Thursday, 19 November 2020

(10.02 am)

SIR BRIAN LANGSTAFF: Good morning, Dr Giangrande. Can you hear me?

A. I can hear you perfectly, Sir Brian.

SIR BRIAN LANGSTAFF: And you can see me?

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

SIR BRIAN LANGSTAFF: That's quite a good start. The reason I say that is for your benefit and for the benefit of those who are watching remotely -- I'll describe the scene to you in a moment -- there have been one or two gremlins, I'm afraid, with the transmission online generally. They may affect us this morning. It's not here at the Inquiry but between the Inquiry and the general world, maybe you as well. We have server problems, and if they cause us problems, I just hope that you and everyone else will bear with us. I hope -- that's the best I can say -- I hope -- that they don't come back to be real problems and that what I'm saying now will simply be forgotten by the end of the day.

But let me tell you what you are facing as you look at your screen. In this room there are a handful of lawyers. There are three lawyers from the Inquiry, there is your own counsel, Mr Thomas. Then there are

three members of the Inquiry staff and Mary, who will swear you, administer the oath, in a moment or two, together with a technician whose job it is to show the various documents that we will be referring to.

But it's not just us you're talking to, it is a very large number, probably round about 200, of those who are interested in the Inquiry from different perspectives and they are watching remotely. Many would have wished to be here, you may well have wished to be here yourself, and it will have been my wish that that could have been the case. But it isn't because of the virus, the coronavirus this time, and as a result we are where we are and I'm afraid that we have no option, if we are to continue, but to screen your evidence remotely. So you will be seen by lots of people, you will be heard by lots of people. There will be a running transcript which will be corrected at the end of the day to make sure it is faithful to what you actually said, and that's where we are.

So you now understand what the position is, Mary will now ask you to take the oath.

DR GIANGRANDE, sworn

Questioned by MS RICHARDS

SIR BRIAN LANGSTAFF: Dr Giangrande, I should have asked, you are, I think, at home in your own with your wife?

A. I am indeed, yes.

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

A. I can hear you perfectly and see you perfectly. I have no problems with internet connection myself.

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

You qualified as a doctor in Manchester in 1979?

A. Yes.

Q. And your statement tells us that from 1979 to July 1981 you held various house officer and senior house officer posts in Manchester?

A. Yes.

Q. Can you assist us with the extent to which you undertook any haematology work during that time?

A. After I got full registration, that is after my house jobs, I then undertook a rotation at the University Hospital of South Manchester, colloquially known as Withington Hospital, and that involved rotating round the four sections of pathology, because I knew I was likely to head in that direction career-wise, and that involved spending three months in each of microbiology, chemical pathology, histopathology and haematology.

The haematology I did was largely laboratory-based. Most of the clinical haematology was at Manchester Royal Infirmary.

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

A. I did. He was the microbiologist -- the virologist, I'm sorry, in the microbiology department. And I met him -- of course I had no idea at that stage that he had any interest in the haemophilia world, and I didn't know I was going to be moving to that world either at that stage, but that's where I got to know him first.

Q. You then moved to London in August of 1981. You were an SHO in renal medicine at the Hammersmith?

A. Yes.

Q. Then you moved to St Mary's in an SHO position in metabolic medicine?

A. That's right.

Q. Just dealing first with the time spent in renal medicine, did you come across any dialysis patients who had been infected with blood-borne viruses at that time?

A. No, it was very much an area of -- where they took a lot of precautions, and it was something that was greatly feared, so, you know, great precautions were taken, absolutely, because if a machine got contaminated, the potential consequences were enormous.

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

that you first came across reference to AIDS.
A. That's right. I mean, the first death from AIDS in the United Kingdom was reported in December of 1981: a patient died in the Brompton Hospital. And of course, others were -- patients, sadly, were falling ill at the time. And it was the subject, particularly based in West London, of educational materials and talks.

In fact, I remember one talk particularly well because Dr Pinching, who had previously been at the renal unit at Hammersmith Hospital, had moved at roughly the same time as me, and I remember very well a talk he gave on AIDS when the cause was completely unknown, and indeed I remember him telling us about a paper published in The Lancet which was implicating, of all things, amyl nitrate/poppers, but it was a respectable paper, published in The Lancet, from a very reputable group in the US. So it was taken seriously at the time.
Q. So that would have been late 1981 or the first part of 1982?
A. 1981 was when I was there. I did look up -- the publication on amyl nitrite was published in The Lancet on February 20th. So because these educational talks tend to be given quite soon after

the publication, I would guess that lecture was probably March, perhaps April of -- of '82. I'm sorry if I said '81. But '82.
Q. And then you completed your MRCPath qualification I think at this time?
A. No, I think -- it was the MRCP qualification in -- I think I got it in June. The MRCPath came later, it was '86.
Q. We will get to that in a moment, then.

You then, I understand from your statement, moved to Switzerland, where you worked from August 1982 to July 1983, including six months of haematology work. What can you tell us about that?
A. Yes. I mean, the background -- first of all, it was a European exchange scheme that I applied for. The Hammersmith Hospital at the time was part of what was called the Royal Postgraduate Medical School and there was an opportunity to spend a year abroad, so I applied for that.

And when I moved to Switzerland originally, they let me do six months in internal medicine, then they said: what would you like to do for the rest of your time here? And thinking of my future career, I decided to do haematology.

It was a very exciting time when I was there in

Switzerland, there was a lot going on in haematology, and that's what made me determined to move into haematology.
Q. Do you recall whether there was any consideration or discussion at that time, '82 through to July 1983, about the risks of AIDS that could be associated with the use of blood and blood products?
A. Not when I was in Switzerland. Not at all. In fact, at the haematology department where I worked we did a lot of bone marrow transplantation, and they specialised also in treatment of patients with aplastic anaemia. So very intensive use of blood products. And at that stage there was no concern at all about HIV.

Indeed, actually, in I think September or October of that year, I was offered a plasma-derived hepatitis B vaccine, and that was new to Switzerland, it had been produced in the United States, it wasn't yet available in the UK, and it's produced from plasma of American donors, and the whole point is it contains hepatitis B from plasma of these donors, it's not a recombinant vaccine, and it was offered to me by the hospital, and they wouldn't have offered it to me had there been any concern, and equally I took it without any concern.

Q. So --
A. I should add, by the way, I am aware in retrospect, from one of the papers that you sent me, that in a report dated April 24, 1983, there were -- and I didn't know this at the time -- four cases of AIDS that had been reported in Switzerland.

Actually, one of those was a resident from the US who had come back for treatment of his final illness.
Q. So no discussion at all in the period that you were undertaking haematology work of AIDS?
A. No, none at all.

Actually, the story in Switzerland is quite an interesting one, because the head of the Swiss Blood Transfusion Service was a man called Professor Alfred Hässig, and after a very stellar career as head of the Swiss Transfusion Service based in Berne, when AIDS came along, he was actually a bit of an AIDS denier, if you look up some of his work, and felt that HIV was related to stress and nutrition, and Switzerland didn't introduce HIV screening of blood donors until May of 1986. Indeed, there was no -- so there was no screening of donors, there was no heat treatment of the local cryoprecipitate -- lyophilised cryoprecipitate they used to treat

haemophilia. And, in due course, Professor Hässig was actually prosecuted and got a year's suspended prison sentence in 1998 for criminal negligence.

Q. That is information you have gleaned subsequently, as I understand it?

A. Yes. Of course, yes.

Q. Your next position was at the Westminster Hospital from August of 1983 to November of 1984, where you were a registrar in haematology under Professor Barrett?

A. Yes, that's right.

Q. What did that work entail?

A. Well, the interest of the Westminster Hospital was very much bone marrow transplantation, and indeed Professor Barrett, who is still active actually, clinically, I understand, is -- that was what the Westminster was known for. So it was a general haematology hospital as well but the main interest was the treatment of the malignant disease.

Q. Westminster was or did operate as a haemophilia centre, and this was the first time, as I understand it from your statement, that you had any involvement with patients with bleeding disorders, but that involvement was limited to one patient; is that correct?

A. Well, that's the only one that I remember. We have to remember that the Westminster Hospital was just across -- and by the way, the Westminster Hospital we're talking about just to clarify is not to be confused with the Chelsea and Westminster Hospital, which many people will know. The Westminster Hospital, which closed in 1992, was literally a few hundred yards from the Houses of Parliament and just north of Lambeth Bridge.

That's important because literally ten minutes away was St Thomas' Hospital, which of course was a reference centre, with dedicated haemophilia treatment, experts and facilities.

The Westminster Hospital didn't have any of that. So, you're right, it was technically classified as a haemophilia centre. I only recall one very -- and I have to say -- inspirational patient, I very much enjoyed talking to him, who had haemophilia B, and he used to come in for periodic self-infusion. Like many adult patients at the time, he wouldn't trust a junior doctor with his veins, of course.

Now, there may have been other patients, and I'm sure you are going to show me some treatment records from the UKHCDO database, but I only recall one patient with haemophilia B.

Q. In fact, I am not going to show you any records relating to Westminster. Such records as we have do suggest a very small number of patients indeed.

Can you recall, in relation to that one patient with whose treatment you were involved, what the product was or the treatment was that he was treated with?

A. I'm afraid I can't remember offhand. I know that he died a couple of years ago, when he must have been in his 70s, perhaps even beyond that. But he was a very inspirational guy. And it's no exaggeration to say, I think, you know, he helped me develop an interest in haemophilia actually.

Q. You attended the AGM of the UKHCDO in October 1983, and we'll just have a look --

A. Yes, I mean, as background, I have to say it was a slightly extraordinary situation, because I must have been by far the most junior person there, and quite why -- I say this after a career as a boss in a haematology department myself -- someone who's been in the job for two months suddenly gets asked to go to a meeting, I really don't know and understand. I would guess Professor Barrett realised the meeting was potentially important at this time, received a letter with an agenda, and I happened to be the

first doctor that walked past his door.

Again, it was a decision that -- one of these fortuitous things in life that really lays the part out for future career paths, because, again, I developed an interest. But I was surprised to be sent.

Q. We'll just have a quick look at it. As much as anything for the benefit of those who are following your evidence, doctor.

It's PRSE0004440, please Soumik.

We can see from this, this is the meeting on 17 October 1983 chaired by Professor Bloom. And if we go down the list -- and there's a large list of attendees. If we just keep going down the page, we can see your name appears there representing the Westminster Hospital:

"Dr PLF Giangrande, Westminster Hospital, London."

A. Yes.

Q. If we just go over the page, again, we can see a very long list of actual attendees.

Then if we go to the third page, if we go towards the top of the page, please, Soumik, we can see there Dr Barrett, Westminster Hospital, has given his apologies and represented by you. So you were

there in Professor Barrett's stead?
A. Yes, he was then -- they call him doctor, but he was Professor Barrett.
Q. Can we go to page 10, please, Soumik.
You'll see here, Dr Giangrande, a reference under "Any Other Business" to AIDS and an issue being raised by Dr Chisholm, who was a director of the haemophilia centre in Southampton, and a discussion about reversion to cryoprecipitate. And then a view expressed by Professor Bloom, a discussion ensuing, and then at the end of the page an agreement being recorded.
If we just go to the next page, you'll see, under paragraph 10, "Current situation regarding AIDS", a presentation of a paper by Dr Craske?
A. Yes.
Q. First of all, do you have any recollection of that meeting?
A. I do, and in fact what I remember from that meeting, and I have a striking visual memory of it, is indeed Dr Scott giving details of the case of a patient that had died -- the first death. It was a case that was reported subsequently in The Lancet in November, and I have to say that made a big impression. I can still see him in front of me, to my left, two rows along,

and I remember that presentation vividly. It was a shock to me, to be honest.
Q. Dr Scott, again, for the benefit of those who are following your evidence, was a Haemophilia Centre Director in Bristol --
A. Bristol.
Q. -- and that was the patient who was the first haemophiliac patient to die in the UK in August of 1983.
A. Yes.
Q. Your statement suggests, I think, that this was the first time you knew of the association between blood products and AIDS; is that correct?
A. Yes. Yes, this made a big impact on me.
Q. Do you recall anything of the discussion that we've seen recorded in the minutes about cryoprecipitate and Professor Bloom's views about there being no proof?
A. No, I'm afraid I don't recall anything about that discussion. It wouldn't have meant much to me at all, I'm afraid, at such a junior role.
Q. We can see that you then attended the AGM the following year in 1984, and again we'll just put that up on the screen. It's PRSE0003659.
A. Yes. While that's coming up, I mean, that was in Cardiff, and I remember it well. One of the good

things about that meeting was after this meeting in Oxford, it was decided to have an educational day before the annual general meeting, and so it was ideal for someone like myself in training. And, indeed, I remember Professor Mannucci actually attended this meeting in Cardiff and gave a lecture during the educational day.
But I attended the AGM on behalf of Westminster in '84 and '85 and, I believe, '86 as well.
Q. Other than the educational day, I think we've also heard it referred to as a scientific day --
A. Well, scientific.
Q. -- and the attendance of Professor Mannucci. Do you have any other recollection of the discussions at that meeting?
A. I'm afraid I don't.
Q. In terms of the work that you were still undertaking in Westminster at that time, was AIDS an active issue for the Haematology Department at Westminster?
A. Not particularly. Although, I do remember in '84 in September that Cheingsong-Popov paper was published in The Lancet in September. It was 1 September. And, actually, one of the authors was then Dr Brian Gazzard and, although he gives his affiliation as St Stephens in that paper, which is part of the Westminster group,

he was a consultant gastroenterologist at Westminster Hospital. So, clearly, it was -- you know, something that was talked about, and we knew about it. So I certainly remember that particular publication.
Q. Sticking with 1984, a little earlier in 1984, there's an Armour document that refers to you, Dr Giangrande. Could we, Soumik, please have ARMO0000148.
A. Yes.
Q. We can see this is a letter dated 29 May 1984 from Armour Pharmaceutical Company. It's described as, in terms of the subject, being "Heat-treated factorate/CTX: additional investigators." And it's addressed to -- can we just go up to the top of the page again, Soumik -- we can see it's addressed to the Medicines Division of the Department of Health and Social Security. Then the letter says this:
"We wish to include the following additional investigators on the above CTX ..."
And then there are three names listed. The second is Dr Oscier at Bournemouth. A third is Dr Winter from whom the Inquiry has already heard. But the first name is yours, Dr Giangrande, Westminster Hospital.
What, if anything, can you tell us about this and any involvement in the investigation in relation

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

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

Factor VIII.
Q. So you have no recollection of actually being involved as an investigator in the use of the product?
A. I'm sorry to say I have no recollection. I say thank you for showing it to me so far in advance, but, despite that, I have no recollection of it.
Q. Now, in 1985, I think, you've already referred to your attendance at the AGM of UKHCDO in Oxford. By this time, your statement tells us, you were a lecturer and honorary senior registrar in haematology at Westminster and Charing Cross Medical School.
A. Yes. So what happened -- by the way, my position as lecturer was basically the same as a senior registrar, so it wasn't a purely academic *position*. My career was a little bit unusual because, in those days, most people moved to a different hospital to be a senior registrar and often undertook a period of research in-between being a registrar and senior registrar. I did the reverse. I did my research after I got my MRCPath. Equally, I stayed within the same hospital group.

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

marrow transplantation, and I needed greater exposure to general haematology. And I knew that if I got that position, I would be moved to Charing Cross Hospital and a district general hospital for rotation, and a Blood Transfusion Service as well. So I went for the job, and I got it, and I moved virtually straight away, I think, to Charing Cross Hospital at the end of 1984.
Q. And your statement says that you rotated between three hospitals: Charing Cross, Westminster and Roehampton.
A. That's right. And, indeed, in Roehampton, that's where she then was, Dr Christine Lee was, and I met her there, and she was doing a great job actually turning a -- what was basically a laboratory haematology service into a clinical haematology service, and I learnt a lot there. That's where I first got to know the now Professor Christine Lee.
Q. To what extent did your work during that period at any of those three hospitals involve the care of patients with bleeding disorders?
A. Well, it didn't include haemophilia specifically because Charing Cross, and certainly Queen Mary's Roehampton, they were not designated haemophilia centres. But it would be fair to say that my interest in coagulation as a field developed while I was at

Charing Cross. And, you know, there'd be anticoagulant patients, investigation of clotting problems, but I wasn't specifically dealing with any patients with congenital bleeding disorders.
Q. You then, I think, took your MRCPath qualification in 1986?
A. I did, yes. In the summer -- I think about June of 1986 I passed it.
Q. Then at the end of 1987, you moved to the Royal Free Hospital as a clinical research fellow under Dr Kernoff and remained in that post for two years. What can you tell us about that work?
A. Yes. Well, basically, after I got my MRCPath -- the MRCPath is a qualification which is regarded as an exit qualification, so with that you can then apply, technically, for consultant positions. I felt a bit young and inexperienced despite that, and more than that, I wanted to develop a research interest and indeed go on and get a research -- higher research degree.

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

year and asked in '87 whether I could possibly come and work in a research capacity there. He accepted me using their own research funds.

Q. I'm going to ask you in a moment about involvement in a recombinant trial, but before we get to that, what was the primary focus of the research that you undertook at the Royal Free?

A. It was related to immune function in people with haemophilia and addressing the question about whether treatment could influence the progression of HIV. So it was related to that important question of whether high purity products could affect the progression of HIV in people with haemophilia.

Q. Was that work purely research and laboratory-based, or did you undertake clinical work in relation to patients for the purposes of the research?

A. For that research, it was purely laboratory work. So I produced my own monoclonal antibodies, we did flow cytometry, we analysed blood samples, and I wasn't involved specifically with patients for that aspect. But as you rightly say, after I got to the Royal Free Hospital, Peter Kernoff took on a clinical trial involving recombinant Factor VIII. And he asked me to take charge of the care of two patients enrolled in that study, which was of the first brand of

recombinant Factor VIII to be licensed in this country, which came to be known as Kogenate. So I looked after them, and actually that formed a chapter of my subsequent MDA thesis.

Q. What practical clinical involvement did you then have with those patients?

A. Well, I had to follow them closely. So, as with all clinical trials, there was a very strict protocol, and I had to arrange the follow-up, the blood tests, and arrange the treatment; the supplies. So it was important that we followed the menu, if you like, because that's what a protocol is. It's a very complex menu. Blood samples have to be taken on schedule. So I looked after them for that clinical trial period.

Q. Did you, whilst you were at the Royal Free, have any involvement in the care and treatment of patients with HIV in relation to their HIV, other than in relation to the recombinant trial that you've described?

A. Clearly, as with any, you know, research centre, I was -- although not looking after the patients, I was closely following and involved in all the clinical meetings about patients and listening to lectures. So, absolutely, I would have been involved, and as -- I know you've spoken to Professor Lee, and

she's told you about the research she was doing, so of course I followed that closely.

Q. We know from other evidence, documentary and indeed Professor Lee's evidence, that the Royal Free Hospital had stored sera samples; essentially, a bank of samples that had been built up over a number of years.

Did your research or any aspect of it involve the use of stored samples?

A. No, I don't believe it did because my work focused very much on looking at the cellular material. So, in other words, we were looking at the lymphocytes of patients, and the sort of stored samples which the Royal Free had would not have contained lymphocytes. So I can give a categorical "no" to that.

Q. And then there's one document from your time there I'm going to invite you to look at. Soumik, it's BAYP0000016_011, please. If we can go to the second page, please.

So we can see this is an internal Cutter document. It's dated 28 July 1989. The subject is "Trip report to the UK, 26 and 27 July 1989." Then it describes a visit to the Royal Free Hospital. And if we could go down the page, please, Soumik, we can see there it refers to a meeting with Dr Kernoff, Dr Giangrande and a sister, and it refers to concerns

Dr Kernoff was expressing about a patient's liver status. It goes on to say this:

"In fact, this problem represents a true matter of conscience for him in an extend which may be considered surprising from a pure medical point of view, considering the medical past history of this patient. But perhaps understandable from his point of view is he's involved in several civil lawsuits investigating responsibilities for the contamination of haemophiliacs with HIV. This was a confidential remark made by Dr Giangrande after this meeting and previous one in May."

Then the next paragraph refers to Dr Kernoff having consulted other hepatologists and:

"... debated this question in detail with Professor Bloom, whose first reaction when he heard about the patient's problems for the first time had been to suspect Koate HS of being a possible HBV contaminant."

And the discussion continues.

Can I ask you, first of all, and without giving any details of the particular patient, for reasons you will understand, what was the issue here about -- that was giving rise to particular concern on Dr Kernoff's part?

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

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

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

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

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

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

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

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

involvement --

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

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

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

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

A. No.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Then he goes on to say this:

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

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

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

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

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

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

A. Thank you for showing Mannucci's reply.

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

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

contact him before that.

Q. It tells us in the second paragraph:

"I confirm I've never received from you or other people any amount of 8Y, even though, of course, the letter of request that I wrote is a fact indeed that cannot be denied. I do not remember more details about the matter. I may only grasp that at the time I was interested in the comparison of various plasma-derived VWF Factor VIII concentrates in the correction of the laboratory abnormalities in patients with type 3VWD, but I know for sure I never managed to use 8Y for this purpose. It is very unfortunate that I did use the word "smuggling". Yet, I am sure that you grasp that in the Italian language, inverted commas are often used to emphasise something, rather than to cite literally actual words. In other words, the term was used as a sort of joke without any relationship on the literal significance of the word. I'm sorry if I caused any trouble to you, but I reiterate once again that you did never fetch any plasma derivative from the UK to Milan when you were with us."

SIR BRIAN LANGSTAFF: On the face of it, it looks as though this proposal never came to pass, but it was a proposal not for someone to take their own treatment

on holiday, but for product which was NHS product given to a hospital for NHS patients to be taken to treat other patients in Italy; Italian patients. That was the proposal.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: I don't think it helps us in the Inquiry one way or the other, but it's a curious letter.

MS RICHARDS: Yes, and we don't, I think, know what, if any, response Dr Smith made to it.

SIR BRIAN LANGSTAFF: It's a very strange -- on one level, it's a very strange request for a clinician to make of another.

Does it perhaps indicate that the relationships between those people practising in the field of haematology throughout the world may have become quite familiar with time?

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

SIR BRIAN LANGSTAFF: It is, I think.

A. I'm sorry. I'm sorry, I didn't quite understand the question. Would you --

SIR BRIAN LANGSTAFF: One has to ask why he would be asking or expecting, at least on the basis of the first letter, that others would take product from their own health system in order to supply a fellow

haematologist in another system.

A. I think he -- again, it's difficult for me to be certain, but I think it's not entirely proven that he is asking for product to be taken out of stock free of charge from the Oxford Haemophilia Centre's own personal stock.

We have to remember that Dr Smith was working for the PFL, the Plasma Fractionation Laboratory. They were actually making -- they were manufacturing this product, and, indeed, Dr Smith was very much one of the people involved in the development of 8Y. So my interpretation is, he was basically asking for free samples of a product directly from the producer of that product, and, in other words, in order to expedite delivery, to ask somebody who visited the UK fairly frequently or was going over for a meeting basically to exact a courier. That's how I understand it. I don't believe he's asking for Oxford Haemophilia Centre stock. It's very important to distinguish, and I know we haven't talked about Oxford yet, that at the time the Oxford Haemophilia Centre was sharply divided. There was the clinical centre and NHS unit, and there was a production and development laboratory.

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

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

A. Yes --

SIR BRIAN LANGSTAFF: I take your point, and I am very grateful that you made it. Thank you.

MS RICHARDS: Before we turn to your appointment in Oxford, Dr Giangrande, can you just assist us with how and when your knowledge of the risks of transmission of hepatitis, and in particular non-A, non-B hepatitis, how had that developed in the course of your medical training and the various research and clinical placements you've told us about?

A. Well, to begin at the beginning, when I was a medical student, one of the medical students I was sharing a house with developed overt hepatitis B with jaundice, and that would have been about 1976. So, clearly, you know, I did a lot of reading on the topic at the time and was aware of the distinction between hepatitis A and B, and I was aware at the time that those did not account for all the cases of known hepatitis.

When I was working in Manchester as a Senior House Officer in that rotation where I met Dr Craske, it was very much a laboratory-orientated work that I was doing, and one of my roles was, indeed, to

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

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

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

I have followed in the transcripts and the

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

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

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

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

as consultant haematologist at the Oxford Haemophilia Centre.

A. Yes.

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

A. Yes.

Q. You replaced Dr James Matthews?

A. Yes.

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

A. Yes.

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

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

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

A. Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

People came when they wanted to throughout the week.

But the most important element of the work, as far as I'm concerned, was seeing the cases that needed to come in for treatment, because when I started there prophylaxis was not used. We did have home treatment. So the number of patients seen with bleeds was much higher than the current staff would experience now, for instance.

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

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

itself.

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

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

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

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

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

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

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

So I have to say the relationship worked

extremely well on both planes.

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

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

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

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

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

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

was a six-month job working in the haemophilia centre.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. Sorry, carry on.

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

about haemophilia, knew all the patients well.

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

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

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

SIR BRIAN LANGSTAFF: Yes, indeed.

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

we can please, at 11.45. So 11.45.

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

SIR BRIAN LANGSTAFF: Yes.

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

(11.14 am)

(A short break)

(11.45 am)

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

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

SIR BRIAN LANGSTAFF: What's the paragraph number?

MS RICHARDS: It's paragraph 83.

SIR BRIAN LANGSTAFF: Thank you.

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

you. If we go to the bottom half of the page, please.

Dr Giangrande, you will see you were asked about how the care and treatment of patients with HIV and AIDS was managed at the Westminster Hospital and the Oxford Centre, and in 83.1 you have said in relation to the Westminster Hospital you have no information. Is this correct, that you were not involved in the care of any patients with HIV or AIDS at Westminster?

A. Absolutely right. That's correct.

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

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

We'll come back to hepatology and hepatitis separately.

Follow up to an infectious diseases expert.

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

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

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

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

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

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

clinical trials to participate in, did a patient need admission and certain treatment, that was not my link. We've got to be clear about that. That was not my role. That was the prime role of the infectious diseases team, who were right next door to us, and with whom we had very good and close collaboration.

I hope that's clarified that?

MS RICHARDS: I just want to look at --

SIR BRIAN LANGSTAFF: Just pause for a moment.

We are asking about the top of the page, are we?

"c. What information was provided to patients about the risks and benefits ..."

A. Yes. So --

SIR BRIAN LANGSTAFF: You were present at the consultations, as I understand it, when you first started, because you set up the joint consultations?

A. Yes, I would have been involved in those consultations. Yes, that's certainly true.

SIR BRIAN LANGSTAFF: So you would have heard the information that was provided then to those patients.

A. Yes. I'm sorry if I --

SIR BRIAN LANGSTAFF: And that -- insofar as information was given to the patient about risks and benefits of treatment, that isn't a treatment decision because the treatment decision presumably is reached jointly by

patient and doctor. The patient is a participant.

A. I see your point and I fully accept your point.

SIR BRIAN LANGSTAFF: Was there a reason why you said you weren't able to answer that question?

A. I think what I was -- in other words, I was certainly involved in the clinics at the very early stage. So, in other words, I set the clinics up as soon as I arrived in Oxford in around -- sorry, in April '91. And then I remained running the combined clinics with the infectious diseases people until, if I had to guess, probably '95, that sort of period.

At that stage, the combined clinics, I was not attending them, for the simple reason that then the patients with haemophilia were -- there were patients with other HIV -- you know, triggered by other things, and therefore I did not attend the clinics, because the patients with haemophilia only formed a minority.

So I guess what I'm trying to say is, looking back at a period, you know, lasting until 2015, it's true to say I was in the clinics in the very early years but when the more complicated treatments became available (for instance HAART, which became available in around '96, going from memory) I was not involved in that stage. But I quite accept that at the beginning I was present and I would have discussed

some of the then basic and initial treatments for HIV. But I was not for most of the time that I was working in Oxford. Most of the time the patients were followed up just by the infectious diseases team.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: I just want to look at one document. It's from patient records but I'm not going to be asking you about the specific patient, it's just to see how, in practice, the clinics operated.

Could we have JEVA0000013, please, Soumik.

So it's slightly faint. We can see it's a letter from you, May 1991, so not long after you had arrived in Oxford, about a particular patient. And if we go further down the page, second main paragraph, it says:

"We have taken the opportunity to review this patient's general condition."

SIR BRIAN LANGSTAFF: Could I just raise -- the name of the patient appears to be there.

MS RICHARDS: Yes, that's with the consent of the patient's relative.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: It's not intended to be anonymous. But I am not going to ask you about the specific care of the individual.

So we can see that in the main paragraph, second main paragraph, there's a reference to reviewing the condition -- to CD4 counts. And then a decision:

"We have decided to start treatment with co" --

That is Septrin, isn't it, I think we can see there?

A. It is, yes.

Q. It's said it will be permanent treatment.

Then if we go on to the second page, so this is picking up in 1993, so this is approximately two years later, and this is a letter to Dr Conlon -- so this is now the infectious disease specialist, is it?

A. Yes.

Q. Then we can see reference to a combined clinic, reference to the full blood count, a decrease in white cell count likely to be due to the Septrin therapy and a suggestion that the patient stop taking Septrin.

So I don't know whether those documents assist generally in trying to give a clearer indication of the timeline here. In May of 1991, the first document we looked at, there's no reference there to a joint clinic, and it looks like the letter you're writing is to the GP. So is it fair to infer that -- it's only a month or so after you have arrived -- there was at that point no joint clinic?

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

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

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

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

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

Q. So we can infer, I think, from this that between May 1991 and July 1993 the joint clinics were set up?

A. Yes, I can't -- it was -- it started fairly soon, that I can say, but I can't remember when -- certainly they will have been set up sometime in 1991.

Q. Was Septrin, as a treatment, already in use in Oxford by the time you arrived?

A. I think it was because the previous treatment, which

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

Q. And the reference to the "combined clinic" in this letter is to the joint clinics with Dr Conlon and, as I understand your earlier answers, you think that those -- the joint clinics came to an end sometime in the mid-1990s?

A. Yes. And I say -- why they came to -- it's a bit like our orthopaedic clinic, actually, but that's a separate story, where -- but as regards the HIV clinic, what happened was the people seen in the clinic that I set up originally were exclusively people with haemophilia. And in contrast to other cities, certainly London, people from other risk categories were never seen in this combined clinic. There wasn't the demand. There was a genito-urinary department down at the Radcliffe Infirmary that saw a few patients, but the decision was then taken to unify everything up on the Churchill site. And that was certainly, I would guess -- certainly by '96, probably 1995. This was when the more complex therapies came into being.

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

Q. So just in terms of how patients would receive their care once the joint clinics had ceased to operate, whenever precisely that was, a patient would then have an appointment with the haemophilia centre, at least if they were a severe patient requiring their regular out-patient reviews, but would have a separate appointment with the infectious diseases unit that would be managed by the infectious diseases unit, is that correct?

A. It is correct, but I want to expand on that and to say there was extremely close collaboration between the two. I emphasise they were neighbours of ours and we had very good working links with them. So it's not that we corresponded simply by letter as one might infer from these two letters you are showing here. We had regular meetings between the two teams to discuss the patients. And, furthermore, there was the social worker that I told you who stayed until the end of the 1990s, she was much a link between the two.

What we tried to do, just as happened for the

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

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

A. Yes.

Q. So could we have WITN3311003.

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

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

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

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

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

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

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

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

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

I think it's fair to say when I arrived from Milan, all the patients in Milan had been tested and informed of their diagnosis. In fact, Professor Mannucci published the results of the Milan cohort in the Annals of Internal Medicine on 1 March 1990, and he found that 82 per cent of the 236 patients had tested positive for HCV. Furthermore, the Italian Blood Transfusion Service had introduced screening of blood donors sometime in 1990.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

patients for hepatitis C but it had been done on the basis you think of stored samples?
A. I have no doubt about that. That's my clear impression. And that would be the first generation assay.
Q. Then in the period of time that followed from your arrival to around the end of 1993, there was a second round of testing. Would it have been a first round for some patients, do you think?
A. Well, as I say, it was very helpful for me to read the transcript and indeed some of the letters that you had included in the presentation on the Oxford Haemophilia Centre because those are letters, as I'm sure you saw, I was not copied in to, and I was not present at some of the meetings that clearly took place with the virologists.

But it was a large number of patients. I was surprised at the number. I've got it written down. It was about 400 patients who had been tested. So mainly haemophilia and a small number with von Willebrand's disease. So I think people were retested or tested for the first time on fresh samples. And not all of those -- I mean, the PCR testing really came in towards the bottom end of the -- I think probably 1992 I began to see results of

that.
Q. In relation to the testing on fresh samples, what is your best understanding of the information that was given to patients about the purpose for taking the samples?
A. Well, that is where I now have my doubts because very clearly there was a formal HCV study. I saw that on the results that came back, and I had seen it in notes as well. So one of the nurses that would go out, they put HCV study, and there was nothing about -- you know, more detailed than that.

As I say, I had assumed that consent was sought, and I've explained that I thought it would be difficult, particularly when partners are involved, to take samples. But I must be honest and say I have my doubts about that now. But without actual notes, it's difficult to say.
Q. If the purpose of taking the samples was explained to a patient and consent sought, would that have been -- and I'm talking now the period '91 through to -- onwards, so when you are there. Would that have been done by a nurse or by a doctor, typically?
A. The vast majority of cases, undoubtedly the nurse. And, indeed, the nurses -- because there were a lot of patients to get through, as I told you, they went out

to people's homes as well. But, you know, the nurses had the role of collecting the blood samples. I'm not saying doctors didn't collect blood samples on people that turned up to clinic, but my clear recollection and impression is that the nurses were responsible for collecting the blood samples.
Q. Do you recall any discussions you had with patients during this period in which you told patients you were going to be testing them for hepatitis C?
A. Certainly, when I have tested people for hepatitis C, I have always sought consent, and it's never been with pre-counselling, as I've said in my statement to the Lindsay Tribunal, and I wouldn't have written it down if I'm really honest. I would have told -- just put it in the notes that I was doing it. But I wasn't really involved in that initial round of the HCV, the formal study. I was not involved in that.

My work -- when I came -- I mean, following on from the point you made earlier, I think most of my work when I arrived was actually -- I was the one dealing with the wards which were much busier. I was doing the clinical stuff. Dr Rizza tended to stay in the haemophilia centre and deal with more of the admin and that sort of thing.
Q. And then in terms of when the test result came back,

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

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

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

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

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

of regular patients that were informed first.

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

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

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

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

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

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

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

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

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

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

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

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

storage.

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

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

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

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

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

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

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

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

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

Q. Carry on.

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

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

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

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

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

It is DHSC0004294_002, please, Soumik. Now,

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

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

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

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

A. I don't, and, to be honest, I'm a bit surprised that someone from the Department of Health phoned me. I'm not sure why they would have; you know, what that was about. It could have been -- I hope we're going to talk about this later -- The Haemophilia Society hepatitis C report.

Q. I think if we just go to the next page, we might see a little more about the context.

A. Yes.

Q. It looks as though -- the context was Lord Morris had asked Department of Health ministers to look into allegations of testing without consent.

A. I see. Okay. Well, in that case, it's very -- that's really interesting because, I have to say, if we go back to the previous one, clearly now my views have changed. I don't believe that. Could we just --

Q. Could we go back to the first page, please, Soumik?

A. I mean, clearly, this was a broad generalisation, but I'm afraid I can no longer say that I'm confident patients would have been aware that tests for the virus were being done.

Now, of course, like a lawyer, one can read that sentence now and think about it in several ways, that patients knew the test was generally available and that there were testings being done. But I take this

to mean that I was saying patients were aware that tests were being done on them for hepatitis C, and I'm afraid I can no longer say that with confidence. I've read the many statements. I'm sure some were, but I'm not -- as a generalisation, I don't believe that to be true.

SIR BRIAN LANGSTAFF: Can you actually remember having that view at the time?

A. Sir Brian, the honest answer is I -- as I said when we were talking about my evidence to the Lindsay Tribunal, I think what gave me that impression was the fact that the sexual transmission study -- I just assumed that patients had been told and their partners were told that the test was being done. I thought that was a reasonable assumption, but --

SIR BRIAN LANGSTAFF: So the answer is: yes, you did think that. You have changed your mind. You thought that because it was a reasonable assumption to make?

A. Yes. I have changed my mind, yes.

SIR BRIAN LANGSTAFF: So the assumption was that everything was being done as it ought to have been done, if I put it in those terms?

A. Yes.

MS RICHARDS: I want to then come on to the arrangements for care and treatment for hepatitis C and monitoring

liver function and progression of liver disease.

We know already of the clinics under Dr Trowell, and you've made reference to them. In 1991, when you arrived, were those undertaken as joint clinics, or were they clinics held by Dr Trowell and her team?

A. They were held by Dr Trowell, and she didn't have a team with her -- well, she obviously had a team, but they were based over at the John Radcliffe Hospital, but she ran those clinics alone. We did not sit in with her at those clinics. And, to be honest, what we tried to do was to -- the patient would see her, and then if they were coming for their six-monthly follow-up, we would do that -- you know, we would co-ordinate it that way.

So, no, as a general rule, we did not sit in with her. But, obviously, she's in the building with us. We would not in such a co-ordinated way as with the HIV team, we didn't sit down and have a separate meeting, but this was an opportunity to exchange news and information about individual patients.

Q. And in terms of decisions on treating patients in the early days with alpha interferon, and then with pegylated interferon, ribavirin, et cetera, did you or the Haemophilia Centre have involvement with those decisions, or were those matters that were solely

dealt with by Dr Trowell?

A. They were solely dealt with by Dr Trowell. But I would say sometimes I would write her a letter, and I would actually -- you know, I like, when I write a letter to a colleague, to pose a specific question: is this person a candidate for interferon therapy? So I would pose the question, if the patient is not already followed up, and she would provide the answer to that.

Q. I'm going to ask you to look at some guidelines on the diagnosis and management of chronic liver disease which you have exhibited to your statement. Soumik, it's WITN3311008.

We can see from the top of the page these are published in 1995. They are guidelines on the diagnosis and management of chronic liver disease in haemophilia, and it's co-authored by Professor Preston Professor Dusheiko, Professor Lee, Professor Ludlam and yourself, comprising the working party on chronic liver disease in haemophilia on behalf of UKHCDO.

A. Yes.

Q. If we just look at some of the broad guidelines that were here set out, we can see if we go -- well, in the first paragraph, it talks about:

"Virtually all haemophiliacs treated with

clotting factor concentrates before 1985 have been exposed to hepatitis C virus. Almost 100 per cent of these are HCV antibody positive."

And then there's reference to the propensity to cause chronic liver disease and hepatocellular carcinoma now emerging as a complication of chronic HCV infection.

If we then go down two paragraphs, please, Soumik, to beginning "the working party," so third paragraph, the guidelines say this:

"The working party wish to stress that, wherever possible, close collaboration should be established between the Haemophilia Centre Director and a consultant hepatologist and that the latter should play an important role in the management of haemophiliacs with chronic liver disease. The patients should be kept fully informed of the results of all laboratory tests, including antibody status. The clinical implications of the findings should also be discussed."

Then under the heading "Diagnosis of HCV infection", there is a recommendation that:

"All patients who've been treated with blood products should be tested by a second/third generation HCV antibody test."

And then we can see the bottom of that paragraph talking about:

"Decisions with respect to treatment with interferon should be made through consultation with a hepatologist."

If we go to the top of the next column, please, we can see under the heading "Sexual transmission of HCV" there's an estimate of the risk -- less than 3 per cent -- and it's said that:

"The current data on the rate of sexual transmission and the advantages of barrier contraception should be discussed. Patients should be encouraged to take a joint decision with their sexual partners."

We can then see in the next paragraph that it's recommended that:

"HCV testing should be offered to all sexual partners of HCV-antibody-positive patients."

Then we have recommendations for follow-up. So if we scroll down the page a little, please. Thank you.

So point 1 is:

"HCV-infected patients known to have abnormal AST or ALT levels should attend for review at approximately four-monthly intervals."

And then there is further recommendations of -- as to how to determine ALT and AST levels in paragraph 2.

Then if we go to the bottom of the page, there is a paragraph headed "Treatment with interferon Alpha". If we go over the next page. Top of the second page. We can see there's then a discussion about response to interferon, and then the second paragraph says:

"With this background, the working party wish to make the following recommendations."

And then we see a recommendation for consideration of treatment with interferon for patients with biochemical and serological evidence of chronic HCV-related liver disease.

There's reference then to genotypes and determination of genotypes.

And then if we go -- we can see, in fact, in the right-hand column role of liver biopsies. The specific recommendations about when liver biopsies should be considered.

And then under the heading "Other investigations", we can see recommendations for endoscopy. Every five years for patients over the age of 45 and/or those who have been infected with HCV for

30 years. And then there's a suggestion that this interval could be reduced in patients who are co-infected with HIV.

Then a reference to abdominal ultrasound for patients over the age of 45 as part of screening for hepatocellular carcinoma, and specific recommendations for ultrasounds and alpha-fetoprotein determination for patients known to have cirrhosis at approximately four-monthly intervals.

And then finally we can see a discussion about advice on alcohol consumption, and on the final page a discussion about circumstances in which liver transplantation may need to be considered.

Now, as far as you're aware, were those guidelines followed at Oxford through the liver clinics by Dr Trowell and her successor?

A. Yes. Before I -- just to say, I think all those important topics were, indeed, the headlines of my HCV checklist. It's interesting that they are the same things.

Yes, I mean, broadly speaking in terms of follow-up, the average patient was seen every six months rather than, say, four months. Some were seen -- the threshold for seeing Dr Trowell was quite low, actually, so some patients were followed up on

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

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

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

A. Yes, I did, yes.

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

trying to achieve?

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

Q. Now, the --

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

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

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

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

working party.

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

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

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

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

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

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

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

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

A. Yes.

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

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

we would were approached, would have been in relation to that, because BPL was not the first company to produce high purity products.

Q. Do you recall whether you decided to use high purity products in that period?

A. I can't remember but clearly the annual returns will show that very clearly.

Q. Then, in terms of the period which you have identified in your statement as being from 1995 to 2004, when there was a tendering exercise run by the Trust, what was your role, as centre director and consultant haematologist, in that exercise?

A. So the Trust would run the procurement and, because of the volume, it had to be advertised internationally as well. So what would happen is we would -- it wasn't just me -- and David Keeling and our manager, we would meet up and we would set out the sorts of products we wanted, and the brand would then be decided by the procurement. So if we say we wanted a high purity Factor IX product or we wanted a recombinant albumin-free, that sort of thing.

Q. So you would say to the Trust the type of product you wanted?

A. Yes.

Q. Is this correct, that you wouldn't specify the

manufacturer?

A. Correct.

Q. And that --

A. That would have been put out to advertisement. That's correct.

Q. In terms of prophylaxis, your statement estimates that was introduced in 1995 or thereabouts?

A. I think that's about right, that's about right, because firstly, of course, the confirmation of viral safety of 8Y only came in, I think, 1993, but my recollection certainly is that we had a lot of patients in the orthopaedic centre, the neighbouring Nuffield Orthopaedic Centre. There was actually a children's ward, and every day there would be patients on that ward, and indeed we had, in those days, a Friday ward round with Professor Robert Duffy, who was the head of the Nuffield Orthopaedic Centre, who also, fortunately for us, took -- you know, he had a principal interest in haemophilia.

So I think that's right. Prophylaxis started -- in the sense of prophylaxis for general regular treatment, on a twice or three-weekly times a week, started in around 1995.

Q. Now, part of your responsibility as centre director at Oxford for a number of years after you arrived was the

management of the database that was still then at Oxford.

A. Yes.

Q. And the evaluation of the annual returns and so on, which you undertook I think for a number of years with Ms Spooner?

A. Yes.

Q. Can you describe to us what that entailed on your part?

A. To be really honest, Rosemary Spooner really did most of the work, if I'm really honest. So the data would come in to her, and Ms Spooner would be prepared, if necessary, to go to other haemophilia centres, actually, to collate data. She's been known to do that. And a report would be generated -- it was always on an annual basis rather than a financial year. That changed later on. In about October of that year, or September/October of that year, a report would be drafted up.

It was, if I'm honest, somewhat formulaic, in the sense you could take the previous year's report and sort of add on. So, in other words, there would be a breakdown of the products used, there would be a graph to which you would add another point showing what was the factor consumption in, say, 1993. And

there would be a commentary on the product usage.

So it was a simple report, and I think the subsequent reports were much more sophisticated and complex, but I think it was -- it was a very useful report. It was a somewhat formulaic report, I would have to say.

Q. I'm going to ask you to look at one example. In fact, the 1993 report.

Soumik, it should be HSOC0024849.

So we can see this is "Annual Returns for 1993", and it refers to "attached tables and graphs":

"Returns were requested from 107 Centres ... received from 102 Centres ... some queries outstanding."

Then we can see in the second paragraph it gives information about numbers of patients with haemophilia A, with Christmas disease, as it was still then being referred to, with von Willebrand's disease. Then we can see under the heading "Treatment of patients", there's a summary of numbers receiving therapy including home therapy.

If we go over the page, we can see the first two paragraphs give further summaries in relation to units of different types of products used and then we have reference to table 8 giving an analysis of the causes

of death. And I just wanted to ask you a little bit more about that, if I may.

It says:

"Table 8 gives an analysis of the causes of death in the 110 patients with haemophilia A, 6 with Christmas disease and 10 with von Willebrand's patients who died in 1993. AIDS was the commonest cause of death - 59 (47 per cent), with cerebral haemorrhage and liver disease 12, 10 per cent joint second. There were nine cancer deaths (including one case of hepatoma), and seven patients died from ... heart disease and six from pneumonia (not PCP). The cause of the death of ten patients was not known ..."

Then further details in relation to deaths of patients diagnosed as having AIDS in Table 9 and Table 10 showing the HIV status of the patients known to have died.

So we can see from the report part of the purpose of it was to summarise the information about numbers of patients and type of treatment. What was the particular purpose of gathering together the data on causes of death?

A. It was of interest, and if you look at previous annual general meetings, people wanted more -- they wanted this sort of information. And I think it's relevant

to include it.

Q. If we just go to table 8, Soumik, it's I think it's probably page 10. Can we turn it round so that we can view it properly.

A. It's all right -- if you can't, I can turn my head, so you can tell me what you want.

Q. Yes, I am thinking also of those watching. Can we turn it?

A. I can read it. Please don't trouble yourself. I can read it.

SIR BRIAN LANGSTAFF: Just take it slowly so that those who are watching at a distance can turn their heads and follow it.

MS RICHARDS: So if we see in relation to AIDS, which is the first column, we can see that there are three categories of patient, and would I be correct in understanding that broadly correlates to severe haemophiliacs, moderate haemophiliacs, and mild haemophiliacs?

A. Yes. It's interesting to note, by the way, at this stage we were defining severe -- it may be of relevance, discussions you may wish to raise later about others matters, "severe" was defined as less than 2 per cent. From 2001 onwards, we switched to a definition of less than 1 per cent, but it's

interesting to see it was still in the UKHCDO returns as less than 2 per cent. But that's right. Severe, moderate, mild.

Q. And then we can see in relation to severe haemophiliacs, we can see 2 severe haemophiliacs have died in the age range 10 to 19; 12 in the age range 20 to 29; 17 in the age range 30 to 39; 7 in the range 40 to 49; 9 aged 50 to 59; 2 aged 60 to 69. And then we can see that in terms of those with moderate haemophilia, again, 2 deaths in the age range 10 to 19; 3, 20 to 29; 1 in the age range 30 to 39; 1, 40 to 49, and 1, 50 to 59. And then in terms of the mild haemophiliacs, one death in the age range of 30 to 39, giving us the total we see there of 59.

This obviously is a snapshot but a snapshot of a particular year. What kind of data on death and causes of death was this analysis based on? What information did Ms Spooner and the centre have access to?

A. These data, of course, formed the germ of several much more sophisticated analyses, including our report in Nature in 1995, and very specifically an analysis of age as well, which we published in The Lancet, so the impact of age at the time of infection on the progression of HIV.

As regards the source of the information, this was predominantly from death certificates. And in 1988, so before I came to the haemophilia centre, UKHCDO set up a system which I understood from Professor Hay's transcript is still in operation. And that is: people on the national database were flagged up by the Office of National Statistics, and copies of death certificates were automatically sent to the secretariat showing the -- so if someone died, the death certificate would be sent, and it was paid for, to the secretariat.

Now, in the studies that we will talk about later, like the Nature 1995 one, we went a little bit further. I see on the left of this is "AIDS" and two asterisks and I'm going to ask you if there's any -- you know, what that note refers to. Does it say it is just from death certificates or information from centres?

Q. No. If we go two pages further on, we can see what it is.

A. I'll just tell you the reason I'm saying that. Because very clearly (and this was an issue we specifically address in the Nature 1995 paper) many people, especially in the early days, were very reluctant to see "AIDS" on a death certificate.

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

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

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

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

A. Okay.

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

A. So what I would say is clearly --

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

information.

A. Yes.

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

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

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

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

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

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

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

SIR BRIAN LANGSTAFF: Thank you.

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

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

A. Thank you.

(1.02 pm)

(Luncheon Adjournment)

(2.05 pm)

MS RICHARDS: Dr Giangrande, we've been looking at the report on annual returns from 1993 and you made reference to the publication in Nature and so for the sake of completeness we'll just look at that now.

Soumik, it's HCDO0000264_095.

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

A. It is, yes.

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

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

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

Pausing there, that would have been the cause

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

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

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

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

A. That's absolutely right, Sir Brian.

And I would also point out there is -- and maybe Ms Richards will refer to it -- we did write a specific paper focusing on mortality due to liver disease in the haemophilic cohort, and that was published in The Lancet in 1997. So we have a paper -- if you don't have it, I'm very happy to provide it -- focusing specifically on that.

SIR BRIAN LANGSTAFF: Yes. Thank you very much.

MS RICHARDS: Yes, I think we've got four papers but not that one available today. We do have it, in any event.

A. If you have it, excellent.

Q. Returning then to the Oxford database, Dr Giangrande, and the issue of patient consent, you've said in your statement -- it's paragraph 116.1, I think.

So, Soumik, could we have WITN3311003, and if we could go to page 62. If we go to the next page, sorry.

You've said this, go down the page:

"During my time at Oxford, from 1991 to 2015, written consent was not requested from patients for their data to be entered and stored on the UKHCDO national database.

"116.2. After the introduction of the Data

Protection Act, and after some discussion within the UKHCDO, the group [that's the UKHCDO's data management group] agreed that patients would be informed that their data was being collected and stored but consent would not be sought. A leaflet was produced ... for patients explaining this situation, which was distributed to haemophilia centres."

Then you say as far as you can recall that was handed out in Oxford, and as far as you can recall most patients in Oxford were already aware of the existence of the national database, and you say you don't recall patients expressing concern to you.

So --

A. First of all, can I -- I'm sorry.

Q. Yes, carry on.

A. Yes, I'm very happy to expand on this.

It's certainly true when I started in Oxford written consent was not requested from patients and when I left that was the same position. And I have read the transcript of Professor Hay's contribution.

Let me say that this has been a subject of a lot of debate within UKHCDO and my view is that we should get written consent from patients to have their data entered on the national database. Furthermore, I'm on record as saying that.

It wasn't really an issue for me in my first years in Oxford, but the issue came to a head in the late 90s, when several other colleagues expressed concern about sending data to Oxford. Sometimes that was the doctor themselves, other times, as in the case of a colleague in Southampton, who is mentioned in one of the documents you've sent me, she was passing on the feelings of patients. And similarly, concern was expressed by a colleague in Sheffield.

So this made collection of the annual returns quite difficult. St Thomas' refused to send data to us from 1996 onwards and it was particularly difficult for us to produce the 1998 annual return. And, indeed, at the annual general meeting of the UKHCDO in 2000 you will see a statement to that effect. It says: Paul Giangrande and Rosemary Spooner have "soldiered on".

So this led to a lot of discussion within UKHCDO, and I must admit -- I'm going to quote some documents from among the ones you shared with me -- the path I thought we were on is that we were going to be seeking consent from patients. And indeed, in my testimony to the Lindsay Tribunal in 2001, I used the future tense, saying we will be collecting information from patients.

Now what changed all that was a meeting in 2002, which I will refer to. But just going through -- and I've made some notes here, which are entirely from the documents you've shared with me, so there is nothing new that I'm contributing.

In around 1999 the database we held in Oxford was going to change, and we had very good support from Rob Hollingsworth, who of course is the Manchester IT man, and we were going to change the software, and I was asked to come up with a draft protocol.

You have this document. It's dated 20 December 1999, and one of the opening words is:

"Information about an individual will be added only if he or she consents."

Looking at other excerpts from UKHCDO executive meetings, I note, for instance, on 11 February we have comments from both Professor Christine Lee and Professor Charles Hay about informed consent.

These are the words of Professor Hay:

"Consent needs to be obtained in writing, which was a major undertaking. Some patients would, of course, refuse. CL [Christine Lee] reminded Charlie Hay 'that they had discussed splitting the database into those giving consent and those who did not'.

"UKHCDO executive committee 5 June 2000, Christine Lee refers to contingency plans if the patient consents are not obtained by the end of the year.

"Data management group 8 August 2000. In the minutes, Dr Giangrande's view is that consent will be obligatory for research purposes in an anonymous format."

The first meeting of the new advisory board, under the constitution of UKHCDO, was on 11 September 2000. I was not present. Charles Hay is quoting in the minutes as saying:

"From the end of this year, UKHCDO needed to take steps to get consent from their patients. This information could be collected on a prospective basis, i.e. the next time the patients attended the clinic. There was no need for doctors to write to the patients for this consent. Dr Brown asked if there were any problems with electronic transfer of data. Dr Hay said no."

I, in a letter to Frank Hill on 11 July 2001, which was about The Haemophilia Society's HCV project, note, because I'm requesting release of information to the patients:

"I am sure that you will recognise that the

implementation of proposed changes to the database very much requires collaboration from The Haemophilia Society, and this presents an opportunity to show good intent in our collaboration."

But, on the data management group meeting of 7 February 2002, there was a complete reversal of policy.

"It was agreed [I'm quoting from the minutes] that patients would be informed but not consented."

This was largely driven by the contributions from Karin Pappenheim, the then CEO of the Haemophilia Society, and Susan Schonfield, who was from the London consortium, that is, the purchasers, and she was attending the data management meeting for the first time.

So there was a reversal of policy. But I want to make clear it is my view that patient consent should be sought for the database, and I really see no problems in doing so.

Q. Do you have any insight as to why that issue was so long debated within the UKHCDO and why it was not resolved more swiftly and straightforwardly?

A. I don't. And it leads me on to another issue, and that was the new constitution of the UKHCDO, which came into place in 2000. The first meeting, I told

you, was on 11 September. Before then, we had an executive committee where a representative from each haemophilia centre attended a meeting.

Under the new constitution, which is on the website, we have an executive committee, so the name remains the same, and we have four members. We have an elected chairman, a vice-chairman, a treasurer, and a secretary. According to the constitution they meet three times year and then the advisory board meets up with them.

But I've never seen minutes from the executive committee under the new constitution, and it's impossible for me to trace who said what to whom and therefore answer your question properly. I don't know all the discussions that took place but there clearly was a complete reversal of policy in early 2002.

Q. You had in the 90s, is this fair, two roles: you were director of the Oxford Haemophilia Centre, and then you were, because of the historic location of this information and the submission of annual returns to Oxford, you were, along with Ms Spooner, the recipient of data received from haemophilia centres across the country?

A. Yes.

Q. Can I ask you, first of all, in relation to your role

as Haemophilia Centre Director in Oxford, was there anything that precluded you from at least obtaining written consent from your patients to the provision and retention of their data?

A. Well, the Oxford database was inspected, I've forgotten the precise date, by the Caldicott Guardian. And the Caldicott Guardian, of course, for those that don't know, and clearly you do, is a responsible senior person within a hospital who has responsibility for making sure that data are cared for properly on behalf of the patients.

And during that time, the Caldicott Guardian who was based in Oxford, I'm not going to mention a name, was entirely satisfied with the arrangements that were in place. But I can't really introduce in my own Trust a consent form on my own.

Q. In relation, again, still to your patients at Oxford, do you know the extent to which, prior to your arrival in 1991, patients had been told that confidential data, including data about HIV status and so on, was being collected and analysed centrally for purposes other than their own clinical care and treatment?

A. It was not something that was hidden from patients, and I would say the following. I recognise that not everybody, of course, is a member of The Haemophilia

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

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

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

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

in the '90s, or --

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

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

A. That's true.

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

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

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

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

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

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

A. 2002.

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

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

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

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

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

A. Yes.

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

A. Exactly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The concerns about publication of the data?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

haemophilia community.

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

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

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

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

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

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

normal clinical practice it's the clinician who had been looking after the patient would request such permission.

Q. I want to move to ask you, relatively shortly because it is quite well documented, about recombinant.

There was a recommendation by UKHCDO in its 1997 guidelines in support of recombinant. And, as I understand it, at the point in time at which that recommendation was made, there was still no form of national funding available for recombinant.

A. That's right. The recommendation was actually produced and reached in 1996 but it was published right at the beginning of 1997. But actually the recommendation was made I think in October or November of 1996.

Q. If we look at some comments you made or you are recorded as having made in a newspaper article.

Soumik, it is BPLL0016004_007.

We can see this is dated May of 1998. And if we look in the middle column.

Sorry, could we have the whole document, Soumik.

If we look in the middle column, we can see that children under the age of 16 are going to start to receive recombinant. And then it says Scotland, Wales and Northern Ireland had already started phasing in

recombinant product for all patients.

And then there are some comments from you in the two columns towards the right of the page. Picking it up towards the bottom of the article, in the bottom right-hand corner, you say -- or the article says:

"The Government's new policy has improved the situation somewhat but it is still not good enough, says Dr Giangrande. 'I feel like Oliver Twist asking for more. But we won't be fully satisfied until ..."

And then can we go over the page, please:

"... all UK patients get recombinant factor VIII. This is an unfair, ageist policy. And what happens when someone turns 16? It's unworkable.'"

Then the article refers to the risk of viral infections from American plasma. And then, under the heading "Counselling effort", you are reported as saying:

"'For a significant minority of my patients, American plasma is the arch-enemy' ... 'What needs to be made clear is the immense amount of time and effort spent counselling patients about all these issues.'"

First of all, was that an accurate reporting of your views?

A. Yes, I think it is. And that point about patients

wanting British plasma is a very important one.

I remember a case very vivid actually of a patient that was referred to our surgery, orthopaedic surgery. He had septic arthritis. And he was referred to us from Devon. And he had to go to surgery in the evening and he was writhing in pain and crying. I went to treat him and as I went to, you know, inject him, he suddenly became lucid and he looked at me and said, "That's not American plasma, is it?" I said, "No, no, this is BPL, it's 8Y", and he was reassured and then he went back to writhing on the bed. And, you know, it is -- it was a big issue for patients that I dealt with.

Q. Then we will just look at one more document in relation to recombinant, which is a letter published in the Journal of Thrombosis and Haemostasis from you in 2003.

It is WITN3311004, please, Soumik.

I just wanted to invite your observations on two passages, so we can see the heading, "Treatment of hemophilia: recombinant factors only? Yes".

If we look in the paragraph on the right-hand side, top of the page, the last few lines of that paragraph, you refer to the vCJD crisis raising anxieties in the haemophilia community around the

world. And then you say this:

"In the UK, we have had to counsel many patients who were notified in early 2001 that they had been treated with batches of [Factor VIII] and FIX concentrates issued in 1996/1997 to which a donor had subsequently died of vCJD had contributed plasma. These patients would have been spared this ordeal if recombinant products had been widely adopted for the treatment of haemophilia as soon as they were licensed in 1994."

So does this remain your view of the historic position?

A. It does. I would say -- for a global audience, I would have to point out that in fact in the US and Canada actually Factor VIII was licensed for -- recombinant factor was licensed in 1992, as it happens. But -- and I've just really noticed that. I've quoted the UK date of 1994. But it remains my view.

Q. If we go to the second page, please, Soumik.

Just picking it up at the bottom of the left hand column. Go down the page. You say this:

"The reality is that it is simply the increased cost of recombinant concentrates compared to conventional plasma products, rather than rational

scientific arguments, which is the principal obstacle to their wider use. In view of all the problems associated with viral infections in people with haemophilia over the last two decades, it is clear that there is indeed much wisdom in Aldous Huxley's aphorism that the lesson of history is that the lessons of history are never learnt."

Your view expressed there, and you have repeated it in your statement, was that one of the principal reasons -- here you are suggesting the principal obstacle to the use of recombinants was funding?

A. Yes. I mean, in 2003 that was clear. If we had this discussion in about 1994/95, '96 even, there would be room for rational argument. Rational argument over, for instance, the fact that the early recombinant Factor VIIIs contained human albumin. So is that a risk factor? Have we truly eliminated the risk? There could have been some rational discussion about the incidence of inhibitors, for instance.

But by 2003, when this article was written, those discussions had been resolved. It was purely finance.

Q. In your statement, and this is WITN3311003, please, Soumik, if we go to page 43, I'm going to try.

Yes, bottom of the page -- so if you can go to

the bottom, please -- you say, in paragraph 95.2:

"In my view, there were three obstacles to the immediate introduction of recombinant Factor VIII (which became available earlier than recombinant [Factor] IX) in the UK."

The first you refer to is lack of consensus among the medical community, to which I think you have just alluded.

A. Yes, but I think that was fair. That is not a criticism of medical colleagues. I think it was perfectly reasonable to spend a year or two debating this. And UKHCDO I think did well putting together an internal committee of some of the older and then younger members to come up with consensus. So that's not a criticism, it's a fact.

Q. Then if we go to the top of the next page, please. The second paragraph, the second reason you give is cost. Self-evident. I don't need to ask you to comment further on that.

The third point you make is this, you say:

"It is my opinion, but I have no evidence to support this contention, that concerns about the future and viability of BPL's fractionation facility may have delayed the authorisation of the use of commercially sourced recombinant FVII by the

Department of Health."

I understand you say there's no evidence for it. What's the basis for your opinion, however?

A. Well, it was discussed, not only in the UK. In fact, the question was asked rhetorically by Professor Geoff Savidge in one of the minutes; he said: what will happen to BPL after this?

In my experience, globally as well, working with the World Federation of Haemophilia, this is a problem that has been faced by many fractionators in other countries, because there's often been, if you take European countries, a national fractionator. Sometimes that's a state-owned one, sometimes it's actually a commercial one working effectively as a national fractionator. So Grifols in Spain, LFB in France, and Italy has a similar arrangement.

The point is this, that if you take Factor VIII out of the equation, suddenly the economics of fractionation tumbles down, because the principle is worked on taking plasma, making albumin, immunoglobulin, vaccines and Factor VIII. If the Factor VIII is not going to be bought locally, then what do you do?

Now, in the end, this was solved by BPL starting to sell products abroad, and I think that helped

maintain them for a while. And it's interesting when you look at the costings -- again, you have shared several documents with me on this, including something I did for The Haemophilia Society -- it's interesting that when you look at the costings, for instance Lord Hunt does one, he is basing it purely on the volume of Factor VIII or Factor IX that needs to be bought, plus, you know, the price of recombinant Factor VIII.

But I was interested to see in the equation there is no mention of the impact on the fractionation facility, but clearly there is an impact. And it remains my view, and I don't think I'm alone in thinking this, that the impact of us not buying Factor VIII from a British fractionator compromises the financial viability of fractionation.

Q. I want to ask you next about the vCJD notification process, and I'm going to do so by reference to an article that you exhibited to your statement.

Soumik, it is WITN3311009, please.

This is a 2010 article:

"Risk reduction strategies for [vCJD] disease transmission by UK plasma products and their impact on patients with inherited bleeding disorders."

If we could go please, Soumik, to page 3.

Bottom of the page.

We can see, if we go to the bottom, please, under the heading "Management of early plasma products recalls", picking it up five lines from the bottom:

"The 1997 product recall letters from BPL to haemophilia centres cited the following advice that had been provided by the ethics committee local to the NCJDSU: 'the recipients (patients) should not be informed that the product that they ..."

If we go over the page, top of the next page:

"... had received has been recalled for this reason [subsequent diagnosis of vCJD in donor]. In response to queries raised by clinicians and hospital trusts about this directive, the DH confirmed to medical directors that patients who had received implicated blood products should not be informed. This was based on three considerations: first, that it was not known (the word used was 'unlikely') whether vCJD was transmissible by blood products; secondly, that there was no diagnostic test in existence, and finally that no preventative treatment was available. The consensus given by the DH at the time was that patients would 'not benefit from this knowledge, and that uncertainty created by informing patients could cause unjustified worry and create a permanent blight

on their lives'."

Then it says this:

"However, many haemophilia physicians either directly informed patients who had received an implicated batch, or provided all their patients with information about vCJD, giving them the option to be informed whether or not they had received an implicated batch(es)."

Then the article goes on to discuss the establishment, in 2000, of the CJD Incidents Panel, which then provided advice for the subsequent notifications.

Am I know right in understanding, Dr Giangrande, that you were one of the clinicians who decided that you would notify patients in 1997?

A. Yes. But I want to make it clear I wasn't alone, and I am pleased to see the great majority of clinicians did. In fact, I believe Christopher Ludlam, writing on behalf of UKHCDO, wrote a letter, I think it was to The Lancet, setting this out.

Now, the purpose of the recall, of course, was to let us in haemophilia centres know about this and to take back any material from those implicated batches and send them back.

I don't believe the '97 recall affected any

Oxford patients. The 2001 recall did. It affected 85 of our patients in 2001.

But clearly most of us felt that this was not a tenable option. And it wasn't a tenable option for a number of reasons. Firstly, there is something about -- we can do something about this. We have to learn, again, from the lessons of history. And the option we have, if we are being told -- I mean, why are you telling us this? I would say to BPL. If you are suggesting there's a risk to the patient, then we have to do something about it. And that something is to offer patients the chance to switch to a plasma product made from material which doesn't carry a risk of variant CJD, so, a drastic change in policy for us in Oxford, but to switch from BPL, British volunteer donor plasma, to American-sourced plasma. And that's what we did.

I'm pleased to say many other colleagues in the UK did that as well. The other issue, of course, is that I know from my work with the WFH that you can't hide this from patients. And I think it's important to be upfront and truthful with the patients because The Haemophilia Society would definitely have come to have heard about this and I think -- it simply was not tenable not to tell patients. And there was something

we could do to minimise future risk.

Q. We have a sample letter sent by you and Dr Keeling in December 1997 to your patients, and it refers, as well as notifying the patient and providing information, to a meeting you had arranged in a lecture theatre at the John Radcliffe Hospital on 15 December 1997 to present the evidence and discuss the matter, and to which the patient was invited. What was the purpose of that meeting? Did it take place?

A. It did take place, but -- and I should explain that the John Radcliffe Hospital is our sister hospital and it's a couple of miles away. I anticipated a very large audience, which is why I booked one of the major lecture theatres at the John Radcliffe. Admittedly this was shortly before Christmas, but actually only a handful of patients turned up.

I think, to be honest, by this stage patients -- and I used the word in other articles -- were quite sanguine about variant CJD, and I think the risk to the patients -- it was something we shared with the patient community. I had been eating beef, my family's been eating beef, we're all at risk of variant CJD.

The problem had arisen back in 1984. I think people had been reassured that no people with

haemophilia had developed variant CJD. So all I can say is that I was surprised that so few people turned up. But it didn't create a stir.

Having said that, quite a lot of our patients did take up the offer to switch to American plasma. We used Alphanate.

Q. Then, as you already alluded to, you wrote to patients again in 2001. And then I think thereafter the patient notification exercise was the one we explored with Professor Hay, which was organised, as it were, centrally through the Health Protection Agency and UKHCDO.

A. Yes.

Q. There's an observation in a document you authored and I wanted to ask you to comment on. It's DHSC --

A. Can I -- are you going to mention the international dimension of the 2004 recall? Because I think that's important to emphasise.

Q. You can do that now if you wish, doctor, before we look --

A. Remember that the 2004 notification exercise took place in September 2004. We were told on 9 September about this, and we had to send letters to patients by 20th September.

Now, actually, the point is that although this

notification affected us in the UK, BPL who was -- we were expected to tell people who had received British plasma products in the period 1980 to 2001 that they were at risk of developing variant CJD. Was anyone abroad told this? No, they weren't. And this meeting actually -- sorry, this notification happened to take place just before the World Federation of Haemophilia Congress in Bangkok.

I have to say we set up -- this generated a lot of anxiety and, indeed, anger in the international community, because BPL had exported British products to over 30 countries around the world and in this article, the one that you have on the screen at the moment, somewhere further down there are 13 countries listed that had received implicated batches. But, in fact, I think it was 36, actually, countries had been receiving these products. And BPL, or the British Government, did not make any attempt to contact individual physicians abroad in other countries.

Inevitably, of course, patients in other countries learnt about this, and we set up a symposium -- which was packed -- in October 2004, at the WFH congress, at the beginning of October.

We were lucky to get as speakers Bruce Evatt, of CDC fame, who had taken a leading role in the HIV

drama of the 80s, James Ironside also spoke. I gave a summary of the UK position.

And I'm pleased to say that WFH took a lead. They produced -- they had circulated copies of the implicated batch numbers to the affected countries, put the details on the website, and the president of WFH joined me in a meeting with BPL immediately after that October meeting in Bangkok, and in the end what BPL did -- or the British Government -- they sent notices to the health ministers of the various countries inviting them to seek information from the local British Embassy. But no contact was made with any physicians.

Q. Then the documents I'm going to ask you to look at, which is about the impact on patients, is at DHSC0006838_071.

We can see it's "The UK Experience, Treater and Patient Association Perspectives", and these are presentations given by you and by Karin Pappenheim.

If we go to the next page, we can see the heading, "Communicating Risk: The Example of vCJD, The UK Experience: The Treater Perspective".

And then if we can go to the next page, please. Could we zoom in on the third paragraph, under the heading, "What was the reaction of our patients?",

please, Soumik.

So this was your observation:

"As a general rule, the reaction was surprisingly phlegmatic. Many recognised that, in contrast to previous outbreaks of HIV and hepatitis, vCJD is an issue which faces all of us who live in the UK, and not just the recipients of blood products."

Which is I think effectively your evidence a few moments ago. But then you say this:

"However, there were several notable exceptions where real and persisting anxiety has been generated, including several patients who have consulted me because they are convinced that they are harbouring vCJD."

A. That's true, yes. This, by the way, for those that aren't aware, was a World Federation of Haemophilia meeting in Montreal.

Q. Then if we could go a little further down the page, Soumik, to the paragraph under the heading "Were there any other consequences?" And you said this:

"One unexpected consequence was that some patients who had received these batches were regarded as being at high risk of transmitting infection themselves. There were several instances of patients being denied surgery, dental work, or endoscopy

because of the implications for surgical instruments. Advice was sought from the Department of Health, and although guidelines are expected to be published, these have not yet been forthcoming at the time of writing."

To what extent was that problem of patients being denied surgery, or we've heard cases of patients' surgery being deferred, and the issue over accessing dental care and endoscopies. To what extent was that a problem in Oxford, and how, if at all, was it resolved?

A. It became a much bigger problem, of course, after the 2004 notification because we've got to remember that here we're talking about the 2001 notification. But if I could squeeze them both together, I would say the biggest impact was undoubtedly dental work.

We were lucky in Oxford because we had a good dental service that operated initially in the Nuffield Orthopaedic Centre, and then for a number of years we had a dental service actually within the Oxford Haemophilia Centre. And then because of budgetary cuts, it was moved to the East Oxford Health Centre, but still patients could be seen.

But a lot of patients did have problems outside the immediate Oxford area, and certainly in relation

to the 2004 notification, it was a serious issue. And, indeed, I wrote a letter to the British dental journal, which you will find in my list of publications, together with Andrew Brewer who was a dental surgeon in Glasgow. Because the British Dental Journal obviously goes to all dentists, we wanted to make some reassuring noises, if you like, to the dental community.

So I think for my patients in Oxford, the biggest single impact was the dental work. Endoscopy wasn't an issue for the patients. It was for us because, of course, of this issue which others have talked about of quarantining endoscopes, one endoscope per person which had cost implications, but the patient still got their endoscopy.

Q. I want to then move to the topic of compensation in relation to HCV and The Haemophilia Society's campaign. Could we have, please, on screen SKIP0000031_082.

We can see this is a document, "Report of the Hepatitis C Working Party to The Haemophilia Society, June 2002". If we go to page 4, please, Soumik, we can see there in paragraph 1 identified the membership of the working party, which included yourself, Professor Preston, Dr Makris, and Karin Pappenheim

from The Haemophilia Society, as well as others.

Dr Giangrande, I'm not going to ask you about the detail of the recommendations because we have the report, but could you just outline briefly how this working party came about and what the purpose of reporting was?

A. The party was convened by The Haemophilia Society. So I don't know the background to that. We were just invited and naturally all agreed.

The background was to try and get financial assistance for people who had been affected by hepatitis C. Note, not just the patients but also various families. It was partly as a consequence of the famous agreement whereby people signed away rights for compensation in relation to the payment made for HIV. And the purpose of this which took -- it was convened in, I think, September of 2001; we reported in June of 2002 -- was basically to come up with a simple costed measure. And we did this looking at systems that operated in other countries and seized upon the Canadian model which seemed a particularly good one.

We also sent out questionnaires on behalf of The Haemophilia Society to our patients in Oxford. We sent out 150 from Oxford, and also our colleagues in

Sheffield sent out a similar questionnaire. How had hepatitis C affected them in their lives, in terms of their working lives? Could they get mortgages, life insurance, that sort of thing? Had it affected their income?

Then we came up with a five-stage plan which offered compensation, or assistance shall we say, according to the level of patients being affected. I think the Skipton Fund in the end came up with -- and, by the way, after this report launched, we had a meeting in the House of Commons with Hazel Blears, the then health secretary, and there was another MP there. And this led to various discussions which, in the end, led to the Skipton Fund being set up with a simpler model, a two-stage system, but the money was pretty similar.

The costing worked out at, going from memory, £52.6 million for five successive years. This model proposed one thing which has still not been achieved, and that is coming back to something I was saying in the morning session. Level 1 offered compensation or assistance of £7,500 to people who had been exposed to HCV but didn't have persistent infection. That is, they'd cleared it spontaneously. The reason for that was we felt that being told you had hepatitis C,

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

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

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

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

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

just looking at? The report?

A. Yes.

Q. Then you identify what appear to be:

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

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

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

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

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

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

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

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

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

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

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

A. That's absolutely true.

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

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

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

(3.16 pm)

(A short break)

(4.00 pm)

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

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

I think it's probably page 84, Soumik.

SIR BRIAN LANGSTAFF: Paragraph 162?

MS RICHARDS: 152.

SIR BRIAN LANGSTAFF: Thank you.

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

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

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

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

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

So this is a document headed "UK Scientific

Advisory Group Meeting ... May 1992". The participants are five clinicians. I think we've heard from all of them now, and you're the last, and I'm afraid the first I'm asking about this. Then we can see representatives from Armour present.

It's obviously a meeting in London. There's a reference to dinner and lunch and so on. Then, "Subjects for Discussion":

"What does the Panel want from Industry?"

And then 2:

"EEC Directives on self-sufficiency and 'unpaid' donors and their impact on the UK plasma industry.

"a. Problems.

"b. Solutions."

And then:

"Concerns from the market."

Can you recall what the scientific advisory group or this panel was or what your involvement in it was?

A. The first thing I want to point out is that in my statement you will see very clearly that I declared right from the start, before you showed me this document, that I had done advisory work for Armour. So this is nothing new and I want to make that clear. So I had declared that.

These sort of meetings were held just occasionally, and advisory boards, I find them very useful actually. They are an opportunity for clinicians, either nationally or internationally, to focus on topics of current interest.

I have no recollection of this meeting, obviously, so long ago, but I think it's clear from the agenda there's nothing really overtly promotional about this, it's really to share a view.

One of the things that I do remember that came out of this which I found really useful was that -- in terms of communication to and from industry, Robert Christie used to produce some very good summaries of literature.

Remember, this is a time, 1992, before the internet, and he used to send out very good summaries of publications in the field of haemophilia. And I found that particularly useful actually.

But there's nothing overtly promotional about this. These are meetings of genuine interest. I found them very interesting.

Q. I understand you don't have recollection of this particular meeting, back in 1992. In terms of the subjects for discussion, can you assist us with why the issue of unpaid donors and impact on UK plasma

industry might have been a topic for conversation?

A. I'm afraid I can't. I mean, this has been an ongoing issue. And I think it's interesting to see, and I noticed when you sent me this document, "unpaid" is in quotation marks, and I do feel -- I do remember that many in the industry feel that sometimes the distinction between paid and unpaid donors is not entirely clear. It's certainly the case in some countries, and there's a lot of literature on this, and it's probably best addressed to someone working in transfusion, but they get some form of recompense, be it a couple of days' paid leave or travel vouchers or other things. So I think that is why that is in quotation marks.

But I think this has been a debate for a long time now, the question of the safety of paid donors. And I'm not a transfusion expert at all. I presume you will be speaking to some. But I think the feeling is that now they are no longer seen as the pariahs that they were once seen as.

Q. More generally, and you're right that your statement has provided information about consultancy work for pharmaceutical companies and so on. More generally, do you have any experience of any particularly lavish hospitality or gifts or approaches of that kind from

pharmaceutical companies?

A. Not gifts. I mean, clearly I have been -- over time, received support from pharmaceutical companies, often to travel to conferences, for instance. These are very strictly regulated, and I think things probably have changed since the 70s and 80s. My first ever trip for a work-related thing was actually in December 1991, when I went to the US. And certainly nowadays these are regulated and, indeed, policed. And, you know, long gone are the days of staying in luxury hotels, or going to meetings which are, you know, not strictly business.

So I have been abroad with companies but they have been conducted by companies for *bona fide* meetings and in compliance with APPI regulations at the time.

Q. If we could look at a set of UKHCDO minutes, it's HCDO0000452, please. It's the minutes of a meeting in 1994.

If we could go to page 6, please, Soumik.

We can see paragraph 8 is "Declaration of Interests". It says:

"Dr Mayne was invited to speak on this item. She said that Declaration of Interests was required by the Constitution. The document gave the framework for

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

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

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

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

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

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

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

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

SIR BRIAN LANGSTAFF: Paragraph?

MS RICHARDS: 125, sir.

SIR BRIAN LANGSTAFF: Thank you.

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

So paragraph 125.1, you have said there that:

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

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

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

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

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

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

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

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

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

So I hope that gives you a summary. It was linked to the new consultant contract, yes.

Q. Just so that people understand the wider implications of it, the consultant contract's a national contract. This isn't something particular to Oxford.

A. No, it was a national contract. The new contract, as we now call it, was obligatory for any consultant taking up a post after 2003. The people already working for the NHS as a consultant could opt to stay on the old contract if they wished. So there had to be some incentive to switch. And it was the loss of that 10 per cent cap that was, I guess, the incentive for many.

Q. Now, just dealing with UKHCDO as an organisation, you have already told us or given us some insight from your perspective. But as a junior doctor in the 1980s attending those three or four AGMs at key times '83, '84, '85, '86, do you have any particular perspective as to how the AGMs operated? The ability of --

A. I heard others say that it was a bit like going to a sort of shareholder meeting. You know, the floor, there may be some questions, but all the key decisions are taken by the key people.

I have to say that the people in the top reference centres merited the respect of others.

I think they were also -- on a personal level, I must say this -- very approachable. And as a junior person, I found all of them very open. They were not in any way difficult to work with. I found them all very, very pleasant.

But I think, inevitably, there were just a few reference centres at the time. I would say it's not -- it wasn't entirely democratic, but I was impressed with the key people at the time, on a personal level.

Q. Do you have any insight into -- and I'm now talking about from the 1990s when you were involved directly in UKHCDO. Do you have any insight into how the Chair was chosen? We heard from Dr Colvin that he effectively got a phone call out of the blue from Dr Rizza asking him to be Chair. Do you have any knowledge of that?

A. It is voted on. It is voted on. I didn't know about the Brian Colvin situation. All I can say is that certainly the current position, and for long as I remember, it's always been down to a vote. So the officers are elected.

So I think it's -- I think modern -- the modern UKHCDO, apart from that change in the constitution which I think was retrograde. I have to say I think

having an advisory board and an executive committee, I think that was a retrograde step which disenfranchised many people, but I recognise that was democratically voted upon; it wasn't imposed on anyone. But I think, overall, it's a very democratic group of people. And I think that if you look at the chairpeople there's a nice mix of younger people as well as older experienced people, and I think it's important that we have people from some of the smaller haemophilia centres as well as the big centres so everybody gets a crack of the whip.

So, overall, I think it's an example internationally, and it is an example actually which has been copied. If you look at the Italian system, which I know well, for instance, they have modelled it effectively on the British system, as have the Australians.

Q. There are some references in UKHCDO minutes -- I'm not proposing to go through the detail of the minutes, but you're expressing reservations or concerns about UKHCDO receiving support, financial support, funding, from pharmaceutical companies.

A. Yes, I do feel that. I mean, to be honest, leaving the database aside, UKHCDO is not an organisation that requires vast amounts of money. After all, all it

does is meet a few times in an office somewhere and, you know, everyone is paying their travelling expenses from their Trusts. So it's not an organisation that requires a lot of funding.

I do think it is best for UKHCDO to not take money from pharmaceutical companies. And allow me to extend the question by saying I think the same is also true of patient societies. And, you know, organisations like the UK Haemophilia Society and patient organisations around the world are all too often dependent on money from pharmaceutical companies to survive.

One of the recommendations, if I may put in a bid, that I'd like to see come out of the Infected Blood Inquiry, if I may, is I do think there should be a guarantee of financial support for the UK Haemophilia Society. And that is a recommendation that also came out of the Lindsay Tribunal as well. And I think it is important that patient societies as well as doctor organisations be freed from links to pharmaceutical companies.

Q. We've heard some reference from clinicians to something called the haemostasis club. Was that something that you were familiar with?

A. No. I read that -- I believe Dr Mitchell mentioned

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

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

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

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

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

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

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

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

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

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

whether they would be prepared to do so."

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

A. Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

devolution, rather, took place.

So really it was very Oxford-centred, both for HIV and for hepatitis C.

Q. This morning I asked you about whether you had had any involvement in the HIV litigation and you said you hadn't in the large class action but you had been asked to comment on one or two letters by your Trust.

Without asking you to go into details about any individual patient's care or any individual case, can you recall broadly what kind of issues you were being asked to comment on?

A. I'm afraid I can't, because this is going back a really long time. I'm really sorry, I can't.

Q. You also said, when we were discussing the question of consent, and this is talking about the issue of hepatitis C and testing in the early 1990s, that you wouldn't at the time have recorded -- or, you wouldn't necessarily have recorded the taking of consent in the notes, you might have just recorded that you were doing the test. Did your practice in relation to that and recording the taking of consent change over time, and if so when?

A. No, it didn't. But for HIV there was a form where we had to tick a box on the HIV form saying that we had taken consent. For the typical follow-ups, for most

of the time we used a pre-printed *pro forma* and at the end we would put which bloods had been taken.

So, no, it's not something that I personally did.

Q. Did you have patients at the Oxford centre who tested positive for parvovirus?

A. We never tested anyone for parvovirus. I think it was only a few research cases where that was done or where there were very obvious cases. And despite having had children under our care, I never came across a case which convinced me that a patient had parvovirus. So I never did any serological tests for parvovirus.

Q. You referred in your evidence earlier to audits of haemophilia centres. Is it your understanding that this was only undertaken in respect of the comprehensive care centres and not the smaller centres that didn't meet the criteria?

A. That is a fact. I believe that that system may now change. And originally audits, when they were introduced, were on a three-year basis, then there was a five-year basis, but I believe that the plan is now to extend that. And I think it should happen.

By the way, the audits, I think they are extremely useful. The typical way it's done is for a doctor from another centre, a nurse from another

centre and a patient from another centre to come and spend time and look into how the centre is run.

They also have the right to send out 30 anonymous questionnaires to patients. So randomly they come and they choose 30 sets of notes. And those letters get sent off to patients that are randomly chosen, and they can then feed back anonymously to the auditors how they feel about care in the individual centres.

I found audits to be extremely useful because if there were defects that were highlighted, I found that management did respond to that and would make, you know, some changes.

Q. Is this correct, that this was a system introduced and implemented by UKHCDO itself? It wasn't an externally imposed system?

A. No, that's absolutely right. It was UKHCDO that did it. And interestingly, other countries are now beginning to copy that model. Certainly Ireland now has audits.

Originally I believe Ireland wanted to come into the UK system, but that never happened. And I know -- I was speaking to a former colleague just a few weeks ago, and I believe there's going to be a European system of audit which is going to be set up, which

will not duplicate current audits, so UK centres won't participate, but there a lot of centres in Europe that are not. So the concept of audit was pioneered by UKHCDO and it's been copied elsewhere.

Q. Do you know when it was introduced by UKHCDO?

A. It's clearly in the notes and -- in the minutes, because -- it's not something I'd focused on, but the person who initially did it was Jonathan Wilde. So I don't know if you can do PDF searches on your documents but "audit" and "Jonathan Wilde" will pick that up.

Q. You referred to the participation of a nurse and a patient in the audit process. I may be wrong but I think such audits as I've seen from the 1990s involved only a clinician. Do you know when the introduction of the patient came about?

A. No, this was, I would guess -- because the last audit I had when I was in post was 2010, and that certainly had one. It would be the one before then. So if I had to guess, it would be around 2005. If I had to give a guess.

Q. What was the system in place at the Oxford Centre for ensuring that patients were made aware of their entitlement to Stage 2 Skipton payments?

A. I think that was very much the responsibility and --

responsibility -- the nurses very much did that, and it would come up, I think, as part of the follow-ups as well.

So I think we will have picked up all the appropriate patients. We were very conscious of that.

Q. You referred earlier to the sale of UKHCDO annual reports to third parties for a modest amount. Do you know what -- when you say "modest amount" --

A. Probably of the order of £200, something like that. That's going to be a pretty good ballpark figure. I mean, it's not thousands and it's not a tenner. Going from memory, it's going to be around -- it was around £200.

Q. What does UKHCDO -- or, what did UKHCDO do with the money received from the sales of the reports?

A. That I don't know. It was obviously paid to UKHCDO and it went into their coffers.

Q. Then, I think finally, can you look back at your statement. WITN3311003.

Can we go to page 17, please, Soumik.

I'm just going to show you three short questions and answers and then ask you about them.

So, question 28, you were asked:

"What was your understanding of the relative risks of infection from the use of commercially

supplied blood products and the use of NHS blood products?"

And your response was:

"My knowledge would have been informed from teaching, medical journals and lectures. I cannot give any specific dates."

Then if we go down that same page, you were asked in question 30:

"When you began work as a Senior Registrar in Haematology at the Westminster Hospital ..."

So I think that would have been roughly 1983:

"... what was your knowledge and understanding of the risks of the transmission of hepatitis ... from blood and blood products?"

And then you are asked:

"What were the sources ... [and] how did that ... develop over time."

And your answer, in 30.2 was:

"[Your] knowledge would have been informed from teaching, medical journals and lectures. I cannot give any specific dates."

Then if we go over the page, the last question and answer I want to ask you to look at, bottom of the page, question 34, you were asked:

"What was your understanding of the nature and

severity of the different forms of blood-borne viral hepatitis and how did that understanding develop over time?"

You have given the same answer:

"My knowledgeable would have been informed from teaching, medical journals and lectures. I cannot give any specific dates."

Dr Giangrande, it might be said, and indeed it has been said by a representative of Core Participants, which is why I'm asking you about this, that you have not actually answered the questions that you were being asked, which asked you to set out what your actual understanding at the relevant times was in the respects identified.

Can I invite your comment on that and ask you to explain why the questions weren't answered, if you accept that they weren't.

SIR BRIAN LANGSTAFF: There are two separate questions, I think, there: first, to comment, and then the answer why didn't you say what your understanding was, rather than what your source of understanding was?

A. Yes, that is a very fair point.

I think what I was trying to say when I read that -- I mean, I have to say -- what I was trying to say is that I didn't remember the particular times and

journals that I had read.

You know, I couldn't say, "In 1976 I knew the following". I just had -- I couldn't give a logical sequence of my memory of events from so long ago. I agree it's not a helpful answer. I think we've been able to explore it in much more detail in oral evidence today, but I agree it's not a detailed or helpful correct answer.

MS RICHARDS: If you would just give me a moment, sir.

Sir, whilst I just check whether there are any further questions, are there questions that you have for Dr Giangrande?

SIR BRIAN LANGSTAFF: I have one or two but you may want to check first.

MS RICHARDS: I'm simply asked to press you, Dr Giangrande, on why you didn't answer the question in relation to knowledge of risk.

A. To be honest, this was a very long document and I did my best. It's taken a lot of time. I honestly just felt, looking at that, that I couldn't remember in detail. I just couldn't give precision time points of what I knew when. I couldn't say I read this particular paper, what my view was at a particular time. I just couldn't do that.

Questioned by SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: Yes.

Two or three questions. They may seem to dot around a bit. They are about different matters.

When you came back from Italy and found yourself in Oxford, you said, I think -- this was in 1990 -- that you were a little surprised that blood testing, that is for hepatitis C, had not yet been introduced here. It had been introduced in Italy, what, for hepatitis C?

A. So I got a reasonable explanation when I said I was surprised, it's because they'd introduced -- they used the first generation assay. So I was surprised, but I got a very reasonable explanation. And that was that the second generation assay, which was the one introduced in the UK in September 1991, was regarded as more reliable.

And in fact, to give a good example of that, in 1992 there was a multi-centre study of the risk of sexual transmission of hepatitis C in patients with haemophilia, and patients from three centres were enrolled: Milan; Worcester, Massachusetts, that is in the United States; and Sydney.

There were 106 patients tested, and their partners. And this was published in -- I don't know which month, but it was in 1992 and Breckler was the

first author. And looking at the sexual partners, five of the sexual partners, that is 2.7 per cent, tested positive with the second generation assay but no partner tested positive with the first generation assay.

So let me be clear, I'm not suggesting that there was -- it was bad practice that hadn't been introduction of screening of blood donors in 1991, I merely expressed surprise. I'm not an expert virologist, I didn't understand the difference, so when I came I got a perfectly good and logical explanation for the difference.

SIR BRIAN LANGSTAFF: Well, the description in 1990 can't have been by reference to a study which wasn't completed until 1992, but as I understand, what you are trying to tell me is that it was thought the second generation test would be more specific.

A. That's correct. I was jumping ahead to give you an example to show in retrospect that was actually right. But I think already there were some doubts that the first generation test was not entirely accurate. And, in fact, just to build on that, when I was in Milan, I saw an example of the other way around: somebody reported as positive when they weren't. That was important -- I got dragged into this merely because,

you know, speaking English, there was a clinical trial of a concentrate, and on original testing with the presumably first generation assay somebody had come back as positive. Of course, this has huge implications for a clinical trial. But with whatever confirmatory test they did, they found actually it wasn't positive, and I remember having to draft the letter to explain all of that.

So what I'm saying is already, by the end of 1990, there were some doubts about the reliability of the first generation assay. And the reason for that is because in the assay the antibody is directed against one particular portion of the hepatitis C virus, whereas in the second generation assay they incorporate three separate bits of the virus.

SIR BRIAN LANGSTAFF: Yes. Is it your understanding that in Italy in 1970, the blood transfusion or their equivalent of the Blood Transfusion Service had introduced ALT testing?

A. 1970?

SIR BRIAN LANGSTAFF: 1970, yes.

A. I've no idea about 1970. I was at school in 1970.

SIR BRIAN LANGSTAFF: But just that you may have picked it up when you were in Milan working with the blood services there.

A. You know, I wasn't working for the transfusion services there, so I have no idea about what happened in 1970, I'm afraid, Sir Brian.

SIR BRIAN LANGSTAFF: I see. Apart from the anecdotal test you have given, was there any general feeling in Italy that they shouldn't have introduced the test? I take it from the expression, you're being surprised there was no such feeling?

A. I'm sure they will have moved on. What I'm saying is I wasn't an expert. I didn't -- you know, I assumed that the same test would be used in England. So I've never had cause to discuss with colleagues now in Italy, you know, when they went over to the second stage assay, were there problems? Had patients been infected because first stage assays had been used?

SIR BRIAN LANGSTAFF: Thank you.

The second matter really relates to the question of communication and consent, what was said to patients. And at one stage in your evidence, you said that if the question of sexual transmission came up -- this was in respect of those who you were talking to who had been diagnosed -- of being HCV positive -- if it came up, the risk would be low.

It's the expression "if the question of sexual transmission came up". That would suggest that it was

the patient who was raising it, rather than you. Would that be fair, or not?

A. I'd have to remember and look back at the transcript exactly in what context I said that. I think probably what I was talking about was before we had information.

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

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

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

A. I suppose so, yes.

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

A. Yes.

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

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

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

SIR BRIAN LANGSTAFF: So you objected to data being given

without consent. You knew that other centres, at least St Thomas' and maybe other centres too, did not give their data for that reason. Did you think it appropriate not to send the data of Oxford to the Manchester database?

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

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

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

A. Yes.

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

A. That's right. So the way things had operated is that after patients began to switch to recombinant products in the UK, the British Government, because BPL is owned by the Government as an integral part of the NHS, they had to find new markets. And they started selling the coagulation factor products abroad quite widely, and in particular the Middle East and also South America. And I have to say they had quite success. They had -- after all, these were seen as British, originally volunteer donors, and the products also were reasonably priced because the plasma was

free, whereas many other companies had to pay for plasma, and the prices were attractive. So they were quite successful in that.

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

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

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

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

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

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

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

SIR BRIAN LANGSTAFF: Right.

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

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

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

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

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

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

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

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

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

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

Questioned by MR THOMAS

MR THOMAS: Good afternoon, Dr Giangrande.

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

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

If we go down to the bottom of that page, at item 9, we can see the item under discussion is annual returns for 1994, where you presented a written report. If we go on to the following page, please, we

can see four lines down, or, in fact, three lines down, we have the record Dr Hay suggested the price charged to commercial companies for a copy of the report should be raised from £50 to £200 per copy.

And then looking at the last two lines:

"It was agreed that the pharmaceutical companies should be asked to pay £200 per copy for the report."

So it appears from that, Dr Giangrande, that it was £50 until February 1996, and then raised to £200. I think you said you thought it was about £200. Is that right?

A. Yes, yes. Going from memory, that's the figure that I had, so thank you for highlighting that. I hadn't seen that in the documents.

Q. The second issue is this. You were asked by the chair that -- was it professional comity that was a factor in you continuing to submit the data to the database when it turned to Manchester, and you said yes.

You had referred earlier, a few moments before that, to the Haemophilia Society being aware and being supportive of the database. If The Haemophilia Society or if you had learned that The Haemophilia Society had been expressing any unease about the database being used in this way, might that have made a difference to you in 2002?

A. Yes. I mean, the fact -- I was reassured by the fact that clearly The Haemophilia Society supported the status quo.

Q. All right.

Lastly, it's this: again, just a few moments ago you were asked about the switch to recombinant within the UK coinciding with the sale overseas of the BPL products.

At the time that the BPL products were being sold overseas, had the same product been withdrawn in the UK formally or was it still available but the decision had been taken by the centres that they would switch to recombinant?

A. Yes -- no, thank you for raising that point, because I noticed that as well. It was not formally withdrawn unsafe, it was simply that we preferred to use what we perceived to be a better product.

MR THOMAS: Thank you, doctor.

A. Thank you very much.

SIR BRIAN LANGSTAFF: Thank you, Mr Thomas.

Really, building on the comments you made at the end there, Dr Giangrande, describing how the oral evidence of those who were infected and affected had given a real understanding of what, on the printed page, might seem to be a less colourful, compelling

story, your evidence itself has shown I think, and I'm sure you would agree, the great value of hearing orally from witnesses.

In particular, in your case, there have been a number of occasions on which, if you will forgive my putting it this way, I don't mean any discourtesy, your evidence has been fulsome where your statement was perhaps rather terse. And you have explained that that was because of the length of the document. It's far easier sometimes, I suspect, to give evidence orally, and it's been, for that reason in particular, important for us to have heard from you and heard you expanding upon the various matters you have. And, indeed, for correcting a number of the matters which you had originally put out in writing and had time to think about, and we now understand what your position is on a number of points which otherwise, had we simply relied upon the statement, we might not have turn.

So thank you for that. And thank you for the lively way in which you've expanded. In fact, you have been fully prepared to give us the benefit of your experience not just in the UK but given us something of a flavour of Europe from time to time, where plainly you have had a considerable involvement.

And that, together with the issues which your evidence has highlighted, over consent, communication and the aftermath of the testing, has been very informative.

So can I thank you on behalf of the Inquiry for your evidence thus far.

A. Thank you so much, Sir Brian. I really appreciate your words. And I wish you every success in the hard work and task you have.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Sir, that is it for this week, and we are not sitting next week.

We resume on Tuesday, 1 December, for the evidence of Professor Ludlam, which will be heard over the four days, Tuesday, Wednesday, Thursday, Friday, of that week. And then the week after that we hear evidence, also relating to Scotland, from Dr Pettigrew, Professor Hann and Professor Lowe.

SIR BRIAN LANGSTAFF: And the following week, is that a full five-day week?

MS RICHARDS: Yes, the second week is a full five-day week.

SIR BRIAN LANGSTAFF: So we have nine days of evidence on the trot, as it were, split only by the weekend, beginning on 1 December?

MS RICHARDS: Yes.

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

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