis C
24 testing more generally.

25 It is DHSC0004294_002, please, Soumik. Now,

1 this is not an email to you, but it's an
2 interdepartmental Department of Health email from
3 Charles Lister, who was an official within the
4 Department of Health to others within the department
5 of health, and it says this:

6 "Dr Giangrande gave me the following comments by
7 phone. This is a summary of what he said from my
8 notes and has not been verified by him. Throughout
9 the '80s, doctors and patients were aware of the
10 potential exposure to non-A, non-B but there was no
11 test. In 1989, the hepatitis C virus was discovered.
12 Throughout 1991 and 1992, the first testing for
13 hepatitis C was applied to haemophilia patients in the
14 UK. Patients' stored samples were generally used.
15 This was a [sic] much to test the test as to test the
16 patient. There was a timelag of one or two years in
17 telling patients because no-one was sure until then
18 what the results meant. However, he was confident
19 that patients would have been aware that tests for the
20 virus were being done."

21 Then there's a reference to the reliability or
22 otherwise of the early hepatitis C-test.

23 Now, I don't know whether you have any
24 recollection of a discussion of this issue with
25 Mr Lister?

1 A. I don't, and, to be honest, I'm a bit surprised that
 2 someone from the Department of Health phoned me. I'm
 3 not sure why they would have; you know, what that was
 4 about. It could have been -- I hope we're going to
 5 talk about this later -- The Haemophilia Society
 6 hepatitis C report.
 7 Q. I think if we just go to the next page, we might see
 8 a little more about the context.
 9 A. Yes.
 10 Q. It looks as though -- the context was Lord Morris had
 11 asked Department of Health ministers to look into
 12 allegations of testing without consent.
 13 A. I see. Okay. Well, in that case, it's very -- that's
 14 really interesting because, I have to say, if we go
 15 back to the previous one, clearly now my views have
 16 changed. I don't believe that. Could we just --
 17 Q. Could we go back to the first page, please, Soumik?
 18 A. I mean, clearly, this was a broad generalisation, but
 19 I'm afraid I can no longer say that I'm confident
 20 patients would have been aware that tests for the
 21 virus were being done.
 22 Now, of course, like a lawyer, one can read that
 23 sentence now and think about it in several ways, that
 24 patients knew the test was generally available and
 25 that there were testings being done. But I take this

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1 to mean that I was saying patients were aware that
 2 tests were being done on them for hepatitis C, and I'm
 3 afraid I can no longer say that with confidence. I've
 4 read the many statements. I'm sure some were, but I'm
 5 not -- as a generalisation, I don't believe that to be
 6 true.
 7 **SIR BRIAN LANGSTAFF:** Can you actually remember having
 8 that view at the time?
 9 A. Sir Brian, the honest answer is I -- as I said when we
 10 were talking about my evidence to the
 11 Lindsay Tribunal, I think what gave me that impression
 12 was the fact that the sexual transmission study --
 13 I just assumed that patients had been told and their
 14 partners were told that the test was being done.
 15 I thought that was a reasonable assumption, but --
 16 **SIR BRIAN LANGSTAFF:** So the answer is: yes, you did think
 17 that. You have changed your mind. You thought that
 18 because it was a reasonable assumption to make?
 19 A. Yes. I have changed my mind, yes.
 20 **SIR BRIAN LANGSTAFF:** So the assumption was that
 21 everything was being done as it ought to have been
 22 done, if I put it in those terms?
 23 A. Yes.
 24 **MS RICHARDS:** I want to then come on to the arrangements
 25 for care and treatment for hepatitis C and monitoring

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1 liver function and progression of liver disease.
 2 We know already of the clinics under Dr Trowell,
 3 and you've made reference to them. In 1991, when you
 4 arrived, were those undertaken as joint clinics, or
 5 were they clinics held by Dr Trowell and her team?
 6 A. They were held by Dr Trowell, and she didn't have
 7 a team with her -- well, she obviously had a team, but
 8 they were based over at the John Radcliffe Hospital,
 9 but she ran those clinics alone. We did not sit in
 10 with her at those clinics. And, to be honest, what we
 11 tried to do was to -- the patient would see her, and
 12 then if they were coming for their six-monthly
 13 follow-up, we would do that -- you know, we would
 14 co-ordinate it that way.
 15 So, no, as a general rule, we did not sit in
 16 with her. But, obviously, she's in the building with
 17 us. We would not in such a co-ordinated way as with
 18 the HIV team, we didn't sit down and have a separate
 19 meeting, but this was an opportunity to exchange news
 20 and information about individual patients.
 21 Q. And in terms of decisions on treating patients in the
 22 early days with alpha interferon, and then with
 23 pegylated interferon, ribavirin, et cetera, did you or
 24 the Haemophilia Centre have involvement with those
 25 decisions, or were those matters that were solely

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1 dealt with by Dr Trowell?
 2 A. They were solely dealt with by Dr Trowell. But
 3 I would say sometimes I would write her a letter, and
 4 I would actually -- you know, I like, when I write
 5 a letter to a colleague, to pose a specific question:
 6 is this person a candidate for interferon therapy? So
 7 I would pose the question, if the patient is not
 8 already followed up, and she would provide the answer
 9 to that.
 10 Q. I'm going to ask you to look at some guidelines on the
 11 diagnosis and management of chronic liver disease
 12 which you have exhibited to your statement. Soumik,
 13 it's WITN3311008.
 14 We can see from the top of the page these are
 15 published in 1995. They are guidelines on the
 16 diagnosis and management of chronic liver disease in
 17 haemophilia, and it's co-authored by Professor Preston
 18 Professor Dusheiko, Professor Lee, Professor Ludlam
 19 and yourself, comprising the working party on chronic
 20 liver disease in haemophilia on behalf of UKHCDO.
 21 A. Yes.
 22 Q. If we just look at some of the broad guidelines that
 23 were here set out, we can see if we go -- well, in the
 24 first paragraph, it talks about:
 25 "Virtually all haemophiliacs treated with

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1 clotting factor concentrates before 1985 have been
 2 exposed to hepatitis C virus. Almost 100 per cent of
 3 these are HCV antibody positive."
 4 And then there's reference to the propensity to
 5 cause chronic liver disease and hepatocellular
 6 carcinoma now emerging as a complication of chronic
 7 HCV infection.
 8 If we then go down two paragraphs, please,
 9 Soumik, to beginning "the working party," so third
 10 paragraph, the guidelines say this:
 11 "The working party wish to stress that, wherever
 12 possible, close collaboration should be established
 13 between the Haemophilia Centre Director and
 14 a consultant hepatologist and that the latter should
 15 play an important role in the management of
 16 haemophiliacs with chronic liver disease. The
 17 patients should be kept fully informed of the results
 18 of all laboratory tests, including antibody status.
 19 The clinical implications of the findings should also
 20 be discussed."
 21 Then under the heading "Diagnosis of HCV
 22 infection", there is a recommendation that:
 23 "All patients who've been treated with blood
 24 products should be tested by a second/third generation
 25 HCV antibody test."

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1 And then we can see the bottom of that paragraph
 2 talking about:
 3 "Decisions with respect to treatment with
 4 interferon should be made through consultation with
 5 a hepatologist."
 6 If we go to the top of the next column, please,
 7 we can see under the heading "Sexual transmission of
 8 HCV" there's an estimate of the risk -- less than
 9 3 per cent -- and it's said that:
 10 "The current data on the rate of sexual
 11 transmission and the advantages of barrier
 12 contraception should be discussed. Patients should be
 13 encouraged to take a joint decision with their sexual
 14 partners."
 15 We can then see in the next paragraph that it's
 16 recommended that:
 17 "HCV testing should be offered to all sexual
 18 partners of HCV-antibody-positive patients."
 19 Then we have recommendations for follow-up. So
 20 if we scroll down the page a little, please. Thank
 21 you.
 22 So point 1 is:
 23 "HCV-infected patients known to have abnormal
 24 AST or ALT levels should attend for review at
 25 approximately four-monthly intervals."

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1 And then there is further recommendations of --
 2 as to how to determine ALT and AST levels in
 3 paragraph 2.
 4 Then if we go to the bottom of the page, there
 5 is a paragraph headed "Treatment with interferon
 6 Alpha". If we go over the next page. Top of the
 7 second page. We can see there's then a discussion
 8 about response to interferon, and then the second
 9 paragraph says:
 10 "With this background, the working party wish to
 11 make the following recommendations."
 12 And then we see a recommendation for
 13 consideration of treatment with interferon for
 14 patients with biochemical and serological evidence of
 15 chronic HCV-related liver disease.
 16 There's reference then to genotypes and
 17 determination of genotypes.
 18 And then if we go -- we can see, in fact, in the
 19 right-hand column role of liver biopsies. The
 20 specific recommendations about when liver biopsies
 21 should be considered.
 22 And then under the heading "Other
 23 investigations", we can see recommendations for
 24 endoscopy. Every five years for patients over the age
 25 of 45 and/or those who have been infected with HCV for

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1 30 years. And then there's a suggestion that this
 2 interval could be reduced in patients who are
 3 co-infected with HIV.
 4 Then a reference to abdominal ultrasound for
 5 patients over the age of 45 as part of screening for
 6 hepatocellular carcinoma, and specific recommendations
 7 for ultrasounds and alpha-fetoprotein determination
 8 for patients known to have cirrhosis at approximately
 9 four-monthly intervals.
 10 And then finally we can see a discussion about
 11 advice on alcohol consumption, and on the final page
 12 a discussion about circumstances in which liver
 13 transplantation may need to be considered.
 14 Now, as far as you're aware, were those
 15 guidelines followed at Oxford through the liver
 16 clinics by Dr Trowell and her successor?
 17 A. Yes. Before I -- just to say, I think all those
 18 important topics were, indeed, the headlines of my HCV
 19 checklist. It's interesting that they are the same
 20 things.
 21 Yes, I mean, broadly speaking in terms of
 22 follow-up, the average patient was seen every six
 23 months rather than, say, four months. Some were
 24 seen -- the threshold for seeing Dr Trowell was quite
 25 low, actually, so some patients were followed up on

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1 a yearly level. She certainly offered endoscopy. We
 2 certainly offered -- the alpha-fetoprotein test was
 3 done, and we didn't do ultrasound. But these are
 4 things which, broadly speaking, she did cover.

5 She was not enthusiastic about the use of
 6 interferon, I must say. And I think -- perhaps, older
 7 and wiser, I think probably she was right, because the
 8 side effects are severe. But we didn't have many
 9 patients who were put on interferon in the early days.
 10 We did do genotyping, and genotyping came in
 11 probably -- we were not one of the first centres to
 12 introduce it, so I would suggest '93, possibly
 13 even '94. And I know that genotyping was used to
 14 select or exclude patients. It was weighed up in the
 15 balance. So, broadly speaking, I think that covers
 16 very well the follow-up of our patients in Oxford.

17 **Q.** Oxford was, as you told the Lindsay Inquiry, one of
 18 the few centres that was in the unusual position of
 19 having long-standing established links with the
 20 hepatologist through the arrangements with Dr Trowell,
 21 and I think in your Lindsay evidence you referred also
 22 to Sheffield in that respect?

23 **A.** Yes, I did, yes.

24 **Q.** What was the purpose of the UKHCDO and the working
 25 party in producing these guidelines? What were you

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1 trying to achieve?

2 **A.** I think really to -- I mean, UKHCDO produced
 3 guidelines in a whole range of areas, so all areas of
 4 haemophilia care, from genetics to how to manage
 5 inhibitors, and I think the idea was to tell all
 6 haemophilia centres -- and, you know, we've got some
 7 real experts there on the panel there, Geoff Dusheiko
 8 from the Royal Free Hospital, and Eric Preston -- what
 9 should be offered to patients with haemophilia in all
 10 centres. It was to set a sort of standard.

11 **Q.** Now, the --

12 **A.** And I think review the evidence as well. I think the
 13 evidence and the cited literature is all very useful.

14 **Q.** The Inquiry has heard evidence of very variable
 15 practice nationally in relation to the care of
 16 patients with hepatitis C in the 90s and onwards.

17 Do you know whether the working party on chronic
 18 liver disease in haemophilia monitored whether these
 19 guidelines were being implemented in haemophilia
 20 centres across the country?

21 **A.** I mean, the working party certainly didn't, but
 22 I would imagine that Eric Preston, who was very active
 23 as a speaker and at various meetings, and also
 24 Geoff Dusheiko, I am sure they would have promulgated
 25 them themselves, but it was never a role of the

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1 working party.

2 Having said that, one of the -- now I think
 3 about it, one of the -- you may know that haemophilia
 4 centres have always been subject to audit.
 5 I forgot -- well, I say "always", I've forgotten when
 6 the audit process came in, but one of the purposes of
 7 the audit, one of the things on the checklist of the
 8 audit, was to check that people were following
 9 guidelines. Although now I think about it, that
 10 really only applied to the comprehensive care centres,
 11 so I think you are talking about the much smaller
 12 centres. So the answer to that must be, now I think
 13 about it, there was no way of following up to make
 14 sure smaller centres were following these standards.

15 **Q.** Now I want to move to the question of arrangements for
 16 the purchase or procurement of blood products and
 17 treatments for patients with bleeding disorders.

18 When you arrived in 1991, you have described in
 19 your statement that for the period from then to
 20 around 1995, your recollection is that the projects
 21 that were used at the centre were Factor VIII and
 22 Factor IX concentrates from BPL.

23 **A.** That's my recollection. Certainly there wasn't any --
 24 I don't remember any tendering process at that period.
 25 I believe we just got Factor VIII and Factor IX. We'd

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1 pick up the phone -- there was no budget that I was
 2 managing, that's correct.

3 Then that was followed by a period in which we
 4 definitely had a formal procurement, and that was run
 5 by the Trust.

6 Then the third and final phase, that started
 7 in 2004, and I retired in 2015, that was at a purely
 8 national level, and I think others will have spoken
 9 about that, in which I had no involvement.

10 **Q.** So just dealing, first of all, with the 1991-1995
 11 period, and I have assumed -- please correct me if I'm
 12 wrong -- that all the concentrates that were being
 13 used at Oxford would be heat-treated?

14 **A.** Yes.

15 **Q.** Other than receiving concentrates from BPL, do you
 16 recall any approaches from commercial pharmaceutical
 17 companies in that period attempting to persuade you to
 18 use their products instead?

19 **A.** There may have been in terms of the high purity
 20 products. I'm thinking of Armour, Monoclate-P.
 21 I mean, clearly if we look at the annual returns we'll
 22 see that. But a hot topic in the period of 1989 to
 23 1994 was the question of high purity products,
 24 particularly for the HIV positive patients. I think
 25 the only circumstance in which that could arise, that

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1 we would were approached, would have been in relation
 2 to that, because BPL was not the first company to
 3 produce high purity products.
 4 **Q.** Do you recall whether you decided to use high purity
 5 products in that period?
 6 **A.** I can't remember but clearly the annual returns will
 7 show that very clearly.
 8 **Q.** Then, in terms of the period which you have identified
 9 in your statement as being from 1995 to 2004, when
 10 there was a tendering exercise run by the Trust, what
 11 was your role, as centre director and consultant
 12 haematologist, in that exercise?
 13 **A.** So the Trust would run the procurement and, because of
 14 the volume, it had to be advertised internationally as
 15 well. So what would happen is we would -- it wasn't
 16 just me -- and David Keeling and our manager, we would
 17 meet up and we would set out the sorts of products we
 18 wanted, and the brand would then be decided by the
 19 procurement. So if we say we wanted a high purity
 20 Factor IX product or we wanted a recombinant
 21 albumin-free, that sort of thing.
 22 **Q.** So you would say to the Trust the type of product you
 23 wanted?
 24 **A.** Yes.
 25 **Q.** Is this correct, that you wouldn't specify the

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1 manufacturer?
 2 **A.** Correct.
 3 **Q.** And that --
 4 **A.** That would have been put out to advertisement. That's
 5 correct.
 6 **Q.** In terms of prophylaxis, your statement estimates that
 7 was introduced in 1995 or thereabouts?
 8 **A.** I think that's about right, that's about right,
 9 because firstly, of course, the confirmation of viral
 10 safety of 8Y only came in, I think, 1993, but my
 11 recollection certainly is that we had a lot of
 12 patients in the orthopaedic centre, the neighbouring
 13 Nuffield Orthopaedic Centre. There was actually
 14 a children's ward, and every day there would be
 15 patients on that ward, and indeed we had, in those
 16 days, a Friday ward round with Professor Robert Duffy,
 17 who was the head of the Nuffield Orthopaedic Centre,
 18 who also, fortunately for us, took -- you know, he had
 19 a principal interest in haemophilia.
 20 So I think that's right. Prophylaxis started --
 21 in the sense of prophylaxis for general regular
 22 treatment, on a twice or three-weekly times a week,
 23 started in around 1995.
 24 **Q.** Now, part of your responsibility as centre director at
 25 Oxford for a number of years after you arrived was the

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1 management of the database that was still then at
 2 Oxford.
 3 **A.** Yes.
 4 **Q.** And the evaluation of the annual returns and so on,
 5 which you undertook I think for a number of years with
 6 Ms Spooner?
 7 **A.** Yes.
 8 **Q.** Can you describe to us what that entailed on your
 9 part?
 10 **A.** To be really honest, Rosemary Spooner really did most
 11 of the work, if I'm really honest. So the data would
 12 come in to her, and Ms Spooner would be prepared, if
 13 necessary, to go to other haemophilia centres,
 14 actually, to collate data. She's been known to do
 15 that. And a report would be generated -- it was
 16 always on an annual basis rather than a financial
 17 year. That changed later on. In about October of
 18 that year, or September/October of that year, a report
 19 would be drafted up.
 20 It was, if I'm honest, somewhat formulaic, in
 21 the sense you could take the previous year's report
 22 and sort of add on. So, in other words, there would
 23 be a breakdown of the products used, there would be
 24 a graph to which you would add another point showing
 25 what was the factor consumption in, say, 1993. And

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1 there would be a commentary on the product usage.
 2 So it was a simple report, and I think the
 3 subsequent reports were much more sophisticated and
 4 complex, but I think it was -- it was a very useful
 5 report. It was a somewhat formulaic report, I would
 6 have to say.
 7 **Q.** I'm going to ask you to look at one example. In fact,
 8 the 1993 report.
 9 Soumik, it should be HSOC0024849.
 10 So we can see this is "Annual Returns for 1993",
 11 and it refers to "attached tables and graphs":
 12 "Returns were requested from 107 Centres ...
 13 received from 102 Centres ... some queries
 14 outstanding."
 15 Then we can see in the second paragraph it gives
 16 information about numbers of patients with
 17 haemophilia A, with Christmas disease, as it was still
 18 then being referred to, with von Willebrand's disease.
 19 Then we can see under the heading "Treatment of
 20 patients", there's a summary of numbers receiving
 21 therapy including home therapy.
 22 If we go over the page, we can see the first two
 23 paragraphs give further summaries in relation to units
 24 of different types of products used and then we have
 25 reference to table 8 giving an analysis of the causes

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1 of death. And I just wanted to ask you a little bit
 2 more about that, if I may.
 3 It says:
 4 "Table 8 gives an analysis of the causes of
 5 death in the 110 patients with haemophilia A, 6 with
 6 Christmas disease and 10 with von Willebrand's
 7 patients who died in 1993. AIDS was the commonest
 8 cause of death - 59 (47 per cent), with cerebral
 9 haemorrhage and liver disease 12, 10 per cent joint
 10 second. There were nine cancer deaths (including one
 11 case of hepatoma), and seven patients died from ...
 12 heart disease and six from pneumonia (not PCP). The
 13 cause of the death of ten patients was not known ..."
 14 Then further details in relation to deaths of
 15 patients diagnosed as having AIDS in Table 9 and Table
 16 10 showing the HIV status of the patients known to
 17 have died.
 18 So we can see from the report part of the
 19 purpose of it was to summarise the information about
 20 numbers of patients and type of treatment. What was
 21 the particular purpose of gathering together the data
 22 on causes of death?
 23 **A.** It was of interest, and if you look at previous annual
 24 general meetings, people wanted more -- they wanted
 25 this sort of information. And I think it's relevant

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1 to include it.
 2 **Q.** If we just go to table 8, Soumik, it's I think it's
 3 probably page 10. Can we turn it round so that we can
 4 view it properly.
 5 **A.** It's all right -- if you can't, I can turn my head, so
 6 you can tell me what you want.
 7 **Q.** Yes, I am thinking also of those watching. Can we
 8 turn it?
 9 **A.** I can read it. Please don't trouble yourself. I can
 10 read it.
 11 **SIR BRIAN LANGSTAFF:** Just take it slowly so that those
 12 who are watching at a distance can turn their heads
 13 and follow it.
 14 **MS RICHARDS:** So if we see in relation to AIDS, which is
 15 the first column, we can see that there are three
 16 categories of patient, and would I be correct in
 17 understanding that broadly correlates to severe
 18 haemophiliacs, moderate haemophiliacs, and mild
 19 haemophiliacs?
 20 **A.** Yes. It's interesting to note, by the way, at this
 21 stage we were defining severe -- it may be of
 22 relevance, discussions you may wish to raise later
 23 about others matters, "severe" was defined as less
 24 than 2 per cent. From 2001 onwards, we switched to
 25 a definition of less than 1 per cent, but it's

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1 interesting to see it was still in the UKHCDO returns
 2 as less than 2 per cent. But that's right. Severe,
 3 moderate, mild.
 4 **Q.** And then we can see in relation to severe
 5 haemophiliacs, we can see 2 severe haemophiliacs have
 6 died in the age range 10 to 19; 12 in the age range 20
 7 to 29; 17 in the age range 30 to 39; 7 in the range 40
 8 to 49; 9 aged 50 to 59; 2 aged 60 to 69. And then we
 9 can see that in terms of those with moderate
 10 haemophilia, again, 2 deaths in the age range 10 to
 11 19; 3, 20 to 29; 1 in the age range 30 to 39; 1, 40 to
 12 49, and 1, 50 to 59. And then in terms of the mild
 13 haemophiliacs, one death in the age range of 30 to 39,
 14 giving us the total we see there of 59.
 15 This obviously is a snapshot but a snapshot of
 16 a particular year. What kind of data on death and
 17 causes of death was this analysis based on? What
 18 information did Ms Spooner and the centre have access
 19 to?
 20 **A.** These data, of course, formed the germ of several much
 21 more sophisticated analyses, including our report in
 22 Nature in 1995, and very specifically an analysis of
 23 age as well, which we published in The Lancet, so the
 24 impact of age at the time of infection on the
 25 progression of HIV.

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1 As regards the source of the information, this
 2 was predominantly from death certificates. And in
 3 1988, so before I came to the haemophilia centre,
 4 UKHCDO set up a system which I understood from
 5 Professor Hay's transcript is still in operation. And
 6 that is: people on the national database were flagged
 7 up by the Office of National Statistics, and copies of
 8 death certificates were automatically sent to the
 9 secretariat showing the -- so if someone died, the
 10 death certificate would be sent, and it was paid for,
 11 to the secretariat.
 12 Now, in the studies that we will talk about
 13 later, like the Nature 1995 one, we went a little bit
 14 further. I see on the left of this is "AIDS" and two
 15 asterisks and I'm going to ask you if there's any --
 16 you know, what that note refers to. Does it say it is
 17 just from death certificates or information from
 18 centres?
 19 **Q.** No. If we go two pages further on, we can see what it
 20 is.
 21 **A.** I'll just tell you the reason I'm saying that.
 22 Because very clearly (and this was an issue we
 23 specifically address in the Nature 1995 paper) many
 24 people, especially in the early days, were very
 25 reluctant to see "AIDS" on a death certificate.

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1 Because these are public documents, anyone can ask for
2 a death certificate and so sometimes it would be
3 disguised, say "pneumonia". So one of my roles in the
4 1995 paper -- I can tell you for certain it was 168
5 patients, we say that in the 1995 paper -- I wrote to
6 haemophilia centres along the lines of, "Dear
7 colleague, we've got a report on this man. Could you
8 tell me was this actually HIV-related or not?"

9 So what I'm not -- so for the Nature paper we
10 had those two sources of information. What I'm not
11 clear looking at this table and, I say, that's why
12 I was creating about the asterisk, is this just death
13 certificate information? I think this is reports from
14 haemophilia centres. I think this is filling in
15 a death form.

16 **SIR BRIAN LANGSTAFF:** Shall we have a look at the --

17 **MS RICHARDS:** Yes, the double asterisk doesn't actually
18 give us the answer. If we go on two pages please,
19 Soumik, and if we can switch that.

20 **A.** Okay.

21 **Q.** The double asterisk says "see table 9 for further
22 details" and if we go on to table 9 --

23 **A.** So what I would say is clearly --

24 **SIR BRIAN LANGSTAFF:** If I may just interpose, you're
25 speculating at the moment about the source of

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1 information.

2 **A.** Yes.

3 **SIR BRIAN LANGSTAFF:** There is a clue, I think, in part of
4 the description at the start of the report where it
5 talks about the causes of death, some paragraph that
6 deals with it, where it talks about some centres not
7 having been told or not having identified the cause of
8 death. So it looks as though the information comes at
9 second-hand from the centres wherever they may have
10 got their information. That will be the inference
11 which at the moment I think I would draw from this
12 material, but I may of course be wrong and it's only
13 a very narrow basis so far.

14 **MS RICHARDS:** Just so that others follow, because others
15 won't have the document, if we go on one further page,
16 Soumik, we can see that table 9 is a breakdown of the
17 different conditions of the patients who had died
18 during 1993. So it doesn't tell us the source.

19 **SIR BRIAN LANGSTAFF:** Can we have a look at cancers under
20 that. Is there a detail there?

21 **MS RICHARDS:** No. So if we go over the page to table 10,
22 there is information there about the HIV status of
23 patients known to have died in 1993 and there is there
24 a reference in terms of cancer to one patient being
25 HIV positive, four negative, four not known. So there

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1 may of course have been -- AIDS may have contributed
2 to other death, Dr Giangrande; is that a fair
3 assumption?

4 **A.** Yes, I'm sure that is true. I mean, I quite take the
5 point about speculation. Obviously, it's a very long
6 document, and to suddenly take this all in and give an
7 answer is difficult.

8 What I would certainly say though is that the
9 Nature 1995 paper and subsequent ones are more
10 reliable. I think I can say that categorically
11 because those are using data from death certificates
12 plus information supplied by haemophilia centres. So
13 if I were to use a source, if I wanted to consult
14 a source for information on causes of death, this is
15 useful but it's not as good as the more formal,
16 peer-reviewed publications. Is that a fair summary?

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

18 **MS RICHARDS:** Sir, I note the time. I am happy to break
19 here.

20 **SIR BRIAN LANGSTAFF:** We normally have a break for an hour
21 at this stage to allow us all to have the refreshment
22 that normally comes in the early afternoon. So let's
23 do that now. The same rules apply, of course, and
24 I shall see you back here at 2.05. 2.05.

25 **A.** Thank you.

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1 (1.02 pm)

(Luncheon Adjournment)

2 (2.05 pm)

3 **MS RICHARDS:** Dr Giangrande, we've been looking at the
4 report on annual returns from 1993 and you made
5 reference to the publication in Nature and so for the
6 sake of completeness we'll just look at that now.
7 Soumik, it's HCDO0000264_095.

8 I think this is the publication to which you
9 were referring, doctor?

10 **A.** It is, yes.

11 **Q.** We can see it is entitled "Mortality before and after
12 HIV infection in the complete UK population of
13 haemophiliacs", and the first author is Sarah Darby,
14 and then a number of other co-authors, including
15 yourself.

16 If we go to the third page, please, Soumik, and
17 we look at the bottom half of the page, we can see --
18 picking it up in the last paragraph on the left-hand
19 column, we can see that this was relating to deaths or
20 analysis of deaths between 1985 and 1992, and it says:

21 "During 1985-92, 403 deaths occurred in
22 seropositive patients and for 235 of these the
23 certified cause was AIDS ..."

24 Pausing there, that would have been the cause

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1 given on the death certificate, would it?
 2 **A.** That's right, yes.
 3 **Q.** Then the article continues:
 4 "For the remaining 168 deaths in
 5 HIV-seropositives, there were significant excesses for
 6 many causes indicative of AIDS, including infections,
 7 non-Hodgkins lymphoma and pneumonia, and also
 8 significant excesses for causes associated with
 9 haemophilia. Information received from the
 10 Haemophilia Centres indicates that many of these
 11 patients had in fact developed AIDS, indicating that
 12 in AIDS patients this is a tendency to attribute cause
 13 of death to diseases associated with haemophilia or
 14 AIDS rather than to AIDS itself. However, not all the
 15 excess mortality in patients tested seropositive for
 16 HIV appears to be due to recognised AIDS indicator
 17 diseases, and some may be due to other conditions such
 18 as liver disease."
 19 Pausing there, doctor, in relation to the
 20 168 deaths in patients who were HIV positive, as
 21 I understand it, the point that is being made there,
 22 broadly put, is that AIDS may have been a contributing
 23 factor to those deaths but was not, as a matter of
 24 fact, the certified cause of death; is that correct?
 25 **A.** That's absolutely correct.

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1 And there are two things I'd say. In fact,
 2 following on from what I said earlier, I wrote to --
 3 one of my roles in this publication was to write -- to
 4 identify death certificates that we did not feel
 5 yielded the full truth, and I would write to
 6 colleagues to ask if they were able to share other
 7 information with us.
 8 The other thing I would point out is that the
 9 thing about the excess mortality, the additional point
 10 I want to make, is that the 403 deaths -- you may be
 11 saying that later on -- we would have expected 60 on
 12 the basis of the deaths in the seronegatives, which is
 13 where the 85 per cent excess mortality comes from.
 14 **Q.** Yes. Just to complete the picture, we will just go
 15 over the page. We will pick it up at the bottom of at
 16 that page -- sorry, Soumik, before we finish.
 17 The last five lines on the right-hand side:
 18 "These are the first data thought document that,
 19 in a large and complete population, mortality among
 20 those who by chance were infected with HIV increased
 21 more than tenfold while remaining unchanged over time
 22 in those who escaped infection ... Assuming that
 23 the ..."
 24 If we go to the next page and look at the bottom
 25 half of the page, please -- so if we zoom in on the

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1 bottom half. Thank you.
 2 So, picking it up:
 3 Assuming that the death rate during 1985-92
 4 among infected patients would, in the absence of HIV,
 5 have been close to that for uninfected patients,
 6 60 deaths would have been predicted, whereas 403
 7 deaths in fact occurred, an excess of 343. Thus
 8 85 per cent of the deaths in HIV seropositive patients
 9 are likely to have been caused by HIV. This large
 10 excess, together with the temporal pattern of the
 11 increase in those who became infected, the similarity
 12 of the excess death rate associated with HIV infection
 13 regardless of the severity of haemophilia, and the
 14 large increase in mortality from conditions not
 15 usually associated with haemophilia, demonstrate
 16 particularly clearly the enormity and specificity of
 17 the effect of HIV-1 infection on mortality in this
 18 population."
 19 That's the --
 20 **SIR BRIAN LANGSTAFF:** May I just ask, in relation to the
 21 60 deaths that would have been predicted, that's
 22 deaths in the absence of HIV infection?
 23 **A.** Yes, in other words, looking at the number of
 24 people -- based on -- yes, that's what would have
 25 been -- in a population of that number, whatever the

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1 number was, we would have expected 60 deaths, based on
 2 the observation of the seronegative patients.
 3 **SIR BRIAN LANGSTAFF:** Does the 60 therefore include the
 4 deaths that might have been predicted from
 5 hepatitis C?
 6 **A.** Presumably it does, but no implication is made. It's
 7 just we're saying: that is the mortality observed in
 8 the negatives. And that would include hepatitis C.
 9 So that's absolutely right. But the impact on
 10 mortality of hepatitis became much more later on. So
 11 we may be going on later to discuss subsequent
 12 publications, but at this stage, the peak of mortality
 13 due to, for instance, hepatoma, had not yet been
 14 reached.
 15 So, to answer your very clear question, the
 16 60 would have nominally included hepatitis C as well.
 17 **SIR BRIAN LANGSTAFF:** If the figures you had produced
 18 yourself, that you referred us to just shortly before
 19 lunch, are right, that the figures for deaths from
 20 liver disease were equivalent to the deaths from
 21 bleeding on the brain --
 22 **A.** Yes, and they grow even further.
 23 **SIR BRIAN LANGSTAFF:** -- the liver deaths would be -- tend
 24 to be -- I wonder, you can confirm -- tend to be
 25 associated with hepatitis C infection?

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1 A. That's absolutely right, Sir Brian.
 2 And I would also point out there is -- and maybe
 3 Ms Richards will refer to it -- we did write
 4 a specific paper focusing on mortality due to liver
 5 disease in the haemophilic cohort, and that was
 6 published in The Lancet in 1997. So we have
 7 a paper -- if you don't have it, I'm very happy to
 8 provide it -- focusing specifically on that.
 9 **SIR BRIAN LANGSTAFF:** Yes. Thank you very much.
 10 **MS RICHARDS:** Yes, I think we've got four papers but not
 11 that one available today. We do have it, in any
 12 event.
 13 A. If you have it, excellent.
 14 Q. Returning then to the Oxford database, Dr Giangrande,
 15 and the issue of patient consent, you've said in your
 16 statement -- it's paragraph 116.1, I think.
 17 So, Soumik, could we have WITN3311003, and if we
 18 could go to page 62. If we go to the next page,
 19 sorry.
 20 You've said this, go down the page:
 21 "During my time at Oxford, from 1991 to 2015,
 22 written consent was not requested from patients for
 23 their data to be entered and stored on the UKHCDO
 24 national database.
 25 "116.2. After the introduction of the Data

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1 Protection Act, and after some discussion within the
 2 UKHCDO, the group [that's the UKHCDO's data management
 3 group] agreed that patients would be informed that
 4 their data was being collected and stored but consent
 5 would not be sought. A leaflet was produced ... for
 6 patients explaining this situation, which was
 7 distributed to haemophilia centres."
 8 Then you say as far as you can recall that was
 9 handed out in Oxford, and as far as you can recall
 10 most patients in Oxford were already aware of the
 11 existence of the national database, and you say you
 12 don't recall patients expressing concern to you.
 13 So --
 14 A. First of all, can I -- I'm sorry.
 15 Q. Yes, carry on.
 16 A. Yes, I'm very happy to expand on this.
 17 It's certainly true when I started in Oxford
 18 written consent was not requested from patients and
 19 when I left that was the same position. And I have
 20 read the transcript of Professor Hay's contribution.
 21 Let me say that this has been a subject of a lot
 22 of debate within UKHCDO and my view is that we should
 23 get written consent from patients to have their data
 24 entered on the national database. Furthermore, I'm on
 25 record as saying that.

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1 It wasn't really an issue for me in my first
 2 years in Oxford, but the issue came to a head in the
 3 late 90s, when several other colleagues expressed
 4 concern about sending data to Oxford. Sometimes that
 5 was the doctor themselves, other times, as in the case
 6 of a colleague in Southampton, who is mentioned in one
 7 of the documents you've sent me, she was passing on
 8 the feelings of patients. And similarly, concern was
 9 expressed by a colleague in Sheffield.
 10 So this made collection of the annual returns
 11 quite difficult. St Thomas' refused to send data to
 12 us from 1996 onwards and it was particularly difficult
 13 for us to produce the 1998 annual return. And,
 14 indeed, at the annual general meeting of the UKHCDO in
 15 2000 you will see a statement to that effect. It
 16 says: Paul Giangrande and Rosemary Spooner have
 17 "soldiered on".
 18 So this led to a lot of discussion within
 19 UKHCDO, and I must admit -- I'm going to quote some
 20 documents from among the ones you shared with me --
 21 the path I thought we were on is that we were going to
 22 be seeking consent from patients. And indeed, in my
 23 testimony to the Lindsay Tribunal in 2001, I used the
 24 future tense, saying we will be collecting information
 25 from patients.

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1 Now what changed all that was a meeting in 2002,
 2 which I will refer to. But just going through -- and
 3 I've made some notes here, which are entirely from the
 4 documents you've shared with me, so there is nothing
 5 new that I'm contributing.
 6 In around 1999 the database we held in Oxford
 7 was going to change, and we had very good support from
 8 Rob Hollingsworth, who of course is the Manchester IT
 9 man, and we were going to change the software, and
 10 I was asked to come up with a draft protocol.
 11 You have this document. It's dated
 12 20 December 1999, and one of the opening words is:
 13 "Information about an individual will be added
 14 only if he or she consents."
 15 Looking at other excerpts from UKHCDO executive
 16 meetings, I note, for instance, on 11 February we have
 17 comments from both Professor Christine Lee and
 18 Professor Charles Hay about informed consent.
 19 These are the words of Professor Hay:
 20 "Consent needs to be obtained in writing, which
 21 was a major undertaking. Some patients would, of
 22 course, refuse. CL [Christine Lee] reminded
 23 Charlie Hay 'that they had discussed splitting the
 24 database into those giving consent and those who did
 25 not'.

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1 "UKHCDO executive committee 5 June 2000,
 2 Christine Lee refers to contingency plans if the
 3 patient consents are not obtained by the end of the
 4 year.
 5 "Data management group 8 August 2000. In the
 6 minutes, Dr Giangrande's view is that consent will be
 7 obligatory for research purposes in an anonymous
 8 format."
 9 The first meeting of the new advisory board,
 10 under the constitution of UKHCDO, was on
 11 11 September 2000. I was not present. Charles Hay is
 12 quoting in the minutes as saying:
 13 "From the end of this year, UKHCDO needed to
 14 take steps to get consent from their patients. This
 15 information could be collected on a prospective basis,
 16 i.e. the next time the patients attended the clinic.
 17 There was no need for doctors to write to the patients
 18 for this consent. Dr Brown asked if there were any
 19 problems with electronic transfer of data. Dr Hay
 20 said no."
 21 I, in a letter to Frank Hill on 11 July 2001,
 22 which was about The Haemophilia Society's HCV project,
 23 note, because I'm requesting release of information to
 24 the patients:
 25 "I am sure that you will recognise that the

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1 implementation of proposed changes to the database
 2 very much requires collaboration from The Haemophilia
 3 Society, and this presents an opportunity to show good
 4 intent in our collaboration."
 5 But, on the data management group meeting of
 6 7 February 2002, there was a complete reversal of
 7 policy.
 8 "It was agreed [I'm quoting from the minutes]
 9 that patients would be informed but not consented."
 10 This was largely driven by the contributions
 11 from Karin Pappenheim, the then CEO of the Haemophilia
 12 Society, and Susan Schonfield, who was from the London
 13 consortium, that is, the purchasers, and she was
 14 attending the data management meeting for the first
 15 time.
 16 So there was a reversal of policy. But I want
 17 to make clear it is my view that patient consent
 18 should be sought for the database, and I really see no
 19 problems in doing so.
 20 **Q.** Do you have any insight as to why that issue was so
 21 long debated within the UKHCDO and why it was not
 22 resolved more swiftly and straightforwardly?
 23 **A.** I don't. And it leads me on to another issue, and
 24 that was the new constitution of the UKHCDO, which
 25 came into place in 2000. The first meeting, I told

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1 you, was on 11 September. Before then, we had an
 2 executive committee where a representative from each
 3 haemophilia centre attended a meeting.
 4 Under the new constitution, which is on the
 5 website, we have an executive committee, so the name
 6 remains the same, and we have four members. We have
 7 an elected chairman, a vice-chairman, a treasurer, and
 8 a secretary. According to the constitution they meet
 9 three times year and then the advisory board meets up
 10 with them.
 11 But I've never seen minutes from the executive
 12 committee under the new constitution, and it's
 13 impossible for me to trace who said what to whom and
 14 therefore answer your question properly. I don't know
 15 all the discussions that took place but there clearly
 16 was a complete reversal of policy in early 2002.
 17 **Q.** You had in the 90s, is this fair, two roles: you were
 18 director of the Oxford Haemophilia Centre, and then
 19 you were, because of the historic location of this
 20 information and the submission of annual returns to
 21 Oxford, you were, along with Ms Spooner, the recipient
 22 of data received from haemophilia centres across the
 23 country?
 24 **A.** Yes.
 25 **Q.** Can I ask you, first of all, in relation to your role

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1 as Haemophilia Centre Director in Oxford, was there
 2 anything that precluded you from at least obtaining
 3 written consent from your patients to the provision
 4 and retention of their data?
 5 **A.** Well, the Oxford database was inspected, I've
 6 forgotten the precise date, by the Caldicott Guardian.
 7 And the Caldicott Guardian, of course, for those that
 8 don't know, and clearly you do, is a responsible
 9 senior person within a hospital who has responsibility
 10 for making sure that data are cared for properly on
 11 behalf of the patients.
 12 And during that time, the Caldicott Guardian who
 13 was based in Oxford, I'm not going to mention a name,
 14 was entirely satisfied with the arrangements that were
 15 in place. But I can't really introduce in my own
 16 Trust a consent form on my own.
 17 **Q.** In relation, again, still to your patients at Oxford,
 18 do you know the extent to which, prior to your arrival
 19 in 1991, patients had been told that confidential
 20 data, including data about HIV status and so on, was
 21 being collected and analysed centrally for purposes
 22 other than their own clinical care and treatment?
 23 **A.** It was not something that was hidden from patients,
 24 and I would say the following. I recognise that not
 25 everybody, of course, is a member of The Haemophilia

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1 Society, but The Haemophilia Society was certainly
2 aware because they were present at each UKHCDO annual
3 general meeting when the data were presented. And
4 I personally have written and spoken -- written many
5 articles for The Haemophilia Society and spoken at
6 events where this has been mentioned.

7 Certainly, we encourage our patients to keep
8 records of their treatment. And one of the messages
9 that we've tried to get over to the patients is that
10 it's important to do so because the data are collected
11 for the purpose of the national database. So I
12 believe many of them certainly were aware of it and,
13 indeed, for some patients, it's been a great source of
14 information. I would single out, for instance, women
15 who are potential carriers have often asked us because
16 they want us to trace people they may be distantly
17 related to, to help them determine their own carrier
18 status for haemophilia.

19 So my answer to your question is: no documents
20 were produced. I believe the great majority of
21 patients were aware of the existence of the national
22 database and, indeed, probably, in Oxford, proud that
23 it was in our centre.

24 **Q.** Is that based on an assumption on your part, in part
25 because of the location of the database within Oxford

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1 in the '90s, or --

2 **A.** It was -- inevitably, there's an assumption before
3 I start in 1991, but what I've said equally applies to
4 after I started.

5 **Q.** Is this right, that there was no systematic attempt in
6 Oxford -- and I'm only asking you about the centre of
7 which you were director, not others -- no systematic
8 attempt in Oxford to tell each patient what kind of
9 data was being stored about them and the arrangements
10 for their storage?

11 **A.** That's true.

12 **Q.** We've seen evidence, and I think your own statement
13 refers to it in part, that UKHCDO or National
14 Haemophilia Database was used anonymously, in terms of
15 the information that was collated and provided, to
16 provide data to third parties from time to time?

17 **A.** Yes, it was. So, for instance, the World Federation
18 of Haemophilia -- we produced aggregate reports for
19 the World Federation of Haemophilia, to give one
20 example.

21 **Q.** Were you ever involved in collating information from
22 the database and providing it to pharmaceutical
23 companies?

24 **A.** We did basically sell the annual reports. That was
25 agreed by UKHCDO. So they were able to pay for -- and

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1 I've forgotten -- it was a very modest price. So they
2 were able to get copies of the reports just of the
3 type you've been showing me earlier. But we never in
4 Oxford did any -- they never even asked us, actually,
5 to carry out independent research.

6 **Q.** What year was it in which the National Haemophilia
7 Database transferred from Oxford to Manchester and
8 ceased to be your responsibility?

9 **A.** 2002.

10 **Q.** There's one piece of data produced by Ms Spooner
11 I wanted to ask you about. It's GGCL0000039, please,
12 Soumik. Minutes of an HIV working party in
13 January 1997. But if we could go, please, to page 7,
14 we can see here some information gathered together by
15 Ms Spooner in January of 1997. It says:

16 "45 wives or partners of 43 haemophilia A
17 patients and one partner of a haemophilia B patient
18 are known to have become HIV positive. 10 of the
19 wives of haemophilia A patients have developed AIDS; 8
20 have died. Full details of 7 of the cases have been
21 received and accepted as AIDS cases by CDSC. More
22 information has been requested regarding the other 3.
23 Only wives or partners of patients identified by
24 Haemophilia Centre Directors have been included in the
25 above data."

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1 Is this fair, that this information here might
2 well be an underestimate because this is based upon
3 information provided by Haemophilia Centre Directors?
4 You've already told us, I think, that some directors
5 didn't provide information or didn't provide complete
6 information.

7 **A.** Yes. I think your statement is right, but let's be
8 clear. I suspect that this is a very accurate picture
9 because it was relatively few centres that didn't send
10 us data, and the data wasn't sent to us from really
11 1996 onwards, and I guess this would have been an
12 issue of the transmission sexually of HIV earlier. So
13 while you're right, it doesn't mean they are wildly
14 inaccurate figures.

15 **Q.** So it's unlikely to be an overestimate?

16 **A.** Yes.

17 **Q.** It's possibly an underestimate, but you would say not
18 a wild underestimate?

19 **A.** Exactly.

20 **Q.** Do you know whether there was any more systematic
21 analysis of the numbers of partners or family members
22 infected with HIV?

23 **A.** I'm not aware of any, no.

24 **Q.** Then just still on the topic of data, could we have
25 HCDO0000254_029, please.

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1 So this was a letter from you to Dr Hay in
2 November 2003 expressing concerns about the way in
3 which Dr Hay was using UKHCDO data for presentations.

4 Then we can see in the second paragraph, you
5 talk about the presentation of data coming from the
6 national database, without mentioning UKHCDO. It
7 says:

8 "The rules of the use of UKHCDO data for
9 presentation are very clear: prior written permission
10 needs to be sought through channels set out in our
11 constitution. The data you presented are certainly
12 not in the public domain, and I would hardly imagine
13 that UKHCDO would have granted permission for you to
14 reveal these data at this stage to one of the
15 companies in the setting of a paid advisory meeting."

16 Then in the last paragraph, you refer to an
17 accusation against you in the past of "plundering"
18 data from the UKHCDO database.

19 Can I ask, first of all, whether you are able to
20 expand upon the incident that this correspondence
21 referred to?

22 **A.** I'm afraid I don't recall it, and you only shared this
23 letter with me very recently, so I haven't had a lot
24 of time to reflect on it, and I'm afraid I really
25 can't recall the details. I think it's very clear

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1 already in this letter what I'm talking about, and
2 I can't add to that.

3 **Q.** Just in the last two sentences, there's a reference to
4 you having been accused of plundering data from the
5 database in the past. Can you recall anything further
6 about that?

7 **A.** I can, and let me say that I think one of the good
8 things about UKHCDO is that we can collaborate and
9 very occasionally have terse exchanges. I think
10 that's really one of the recipes for success.

11 So before I answer your question, let me just
12 comment that I think the UKHCDO is an extraordinarily
13 successful collaboration. I've got a lot of
14 experience of haemophilia organisations around the
15 world through my role with World Federation of
16 haemophilia and EHC. And, you know, if you go to --
17 I was thinking of a meeting in Germany, you will have
18 all the senior people mixing. And I was stunned last
19 time I went there. They were all using the formal Z
20 to each other, but there's no collaboration, and
21 that's why with your expert HIV report there is talk
22 of the bond cohort. It's not the German cohort
23 because they don't collaborate.

24 I think one of the recipes for success in an
25 organisation is that people can talk freely and

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1 frankly and have an exchange of opinion. If we've got
2 a project, what have we got to do to deliver it and
3 get it, you know, over the line?

4 Now, what is being talked about here is
5 controversy that followed the publication of the HIV
6 article in Nature and others, and without going into
7 detail, I think it's -- although a lot of -- although
8 the projects had been cleared with UKHCDO, I think
9 there was, and I have to say understandable, there was
10 a little bit of understandable anxiety that data were
11 being published. All I can say is that the project
12 which led to the various publications had been
13 discussed with UKHCDO in advance. But, look, these
14 sorts of exchanges are not uncommon in academic life,
15 and I don't want this one letter, which is probably
16 the only harsh letter you will find in any archives
17 relating, you know, to letters I've written, to in any
18 way give the impression that the UKHCDO collaboration
19 is not a productive one. It is a very good one, and
20 I think the fact that we can exchange harsh words
21 occasionally is no bad thing.

22 **Q.** So this really was the purpose of my question,
23 Dr Giangrande: the reference to learning from the
24 lessons of the past in the last line of that letter,
25 is that a reference to what you've just referred to?

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1 The concerns about publication of the data?

2 **A.** Yes, and if you went me to build on that, I'm very
3 happy to do that. And I think the Nature paper that
4 you alluded to -- that you presented -- when we
5 produced the paper, I thought we had done everything
6 we could to get everybody on board. You will have
7 seen in bold type, at the top, mention was made of the
8 authors and, in equally bold type, UK Haemophilia
9 Centre Doctors Organisation.

10 Unusually for a letter, we were able to print
11 all the names of the haemophilia centres, the
12 institutions, and the doctors. And I can tell you
13 Nature was not happy about that. It takes up a lot of
14 space in a journal. We did that.

15 I have to say, personally, I didn't handle it as
16 well as I could. I was younger and naive then, and I
17 think I should have shown the document to UKHCDO
18 colleagues for review beforehand, and that didn't
19 happen. But we made sure, and we worked together, and
20 we spoke to make sure that future projects that came
21 out of this would -- we could get it over the line,
22 we'd work, and we'd collaborate, and we did that in
23 a number of ways.

24 You will see the subsequent publications that
25 have come out of the same analysis of the data include

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1 more diverse authors. In other words, authors from
 2 several other haemophilia centres. You will see that
 3 we put as the author for correspondence the Chairman
 4 of UKHCDO at the time, who at the time I think was
 5 Frank Hill.

6 In fact, in one of them, the AIDS 2004 paper, we
 7 went even further. It was anonymous. It was only
 8 when you look at the end you see who the writing
 9 committee is. You won't find that paper if you look
 10 online.

11 So the point is we worked together to make sure
 12 that the project would get over the line by finding
 13 out, you know, what people wanted.

14 **Q.** There's a further publication I want to ask you to
 15 look at on a completely different topic,
 16 Dr Giangrande. It's HCDO0000133_024, please.

17 You will see that this is a retrospective
 18 neuropathological review of prion disease in UK
 19 haemophilic patients, and you are one of several
 20 authors.

21 Dr Giangrande, I'm going to ask you about the
 22 issue of VCJD notification in a few minutes. I just
 23 specifically wanted to ask you about this particular
 24 project. If we go to page 3, we can see in the first
 25 paragraph, it says:

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1 "In order to examine the possibility of
 2 transmission of CJD via large pool clotting factor
 3 concentrates ... we have examined the brains of 33
 4 HIV-1 positive haemophilic patients who had died from
 5 HIV/AIDS or liver disease."

6 Then it refers to the practice of three
 7 haemophilia centres. The three haemophilia centres
 8 involved:

9 "Royal Free, Oxford and Edinburgh to use British
 10 donor source plasma clotting factor concentrate
 11 whenever possible."

12 Does it follow then that amongst the brains of
 13 those who were examined for the purposes of this study
 14 there were Oxford patients?

15 **A.** Yes. I mean, you spoke to Christine Lee, I believe,
 16 about this when you examined her when she was
 17 speaking, but that's absolutely right. She was the
 18 architect of this project, and I think it was a very
 19 important project.

20 So it was using stored brain material from 33
 21 people with haemophilia who had died, obviously, and
 22 who had been treated with British plasma. The
 23 importance of the publication and why it was done
 24 follows on from the change in perception about the
 25 risk of variant CJD in 1996 and 1997.

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1 So with the discussion of the possibility that,
 2 contrary to previous reassurance, British plasma might
 3 transmit prions, the immediate question was: is there
 4 a danger here? Is there a real risk that people with
 5 haemophilia could be developing variant CJD?

6 Analysing this post-mortem material was one way
 7 of answering that question, and it provided a rapid
 8 and reassuring answer. Of the 33 brain samples from
 9 patients heavily treated with British donor source
 10 plasma, both from England and Scotland, no prions were
 11 identified in any of the brain sections. Now,
 12 statistically, it's not possible to say that the risk
 13 of variant CJD is zero with just 33 samples. In each
 14 statistical calculation, there is what's called the
 15 cover, the statistical cover. And to get a figure of
 16 zero, I don't know off the top of my head, but you'd
 17 need many more than that. I believe the figure, if we
 18 go down somewhere in the paper, going from memory, the
 19 risk we said was 11 per cent. It was around 11
 20 per cent.

21 But the point is the study was a reassuring one
 22 for us, and I'm surprised actually that this
 23 publication didn't get more publicity than it did at
 24 the time. I think it's an important publication that
 25 provided reassurance to me, if not to the wider

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1 haemophilia community.

2 **Q.** Was it routine to store brain tissue samples at
 3 Oxford?

4 **A.** Let's be clear. Firstly, by the way, as Professor Lee
 5 said when you examined her, this was before the days
 6 of the Alder Hey business. And let's be clear, none
 7 of these tissues were stored in the Oxford Haemophilia
 8 Centre. I had no knowledge of this. One of the
 9 authors is Professor Margaret Esiri, and she was the
 10 neuropathologist at the Radcliffe Infirmary, and she
 11 had the material and I provided the clinical data.

12 **Q.** Do you know whether the relatives of the patients, the
 13 deceased patients whose tissue samples were being
 14 stored and then studied in this way, had they been
 15 informed of that or asked for consent?

16 **A.** I'm afraid I do not know the answer to that.

17 **Q.** Would you expect that to have been done by you or by
 18 the neuropathologist if it was done?

19 **A.** I would have expected it to have been done by the
 20 person seeking consent for the post-mortem. That's
 21 the usual thing. So if somebody dies, the clinician
 22 normally seeks permission from a relative for
 23 a post-mortem to be carried out. It's not normally
 24 the pathologist's responsibility, unless we're talking
 25 about serious accidents, that sort of thing. But in

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1 normal clinical practice it's the clinician who had
 2 been looking after the patient would request such
 3 permission.
 4 **Q.** I want to move to ask you, relatively shortly because
 5 it is quite well documented, about recombinant.
 6 There was a recommendation by UKHCDO in its 1997
 7 guidelines in support of recombinant. And, as
 8 I understand it, at the point in time at which that
 9 recommendation was made, there was still no form of
 10 national funding available for recombinant.
 11 **A.** That's right. The recommendation was actually
 12 produced and reached in 1996 but it was published
 13 right at the beginning of 1997. But actually the
 14 recommendation was made I think in October or November
 15 of 1996.
 16 **Q.** If we look at some comments you made or you are
 17 recorded as having made in a newspaper article.
 18 Soumik, it is BPLL0016004_007.
 19 We can see this is dated May of 1998. And if we
 20 look in the middle column.
 21 Sorry, could we have the whole document, Soumik.
 22 If we look in the middle column, we can see that
 23 children under the age of 16 are going to start to
 24 receive recombinant. And then it says Scotland, Wales
 25 and Northern Ireland had already started phasing in

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1 recombinant product for all patients.
 2 And then there are some comments from you in the
 3 two columns towards the right of the page. Picking it
 4 up towards the bottom of the article, in the bottom
 5 right-hand corner, you say -- or the article says:
 6 "The Government's new policy has improved the
 7 situation somewhat but it is still not good enough,
 8 says Dr Giangrande. 'I feel like Oliver Twist asking
 9 for more. But we won't be fully satisfied until ..."
 10 And then can we go over the page, please:
 11 "... all UK patients get recombinant
 12 factor VIII. This is an unfair, ageist policy. And
 13 what happens when someone turns 16? It's
 14 unworkable."
 15 Then the article refers to the risk of viral
 16 infections from American plasma. And then, under the
 17 heading "Counselling effort", you are reported as
 18 saying:
 19 "'For a significant minority of my patients,
 20 American plasma is the arch-enemy' ... 'What needs to
 21 be made clear is the immense amount of time and effort
 22 spent counselling patients about all these issues.'
 23 First of all, was that an accurate reporting of
 24 your views?
 25 **A.** Yes, I think it is. And that point about patients

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1 wanting British plasma is a very important one.
 2 I remember a case very vivid actually of
 3 a patient that was referred to our surgery,
 4 orthopaedic surgery. He had septic arthritis. And he
 5 was referred to us from Devon. And he had to go to
 6 surgery in the evening and he was writhing in pain and
 7 crying. I went to treat him and as I went to, you
 8 know, inject him, he suddenly became lucid and he
 9 looked at me and said, "That's not American plasma, is
 10 it?" I said, "No, no, this is BPL, it's 8Y", and he
 11 was reassured and then he went back to writhing on the
 12 bed. And, you know, it is -- it was a big issue for
 13 patients that I dealt with.
 14 **Q.** Then we will just look at one more document in
 15 relation to recombinant, which is a letter published
 16 in the Journal of Thrombosis and Haemostasis from you
 17 in 2003.
 18 It is WITN3311004, please, Soumik.
 19 I just wanted to invite your observations on two
 20 passages, so we can see the heading, "Treatment of
 21 hemophilia: recombinant factors only? Yes".
 22 If we look in the paragraph on the right-hand
 23 side, top of the page, the last few lines of that
 24 paragraph, you refer to the vCJD crisis raising
 25 anxieties in the haemophilia community around the

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1 world. And then you say this:
 2 "In the UK, we have had to counsel many patients
 3 who were notified in early 2001 that they had been
 4 treated with batches of [Factor VIII] and FIX
 5 concentrates issued in 1996/1997 to which a donor had
 6 subsequently died of vCJD had contributed plasma.
 7 These patients would have been spared this ordeal if
 8 recombinant products had been widely adopted for the
 9 treatment of haemophilia as soon as they were licensed
 10 in 1994."
 11 So does this remain your view of the historic
 12 position?
 13 **A.** It does. I would say -- for a global audience,
 14 I would have to point out that in fact in the US and
 15 Canada actually Factor VIII was licensed for --
 16 recombinant factor was licensed in 1992, as it
 17 happens. But -- and I've just really noticed that.
 18 I've quoted the UK date of 1994. But it remains my
 19 view.
 20 **Q.** If we go to the second page, please, Soumik.
 21 Just picking it up at the bottom of the left
 22 hand column. Go down the page. You say this:
 23 "The reality is that it is simply the increased
 24 cost of recombinant concentrates compared to
 25 conventional plasma products, rather than rational

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1 scientific arguments, which is the principal obstacle
 2 to their wider use. In view of all the problems
 3 associated with viral infections in people with
 4 haemophilia over the last two decades, it is clear
 5 that there is indeed much wisdom in Aldous Huxley's
 6 aphorism that the lesson of history is that the
 7 lessons of history are never learnt."
 8 Your view expressed there, and you have repeated
 9 it in your statement, was that one of the principal
 10 reasons -- here you are suggesting the principal
 11 obstacle to the use of recombinants was funding?
 12 **A.** Yes. I mean, in 2003 that was clear. If we had this
 13 discussion in about 1994/95, '96 even, there would be
 14 room for rational argument. Rational argument over,
 15 for instance, the fact that the early recombinant
 16 Factor VIIIs contained human albumin. So is that
 17 a risk factor? Have we truly eliminated the risk?
 18 There could have been some rational discussion about
 19 the incidence of inhibitors, for instance.
 20 But by 2003, when this article was written,
 21 those discussions had been resolved. It was purely
 22 finance.
 23 **Q.** In your statement, and this is WITN3311003, please,
 24 Soumik, if we go to page 43, I'm going to try.
 25 Yes, bottom of the page -- so if you can go to

1 the bottom, please -- you say, in paragraph 95.2:
 2 "In my view, there were three obstacles to the
 3 immediate introduction of recombinant Factor VIII
 4 (which became available earlier than recombinant
 5 [Factor] IX) in the UK."
 6 The first you refer to is lack of consensus
 7 among the medical community, to which I think you have
 8 just alluded.
 9 **A.** Yes, but I think that was fair. That is not
 10 a criticism of medical colleagues. I think it was
 11 perfectly reasonable to spend a year or two debating
 12 this. And UKHCDO I think did well putting together an
 13 internal committee of some of the older and then
 14 younger members to come up with consensus. So that's
 15 not a criticism, it's a fact.
 16 **Q.** Then if we go to the top of the next page, please.
 17 The second paragraph, the second reason you give is
 18 cost. Self-evident. I don't need to ask you to
 19 comment further on that.
 20 The third point you make is this, you say:
 21 "It is my opinion, but I have no evidence to
 22 support this contention, that concerns about the
 23 future and viability of BPL's fractionation facility
 24 may have delayed the authorisation of the use of
 25 commercially sourced recombinant FVII by the

1 Department of Health."
 2 I understand you say there's no evidence for it.
 3 What's the basis for your opinion, however?
 4 **A.** Well, it was discussed, not only in the UK. In fact,
 5 the question was asked rhetorically by
 6 Professor Geoff Savidge in one of the minutes; he
 7 said: what will happen to BPL after this?
 8 In my experience, globally as well, working with
 9 the World Federation of Haemophilia, this is a problem
 10 that has been faced by many fractionators in other
 11 countries, because there's often been, if you take
 12 European countries, a national fractionator.
 13 Sometimes that's a state-owned one, sometimes it's
 14 actually a commercial one working effectively as
 15 a national fractionator. So Grifols in Spain, LFB in
 16 France, and Italy has a similar arrangement.
 17 The point is this, that if you take Factor VIII
 18 out of the equation, suddenly the economics of
 19 fractionation tumbles down, because the principle is
 20 worked on taking plasma, making albumin,
 21 immunoglobulin, vaccines and Factor VIII. If the
 22 Factor VIII is not going to be bought locally, then
 23 what do you do?
 24 Now, in the end, this was solved by BPL starting
 25 to sell products abroad, and I think that helped

1 maintain them for a while. And it's interesting when
 2 you look at the costings -- again, you have shared
 3 several documents with me on this, including something
 4 I did for The Haemophilia Society -- it's interesting
 5 that when you look at the costings, for instance
 6 Lord Hunt does one, he is basing it purely on the
 7 volume of Factor VIII or Factor IX that needs to be
 8 bought, plus, you know, the price of recombinant
 9 Factor VIII.
 10 But I was interested to see in the equation
 11 there is no mention of the impact on the fractionation
 12 facility, but clearly there is an impact. And it
 13 remains my view, and I don't think I'm alone in
 14 thinking this, that the impact of us not buying
 15 Factor VIII from a British fractionator compromises
 16 the financial viability of fractionation.
 17 **Q.** I want to ask you next about the vCJD notification
 18 process, and I'm going to do so by reference to an
 19 article that you exhibited to your statement.
 20 Soumik, it is WITN3311009, please.
 21 This is a 2010 article:
 22 "Risk reduction strategies for [vCJD] disease
 23 transmission by UK plasma products and their impact on
 24 patients with inherited bleeding disorders."
 25 If we could go please, Soumik, to page 3.

1 Bottom of the page.
 2 We can see, if we go to the bottom, please,
 3 under the heading "Management of early plasma products
 4 recalls", picking it up five lines from the bottom:
 5 "The 1997 product recall letters from BPL to
 6 haemophilia centres cited the following advice that
 7 had been provided by the ethics committee local to the
 8 NCJDSU: 'the recipients (patients) should not be
 9 informed that the product that they ..."
 10 If we go over the page, top of the next page:
 11 "... had received has been recalled for this
 12 reason [subsequent diagnosis of vCJD in donor]. In
 13 response to queries raised by clinicians and hospital
 14 trusts about this directive, the DH confirmed to
 15 medical directors that patients who had received
 16 implicated blood products should not be informed.
 17 This was based on three considerations: first, that it
 18 was not known (the word used was 'unlikely') whether
 19 vCJD was transmissible by blood products; secondly,
 20 that there was no diagnostic test in existence, and
 21 finally that no preventative treatment was available.
 22 The consensus given by the DH at the time was that
 23 patients would 'not benefit from this knowledge, and
 24 that uncertainty created by informing patients could
 25 cause unjustified worry and create a permanent blight

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1 on their lives'.
 2 Then it says this:
 3 "However, many haemophilia physicians either
 4 directly informed patients who had received an
 5 implicated batch, or provided all their patients with
 6 information about vCJD, giving them the option to be
 7 informed whether or not they had received an
 8 implicated batch(es)."
 9 Then the article goes on to discuss the
 10 establishment, in 2000, of the CJD Incidents Panel,
 11 which then provided advice for the subsequent
 12 notifications.
 13 Am I know right in understanding, Dr Giangrande,
 14 that you were one of the clinicians who decided that
 15 you would notify patients in 1997?
 16 A. Yes. But I want to make it clear I wasn't alone, and
 17 I am pleased to see the great majority of clinicians
 18 did. In fact, I believe Christopher Ludlam, writing
 19 on behalf of UKHCDO, wrote a letter, I think it was to
 20 The Lancet, setting this out.
 21 Now, the purpose of the recall, of course, was
 22 to let us in haemophilia centres know about this and
 23 to take back any material from those implicated
 24 batches and send them back.
 25 I don't believe the '97 recall affected any

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1 Oxford patients. The 2001 recall did. It affected 85
 2 of our patients in 2001.
 3 But clearly most of us felt that this was not
 4 a tenable option. And it wasn't a tenable option for
 5 a number of reasons. Firstly, there is something
 6 about -- we can do something about this. We have to
 7 learn, again, from the lessons of history. And the
 8 option we have, if we are being told -- I mean, why
 9 are you telling us this? I would say to BPL. If you
 10 are suggesting there's a risk to the patient, then we
 11 have to do something about it. And that something is
 12 to offer patients the chance to switch to a plasma
 13 product made from material which doesn't carry a risk
 14 of variant CJD, so, a drastic change in policy for us
 15 in Oxford, but to switch from BPL, British volunteer
 16 donor plasma, to American-sourced plasma. And that's
 17 what we did.
 18 I'm pleased to say many other colleagues in the
 19 UK did that as well. The other issue, of course, is
 20 that I know from my work with the WFH that you can't
 21 hide this from patients. And I think it's important
 22 to be upfront and truthful with the patients because
 23 The Haemophilia Society would definitely have come to
 24 have heard about this and I think -- it simply was not
 25 tenable not to tell patients. And there was something

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1 we could do to minimise future risk.
 2 Q. We have a sample letter sent by you and Dr Keeling in
 3 December 1997 to your patients, and it refers, as well
 4 as notifying the patient and providing information, to
 5 a meeting you had arranged in a lecture theatre at the
 6 John Radcliffe Hospital on 15 December 1997 to present
 7 the evidence and discuss the matter, and to which the
 8 patient was invited. What was the purpose of that
 9 meeting? Did it take place?
 10 A. It did take place, but -- and I should explain that
 11 the John Radcliffe Hospital is our sister hospital and
 12 it's a couple of miles away. I anticipated a very
 13 large audience, which is why I booked one of the major
 14 lecture theatres at the John Radcliffe. Admittedly
 15 this was shortly before Christmas, but actually only
 16 a handful of patients turned up.
 17 I think, to be honest, by this stage patients --
 18 and I used the word in other articles -- were quite
 19 sanguine about variant CJD, and I think the risk to
 20 the patients -- it was something we shared with the
 21 patient community. I had been eating beef, my
 22 family's been eating beef, we're all at risk of
 23 variant CJD.
 24 The problem had arisen back in 1984. I think
 25 people had been reassured that no people with

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1 haemophilia had developed variant CJD. So all I can
 2 say is that I was surprised that so few people turned
 3 up. But it didn't create a stir.
 4 Having said that, quite a lot of our patients
 5 did take up the offer to switch to American plasma.
 6 We used Alphanate.
 7 **Q.** Then, as you already alluded to, you wrote to patients
 8 again in 2001. And then I think thereafter the
 9 patient notification exercise was the one we explored
 10 with Professor Hay, which was organised, as it were,
 11 centrally through the Health Protection Agency and
 12 UKHCDO.
 13 **A.** Yes.
 14 **Q.** There's an observation in a document you authored and
 15 I wanted to ask you to comment on. It's DHSC --
 16 **A.** Can I -- are you going to mention the international
 17 dimension of the 2004 recall? Because I think that's
 18 important to emphasise.
 19 **Q.** You can do that now if you wish, doctor, before we
 20 look --
 21 **A.** Remember that the 2004 notification exercise took
 22 place in September 2004. We were told on 9 September
 23 about this, and we had to send letters to patients by
 24 20th September.
 25 Now, actually, the point is that although this

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1 notification affected us in the UK, BPL who was -- we
 2 were expected to tell people who had received British
 3 plasma products in the period 1980 to 2001 that they
 4 were at risk of developing variant CJD. Was anyone
 5 abroad told this? No, they weren't. And this meeting
 6 actually -- sorry, this notification happened to take
 7 place just before the World Federation of Haemophilia
 8 Congress in Bangkok.
 9 I have to say we set up -- this generated a lot
 10 of anxiety and, indeed, anger in the international
 11 community, because BPL had exported British products
 12 to over 30 countries around the world and in this
 13 article, the one that you have on the screen at the
 14 moment, somewhere further down there are 13 countries
 15 listed that had received implicated batches. But, in
 16 fact, I think it was 36, actually, countries had been
 17 receiving these products. And BPL, or the British
 18 Government, did not make any attempt to contact
 19 individual physicians abroad in other countries.
 20 Inevitably, of course, patients in other
 21 countries learnt about this, and we set up
 22 a symposium -- which was packed -- in October 2004, at
 23 the WFH congress, at the beginning of October.
 24 We were lucky to get as speakers Bruce Evatt, of
 25 CDC fame, who had taken a leading role in the HIV

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1 drama of the 80s, James Ironside also spoke. I gave
 2 a summary of the UK position.
 3 And I'm pleased to say that WFH took a lead.
 4 They produced -- they had circulated copies of the
 5 implicated batch numbers to the affected countries,
 6 put the details on the website, and the president of
 7 WFH joined me in a meeting with BPL immediately after
 8 that October meeting in Bangkok, and in the end what
 9 BPL did -- or the British Government -- they sent
 10 notices to the health ministers of the various
 11 countries inviting them to seek information from the
 12 local British Embassy. But no contact was made with
 13 any physicians.
 14 **Q.** Then the documents I'm going to ask you to look at,
 15 which is about the impact on patients, is at
 16 DHSC0006838_071.
 17 We can see it's "The UK Experience, Treater and
 18 Patient Association Perspectives", and these are
 19 presentations given by you and by Karin Pappenheim.
 20 If we go to the next page, we can see the
 21 heading, "Communicating Risk: The Example of vCJD, The
 22 UK Experience: The Treater Perspective".
 23 And then if we can go to the next page, please.
 24 Could we zoom in on the third paragraph, under the
 25 heading, "What was the reaction of our patients?",

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1 please, Soumik.
 2 So this was your observation:
 3 "As a general rule, the reaction was
 4 surprisingly phlegmatic. Many recognised that, in
 5 contrast to previous outbreaks of HIV and hepatitis,
 6 vCJD is an issue which faces all of us who live in the
 7 UK, and not just the recipients of blood products."
 8 Which is I think effectively your evidence a few
 9 moments ago. But then you say this:
 10 "However, there were several notable exceptions
 11 where real and persisting anxiety has been generated,
 12 including several patients who have consulted me
 13 because they are convinced that they are
 14 harbouring vCJD."
 15 **A.** That's true, yes. This, by the way, for those that
 16 aren't aware, was a World Federation of Haemophilia
 17 meeting in Montreal.
 18 **Q.** Then if we could go a little further down the page,
 19 Soumik, to the paragraph under the heading "Were there
 20 any other consequences?" And you said this:
 21 "One unexpected consequence was that some
 22 patients who had received these batches were regarded
 23 as being at high risk of transmitting infection
 24 themselves. There were several instances of patients
 25 being denied surgery, dental work, or endoscopy

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1 because of the implications for surgical instruments.
 2 Advice was sought from the Department of Health, and
 3 although guidelines are expected to be published,
 4 these have not yet been forthcoming at the time of
 5 writing."
 6 To what extent was that problem of patients
 7 being denied surgery, or we've heard cases of
 8 patients' surgery being deferred, and the issue over
 9 accessing dental care and endoscopies. To what extent
 10 was that a problem in Oxford, and how, if at all, was
 11 it resolved?
 12 **A.** It became a much bigger problem, of course, after the
 13 2004 notification because we've got to remember that
 14 here we're talking about the 2001 notification. But
 15 if I could squeeze them both together, I would say the
 16 biggest impact was undoubtedly dental work.
 17 We were lucky in Oxford because we had a good
 18 dental service that operated initially in the Nuffield
 19 Orthopaedic Centre, and then for a number of years we
 20 had a dental service actually within the Oxford
 21 Haemophilia Centre. And then because of budgetary
 22 cuts, it was moved to the East Oxford Health Centre,
 23 but still patients could be seen.
 24 But a lot of patients did have problems outside
 25 the immediate Oxford area, and certainly in relation

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1 from The Haemophilia Society, as well as others.
 2 Dr Giangrande, I'm not going to ask you about
 3 the detail of the recommendations because we have the
 4 report, but could you just outline briefly how this
 5 working party came about and what the purpose of
 6 reporting was?
 7 **A.** The party was convened by The Haemophilia Society. So
 8 I don't know the background to that. We were just
 9 invited and naturally all agreed.
 10 The background was to try and get financial
 11 assistance for people who had been affected by
 12 hepatitis C. Note, not just the patients but also
 13 various families. It was partly as a consequence of
 14 the famous agreement whereby people signed away rights
 15 for compensation in relation to the payment made for
 16 HIV. And the purpose of this which took -- it was
 17 convened in, I think, September of 2001; we reported
 18 in June of 2002 -- was basically to come up with
 19 a simple costed measure. And we did this looking at
 20 systems that operated in other countries and seized
 21 upon the Canadian model which seemed a particularly
 22 good one.
 23 We also sent out questionnaires on behalf of The
 24 Haemophilia Society to our patients in Oxford. We
 25 sent out 150 from Oxford, and also our colleagues in

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1 to the 2004 notification, it was a serious issue.
 2 And, indeed, I wrote a letter to the British dental
 3 journal, which you will find in my list of
 4 publications, together with Andrew Brewer who was
 5 a dental surgeon in Glasgow. Because the British
 6 Dental Journal obviously goes to all dentists, we
 7 wanted to make some reassuring noises, if you like, to
 8 the dental community.
 9 So I think for my patients in Oxford, the
 10 biggest single impact was the dental work. Endoscopy
 11 wasn't an issue for the patients. It was for us
 12 because, of course, of this issue which others have
 13 talked about of quarantining endoscopes, one endoscope
 14 per person which had cost implications, but the
 15 patient still got their endoscopy.
 16 **Q.** I want to then move to the topic of compensation in
 17 relation to HCV and The Haemophilia Society's
 18 campaign. Could we have, please, on screen
 19 SKIP0000031_082.
 20 We can see this is a document, "Report of the
 21 Hepatitis C Working Party to The Haemophilia Society,
 22 June 2002". If we go to page 4, please, Soumik, we
 23 can see there in paragraph 1 identified the membership
 24 of the working party, which included yourself,
 25 Professor Preston, Dr Makris, and Karin Pappenheim

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1 Sheffield sent out a similar questionnaire. How had
 2 hepatitis C affected them in their lives, in terms of
 3 their working lives? Could they get mortgages, life
 4 insurance, that sort of thing? Had it affected their
 5 income?
 6 Then we came up with a five-stage plan which
 7 offered compensation, or assistance shall we say,
 8 according to the level of patients being affected.
 9 I think the Skipton Fund in the end came up with --
 10 and, by the way, after this report launched, we had
 11 a meeting in the House of Commons with Hazel Blears,
 12 the then health secretary, and there was another MP
 13 there. And this led to various discussions which, in
 14 the end, led to the Skipton Fund being set up with
 15 a simpler model, a two-stage system, but the money was
 16 pretty similar.
 17 The costing worked out at, going from memory,
 18 £52.6 million for five successive years. This model
 19 proposed one thing which has still not been achieved,
 20 and that is coming back to something I was saying in
 21 the morning session. Level 1 offered compensation or
 22 assistance of £7,500 to people who had been exposed to
 23 HCV but didn't have persistent infection. That is,
 24 they'd cleared it spontaneously. The reason for that
 25 was we felt that being told you had hepatitis C,

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1 because in the early days, without the PCR tests, we
2 couldn't say, "Look, you've cleared it spontaneously."
3 We thought that generated a lot of anxiety and worry
4 which deserved to be rewarded.

5 The second thing I would want to pick up on from
6 this report is that we clearly said that this money
7 should also be available to the relatives of the
8 deceased. And I'm sorry to say that in the initial
9 incarnation of the Skipton Fund, that did not happen.
10 Although, I'm pleased to say that some years later an
11 adjustment was duly made.

12 But that's the sort of background, and I thought
13 it was a good report. I think it had some influence.

14 **Q.** There's a follow-up letter you wrote to the Department
15 of Health in October 2003, so a year or more later,
16 which we'll just look at. DHSC0004421_005.

17 So we can see this is a letter written by you to
18 Dr Hugh Nicholas at the Department of Health,
19 24 October 2003. If we can scroll down a little
20 please, Soumik. You refer to a meeting to discuss the
21 way forward. That you had been unable to attend but
22 Professor Pasi had attended on behalf of the Society.
23 You express surprise that no apparent consideration
24 had been given to a document submitted by the
25 Haemophilia Society. Is that the document we were

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1 just looking at? The report?

2 **A.** Yes.

3 **Q.** Then you identify what appear to be:

4 "Some clear differences of opinion between our
5 group and that which met on October 14."

6 We'll just look at the three points that you
7 were there making. The first is payment to patients
8 who had simply tested positive for HCV antibody, even
9 if they subsequently cleared this. And you say:

10 "It may be difficult for you to appreciate the
11 tremendous anxiety that was generated in the early
12 1990s when patients were tested and informed of their
13 results for hepatitis C. People with haemophilia were
14 among the first cohorts to be investigated and tested
15 systematically, and this group of patients was
16 particularly mindful of problems related to AIDS only
17 a few years beforehand."

18 Then if we go over the page, please, you say:

19 "We think it grossly unfair that patients
20 co-infected with HCV and HIV should not receive
21 additional compensation."

22 You go on to talk about that. And then 3:

23 "Equally, we feel it grossly unfair that
24 compensation should not be offered to the relatives of
25 those who died from hepatitis."

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1 And then you offer to discuss the points with
2 the person to whom you are addressing it.

3 Can you recall whether you had any further
4 discussions with the Department of Health on these
5 points?

6 **A.** I'm afraid I don't any longer have access to it, no.
7 I'm afraid I don't.

8 **Q.** Is it fair to say your letter was prompted by your
9 understanding that there was resistance by the
10 Department of Health to these three matters?

11 **A.** That's absolutely true.

12 **MS RICHARDS:** Sir, I note the time. I've got a few more
13 questions for Dr Giangrande, not too many more, but we
14 obviously need to afford the opportunity to recognised
15 legal representatives in the break to suggest any
16 further lines of question. So could we take a break
17 for 45 minutes?

18 **SIR BRIAN LANGSTAFF:** Yes. So 4.00 in that case.

19 4.00, doctor, if you wouldn't mind. And
20 4 o'clock to everyone.

21 (3.16 pm)

(A short break)

22 (4.00 pm)

23 **MS RICHARDS:** Dr Giangrande, if we look at your statement
24 again -- Soumik, it's WITN3311003 -- and I'll find the

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1 page number I hope ... it's question 152.

2 I think it's probably page 84, Soumik.

3 **SIR BRIAN LANGSTAFF:** Paragraph 162?

4 **MS RICHARDS:** 152.

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

6 **MS RICHARDS:** Yes. So this is a question about the HCV
7 look-back, and reference made to some -- various
8 documents. And then if we go down to your answer, you
9 say that you weren't involved in this exercise and
10 cannot comment.

11 **A.** The reason for that is my colleague, David Keeling, by
12 this stage had risen to become the Vice Chairman
13 of UKHCDO. This was an aspect that, because he was
14 closely involved with it, he dealt with this on behalf
15 of Oxford.

16 **Q.** In that case -- that, effectively, was the question
17 I was going to ask, whether it was dealt with by
18 somebody else or whether Oxford was not involved
19 with --

20 **A.** Yes, I'm sorry if it wasn't clear. I agree that's
21 a short and rather terse answer, and I could have been
22 more helpful.

23 **Q.** Then could we have, please, on screen BART0002460_003,
24 please, Soumik.

25 So this is a document headed "UK Scientific

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1 Advisory Group Meeting ... May 1992". The
 2 participants are five clinicians. I think we've heard
 3 from all of them now, and you're the last, and I'm
 4 afraid the first I'm asking about this. Then we can
 5 see representatives from Armour present.
 6 It's obviously a meeting in London. There's
 7 a reference to dinner and lunch and so on. Then,
 8 "Subjects for Discussion":
 9 "What does the Panel want from Industry?"
 10 And then 2:
 11 "EEC Directives on self-sufficiency and 'unpaid'
 12 donors and their impact on the UK plasma industry.
 13 "a. Problems.
 14 "b. Solutions."
 15 And then:
 16 "Concerns from the market."
 17 Can you recall what the scientific advisory
 18 group or this panel was or what your involvement in it
 19 was?
 20 **A.** The first thing I want to point out is that in my
 21 statement you will see very clearly that I declared
 22 right from the start, before you showed me this
 23 document, that I had done advisory work for Armour.
 24 So this is nothing new and I want to make that clear.
 25 So I had declared that.

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1 These sort of meetings were held just
 2 occasionally, and advisory boards, I find them very
 3 useful actually. They are an opportunity for
 4 clinicians, either nationally or internationally, to
 5 focus on topics of current interest.
 6 I have no recollection of this meeting,
 7 obviously, so long ago, but I think it's clear from
 8 the agenda there's nothing really overtly promotional
 9 about this, it's really to share a view.
 10 One of the things that I do remember that came
 11 out of this which I found really useful was that -- in
 12 terms of communication to and from industry,
 13 Robert Christie used to produce some very good
 14 summaries of literature.
 15 Remember, this is a time, 1992, before the
 16 internet, and he used to send out very good summaries
 17 of publications in the field of haemophilia. And
 18 I found that particularly useful actually.
 19 But there's nothing overtly promotional about
 20 this. These are meetings of genuine interest.
 21 I found them very interesting.
 22 **Q.** I understand you don't have recollection of this
 23 particular meeting, back in 1992. In terms of the
 24 subjects for discussion, can you assist us with why
 25 the issue of unpaid donors and impact on UK plasma

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1 industry might have been a topic for conversation?
 2 **A.** I'm afraid I can't. I mean, this has been an ongoing
 3 issue. And I think it's interesting to see, and
 4 I noticed when you sent me this document, "unpaid" is
 5 in quotation marks, and I do feel -- I do remember
 6 that many in the industry feel that sometimes the
 7 distinction between paid and unpaid donors is not
 8 entirely clear. It's certainly the case in some
 9 countries, and there's a lot of literature on this,
 10 and it's probably best addressed to someone working in
 11 transfusion, but they get some form of recompense, be
 12 it a couple of days' paid leave or travel vouchers or
 13 other things. So I think that is why that is in
 14 quotation marks.
 15 But I think this has been a debate for a long
 16 time now, the question of the safety of paid donors.
 17 And I'm not a transfusion expert at all. I presume
 18 you will be speaking to some. But I think the feeling
 19 is that now they are no longer seen as the pariahs
 20 that they were once seen as.
 21 **Q.** More generally, and you're right that your statement
 22 has provided information about consultancy work for
 23 pharmaceutical companies and so on. More generally,
 24 do you have any experience of any particularly lavish
 25 hospitality or gifts or approaches of that kind from

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1 pharmaceutical companies?
 2 **A.** Not gifts. I mean, clearly I have been -- over time,
 3 received support from pharmaceutical companies, often
 4 to travel to conferences, for instance. These are
 5 very strictly regulated, and I think things probably
 6 have changed since the 70s and 80s. My first ever
 7 trip for a work-related thing was actually in
 8 December 1991, when I went to the US. And certainly
 9 nowadays these are regulated and, indeed, policed.
 10 And, you know, long gone are the days of staying in
 11 luxury hotels, or going to meetings which are, you
 12 know, not strictly business.
 13 So I have been abroad with companies but they
 14 have been conducted by companies for *bona fide*
 15 meetings and in compliance with APPI regulations at
 16 the time.
 17 **Q.** If we could look at a set of UKHCDO minutes, it's
 18 HCDO0000452, please. It's the minutes of a meeting
 19 in 1994.
 20 If we could go to page 6, please, Soumik.
 21 We can see paragraph 8 is "Declaration of
 22 Interests". It says:
 23 "Dr Mayne was invited to speak on this item.
 24 She said that Declaration of Interests was required by
 25 the Constitution. The document gave the framework for

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1 the Declaration of Interests and was based on
2 a document used by the CSM. Dr Colvin suggested that
3 he should write to all Regional Representatives asking
4 for a Declaration of Interests and this was agreed."

5 Just pausing there, is it right to infer from
6 this document, or are you able to assist us more
7 generally, that this was effectively the first time,
8 with the constitution that we know was introduced in
9 the early 1990s, that UKHCDO directors were asked to
10 complete declarations of interests to UKHCDO?

11 **A.** It looks like it. I can't remember anything else
12 before this.

13 **Q.** Before we leave this document, there was also an issue
14 raised here, and it's raised in some other meetings,
15 about the presence of Department of Health
16 representatives at UKHCDO meetings. Do you recall
17 discussions about that and any concerns expressed
18 about Department of Health reps routinely attending
19 UKHCDO meetings?

20 **A.** Yes, it was an issue. I have to say there was one --
21 and I won't mention his name, although it appears the
22 documents -- he was a haematologist, and actually
23 I found it useful that he attended our meeting.
24 I thought it was useful to have a Department of Health
25 representative.

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1 But I can understand that, you know, people
2 would see a perception that, you know, the Department
3 of Health, they are different and, just like
4 companies, should sometimes be excluded. So I think
5 it's quite appropriate that we had links with the
6 Department of Health but equally I think it's
7 reasonable to have private sessions too.

8 **Q.** And then just still on the topic of declarations of
9 interest, if we go back to your statement.

10 Soumik it's WITN3311003. And if we could go
11 please to page 66.

12 **SIR BRIAN LANGSTAFF:** Paragraph?

13 **MS RICHARDS:** 125, sir.

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

15 **MS RICHARDS:** I hope I've got that right. Yes.

16 So paragraph 125.1, you have said there that:

17 "My Trust [so the hospital trust which employed
18 you] introduced a requirement for declarations of
19 interest some years ago. I believe this was in around
20 2004 when the new consultant contract was introduced.
21 I have complied with this."

22 Is it right to infer from that that, in terms of
23 a requirement imposed upon consultants by their
24 employers, there wasn't any requirement until 2004 or
25 thereabouts?

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1 **A.** No, I don't remember it. I mean, what actually
2 happened, to be clear, was under the original -- when
3 I started in '93, there was what was called the old
4 kind of -- what we now refer to the old consultant
5 contract. And there was also a document which
6 remained in place throughout most of my time as
7 a consultant, it's called HSG(93)5, which is conduct
8 of business for NHS employees.

9 Now the thing about the old consultant contract
10 was that it didn't actually -- it was quite loose and
11 it didn't specify hours. So you were allowed to --
12 you know, if someone wanted to come in at ten o'clock,
13 he came in at ten o'clock, but the main thing is --
14 I refer to that, is because of the private practice
15 issue. And there was a limit of 10 per cent. You
16 could do private practice and, you know, do additional
17 work, but it could not be more than 10 per cent of
18 your income.

19 And every year you had to -- you would get
20 a little pink form that would come through, in all
21 the NHS, and you had to say "yes" or "no", have I gone
22 over that 10 per cent. In my case, never. If you
23 did, you were allowed to do it once. If you did it
24 a second time, you would be obliged to move to
25 a maximum part-time contract.

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1 Now, when the new consultant contract came in,
2 actually it was 2003 was the new contract, this
3 changed radically. And what happened was it gave
4 hospitals much more power and influence over the
5 individual consultants. So every year you had to
6 negotiate a job plan and that fixed hours.

7 Now there was an increased salary but one of the
8 incentives was to say: look, if you switch to this,
9 that 10 per cent limit is gone. Whatever you do in
10 your own spare time, that's up to you. If you want to
11 go to advisory boards on a weekend or if you want to
12 see private patients in the evening, you do what you
13 want. So that limit went. But, linked to that, you
14 had to declare an interest.

15 Now I have to say the interests that Trusts are
16 primarily interested in are really quite high level
17 ones. So are you the director of a company? Do you
18 own a care home somewhere? Is a relative of yours
19 Chairman of a company the Trust might be -- you know,
20 you might be -- doing business with?

21 So I would submit the declarations of interest.
22 And by the way, you didn't have to seek permission,
23 you just told the Trust, "This is what I have done",
24 and no-one ever contacted me to say, "Dr Giangrande
25 what's this all about?"

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1 So I hope that gives you a summary. It was
 2 linked to the new consultant contract, yes.
 3 **Q.** Just so that people understand the wider implications
 4 of it, the consultant contract's a national contract.
 5 This isn't something particular to Oxford.
 6 **A.** No, it was a national contract. The new contract, as
 7 we now call it, was obligatory for any consultant
 8 taking up a post after 2003. The people already
 9 working for the NHS as a consultant could opt to stay
 10 on the old contract if they wished. So there had to
 11 be some incentive to switch. And it was the loss of
 12 that 10 per cent cap that was, I guess, the incentive
 13 for many.
 14 **Q.** Now, just dealing with UKHCDO as an organisation, you
 15 have already told us or given us some insight from
 16 your perspective. But as a junior doctor in the 1980s
 17 attending those three or four AGMs at key times '83,
 18 '84, '85, '86, do you have any particular perspective
 19 as to how the AGMs operated? The ability of --
 20 **A.** I heard others say that it was a bit like going to
 21 a sort of shareholder meeting. You know, the floor,
 22 there may be some questions, but all the key decisions
 23 are taken by the key people.
 24 I have to say that the people in the top
 25 reference centres merited the respect of others.

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1 I think they were also -- on a personal level, I must
 2 say this -- very approachable. And as a junior
 3 person, I found all of them very open. They were not
 4 in any way difficult to work with. I found them all
 5 very, very pleasant.
 6 But I think, inevitably, there were just a few
 7 reference centres at the time. I would say it's
 8 not -- it wasn't entirely democratic, but I was
 9 impressed with the key people at the time, on
 10 a personal level.
 11 **Q.** Do you have any insight into -- and I'm now talking
 12 about from the 1990s when you were involved directly
 13 in UKHCDO. Do you have any insight into how the Chair
 14 was chosen? We heard from Dr Colvin that he
 15 effectively got a phone call out of the blue from
 16 Dr Rizza asking him to be Chair. Do you have any
 17 knowledge of that?
 18 **A.** It is voted on. It is voted on. I didn't know about
 19 the Brian Colvin situation. All I can say is that
 20 certainly the current position, and for long as
 21 I remember, it's always been down to a vote. So the
 22 officers are elected.
 23 So I think it's -- I think modern -- the modern
 24 UKHCDO, apart from that change in the constitution
 25 which I think was retrograde. I have to say I think

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1 having an advisory board and an executive committee,
 2 I think that was a retrograde step which
 3 disenfranchised many people, but I recognise that was
 4 democratically voted upon; it wasn't imposed on
 5 anyone. But I think, overall, it's a very democratic
 6 group of people. And I think that if you look at the
 7 chairpeople there's a nice mix of younger people as
 8 well as older experienced people, and I think it's
 9 important that we have people from some of the smaller
 10 haemophilia centres as well as the big centres so
 11 everybody gets a crack of the whip.
 12 So, overall, I think it's an example
 13 internationally, and it is an example actually which
 14 has been copied. If you look at the Italian system,
 15 which I know well, for instance, they have modelled it
 16 effectively on the British system, as have the
 17 Australians.
 18 **Q.** There are some references in UKHCDO minutes -- I'm not
 19 proposing to go through the detail of the minutes, but
 20 you're expressing reservations or concerns about
 21 UKHCDO receiving support, financial support, funding,
 22 from pharmaceutical companies.
 23 **A.** Yes, I do feel that. I mean, to be honest, leaving
 24 the database aside, UKHCDO is not an organisation that
 25 requires vast amounts of money. After all, all it

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1 does is meet a few times in an office somewhere and,
 2 you know, everyone is paying their travelling expenses
 3 from their Trusts. So it's not an organisation that
 4 requires a lot of funding.
 5 I do think it is best for UKHCDO to not take
 6 money from pharmaceutical companies. And allow me to
 7 extend the question by saying I think the same is also
 8 true of patient societies. And, you know,
 9 organisations like the UK Haemophilia Society and
 10 patient organisations around the world are all too
 11 often dependent on money from pharmaceutical companies
 12 to survive.
 13 One of the recommendations, if I may put in
 14 a bid, that I'd like to see come out of the Infected
 15 Blood Inquiry, if I may, is I do think there should be
 16 a guarantee of financial support for the UK
 17 Haemophilia Society. And that is a recommendation
 18 that also came out of the Lindsay Tribunal as well.
 19 And I think it is important that patient societies as
 20 well as doctor organisations be freed from links to
 21 pharmaceutical companies.
 22 **Q.** We've heard some reference from clinicians to
 23 something called the haemostasis club. Was that
 24 something that you were familiar with?
 25 **A.** No. I read that -- I believe Dr Mitchell mentioned

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1 that. I think I did go to one meeting at St Thomas'
 2 Hospital, but only one. As I say, we in our region
 3 had our own what we called blood clubs, and I was
 4 a regular attender of those, but not the one in
 5 St Thomas'.

6 **Q.** Then could we look, please, at SKIP0000031_106 please,
 7 Soumik. So this is a letter from you in August 2011
 8 to Nicholas Fish, the scheme administrator at the
 9 Skipton Fund, and it refers to "Skipton part 2 form
 10 for Oxford patients".

11 You say in the first paragraph that the Oxford
 12 Haemophilia Centre has a large historical cohort and
 13 have records of patients going back many decades.
 14 Then you say this:

15 "I've discussed the various options with our own
 16 hospital managers. I understand they have been in
 17 contact with your office as well. I'm now writing to
 18 let you know that I've received written managerial
 19 approval for us to levy a fee of £75 for the
 20 completion of these forms. We are well aware of the
 21 expectation, as your office has put it, from the
 22 Department of Health that these forms will be
 23 completed free of charge. However, there is a
 24 significant resource issue raised here, and I have
 25 also shared with you the very clear advice from the

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1 BMA that we're entitled to charge for completion of
 2 these forms, which are quite different from statutory
 3 documents such as death certificates, sick notes,
 4 et cetera. I would also make clear that the money
 5 charged will be paid directly to my employers and not
 6 to me personally.

7 "I will therefore be writing to all those
 8 relatives who have submitted part 2 forms to us, and
 9 I enclose a copy of that letter so you are aware of
 10 what we are telling them. Please note, however, I
 11 will continue to complete any new part 1 application
 12 forms that I receive, as these take much less work."

13 Then if we just go, before I ask you about this,
 14 to SKIP0000031_108. So this is a form that you
 15 prepared. "Skipton part 2 application form":

16 "If you would like me to complete the form for
 17 you, please send a cheque for £75 made payable to the
 18 Oxford Radcliffe Hospitals NHS Trust to me here at the
 19 Oxford Haemophilia and Thrombosis Centre.

20 "You may request the return of your application
 21 form to you so that you may approach another doctor to
 22 do this for you.

23 "I could send the clinical records we hold on
 24 your relative to the Skipton office for their review,
 25 although it will be entirely up to them to decide

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1 whether they would be prepared to do so."

2 This, as I understand it, reflects a decision
 3 taken by you and/or your Trust to levy a fee for the
 4 completion of the Skipton form.

5 **A.** Yes.

6 **Q.** Can you tell us, first of all, why you decided to do
 7 that?

8 **A.** Well, it was a significant resource issue for us.
 9 This came hot on the heels of the look-back exercise
 10 for hepatitis which really caused a resource issue.
 11 We're a centre with a large number of patients and not
 12 a lot of staff; we had just two consultants at the
 13 time. Having to deal with all of these forms did
 14 create a resource issue, and even it came up for our
 15 monthly management discussion. I'm not going to
 16 disguise and say otherwise that it was my suggestion
 17 that we consider charging. I should say, we have
 18 a long history of doing all sorts of forms for our
 19 patients. You know, they come to us rather than their
 20 GPs to get passport forms signed and, you know, travel
 21 insurance cancellations, all those things we've always
 22 done, but there was a resource issue. It took a lot
 23 of time.

24 My hope, if I'm honest, was that the
 25 Skipton Fund would reimburse this. Everybody was

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1 issued with a receipt. And if the Skipton form hasn't
 2 done that, I hope coming out of this perhaps the
 3 Skipton form would now be able -- the Skipton office
 4 or its successors would be able to do so.

5 But it was a significant resource issue bowled
 6 over by the hepatitis C scheme. I mean, there's
 7 a limit to the paperwork that centres, especially
 8 large ones, can take on. If you've got just a few
 9 patients, that's easy.

10 Let me say also that no patient ever complained
 11 to me. No patient ever said, "I can't afford it," in
 12 which case, clearly, we would have waived it. And I'm
 13 not going to deny that's what we did.

14 **Q.** Levying a fee of £75 for completion of the form is not
 15 going to alleviate the resource issue that you
 16 identify in terms of time, unless the intention was
 17 that people would be discouraged from submitting the
 18 applications at all.

19 **A.** This is -- I fully accept your argument. You are
 20 absolutely right. It was certainly not to
 21 distinguish -- I know you had this discussion, I
 22 believe, with Charlie Hay about a database fee. It
 23 was certainly not my intention at all.

24 **Q.** It would have left patients, effectively, with no or
 25 little choice. They had to pay if they wanted to be

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1 able to make an application.
 2 **A.** You're quite right too. I'm not going to disagree
 3 with you.
 4 **Q.** Does it not strike you as curious that in
 5 circumstances where an NHS body has through its
 6 treatment caused the infection that gives rise to the
 7 need for financial assistance, that same NHS body then
 8 effectively charges the patient for the information
 9 they require?
 10 **A.** I accept your argument.
 11 **Q.** Do you know whether this system -- I know you retired
 12 in 2015, doctor, but do you know whether this fee is
 13 still levied by Oxford?
 14 **A.** I don't know, I'm afraid.
 15 **Q.** We can ask that question of Dr Keeling.
 16 **A.** No, he's retired.
 17 **Q.** In that case, we can no doubt ask that question of
 18 whoever is currently responsible.
 19 **SIR BRIAN LANGSTAFF:** Well, we can ask the Trust Chief
 20 Executive, can't we?
 21 **MS RICHARDS:** Yes, we can.
 22 Dr Giangrande, I have now got some questions
 23 which have been suggested by the representatives of
 24 core participants, and so they're going to dot around
 25 somewhat from topic to topic.

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1 First is this, and I'm asking you now to go back
 2 to that part of the early 1980s when you worked for
 3 a period of time with Dr Craske. Did Dr Craske tell
 4 you anything or ever discuss with you the work of the
 5 hepatitis C working party or the evidence or concerns
 6 about the seriousness of hepatitis C?
 7 **A.** No, he didn't. I mean, my link with him was --
 8 I mean, he obviously regarded me as a very junior
 9 person. When I was in Manchester I didn't even know
 10 he had any link with the haemophilia community. And
 11 although he was extremely nice to me, I was a very
 12 junior person and he never discussed anything like
 13 that with me personally.
 14 **Q.** In correcting the passage of your statement about
 15 patients being informed of their diagnosis with
 16 hepatitis C, and in the evidence you gave this
 17 morning, do you accept that as a consequence of the
 18 delay or a consequence of a delay in telling patients
 19 that they are hepatitis C positive is that, for that
 20 intervening period, they had no opportunity or
 21 informing partners or GPs or other providers of
 22 treatment to them of the possible risks of exposure to
 23 the virus?
 24 **A.** Yes.
 25 **Q.** Does that concern you?

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1 **A.** Well, I think when you look at the timescale, I mean,
 2 many of these patients had been infected in the early
 3 1970s, so by the time -- we're talking of
 4 a difference, you know -- so let's say -- the evidence
 5 is quite clear that people were infected with
 6 hepatitis C usually with the first dose of concentrate
 7 they received. So for many people that will have been
 8 in the 1970s. So, in terms of proportion, on the
 9 timescale, the difference between 1990 and, let's say,
 10 1992 is a relatively small proportion.
 11 But I accept there was a delay.
 12 **Q.** You may be right it is a small proportion but, of
 13 course, there might be plenty of opportunities within
 14 a year/18-month/two-year period for there to be
 15 interactions with medical staff for the first time,
 16 nurses, opportunity for injuries, particularly for
 17 people who have bleeding disorders?
 18 **A.** I accept that.
 19 **Q.** You told us earlier about the blood club, and this, as
 20 it were, informal gathering of clinicians from the
 21 range of centres in the area for which Oxford had
 22 overall responsibility. Can you recall whether the
 23 specific guidelines we looked at earlier, the
 24 guidelines in relation to the management of chronic
 25 liver disease, were those discussed as far as you can

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1 recall in the blood club?
 2 **A.** No, the majority of the case -- they were literally
 3 case presentations usually. So these were not
 4 academic lectures, they were mainly talking about
 5 interesting or new cases, and there may be some
 6 discussion about how to manage them, alternative
 7 options. It wasn't didactic in that way, of going
 8 through publications. Although it may be relevant to
 9 discuss publications.
 10 **Q.** I'd asked you earlier about whether the UKHCDO, as
 11 a national organisation, or the working party, had
 12 monitored compliance with the guidelines, and you
 13 indicated it hadn't, but did the Oxford Haemophilia
 14 Centre, as the centre with a degree of responsibility
 15 for the centres in the local counties that we referred
 16 to earlier, did you monitor or review or raise with
 17 those other centres the extent to which they were
 18 meeting those guidelines or making available
 19 specialist hepatology care to their patients?
 20 **A.** Well, most of it was actually centralised in Oxford,
 21 so although -- Joan Trowell was not just looking after
 22 patients in Oxford or, you know, from the Oxford area,
 23 she would be seeing patients from the whole region.
 24 And it was only in much later years that actually,
 25 with her successor, that some devolvement --

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1 devolution, rather, took place.
 2 So really it was very Oxford-centred, both for
 3 HIV and for hepatitis C.
 4 **Q.** This morning I asked you about whether you had had any
 5 involvement in the HIV litigation and you said you
 6 hadn't in the large class action but you had been
 7 asked to comment on one or two letters by your Trust.
 8 Without asking you to go into details about any
 9 individual patient's care or any individual case, can
 10 you recall broadly what kind of issues you were being
 11 asked to comment on?
 12 **A.** I'm afraid I can't, because this is going back
 13 a really long time. I'm really sorry, I can't.
 14 **Q.** You also said, when we were discussing the question of
 15 consent, and this is talking about the issue of
 16 hepatitis C and testing in the early 1990s, that you
 17 wouldn't at the time have recorded -- or, you wouldn't
 18 necessarily have recorded the taking of consent in the
 19 notes, you might have just recorded that you were
 20 doing the test. Did your practice in relation to that
 21 and recording the taking of consent change over time,
 22 and if so when?
 23 **A.** No, it didn't. But for HIV there was a form where we
 24 had to tick a box on the HIV form saying that we had
 25 taken consent. For the typical follow-ups, for most

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1 of the time we used a pre-printed *pro forma* and at the
 2 end we would put which bloods had been taken.
 3 So, no, it's not something that I personally
 4 did.
 5 **Q.** Did you have patients at the Oxford centre who tested
 6 positive for parvovirus?
 7 **A.** We never tested anyone for parvovirus. I think it was
 8 only a few research cases where that was done or where
 9 there were very obvious cases. And despite having had
 10 children under our care, I never came across a case
 11 which convinced me that a patient had parvovirus. So
 12 I never did any serological tests for parvovirus.
 13 **Q.** You referred in your evidence earlier to audits of
 14 haemophilia centres. Is it your understanding that
 15 this was only undertaken in respect of the
 16 comprehensive care centres and not the smaller centres
 17 that didn't meet the criteria?
 18 **A.** That is a fact. I believe that that system may now
 19 change. And originally audits, when they were
 20 introduced, were on a three-year basis, then there was
 21 a five-year basis, but I believe that the plan is now
 22 to extend that. And I think it should happen.
 23 By the way, the audits, I think they are
 24 extremely useful. The typical way it's done is for
 25 a doctor from another centre, a nurse from another

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1 centre and a patient from another centre to come and
 2 spend time and look into how the centre is run.
 3 They also have the right to send out
 4 30 anonymous questionnaires to patients. So randomly
 5 they come and they choose 30 sets of notes. And those
 6 letters get sent off to patients that are randomly
 7 chosen, and they can then feed back anonymously to
 8 the auditors how they feel about care in the
 9 individual centres.
 10 I found audits to be extremely useful because if
 11 there were defects that were highlighted, I found that
 12 management did respond to that and would make, you
 13 know, some changes.
 14 **Q.** Is this correct, that this was a system introduced and
 15 implemented by UKHCDO itself? It wasn't an externally
 16 imposed system?
 17 **A.** No, that's absolutely right. It was UKHCDO that did
 18 it. And interestingly, other countries are now
 19 beginning to copy that model. Certainly Ireland now
 20 has audits.
 21 Originally I believe Ireland wanted to come into
 22 the UK system, but that never happened. And I know --
 23 I was speaking to a former colleague just a few weeks
 24 ago, and I believe there's going to be a European
 25 system of audit which is going to be set up, which

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1 will not duplicate current audits, so UK centres won't
 2 participate, but there a lot of centres in Europe that
 3 are not. So the concept of audit was pioneered by
 4 UKHCDO and it's been copied elsewhere.
 5 **Q.** Do you know when it was introduced by UKHCDO?
 6 **A.** It's clearly in the notes and -- in the minutes,
 7 because -- it's not something I'd focused on, but the
 8 person who initially did it was Jonathan Wilde. So
 9 I don't know if you can do PDF searches on your
 10 documents but "audit" and "Jonathan Wilde" will pick
 11 that up.
 12 **Q.** You referred to the participation of a nurse and
 13 a patient in the audit process. I may be wrong but
 14 I think such audits as I've seen from the 1990s
 15 involved only a clinician. Do you know when the
 16 introduction of the patient came about?
 17 **A.** No, this was, I would guess -- because the last audit
 18 I had when I was in post was 2010, and that certainly
 19 had one. It would be the one before then. So if
 20 I had to guess, it would be around 2005. If I had to
 21 give a guess.
 22 **Q.** What was the system in place at the Oxford Centre for
 23 ensuring that patients were made aware of their
 24 entitlement to Stage 2 Skipton payments?
 25 **A.** I think that was very much the responsibility and --

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1 responsibility -- the nurses very much did that, and
 2 it would come up, I think, as part of the follow-ups
 3 as well.
 4 So I think we will have picked up all the
 5 appropriate patients. We were very conscious of that.
 6 **Q.** You referred earlier to the sale of UKHCDO annual
 7 reports to third parties for a modest amount. Do you
 8 know what -- when you say "modest amount" --
 9 **A.** Probably of the order of £200, something like that.
 10 That's going to be a pretty good ballpark figure.
 11 I mean, it's not thousands and it's not a tenner.
 12 Going from memory, it's going to be around -- it was
 13 around £200.
 14 **Q.** What does UKHCDO -- or, what did UKHCDO do with the
 15 money received from the sales of the reports?
 16 **A.** That I don't know. It was obviously paid to UKHCDO
 17 and it went into their coffers.
 18 **Q.** Then, I think finally, can you look back at your
 19 statement. WITN3311003.
 20 Can we go to page 17, please, Soumik.
 21 I'm just going to show you three short questions
 22 and answers and then ask you about them.
 23 So, question 28, you were asked:
 24 "What was your understanding of the relative
 25 risks of infection from the use of commercially

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1 supplied blood products and the use of NHS blood
 2 products?"
 3 And your response was:
 4 "My knowledge would have been informed from
 5 teaching, medical journals and lectures. I cannot
 6 give any specific dates."
 7 Then if we go down that same page, you were
 8 asked in question 30:
 9 "When you began work as a Senior Registrar in
 10 Haematology at the Westminster Hospital ..."
 11 So I think that would have been roughly 1983:
 12 "... what was your knowledge and understanding
 13 of the risks of the transmission of hepatitis ... from
 14 blood and blood products?"
 15 And then you are asked:
 16 "What were the sources ... [and] how did that
 17 ... develop over time."
 18 And your answer, in 30.2 was:
 19 "[Your] knowledge would have been informed from
 20 teaching, medical journals and lectures. I cannot
 21 give any specific dates."
 22 Then if we go over the page, the last question
 23 and answer I want to ask you to look at, bottom of the
 24 page, question 34, you were asked:
 25 "What was your understanding of the nature and

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1 severity of the different forms of blood-borne viral
 2 hepatitis and how did that understanding develop over
 3 time?"
 4 You have given the same answer:
 5 "My knowledgeable would have been informed from
 6 teaching, medical journals and lectures. I cannot
 7 give any specific dates."
 8 Dr Giangrande, it might be said, and indeed it
 9 has been said by a representative of Core
 10 Participants, which is why I'm asking you about this,
 11 that you have not actually answered the questions that
 12 you were being asked, which asked you to set out what
 13 your actual understanding at the relevant times was in
 14 the respects identified.
 15 Can I invite your comment on that and ask you to
 16 explain why the questions weren't answered, if you
 17 accept that they weren't.
 18 **SIR BRIAN LANGSTAFF:** There are two separate questions,
 19 I think, there: first, to comment, and then the answer
 20 why didn't you say what your understanding was, rather
 21 than what your source of understanding was?
 22 **A.** Yes, that is a very fair point.
 23 I think what I was trying to say when I read
 24 that -- I mean, I have to say -- what I was trying to
 25 say is that I didn't remember the particular times and

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1 journals that I had read.
 2 You know, I couldn't say, "In 1976 I knew the
 3 following". I just had -- I couldn't give a logical
 4 sequence of my memory of events from so long ago.
 5 I agree it's not a helpful answer. I think we've been
 6 able to explore it in much more detail in oral
 7 evidence today, but I agree it's not a detailed or
 8 helpful correct answer.
 9 **MS RICHARDS:** If you would just give me a moment, sir.
 10 Sir, whilst I just check whether there are any
 11 further questions, are there questions that you have
 12 for Dr Giangrande?
 13 **SIR BRIAN LANGSTAFF:** I have one or two but you may want
 14 to check first.
 15 **MS RICHARDS:** I'm simply asked to press you,
 16 Dr Giangrande, on why you didn't answer the question
 17 in relation to knowledge of risk.
 18 **A.** To be honest, this was a very long document and I did
 19 my best. It's taken a lot of time. I honestly just
 20 felt, looking at that, that I couldn't remember in
 21 detail. I just couldn't give precision time points of
 22 what I knew when. I couldn't say I read this
 23 particular paper, what my view was at a particular
 24 time. I just couldn't do that.
 25 **Questioned by SIR BRIAN LANGSTAFF**

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1 **SIR BRIAN LANGSTAFF:** Yes.
 2 Two or three questions. They may seem to dot
 3 around a bit. They are about different matters.
 4 When you came back from Italy and found yourself
 5 in Oxford, you said, I think -- this was in 1990 --
 6 that you were a little surprised that blood testing,
 7 that is for hepatitis C, had not yet been introduced
 8 here. It had been introduced in Italy, what, for
 9 hepatitis C?
 10 **A.** So I got a reasonable explanation when I said I was
 11 surprised, it's because they'd introduced -- they used
 12 the first generation assay. So I was surprised, but
 13 I got a very reasonable explanation. And that was
 14 that the second generation assay, which was the one
 15 introduced in the UK in September 1991, was regarded
 16 as more reliable.
 17 And in fact, to give a good example of that, in
 18 1992 there was a multi-centre study of the risk of
 19 sexual transmission of hepatitis C in patients with
 20 haemophilia, and patients from three centres were
 21 enrolled: Milan; Worcester, Massachusetts, that is in
 22 the United States; and Sydney.
 23 There were 106 patients tested, and their
 24 partners. And this was published in -- I don't know
 25 which month, but it was in 1992 and Breckler was the

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1 first author. And looking at the sexual partners,
 2 five of the sexual partners, that is 2.7 per cent,
 3 tested positive with the second generation assay but
 4 no partner tested positive with the first generation
 5 assay.
 6 So let me be clear, I'm not suggesting that
 7 there was -- it was bad practice that hadn't been
 8 introduction of screening of blood donors in 1991,
 9 I merely expressed surprise. I'm not an expert
 10 virologist, I didn't understand the difference, so
 11 when I came I got a perfectly good and logical
 12 explanation for the difference.
 13 **SIR BRIAN LANGSTAFF:** Well, the description in 1990 can't
 14 have been by reference to a study which wasn't
 15 completed until 1992, but as I understand, what you
 16 are trying to tell me is that it was thought the
 17 second generation test would be more specific.
 18 **A.** That's correct. I was jumping ahead to give you an
 19 example to show in retrospect that was actually right.
 20 But I think already there were some doubts that the
 21 first generation test was not entirely accurate. And,
 22 in fact, just to build on that, when I was in Milan,
 23 I saw an example of the other way around: somebody
 24 reported as positive when they weren't. That was
 25 important -- I got dragged into this merely because,

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1 you know, speaking English, there was a clinical trial
 2 of a concentrate, and on original testing with the
 3 presumably first generation assay somebody had come
 4 back as positive. Of course, this has huge
 5 implications for a clinical trial. But with whatever
 6 confirmatory test they did, they found actually it
 7 wasn't positive, and I remember having to draft the
 8 letter to explain all of that.
 9 So what I'm saying is already, by the end of
 10 1990, there were some doubts about the reliability of
 11 the first generation assay. And the reason for that
 12 is because in the assay the antibody is directed
 13 against one particular portion of the hepatitis C
 14 virus, whereas in the second generation assay they
 15 incorporate three separate bits of the virus.
 16 **SIR BRIAN LANGSTAFF:** Yes. Is it your understanding that
 17 in Italy in 1970, the blood transfusion or their
 18 equivalent of the Blood Transfusion Service had
 19 introduced ALT testing?
 20 **A.** 1970?
 21 **SIR BRIAN LANGSTAFF:** 1970, yes.
 22 **A.** I've no idea about 1970. I was at school in 1970.
 23 **SIR BRIAN LANGSTAFF:** But just that you may have picked it
 24 up when you were in Milan working with the blood
 25 services there.

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1 **A.** You know, I wasn't working for the transfusion
 2 services there, so I have no idea about what happened
 3 in 1970, I'm afraid, Sir Brian.
 4 **SIR BRIAN LANGSTAFF:** I see. Apart from the anecdotal
 5 test you have given, was there any general feeling in
 6 Italy that they shouldn't have introduced the test?
 7 I take it from the expression, you're being surprised
 8 there was no such feeling?
 9 **A.** I'm sure they will have moved on. What I'm saying is
 10 I wasn't an expert. I didn't -- you know, I assumed
 11 that the same test would be used in England. So I've
 12 never had cause to discuss with colleagues now in
 13 Italy, you know, when they went over to the second
 14 stage assay, were there problems? Had patients been
 15 infected because first stage assays had been used?
 16 **SIR BRIAN LANGSTAFF:** Thank you.
 17 The second matter really relates to the question
 18 of communication and consent, what was said to
 19 patients. And at one stage in your evidence, you said
 20 that if the question of sexual transmission came up --
 21 this was in respect of those who you were talking to
 22 who had been diagnosed -- of being HCV positive -- if
 23 it came up, the risk would be low.
 24 It's the expression "if the question of sexual
 25 transmission came up". That would suggest that it was

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1 the patient who was raising it, rather than you.
 2 Would that be fair, or not?
 3 **A.** I'd have to remember and look back at the transcript
 4 exactly in what context I said that. I think probably
 5 what I was talking about was before we had
 6 information.

7 I think the evidence that Ms Richards presented
 8 on 9 October sets out in a letter that Dr Rizza wrote,
 9 I think, to Dr Tedder the whole issue of, you know,
 10 what to tell patients. And we really didn't have much
 11 information about the risk of transmission of
 12 hepatitis C sexually until those publications -- so
 13 the publication I mentioned in 1992. And although the
 14 Oxford study hadn't been yet published until 1993, the
 15 results of that presumably would have been known
 16 internally.

17 So I think what I was trying to say was in the
 18 early days, before we had hard facts, clearly it was
 19 not an issue we could give detailed information about.
 20 But as I said, clearly, on our checklist that we
 21 operated, the risk of sexual transmission was very
 22 explicitly stated as something we would talk to
 23 patients about once we had the information. But
 24 I think in the early days the information was very
 25 limited.

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1 **Q.** So when you don't know, might it be perhaps better to
 2 advise the patient that you don't know but there might
 3 be a risk?

4 **A.** I suppose so, yes.

5 **SIR BRIAN LANGSTAFF:** The next question, again, it's to do
 6 really with the question of information. You plainly
 7 feel strongly about the question of personal data
 8 being disclosed when perhaps it shouldn't be. And you
 9 were -- you thought there should be consent for the
 10 transfer of data to the UKHCDO database. That's the
 11 position you made clear in 2002 and afterwards.

12 **A.** Yes.

13 **SIR BRIAN LANGSTAFF:** Your understanding was that the
 14 database did not take that approach in due course, and
 15 you told us about the letters and the communications
 16 that resulted in that, and that that was I think
 17 shortly before Manchester took over the running of the
 18 database.

19 Did Professor Savidge or St Thomas' maintain its
 20 position that they would not send information?

21 **A.** Professor Savidge retired in 2006. And between 1996
 22 and 2006, Professor Savidge did not submit data to the
 23 Manchester database either, as well as the Oxford
 24 database, so for that full decade.

25 **SIR BRIAN LANGSTAFF:** So you objected to data being given
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1 without consent. You knew that other centres, at
 2 least St Thomas' and maybe other centres too, did not
 3 give their data for that reason. Did you think it
 4 appropriate not to send the data of Oxford to the
 5 Manchester database?

6 **A.** It would have been difficult, and I think it would
 7 have been perceived as sour grapes, having lost the
 8 database for a start, and I'm sure that's what people
 9 would have said.

10 I think I just have to accept that we are
 11 colleagues in the UKHCDO organisation. The patient
 12 organisation had expressed support for the current
 13 system. It was in 2000 I noticed that we had the
 14 inspection of the -- about the Caldicott Guardian of
 15 the Oxford database, and he who held a very senior
 16 position within our hospitals satisfied with it. So
 17 I have to say I had made my stand. A decision had
 18 been taken. It seemed to have the general support and
 19 consensus. And I followed Professor Hay's testimony
 20 as to how things have developed. So I went along with
 21 it. To be honest, I did not ever entertain the
 22 concept of not sending information to Manchester.

23 **SIR BRIAN LANGSTAFF:** So for reasons of professional
 24 comity, you took a step which you felt, in principle,
 25 was the wrong thing to do?

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1 **A.** Yes.

2 **SIR BRIAN LANGSTAFF:** The next question is really about
 3 something else which you mentioned. You gave us an
 4 insight from what you said about the meeting of the
 5 World Federation of Haemophilia in Bangkok, about the
 6 fact that BPL had been selling plasma to countries
 7 other than outside the UK. And this became a question
 8 raised because those countries had not been told,
 9 although clinicians in those countries had not been
 10 given to understand that there might be some problem
 11 with it. This was at a time, was it, when the
 12 product, plasma products from BPL, were not being
 13 supplied to haemophilic patients in the
 14 United Kingdom.

15 **A.** That's right. So the way things had operated is that
 16 after patients began to switch to recombinant products
 17 in the UK, the British Government, because BPL is
 18 owned by the Government as an integral part of the
 19 NHS, they had to find new markets. And they started
 20 selling the coagulation factor products abroad quite
 21 widely, and in particular the Middle East and also
 22 South America. And I have to say they had quite
 23 success. They had -- after all, these were seen as
 24 British, originally volunteer donors, and the products
 25 also were reasonably priced because the plasma was
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1 free, whereas many other companies had to pay for
2 plasma, and the prices were attractive. So they were
3 quite successful in that.

4 Now, in 1998, they then started making British
5 plasma products with imported American plasma, and
6 that added a bit to the cost, but the products were
7 still widely used abroad. So given that the edict of
8 the 2004 recall affected people from 1980 to 2001,
9 yes, quite a lot of countries were caught up in that.

10 **SIR BRIAN LANGSTAFF:** So it would follow that a product
11 withdrawn on the grounds of safety from use in the UK
12 was being sold to countries abroad, and that the
13 product was the product of voluntary donation by
14 British citizens, no doubt with the view that it was
15 their voluntary act, their altruistic act, in doing
16 something for other patients in the UK through the
17 Transfusion Service.

18 Did you ever hear any discussion when anyone
19 raised the question what damage it might do to the
20 Transfusion Service if the ordinary British donor had
21 understood the blood and plasma he was giving free was
22 being sold to foreign countries when it was too
23 dangerous to be used in the UK?

24 **A.** I've spoken out about that myself. I had an article
25 in the Independent about that very issue. I gave

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1 a radio interview to the BBC about that issue. And
2 the then Chief Executive of BPL came to see me in
3 Oxford about that issue and explained that basically,
4 you know, the products were being sold, and it was
5 a way of -- they were doing it at cost, but the idea
6 was to subsidise the price of the other products they
7 were making. But, clearly, they were exactly the
8 sorts of questions that you have raised about, you
9 know, what does the man in the street who is donating
10 blood think about his plasma being sold off to foreign
11 countries? I entirely agree.

12 **SIR BRIAN LANGSTAFF:** What was the reaction to what you
13 had written, apart from BPL's chairman coming to see
14 you?

15 **A.** Not a lot. Actually, I remember it well doing the BBC
16 interview because somebody came to interview me, and
17 we talked about -- they said, you know, are you ready?
18 There could be quite some repercussions from this, but
19 there weren't.

20 **SIR BRIAN LANGSTAFF:** Right.

21 **A.** I remember that interview well, actually, because --
22 well, anyway, I remember it well.

23 **SIR BRIAN LANGSTAFF:** That's all that I have to ask.
24 I told you it would be a ragbag of questions.
25 Ms Richards.

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1 **MS RICHARDS:** Dr Giangrande, is there anything further
2 that you would like to say?

3 **A.** Well, I suppose I would just like to conclude I don't
4 want to be seen to be copying what Dr Mitchell said
5 yesterday, but I was going to say the same thing, and
6 that is I've been very moved by the oral evidence and
7 the statements that I've read of the patients and
8 really very impressed by the fortitude. And
9 I recognise it's not easy for them to give evidence in
10 this way, and I'm humbled by their testimony.

11 I wish the Inquiry well. I think you are doing
12 a fantastic and thorough job. I am pleased it is
13 taking place. Some people may say it's too late, but
14 I don't feel so at all. I think there are some
15 advantages. You are able to take on topics to address
16 which other national inquiries have not done, such as
17 vCJD, which is uniquely a British issue, the
18 recombinant issue, and I'm pleased that you are going
19 to be taking evidence from pharmaceutical companies
20 which, rather controversially, the Lindsay Tribunal
21 did not.

22 But I would like to end on a note of optimism.
23 I recognise that you are looking back over these
24 months, but I think looking to the future, we have to
25 recognise that Factor VIII and Factor IX are going to

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1 become the past soon, but there are many exciting new
2 treatments for haemophilia. And I think after
3 a ghastly and desperate past of real tragedies,
4 I think there is real hope now on the horizon for the
5 future generations.

6 **MS RICHARDS:** Sir, I got slightly ahead of myself.
7 I understand that Dr Giangrande's counsel wishes to
8 ask some questions.

9 **SIR BRIAN LANGSTAFF:** Of course. Well, he is fully
10 entitled to. Can we hear you from there or would you
11 come to --

12 **MS RICHARDS:** The microphone won't pick it up for the
13 transcript transmission.

Questioned by MR THOMAS

14 **MR THOMAS:** Good afternoon, Dr Giangrande.

15 Could we turn, first of all, please, to --
16 I hope I've got this right -- document HCDO0000457.
17 Yes, that's the one. Then to page 8 of that document.

18 Now, there's an item -- we can see from the top
19 of this, this is the minutes for the meeting held on
20 12 February 1996.

21 If we go down to the bottom of that page, at
22 item 9, we can see the item under discussion is annual
23 returns for 1994, where you presented a written
24 report. If we go on to the following page, please, we
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1 can see four lines down, or, in fact, three lines
 2 down, we have the record Dr Hay suggested the price
 3 charged to commercial companies for a copy of the
 4 report should be raised from £50 to £200 per copy.
 5 And then looking at the last two lines:
 6 "It was agreed that the pharmaceutical companies
 7 should be asked to pay £200 per copy for the report."
 8 So it appears from that, Dr Giangrande, that it
 9 was £50 until February 1996, and then raised to £200.
 10 I think you said you thought it was about £200. Is
 11 that right?
 12 **A.** Yes, yes. Going from memory, that's the figure that
 13 I had, so thank you for highlighting that. I hadn't
 14 seen that in the documents.
 15 **Q.** The second issue is this. You were asked by the chair
 16 that -- was it professional comity that was a factor
 17 in you continuing to submit the data to the database
 18 when it turned to Manchester, and you said yes.
 19 You had referred earlier, a few moments before
 20 that, to the Haemophilia Society being aware and being
 21 supportive of the database. If The Haemophilia
 22 Society or if you had learned that The Haemophilia
 23 Society had been expressing any unease about the
 24 database being used in this way, might that have made
 25 a difference to you in 2002?

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1 **A.** Yes. I mean, the fact -- I was reassured by the fact
 2 that clearly The Haemophilia Society supported the
 3 status quo.
 4 **Q.** All right.
 5 Lastly, it's this: again, just a few moments ago
 6 you were asked about the switch to recombinant within
 7 the UK coinciding with the sale overseas of the BPL
 8 products.
 9 At the time that the BPL products were being
 10 sold overseas, had the same product been withdrawn in
 11 the UK formally or was it still available but the
 12 decision had been taken by the centres that they would
 13 switch to recombinant?
 14 **A.** Yes -- no, thank you for raising that point, because
 15 I noticed that as well. It was not formally withdrawn
 16 unsafe, it was simply that we preferred to use what we
 17 perceived to be a better product.
 18 **MR THOMAS:** Thank you, doctor.
 19 **A.** Thank you very much.
 20 **SIR BRIAN LANGSTAFF:** Thank you, Mr Thomas.
 21 Really, building on the comments you made at the
 22 end there, Dr Giangrande, describing how the oral
 23 evidence of those who were infected and affected had
 24 given a real understanding of what, on the printed
 25 page, might seem to be a less colourful, compelling

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1 story, your evidence itself has shown I think, and I'm
 2 sure you would agree, the great value of hearing
 3 orally from witnesses.
 4 In particular, in your case, there have been
 5 a number of occasions on which, if you will forgive my
 6 putting it this way, I don't mean any discourtesy,
 7 your evidence has been fulsome where your statement
 8 was perhaps rather terse. And you have explained that
 9 that was because of the length of the document. It's
 10 far easier sometimes, I suspect, to give evidence
 11 orally, and it's been, for that reason in particular,
 12 important for us to have heard from you and heard you
 13 expanding upon the various matters you have. And,
 14 indeed, for correcting a number of the matters which
 15 you had originally put out in writing and had time to
 16 think about, and we now understand what your position
 17 is on a number of points which otherwise, had we
 18 simply relied upon the statement, we might not have
 19 turn.
 20 So thank you for that. And thank you for the
 21 lively way in which you've expanded. In fact, you
 22 have been fully prepared to give us the benefit of
 23 your experience not just in the UK but given us
 24 something of a flavour of Europe from time to time,
 25 where plainly you have had a considerable involvement.

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1 And that, together with the issues which your evidence
 2 has highlighted, over consent, communication and the
 3 aftermath of the testing, has been very informative.
 4 So can I thank you on behalf of the Inquiry for
 5 your evidence thus far.
 6 **A.** Thank you so much, Sir Brian. I really appreciate
 7 your words. And I wish you every success in the
 8 hard work and task you have.
 9 **SIR BRIAN LANGSTAFF:** Thank you.
 10 **MS RICHARDS:** Sir, that is it for this week, and we are
 11 not sitting next week.
 12 We resume on Tuesday, 1 December, for the
 13 evidence of Professor Ludlam, which will be heard over
 14 the four days, Tuesday, Wednesday, Thursday, Friday,
 15 of that week. And then the week after that we hear
 16 evidence, also relating to Scotland, from
 17 Dr Pettigrew, Professor Hann and Professor Lowe.
 18 **SIR BRIAN LANGSTAFF:** And the following week, is that
 19 a full five-day week?
 20 **MS RICHARDS:** Yes, the second week is a full five-day
 21 week.
 22 **SIR BRIAN LANGSTAFF:** So we have nine days of evidence on
 23 the trot, as it were, split only by the weekend,
 24 beginning on 1 December?
 25 **MS RICHARDS:** Yes.

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1 **SIR BRIAN LANGSTAFF:** At ten o'clock?
2 **MS RICHARDS:** Yes.
3 **SIR BRIAN LANGSTAFF:** So those who are watching at
4 a distance ten o'clock, 1 December.
5 Thank you very much.
6 **(5.05 pm)**
7 **(Adjourned until Tuesday, 1 December 2020 at 10.00 am)**
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