Thursday, 22nd October 2020

(10.00 am)

SIR BRIAN LANGSTAFF: Today we hear from Dr Tuddenham.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: May Dr Tuddenham be sworn.

PROFESSOR EDWARD GEORGE TUDDENHAM (sworn)

Examined by MS RICHARDS

SIR BRIAN LANGSTAFF: Dr Tuddenham, if at any stage you want a break, please just let us know, will you?

A. Yes.

MS RICHARDS: Professor Tuddenham, I'm going to start by asking you just to give us an overview of your career. Your statement tells us that you were a senior house officer and registrar in pathology at the United Liverpool Hospitals, '69-'71.

A. Correct.

Q. And then you moved to the University Hospital, Wales, in Cardiff, where you worked under Professor Bloom from March 1972 to the end of 1975?

A. That's right.

Q. And I'll ask you a few questions about that in a moment. You then moved to the States for a period of time. You were a research associate at the University of Connecticut 1976 to 1977?

A. Yes.

stage. Where did you then move on to in 1986?

A. I was able to join the Medical Research Council with my own Research Council-supported group. They first sent me to the National Medical Research Centre at Mill Hill for some retraining in molecular genetics, and then I moved to Northwick Park, where I set up my research group recruiting scientists who I knew or had met while I was at Mill Hill.

Q. And what was the principal focus of your research there?

A. We were going to use the new tools of molecular genetics and protein chemistry and structure function determination to study in more detail the properties and activities of the various components of the clotting mechanism, both at the protein structure function biochemical level and also at the genetic level, and we were using those tools to discover new mutations and identify genes that previously were only known from clinical studies. And we were able to, for example, establish the cause of some rare genetic diseases, and use the knowledge we gained from studying the pathology of abnormal molecules to understand more about the normal structure and function of clotting.

Q. And then you took up a post as a Professor of

Q. What was the work you were undertaking there?

A. I had two projects. One, I was looking at human endothelial cells, which had recently been established in culture so one could study how they reacted to various stimuli and whether they produced Factor VIII or von Willebrand factor, as we then called it, Factor VIII-related protein; and the other project was purifying Factor VIII using immobilised columns of antibodies raised in rabbits.

Q. And then you returned to the UK and you took a post at the Royal Free Hospital, at the beginning of 1978.

A. Yes.

Q. That's going to be the focus of most of my questions, you'll understand but, just to get the dates, you were for the first half of 1978 appointed I think on a locum basis?

A. Yes.

Q. And then your role became permanent in around September 1978 and you were joined in the course of 1978 as a co-director by Dr Peter Kernoff?

A. Yes, that's correct.

Q. You remained in that position until 1986?

A. Yes.

Q. And you were doing work with Speywood during that period which, again, we'll come on to at a later

Haemostasis at Imperial in 1994?

A. Yes, this came about because Northwick Park Research Centre was closed down, and the MRC dispersed the groups who were working there, some of them to a new centre which they set up at the Hammersmith Hospital site, on Du Cane Road, and I was with one of those groups that moved to the new centre, and Imperial College kindly bestowed a professorial chair on me at that point.

Q. Your role there, did that remain a research and academic role or did you have clinical responsibilities at that stage?

A. It remained a research and academic role, although I did interact more with the Haemophilia Centre there, Professor Laffan, and provided some advice on cases, and also was interacting with the clinical teams of the Haematology Department.

Q. Then you returned to the Royal Free Hospital in January 2006, in what capacity?

A. I returned there as Professor of Haemophilia. We established a new chair in the name of Katharine Dormandy, which had been one of her original intentions, and I was also a director of the centre, so that I was clinically in charge of the, by then, much enlarged Haemophilia Centre and Thrombosis Unit,

and my major role, as stated at my interview applying for the post, was that -- if possible, to initiate studies on gene transfer, gene therapy.

Q. So you took over the role of director on Professor Lee's retirement?

A. Correct.

Q. Although director, was your principal work there still the research work?

A. Actually, no. I'd say I was able to devote about 30% of my time to research. There is a large component, of course, of administration. There was a reorganisation going on for the haemophilia services. The Pan-Thames Haemophilia Consortium was considering the future of the service, and there had been a proposal that it should be privatised, which I resisted vigorously. And of course managing a large clinic, both active for patients with haemophilia but several other conditions, and also a thriving and active women's clinic, which was with colleague -- professor now -- Rezan Kadir, an obstetrician, and we were providing an interesting and, I think, very valuable service there.

So I was very active clinically, very active in the management issues as well as running the research.

Q. And that was a place you held until July of 2011?

A. Yes.

Q. And then your statement tells us that your -- you still hold the post of Honorary Consultant Haematologist at the Royal Free. Does that involve any active clinical work or research work or both?

A. Both. I'm active in several trials of gene transfer, gene therapy, and haemophilia A and B.

Q. You were a member of UKHCDO during that first period 1978 to 1986 and you were one of the Reference Centre Directors, and we'll come back to that. I'm going to ask you some questions about that.

You were also on the Medical Advisory Panel of the Haemophilia Society. What did that by and large entail?

A. Yes, the Haemophilia Society would get an advisory panel together on a regular basis, I think it was three or four times a year. And it was relatively informal, the issues of the day were raised and discussed with the chairman and secretary of the Haemophilia Society. The chairman in those days had one of his -- his son was one of our patients, as it happened. Of course it's very much a family concern, haemophilia.

And we would, I would say, debate, discuss, in a sort of fairly relaxed way. But of course the whole

issue of infected blood and AIDS was ever more present, and so there were discussions about such issues, to which I contributed mostly when asked, more about issues of diagnosis and technical aspects of the kinds of assays that we carried out, which were a big focus of my interest. I'd say the more clinical aspects tended to be dealt with more by Peter Kernoff and other colleagues.

Q. And you also sat for a period of time on the Advisory Committee on the Virological Safety of Blood during your MRC time?

A. Yes, I was called back in to that committee.

Q. We'll look at some minutes of decisions of that committee at a later stage of your evidence, Professor.

Can I just take you back, then, to the first half of the 70s, '72-'75, when you were in Cardiff working under Professor Bloom. As I understand it, this was when your interest in haemophilia bleeding disorders was particularly sparked?

A. Yes, I was a lecturer but I was in a training post, and so rotating through the various sub-sub-specialties of haematology, ranging across from management of malignant cases, acute and chronic leukaemia, myeloma, lymphoma, and also laboratory

management, examination of blood films, examination of bone marrow, taking bone marrows, examination of tissue histologies, and so I got a very thorough training in all those aspects.

There was active research in that unit, and particularly interesting, it became to me more and more so, was the research that Arthur Bloom was managing, and he became a mentor to me in the studies that he was undertaking into what were then the unclear and even mysterious relationship between the different Factor VIII deficiency disorders, haemophilia A and von Willebrand disease.

Q. Were there any other particular research projects that you can recall that Professor Bloom was undertaking at that time other than the von Willebrand's research?

A. They were interested in platelet disorders, as well, and he helped me make a first observation of a complication of a platelet disorder which involved the lung, which often gets quoted, but his interest was mainly around haemophilia A and von Willebrand disease, and he had collected a large cohort of patients and families with those conditions which were studied in parallel, trying to disentangle the relative causation, which became a key to much of my later research.

He gave me a couple of other research projects. They were interested in the time at which Factor VIII first appears during embryology, they were studying the distribution of Factor VIII in tissues, its synthesis. So he had a broad research programme. It was very active, it was to my mind the best research programme in the UK at that time on these fundamental issues.

Q. To what extent did you have involvement in any of the clinical practices of Professor Bloom at Cardiff, in terms of his interactions with and treatment of patients?

A. I was -- when the patients came in, as they all did in those days, for on-demand treatment, I would be responsible, when I was in that section of my rotation -- training rotation, for treatment, which of course we gave as quickly and as efficaciously as we could.

Home treatment wasn't at that time developed in Wales. I hesitate slightly but I wasn't aware there was any home treatment at that time. Katharine Dormandy was a pioneer in introducing home therapy, in London. So I would be involved with the immediate treatment.

The outpatient clinical work I would sit in with

Professor Bloom when he was seeing patients and setting up diagnosis and treatment programmes, going on ward rounds, seeing the patients when they were admitted. The usual training role of a trainee haematologist.

Q. Can you recall whether there were any particular discussions, within the department, about the risks of hepatitis at that time?

A. I've racked my brains over that and I can't recall it at all. The risk that we particularly looked at and focused on was inhibitor, the development of antibody to the Factor VIII, which means the patient becomes resistant to treatment. Because at that time we had very few options for treatment for a patient in that situation.

Q. We understand from other documents that the Inquiry has seen that Professor Bloom took a direct and active role in deciding what concentrates and treatments and blood products should be used, and had a number of direct interactions with pharmaceutical companies. Were you involved in any of that or did you observe any of that when you were there?

A. No, I wasn't involved and I didn't observe it.

Q. Do you know whether blood samples were stored in Cardiff in the way we know Dr Kernoff stored samples

at the Royal Free?

A. I'm sure samples were being stored because one would often need to have a particular sample for a particular experiment so it's useful to have samples from a patient with a severe form of haemophilia because we used them in the one-stage assay. And from the patients with von Willebrand disease, where one had several different assays to perform or develop, looking at different aspects of that condition, samples would have been stored. I don't remember there being a plasma bank of any size.

Q. Can we move on, then, to the Royal Free Hospital and the Haemophilia Centre there, which you joined in 1978.

You were, if you don't mind me saying so, relatively young at that point in time when you were appointed, and your clinical practice, in terms of haematology, had been what you just told us about in Cardiff?

A. Yes.

Q. Dr Kernoff, too, I think, was relatively young at that time --

A. Yes.

Q. -- the time of his appointment. What had his route to becoming director been? Do you know?

A. He'd been doing some research in Oxford, and he went from there to work with a Dr Hymie Nossel in New York, and I believe it was there that he became most interested in the aspect of hepatitis and treatment with Factor VIII or Factor IX products. And so he was still working on those projects when he was appointed as the clinical NHS director, and I'd been appointed as Katharine's successor to a senior lectureship, so an academic appointment. So when he eventually came to join us, we were co-directors, which I think is -- was a unique arrangement and I'm not aware of another such arrangement in the UK or elsewhere, but we -- because we had parallel but distinct interests, that worked very well. That I could focus on the academic and research, and he focused -- also on research, but mainly on the clinical service.

Q. And what can you tell us about the facilities at the Royal Free Haemophilia Centre when you arrived in 1978? What did they comprise?

A. On day one it was still very minimal, really. We weren't still using the caravan that had been the place where Katharine saw patients when she started her Haemophilia Centre. We were using part of -- the hospital was newly built, and a purpose-built centre was ready and empty and waiting for us to move into,

but in the first weeks, before we moved in, we just had couple of offices and a small lab area, and we saw patients in the General Outpatients, and patients who came in and needed to come in, went on to the wards.

I moved the centre, once I was appointed, into the new purpose-built area, on two floors on the corner of the hospital, and it was a blank sheet. I had to decide what went where, who did what, and make it up as I went along.

Q. In terms of where the clinical care was done, the sense we got from Professor Lee's evidence yesterday -- obviously she was describing things when she arrived at the beginning of 1983 -- was that there were an area with a number of rooms but all located together?

A. Yes.

Q. And Dr Kernoff was based there.

A. Yes.

Q. And that's where patients were seen. That's where Professor Lee was based, the nursing staff and so on. Were you based on the floor above?

A. Yes. I had my office upstairs near to the lab and my research group.

Q. Again, Professor Lee described to us from 1983 onwards that there were regular meetings. She talked about

Tuesday meetings and Thursday meetings of the whole department to discuss various different matters. What could you -- what can you recall about those?

A. Yes, in our multi-disciplinary team meetings, we were -- a whole principle was to bring everybody together so that everybody knew what was going on, including laboratory staff, and -- because a key to running haemophilia care effectively is to have a well-developed laboratory. It's a clinico-laboratory specialty; our excellence, which is one of the things that attracted me to the specialty. So we would also that have the physiotherapists, the psychosocial workers, social worker, and nursing, of course, and medical staff, and we would go through the aspects of clinical care and technical aspects of laboratory observation and monitoring.

Q. In terms of the treatments policies and practices when you arrived, we've got a description from you in a seminar that you participated in in the 1990s. Could we have RLIT0000022, please, Henry.

This is a -- described as a witness seminar, February 1998, "Haemophilia: Recent History of Clinical Management." A number of people participated, including yourself. And if we could go to page -- Henry, if you look in the bottom right-hand

corner, it'll be page 35, but I'm not sure what page that is electronically. It'll be more than 35. So if you could go 10 pages further on.

So we can see the description here. We can pick it up with Professor Lee's observation at the top of the page. She says:

"In our Centre, we were a bit slow to use large full clotting factor concentrate because it wasn't really until you and Peter Kernoff came that people were started on this treatment, because Katharine had been so taken up with the cryoprecipitate."

Then Dr Matthews makes an observation. And then if we can just see what you then talk about. You say:

"Katharine had a wonderful relationship with her patients. It was maternal in some ways, because she knew them all very well, and their social circumstances. She put a very great deal of effort into ensuring that they would have the best possible circumstances for home treatment. She was a pioneer in that area and obtained, as you mentioned, money for them to have freezers in their own homes in which they kept cryoprecipitate.

"I would say that, to be fair to Katharine, it was difficult, as other speakers have mentioned, to obtain adequate supplies of higher-purity concentrates other

than for surgery, and the Centre's treatment relied very much on cryoprecipitate produced through local Blood Transfusion Centres. Things changed, of course, when Peter Kernoff and I came in after Katharine tragically died, and the concentrates were brought in progressively through battles against the controllers of the finances. Although, to do them justice, they did progressively increase the fraction of local capital that was being expended on imported concentrates until they reached towards the dizzying heights of today. So it was a transitional phase. Katharine was a pioneer and it undoubtedly changed the lives of our patients at that time to have their own freezers filled with locally produced cryoprecipitate".

There was a period of time when you first took up your post when Dr Dormandy was still there, not long, I think, before she died, but you did work with her for a short period of time.

A. Not in the clinic. She had actually become more or less bedridden by the time I arrived and took over, so she was no longer working when I started.

Q. But that is an accurate description, is it, of what your understanding was of how things had been organised at the Centre under Dr Dormandy?

A. Yes.
Q. So predominantly cryoprecipitate, at least for adults.
Your statement suggests that children may already have been on NHS concentrates by then. Is that right?
A. That's right, yes. We were treating children with concentrate. I can't remember giving cryoprecipitate to a child with severe haemophilia. And ... so, yes, that's my recall.
Q. And do you know why children in particular were on NHS concentrate at that point in time; the adults still on cryo?
A. There's an issue of volume, and the concentrate was -- as the clue is in the name -- it's a much smaller volume to give, it's easier to give it, and for children you tend to use very fine needles, especially the youngest children, and cryoprecipitate doesn't easily go through a fine needle. It's very -- it's sticky. It's actually mostly fibrinogen, which is a big, sticky molecule with a little bit of Factor VIII. And so the concentrates were a big step forward for treating small children.
Q. Can you recall the extent to which, at the time you arrived, there was use of commercial concentrates?
A. We had access to some. It was there in the mix. It gradually became the case that we used more and more,

as is shown by all the documents you have from Peter during his time obtaining resources and running the clinical service.
Q. What else was available for treatment in 1978? Was DDAVP being used already at that stage at the centre?
A. No. We didn't get -- we did start using DDAVP pretty soon after Mannucci had described its utility. And the exact time at which we were using it regularly is some time after 1980.
Q. And then, in terms of those with haemophilia B -- and again, I'm just looking at the point in time in 1978 when you and then later Dr Kernoff arrived, was haemophilia B already being treated with NHS Factor IX concentrates at that point?
A. Yes, it was. Yes.
Q. And what treatments were being used for those with inhibitors?
A. Right. Um, for haemophilia A with inhibitors, we didn't have any resource other than to try giving a large dose of Factor VIII. The observation that Factor IX concentrate could be helpful was made by somebody who accidentally gave Factor IX instead of Factor VIII. And, in hindsight, the reason that worked was that the Factor IX concentrates we were using in those days were a mixture of clotting

factors; some of them already activated. Clotting factors circulate in our blood in a precursor or proenzyme form and become activated during the process of forming a clot. But when purifying Factor IX, you end up with a mixture of related factors, some of them active, and so the Factor IX concentrate of the day was actually quite effective in treating patients with antibodies to Factor VIII, because the active factors jumped over the block -- a so-called bypassing agent -- and then that was formally developed into the product called Factor VIII inhibitor bypassing agent fibre which is an activated Factor IX complex concentrate.
So we were beginning to have some new tools, but it was a while before we got the activated Factor VII, NovoSeven. We were struggling with patients with inhibitors.
Q. So the major change, then, that was instituted under the new directorship was the shift from cryoprecipitate for home therapy to concentrates.
A. Yes.
Q. Why was that decision taken?
A. If one makes up cryoprecipitate practically, one soon encounters the fact that it's a variable product. It's got to be thawed. It's very -- the amount of

Factor VIII in it varies quite a lot, so you have to give five or ten bags. You've got to thaw out each one, draw it up, this gloopy material, through large diameter needles into syringes over -- it's time-consuming. And then infusing it is a slow business because of its viscosity.
To go from that to a little bottle with a defined amount of Factor VIII in it that you just add the -- usually water for injection to it, it dissolves pretty quickly; draw it up easily, and give it fairly quickly. That's obviously a big step forward, and it was appreciated by everyone, not just the doctors and nurses; the patients we could say. And the material can be stored in a domestic refrigerator; doesn't have to be in a freezer.
So it had many obvious practical advantages, and also, in the case of requirement to elevate factor level in the patient up towards or in the normal range of surgery -- head injury, life threatening bleeding -- it was much more reliable to achieve that than the use of cryoprecipitate.
Q. So practical considerations, convenience, efficacy. What consideration was given to the relative safety of cryoprecipitate and concentrate?
A. It was pretty early on noticed, by the way, with

cryoprecipitate at first that multiple donor treatments, for example, 5, 10, 20, 50 bags of cryo expose you to 50 donors, and within less than a year of Judith Pool publishing the method for making cryoprecipitate, the fact that there was an increased incidence of hepatitis was reported on. So we already knew that multiple donor exposure enhanced your chances to -- for blood-borne infection; hepatitis.

The fact that in making concentrate one pools hundreds to thousands of donations of plasma, very obviously increases exposure to numbers of donors and, therefore, to whatever transmissible agents they may be carrying.

I believe that was appreciated, but the extent to which that was a risk in numerical terms wasn't sufficiently appreciated, in hindsight. We had already encountered hepatitis in subjects who'd received hundreds by the time they'd been on cryoprecipitate regularly on remand for a year or two or three. They would have clocked up the number of exposures to get hepatitis, and so switching to a product which perhaps in the way -- rather naive way, we considered it, "Oh, well, they've already been exposed. This is not going to change that," was, I think, the kind of appreciation we had at the

beginning.

We didn't see a sudden change just by going to concentrates from cryoprecipitate in the patients we were treating who we'd already been treating for quite a while on cryoprecipitate.

Of course, that changes when you start giving new treatments to new, not previously exposed patients, because instead of their needing to be exposed over several score or hundreds of bags of cryo, the first exposure to a bottle of a concentrate made from hundreds of individuals is going to put the risk straight up there straight way.

Q. When did that realisation occur, as far as you can recall? Was that something known in 1978?

A. That was something that those who were using the concentrates had become aware of by 1978. Certainly, Peter Kernoff was already aware of that from the research he was doing with Dr Nossel in New York. So he came in with the knowledge of that and the intention to study it in detail.

Q. And the decision to shift away from cryoprecipitate to concentrates, was that Dr Kernoff's decision alone? Was that a joint decision; can you recall?

A. Well, I was there giving concentrates to patients and aware of the advantages we've just discussed. And it

was the general agreement that we needed to use concentrates because of the advantages and the fact we could get better control on haemostasis. And it was sort of enthusiastically received across the whole field of haemophilia care that concentrates were the way to go. And I was, you know, impressed by the same arguments for the switch.

Q. In terms of patients who were not severe haemophiliacs, so mild haemophiliacs, and before you started using DDAVP regularly, which I think you suggested was 1980 or thereabouts, so that period, '78 to '80, would mild haemophiliacs have been given concentrates?

A. Yes, they might well have been. Yes.

Q. Just want to look at some of the annual returns with you. I'm not expecting you to remember the data that's recorded in them, Professor Tuddenham, but just so we can see from the returns what products were as a matter of fact being used. So if we could please have, Henry, RFLT0000362.

The annual return is buried deep in this document. Before we turn to it, can I just ask you, do you know what these documents were? We've got a number of them. It says, "Monthly allocation of Factor VIII." This one happens to be from September 1979. And we

can see at the bottom it says:

"Photocopies to ET [which I presume is you] PK [which would have been Dr Kernoff] and PL [presumably the nursing sister]"?

A. Yes, Patricia Lilley. So that's me, Peter Kernoff, and the senior nurse on the unit.

Q. And what is this document? What does it tell us and what was its purpose at the time; do you know?

A. These are the beginnings of treatment -- summaries of treatment records which was, of course, to be developed far more into the National Haemophilia Database eventually so we know every product that each patient has received. So where you've got "GRO-A", that's a patient's name that's been redacted.

Q. It is, yes. Yes.

A. Correct, yes. So we can see what treatment the patient four down -- and it says, "Allocation". I'm thinking aloud. Eight. Ten times 245, so that -- yes, those -- 245; that's the number of units. That must have been concentrate because there's a serial number for the concentrate batch and the date it was given.

Q. If we go on in this document, Henry. It should be, I hope, page 12?

SIR BRIAN LANGSTAFF: Just to clarify, the numbers on the

monthly allocation, is that the number of bottles?
A. I'm puzzled by that too. I'm just thinking -- if we look at patient where it says "20", the patients -- in fact, I think -- you're quite right. Yes. Ten will be the number of bottles because each bottle had 245, yes. So the next patient's been allocated 20 but in fact has used 50 bottles. And so --
SIR BRIAN LANGSTAFF: Curiously, one of those bottles has got 230 in it.
A. Yes, it's a different batch. If you look at the batch number -- (overspeaking) -- it's HL6619.
SIR BRIAN LANGSTAFF: Yes, thanks.
A. Batch-to batch variation. So I think the allocation would be a kind of guess at expected usage, and then what's written in is what they were actually treated with.
MS RICHARDS: Then if we go to page 12, please, Henry, we have the annual return for 1979. So we can see towards the top of the page this is for patients having haemophilia or Christmas Disease, so they're brought together in one document at this time. Total number of haemophiliac patients treated during the year, 130. Number with Factor VIII antibodies, we seem to have two-numbers there, 14 or 12, but let's not worry about that. Number of Christmas Disease

patients treated during the year, 26.
If we go down the page, Henry, we can see there's usage there of cryoprecipitate and NHS factor concentrate, and then larger amounts of Profilate and Factor VIII, so two of the commercial concentrates, and then an amount of Koate and a smaller amount of Hyland. We've then got further down bovine and porcine Factor VIII -- I'll ask you about that later -- and some FEIBA being used. And then for the Factor IX column, we can see it's entirely Factor IX, NHS Factor IX concentrate.
So we can see, by 1979, predominantly concentrates, and of those concentrates, predominantly commercial, rather than NHS for haemophilia A.
A. Yes.
Q. And then if we could go, please, Henry, to page 18 of this document. This is again part of the annual returns for 1979. It's one of the standard forms.
Just so we can understand, these were the forms that were submitted by the Haemophilia Centre to Oxford --
A. Yes.
Q. -- for analysis. And so, as well as the summary we've just looked at, details of every patient, their date of birth, their base Factor VIII level, whether they

had inhibitor, whether they'd been jaundiced, whether they were on home therapy and the type of material, that would all be sent on an annual basis to Oxford at this time?
A. Yes.
Q. Do you know whether patients were aware that data about them, named data about them, was being sent to Oxford at that time?
A. I don't know. I don't recall any discussion about that point. I would think that there was some awareness that the national statistics were being gathered, which were of course crucial for our discussions with the Department of Health.
In fact, this is a side comment: the World Federation of Haemophilia always puts to the development of better and new programmes in developing countries. The first thing you need is to gather statistics, because then you've got some data to present to your Minister of Health. So whether -- I don't remember having a discussion with any patient ever at that time about having details about their treatment sent to a central database.
Q. And then if we could look at the returns for 1980. Henry, that's RFLT0000363. And we can see -- I think the return's now broken down separately, so the first

part of it is haemophilia A and carriers of haemophilia A and von Willebrand, and then there's a separate return for haemophilia B. So we can see the numbers treated here: 125 haemophilia A, 4 carriers, 20 of von Willebrand's. Then If we look at the haemophilia A patients columns, we can see some usage of cryoprecipitate in hospital; a very modest amount used for home treatment. NHS factor concentrate: a small amount used in hospital; a larger amount used for home treatment.
Would that have reflected predominantly the treatment that was being given to children?
A. I think some of that may have gone to adults, but probably most of it was to -- for children.
Q. Then we can see there's a range of different commercial products being used so there's some usage of Profilate, Koate, and Hemofil, and then a much larger amount of Kryobulin -- nearly a million units -- and then a still larger amount of Factor VIII, the Armour product, nearly 2 million units.
So by this time, we can see here clearly on the returns that the move that you've described here towards commercial concentrates is the primary line of treatment.

A. Yes.
Q. Then if we just look over to the von Willebrand's column, do we see there no home treatment for von Willebrand's patients, so it's all hospital treatment?
A. Mm.
Q. It's in fact cryoprecipitate being used as the main treatment at that point, some NHS factor concentrate, and a very small amount of commercial concentrates.
A. Yes. Cryoprecipitate is rich in von Willebrand factor, and particularly the high-molecular-weight form which is most effective in dealing with the problem you have in von Willebrand disease which needs large molecules in the process of forming the first bit of clot, which is a platelet plug. And so it's a very good treatment for von Willebrand disease.
Concentrates have variable amounts of high-molecular-weight von Willebrand factor in them, and it was many years before specific concentrates were developed that were for use in von Willebrand disease. At that time, I see we were -- had issued some of the Factor VIII concentrates, but some of them weren't very effective in those days. The NHS Factor VIII concentrate was pretty effective. So the more you focus on purifying the Factor VIII, the less

von Willebrand factor activity you have, unless you pay attention to concentrating that as well.
Q. If we go on two pages, please, Henry, we can just look at the same return but for haemophilia B. So 25 patients with haemophilia B treated during the year 1980. And we can see the exclusive treatment, both in hospital and at home, is the NHS Factor IX concentrate?
A. Yes.
Q. And then just one last set of returns. We don't have, I think, the returns for 1981 or 1982. We've got the '83 returns. Henry, can we have HCDO0000184_006. We can see again the number of patients at the top. 128 haemophilia A, 4 carriers, 24 von Willebrand's. Then if we look at the pattern of treatment for haemophilia A patients, we can see a relatively modest amount of cryoprecipitate used for hospital treatment. NHS factor concentrate, we can see there the usage for home treatment is much more extensive than the usage for hospital treatment, 1.2 million units. But then again the bulk of the treatment, the commercial concentrates, so we've got for both home and hospital treatments, over a million units of Factor VIII. And then for Koate, over a million units for home treatment, and over 238,000-odd for hospital

treatment. And similar amounts, in terms of hospital and home treatment, for Hemofil and Kryobulin. So again, the bulk of the products are commercial.
A. I'm intrigued to see that NHS Factor IX concentrate is being used. That must have been for the patients with inhibitors. Because it's in the column of haemophilia A patients.
Q. It is. We see there for the first time, I think, there's express reference to DDAVP.
A. Yes.
Q. As I say, we don't have the returns for '81, 82. Then we can see, for von Willebrand's, it's a mix of cryoprecipitate and NHS Factor VIII concentrate.
A. Yes.
Q. And then if we go to --
SIR BRIAN LANGSTAFF: Just before you leave that, underneath the Factor IX concentrate, you have what's described as NHS low hepatitis VIII concentrate. What was the low hepatitis NHS product, as you recall?
A. Yes, I was intrigued to see that too. I don't know. I wasn't aware of such an entity.
SIR BRIAN LANGSTAFF: It suddenly occurred to me, I don't think we've heard anything about that, have we?
MS RICHARDS: No. We know of the hepatitis-reduced commercial products because we've seen the

discussions -- UKHCDO Dr Rizza, et cetera -- in relation to those commercial products. We'll need to do some further digging, sir, I think, in relation to NHS low hepatitis.
SIR BRIAN LANGSTAFF: Please.
A. It's possible -- pure speculation now -- that these were concentrates batches that had been shown to have a lower risk of inducing hepatitis in treating previously untreated patients. I'm speculating. If Peter were around, we'd ask him, but I don't know what they were.
MS RICHARDS: And it's a very small volume usage there.
A. Small volume. If David Lane is questioned at any time in this Inquiry, he should know about it. He was director of the UK fractionation at that time, yes.
SIR BRIAN LANGSTAFF: Yes.
A. Yes.
MS RICHARDS: Then we can look at the haemophilia B return for '83 briefly.
HCDO0000184_051, please, Henry.
And again -- so we see 31 patients with haemophilia B, one carrier. Apart from a small amount of fresh frozen plasma for carriers, and then what's described as "HB Vax", which I'll ask you about in a moment, we can see again it's exclusively NHS

Factor IX concentrate. The reference to "HB Vax", is that to vaccination in relation to hepatitis B?

A. Yes, we were vaccinating by then. I was too, actually. It was the vaccine that was produced from volunteer donors in the New York gay community, who had what we then called the Australia antigen, which was one of the antigens of hepatitis B, and so we were making sure that all our patients and actually staff were vaccinated.

Q. One further document in terms of product usage.

It's CBLA0001244, please, Henry.

This is a letter from you to Dr Lane at BPL dated 23rd January 1981, and you're providing him with an analysis of Factor VIII usage at the Royal Free for the calendar year 1979, and you also refer to the National Haemophilia Centre returns, which we've looked at for certain years, and you say:

"I have no doubt that our usage under most treatment categories has increased in 1980 over 1979. The total usage figure for 1979 ..."

Was just over 3 million units, and then 1980, 3.4 million units.

"The numbers of patients involved was not I think significantly different ..."

Then, just so we can see the attachments that

we've found to this letter, if we could go to the next few pages, we can see here "Haemophiliacs treated with human Factor VIII in 1979", and you've set out there the patient group by reference to: inhibitors, severe, moderate and mild. And we can see there the relative usage and then the usage in terms of surgery.

And then just so you can see what else you've written in closing, Dr Tuddenham, if we look briefly at the next two pages, there's a table entitled "Factor VIII Units Used by Haemophilia Centres in 1979", and then the final page, "Haemophilia A Patients known at Haemophilia Centres on [31st December 1979]".

Why were you sending this material to Dr Lane; do you remember?

A. No. I'll have to speculate. He was interested in development of new methods for purification, and I think he was interested in projecting future need. But more than that I can't say.

Q. If you just go back to the letter, the first page, the letter tells us that you're using more products for roughly the same number of patients. Do you know why that was?

A. We were improving the treatment and management of haemophilia. We got more home therapy so patients

could treat immediately when they felt they had a bleed, when patients were gaining confidence in coming in, and having surgeries. It was just -- improving management of haemophilia involves using larger amounts of replacement therapy.

Q. Then could we look at, there's a handful of sets of minutes I wanted to look at briefly with you, Professor Tuddenham. The first is CBLA0000383 -- sorry, I think I've written that down wrongly, I think, Henry. It's CBLA0000838. Thank you.

We can see it's described as a "Third meeting of directors of haemophilia, associate haemophilia and blood transfusion centres", for -- and then we can see the regions there: East Anglia, North West Thames and North East Thames. And the date of the meeting is 1st September 1978.

If we go to the next page we can see the list of those attending, so it's what I think was referred to as a supra-regional meeting, with a number of regions gathered together, and we can see that you were there, Dr Kernoff was there, Dr Goldman was there, and Mrs Britten was there from the Royal Free. And then a number of others from other hospitals, including Professor Ingram from St Thomas'.

If we could just turn to the third page, Henry, no

the fourth page, sorry. You'll see halfway down the page there's an item in the minutes headed "Distribution of NHS Factor VIII concentrate", and there's a reference in the third line to:

"In April 1978 Dr Dormandy, [you], Dr Ardeman, Dr Davies and Mrs Britten met to try and sort out the distribution of the 360 bottles per month of NHS concentrate allowed to the North West Thames, bearing in mind that the requirements at the region were much more than this."

I don't need to go into the detail of it with you, but the source of NHS concentrate for you, did you get that from the Regional Transfusion Centre or from BPL? This looks like it's the Regional Transfusion Centre at that time.

A. At that time, it must have been the Regional Transfusion Centre.

Q. We've heard from others or seen reference in other documents in some regions to there being shortages of NHS concentrate and specified allocations. Is that what the position was for the Royal Free at this time?

A. Yes, we were in need of more factor concentrates than the NHS could supply, the NHS concentrate. I do remember this meeting. It was the last occasion that Dr Dormandy was involved actively with any such

meetings, and I picked her up and drove with her to where we held the meeting and took her home afterwards. It was the last time I saw her, actually. And so, yes, we were trying to decide on fair distribution of a limited resource.

Q. If we go to the next page, please, there's a discussion about shortages and Dr Lane's perspective and so on which I don't need to ask you about, but if we pick it up in the fourth paragraph, beginning "Dr Kernoff felt":

"Dr Kernoff felt that this did not solve the problem ..."

That was an issue about allocation.

"... it merely passed it to someone else; it increased the Royal Free's use of concentrates and they were already overrunning their budget. The problem needed to be dealt with at a regional, supra-regional and national levels."

Then he says this:

"Only 20% of the Royal Free's requirements were being met with the NHS concentrate at present. Despite this, and in accordance with the Reference Centre Directors' recommendations, it was the intention to switch home treatment patients from cryoprecipitate to concentrate."

So, pausing there, we can see that this wasn't just a patient-by-patient shift. As it were, there's a policy decision recorded here from the Royal Free?

A. Yes.

Q. From you and Dr Kernoff?

A. Mm-hm.

Q. And then this is said:

"Half the home treatment patients at the Royal Free were still using cryoprecipitate and this was felt to be an unacceptable state of affairs."

That's quite a strong way of putting it. Do you know why Dr Kernoff thought it was unacceptable to be using cryoprecipitate?

A. The short answer is "no", because I didn't discuss this with him at the time, but I think it's fair to speculate that that's unacceptable because of the just practical difficulties of handling, managing, making up and transfusing this primitive, as it seems by comparison to the freeze-dried concentrate, cryoprecipitate material.

Q. The minutes continue:

"If NHS concentrate was not available then commercial concentrate would have to be bought."

And the returns show us that that's exactly what happened.

Then this:

"... the extra cost might not be very great since the cost of cryo to the Royal Free was not inconsiderable and, taking into account the unitage, it worked out at almost the same price as commercial concentrates."

I don't think we've seen this elsewhere so far, Professor Tuddenham. This suggests that the Royal Free was having, at that time, to actually pay for cryoprecipitate.

A. Yes.

Q. Can you recall anything about that?

A. No. No. Peter dealt with all of that. But it is impressive that it's almost the same price. We were using a lot of cryo.

Q. And then there's just one further passage in these minutes.

If we could go on two pages, please, Henry.

If we look at the paragraph in the bottom half of the page, it's headed "Possible problems of blood donations from family members of patients on home treatment":

"Dr Kernoff mentioned an incident that had taken place at the Royal Free Hospital where the mother of a patient on home treatment pricked herself and

subsequently developed hepatitis. Before becoming ill, she had donated blood which had apparently been administered to a patient ... The boy himself was positive to hepatitis B antigen although remained asymptomatic."

Pausing there, is it correct to read this as the mother developed hepatitis B?

A. Yes.

Q. Then this:

"Dr Kernoff pointed out that family members of patients on home treatment should be considered high risks for transmission of hepatitis and should not be allowed to donate blood."

I don't know whether you recall anything about this particular incident?

A. No, but her son clearly was a carrier of hepatitis B, and handling blood from someone who is a hepatitis B carrier is a notoriously high risk for transmission. And as we see happened here.

MS RICHARDS: I'm going to turn to some UKHCDO minutes.

Sir, I note the time, it's 11. Is that a convenient point at which to take the first break?

SIR BRIAN LANGSTAFF: Yes, it is.

We have a break every morning for a coffee or refreshment, and normally it's 45 minutes, so we'll

take that 45 minutes, and quarter to 12, if you please.

MS RICHARDS: Sir, if you could explain to Professor Tuddenham the position in relation to discussing evidence.

SIR BRIAN LANGSTAFF: Yes, I will.

Professor, you're giving evidence. You must not talk to anyone, whoever they are -- it includes counsel, those with you, and so on -- about your evidence, either what you have said or what you think you may be asked to say. You can talk about anything else you like.

Thank you.

(11.02 am)

(A short break)

(11.43 am)

MS RICHARDS: Professor Tuddenham, there's a set of minutes I want to look at briefly with you.

It's HSOC0010549, please, Henry.

This is minutes of a meeting of the Haemophilia Centre directors, 13th November 1978, so it's the big meeting not the Reference Centre Directors meeting.

If we go to the fourth page -- sorry, Henry, my apologies, it should have been the third page -- we can see just above the "Present at Scientific Session

Only" we've got your name. So you were in attendance at the meeting.

If we go, please, Henry to page 12, using the numbered pagination at the top of the page. Excellent, thank you.

We can see halfway down, just over halfway down there's a heading:

"Supplies of Factor VIII concentrates, the DHSS Contract and the Price of Commercial Factor VIII."

There's a fairly lengthy discussion which I don't need to trouble you with the detail but if we turn on two more pages -- please, Henry -- we see, picking up on the point we saw being made by Dr Kernoff in that last set of minutes, here, four lines down:

"Dr Tuddenham said that the cost of cryoprecipitate to his Centre is purchased from Edgware Blood Transfusion Centre and calculated on their assay of the Factor VIII content worked out at 7.5 pence per unit. The cheapest price for commercial concentrate is close to this figure and occasionally below it."

So that's your observation.

Then:

"Dr Wensley ..."

I think he was Manchester.

"... on the other hand estimated that the cost of making cryoprecipitate was about one-third of the cost of making concentrates."

Was cryoprecipitate an actual hard financial cost to the Royal Free? That's what the minutes seem to be suggesting.

A. Indeed. Otherwise, I wonder why I would have bothered to work it out. I think it must have been priced per unit. And we were used to paying for blood product pro rata, plasma, fresh frozen plasma, platelets. That's certainly what that implies.

Q. There seems to be a very stark difference there between the cost that you're experiencing from Edgware Blood Transfusion Centre and what Dr Wensley is describing.

A. Yes --

Q. Do you know what -- sorry, carry on.

A. Yes, I'm just thinking of the cost. You've got to buy the plastic-ware. The donors give their precious blood, from which the plasma is obtained, free. Then you've got to spin it down, put it into a freezer, and then partly thaw it, squeeze off the excess, and freeze it again. So it's quite labour intensive. And you've got your staff equipment and so on. So -- however, how Dr Wensley would know the cost of making

it, presumably, he's a transfusionist who was running a centre.

Q. No, Dr Wensley was the Haemophilia Centre Director at the Manchester Royal Infirmary.

A. Okay, so he must have talked to the people who were making his cryoprecipitate and worked it out from that. I mean --

Q. Do you -- I'm sorry --

A. Well, I suppose if that's the case, they were adding on a percentage amount for profit to pay for other -- and it's not -- it was a -- the Edgware Blood Transfusion Centre, of course, is a not for profit operation, within the healthcare service, and, if they chose to make that profit on their cryoprecipitate, that was their commercial decision.

Q. Do you know whether the relative cost of cryoprecipitate was a factor in Dr Kernoff's decision making about using commercial concentrates more than cryoprecipitate?

A. I should think it must have entered into it, yes.

Q. There are some UKHCDO meetings, both Reference Centre Director meetings and the bigger meetings of all directors, in the course of 1981 at which a particular issue was discussed on a number of occasions and concern expressed, about a proposal to take control of

purchasing and supply away from Haemophilia Centre Directors, and give that control to Regional Transfusion Centre Directors, or Regional Transfusion Centres. I can show you the minutes if need be, but do you recall that debate at all?

A. No.

Q. Well, let me just show you what Dr Kernoff wrote about it then, rather than asking you about what was said in more general terms in the minutes.

If we go to OXUH0000886_002, please, Henry.

This is a letter from Dr Kernoff to Professor Bloom, 28th September 1983, so this picks up on the issue of centralised purchasing two years after it was discussed in strong terms by the Haemophilia Centre Directors.

And we can see Dr Kernoff saying he's concerned to hear this idea had been voted again and he was very much opposed to it.

And then the second paragraph, last sentence, he says he thinks:

"... that the proposal should be resisted by the Haemophilia Reference Centre Directors as vociferously as possible."

I just want to -- he encloses a paper. I just want to ask you about the paper. So if we go to the

next page we can see he sets out a number of concerns. And if we look at just four of the points, I think.

Point 4, "Control of usage", he says:

"Responsibility for usage of and expenditure on an essential drug must lie at the point of consumption - ie, with Haemophilia Centre Directors. It will be ethically and legally impossible to restrict usage by imposition of cash and supply limits ..."

So that's one of the points he makes.

If we then go to point 6 -- just a little bit below that, please, Henry -- we can see this is September 1983:

"Increased concern about AIDS/hepatitis requires central control."

His response is to say:

"Not so. Maximum flexibility and ability to respond quickly to changing circumstances can only be achieved if responsibility for selection of type of material/brand/formulation remains with those who have most intimate knowledge of the subject."

Then if we go over the page, under the first paragraph, "Mechanics of Purchasing, he says:

"Tendering and contracting must involve very close collaboration between Haemophilia Centre Directors, financial/administrative personnel and the companies."

Then last point before I ask you about this -- if we go down the page, Henry, towards the second half of the page, thank you.

If we see the third paragraph down on the screen, he says, sets out a concern:

"... the supply of Factor VIII may be restricted, and this will be contrary to the interests of patients. Haemophilia Centre Directors will not tolerate interference with supply by the BTS, because the BTS has no responsibility for patient care."

It's clear this was a matter that Dr Kernoff was very concerned about. He wanted, for some of the reasons we see alluded to there, Haemophilia Centre Directors such as himself to retain control and be actively involved in purchasing.

Is this something that you recall being discussed with Dr Kernoff as a particular concern at the time?

A. No. I don't recall that at all. Reading these letters has been quite an eye-opener to me. Nowadays we do it all centrally but it's done as a billing process in which we're involved, not just haemophilia doctors, but patients and the Department of Health, and subsequently have achieved extremely good pricing. Best in the world, actually -- I mean lowest. It's called best, but for product of equal quality. That's

become more complicated, of course, since there's many more different advanced products now.

But back then, Peter's insistence on local decision, I can see the force of the arguments he uses for it. But -- and I wasn't aware of it at the time. He took care of all that.

Q. But that possibly answers my next question but I'll ask in any event, Professor Tuddenham. We've seen from other documents, which I won't trouble you with now, Dr Kernoff being actively involved, consistent with what he says here, with choosing which particular pharmaceutical company or companies will receive the contract for a given year's supply. Did you have any involvement in that or was that solely the province of Dr Kernoff?

A. That was solely his province.

Q. Before I turn to ask you about issues relating to risks involved in hepatitis and HIV, there's just one further issue about products I wanted to explore with you at this stage. Porcine factor, which we've seen alluded to -- some usage of in the annual returns, and was something you were quite closely involved with in the early 1980s?

A. Yes.

Q. I'm going to ask you to look at one document -- I

think we've got a range of documents from you, including some published papers on the topic, but we'll just look at one. It's ISPN0000156_101 -- IPSN, sorry, IPSN0000156_101. Sorry, Henry.

These are some notes of a lecture you gave in Toronto -- I've got a note it's 1981, which sounds about right. Do you think that's right? Because the document itself is undated. I think that's put together from the reference to the 1976 World Federation, then "After almost 5 years", so it would seem to fit being around 1981.

A. Yes.

Q. There are two particular issues that you're talking about in this lecture. One is about a fractionation process using polyelectrolytes?

A. Yes.

Q. And then you talk specifically about porcine Factor VIII.

Before we come on to the latter, could you just explain briefly, and in terms that those of us who are not scientists will understand, the issue in relation to polyelectrolytes as a new method?

A. Yes, it's a solid phase process where the polyelectrolyte whose chemistry is described in the side is packed into a column, through which fluids can

be passed, and the property of the polyelectrolyte surface is that it exposes a certain charge density. And the solutes, that is the -- whatever is dissolved in the fluid you flow over it, be it plasma or cryoprecipitate, they will differentially absorb onto the surface depending on the charge and distribution of charge, and you can then wash, and whatever didn't absorb gets washed off, so you're left with those that are absorbed onto the solid polyelectrolytes, and then you can elute them, wash them off again, with a different solution, that detaches them progressively, and you can arrange it to detach some before other of whatever is absorbed.

So this a purification step, a solid phase purification step, which turned out to be very attractive for purifying Factor VIII and von Willebrand factor, because it had the property that the von Willebrand factor and Factor VIII stuck together, but you could take off the Factor VIII leaving the von Willebrand factor behind and make a good advance in purification of the Factor VIII away from everything else and von Willebrand factor, which is its natural carrier in the blood.

And that's very advantageous with pig Factor VIII, which, like human Factor VIII, and like, actually, in

the blood of all vertebrates, down to bony fish, they circulate together, Factor VIII and von Willebrand factor, but the pig von Willebrand factor, when you give it to humans, has an undesirable property that it causes platelets, these little particles that plug up wounds, to aggregate in the circulation, and that can be quite dangerous. So purifying pig Factor VIII von Willebrand factor complex on these columns delivers you a highly purified pig Factor VIII without the undesired pig von Willebrand factor.

Q. And we've seen reference to the polyelectrolyte material in correspondence from Speywood. Was this work that was being undertaken with your assistance by Speywood at the time?

A. I was working with them at the time, and they supplied me, they supplied us with pig Factor VIII, that we used in -- I think it was a landmark paper, really -- treating patients with inhibitors of Factor VIII, who make antibody to human Factor VIII but less so towards animal Factor VIII, and therefore the animal Factor VIII was able to correct the defect, ie, for the -- in the haemophilic blood that you couldn't treat with human Factor VIII, you could treat with pig Factor VIII.

So we had good results with that and some patients

were able to carry on using pig Factor VIII for years. Others did make an antibody to the animal as well, but it particularly helped me in my research efforts purifying human Factor VIII to have, as a first step, using polyelectrolyte which Speywood supplied to me.

Q. If we go to the last page of this document, please, Henry. First paragraph, you say this:

"Porcine Factor VIII is, of course, used for the treatment of inhibitor patients. Thrombocytopenia has been virtually eliminated as a side effect, and other adverse reactions are much less severe than with previous animal preparations. Haemophilia centres which have used Hyate:C [so that's the porcine Factor VIII product sold by Speywood, I think] report dramatic improvements in the lifestyle and morale of their inhibitor patients."

Then you say this:

"The possibility of porcine Factor VIII:C being used for non-inhibitor patients in countries with a shortfall of human Factor VIII should now be seriously considered. Of course, viral hepatitis is not present in porcine plasma, and the product thus presents no risk of infection."

And then if we just go to the very bottom of the page, you talked about various other points, and then

you say:

"We feel a higher purity Factor VIII concentrate at a yield significantly above the conventional offers excellent prospects for the treatment of haemophilia in the 1980s."

Turning back to that first paragraph, we have seen from the annual returns for the Royal Free porcine Factor VIII being used in what looks like inhibitor patients only. Was porcine Factor VIII ever used more widely in the first part of 1980s for non-inhibitor patients in the UK?

A. No, it wasn't. We had in Oxford a whole period in the 1950s when it was used because there weren't supplies of human Factor VIII. But it was only used for short procedures like surgery. So we never did actually transfer over to using pig Factor VIII against human. Can I have a short break?

Q. Yes, absolutely. I think a five-minute break, sir?

SIR BRIAN LANGSTAFF: Yes, absolutely. Would five minutes be okay?

(12.01 pm)

(A short break)

(12.06 pm)

MS RICHARDS: Professor Tuddenham, do you know why porcine Factor VIII wasn't, following your optimism in 1981,

used other than for patients with inhibitors? Was not enough of it made, or were there other concerns?

A. The concern was that, although some of the patients we treated who had inhibitors to Factor VIII did not subsequently develop inhibitor to porcine, most of them eventually did.

It's still, by the way, used in the rare condition acquired haemophilia, which is an autoimmune condition mostly in older patients, people, whose immune system goes out of regulation and they start making antibodies to their own Factor VIII. It works very well there. And it still can be used in some patients with congenital haemophilia who have antibodies.

But in the general case, it's regarded as -- there's no reason to use it generally in haemophilia A without inhibitors because we have access to large amounts of recombinant and plasma-derived safe product.

At that time, supplies were limited, and I was thinking of it as a cheaper way to provide treatment in low and middle-income countries. And originally, when Macfarlane developed these animal concentrates at Oxford, the reason was that there was very little access to human plasma-derived Factor VIII, whereas he could access huge amounts from normal agricultural

slaughterhouse sources. And so it was a breakthrough in its day. The further purification made a very useful product; we now have it in a recombinant form. But as a treatment, it never really came in as a general treatment.

It could have been used as a way to spare use of, at that time, a very risky, dangerous human-derived factor concentrates, but it never was so used.

Q. I wanted to turn then specifically to the risks of human concentrates and start, first of all, with hepatitis.

You describe in your statement an early experience of learning about hepatitis in 1969. Could you just elaborate upon that? It's paragraph, I think, 24 of your statement if you need to look back at it.

A. Yes. My senior registrar, Dr Brown, had experience with a patient which was written up, and it's in the documents available -- it's published in The Lancet -- a patient who'd been treated with a fairly large amount of cryoprecipitate but then developed hepatitis B, as became apparent, and he died from it.

So I was introduced to the danger of blood transmitted infection at the very first stages when I first came into contact with treating haemophilia.

Q. And then the observation you made in your statement

was that non-A, non-B having been detected, you've said it seemed quite mild compared to hepatitis B without the dreaded fulminant hepatitis that occurs with hepatitis B.

What was the basis for the view that non-A, non-B hepatitis was mild at that time?

A. Just that most patients had a transient, as it seemed then, illness with a modest elevation of the enzymes we used to track inflammation and damage in the liver, the so-called transaminases, and then appeared to get better and had no apparent -- clinically apparent -- problems. It was only when we came to follow them up carefully over subsequent months and years that we saw there was ongoing liver damage, and we started to track that using liver biopsy. And you could see the effect of the chronic inflammation in the liver leading to fibrosis and loss of active liver function, eventually leading to liver failure and liver cancer. But at the start, it appeared to be mild compared to hepatitis B, whereas, as we saw, can lead fairly rapidly to death.

Q. As I understand it, the observations of non-A, non-B being mild was about the acute stage?

A. Yes.

Q. Comparing the acute stage. But it's also right -- and

indeed Professor Lee referred us to a paper or case report she had written on it -- you could have fulminant hepatitis in non-A, non-B hepatitis?

A. Yes, you can, but rarely, I gather. You can also recover from non-A, non-B hepatitis and clear it naturally, which doesn't happen, I think, with hepatitis B.

Q. Do you recall whether you saw at the time the World in Action documentary, December 1975, which looked at the donor pools in the States which were used then to make the concentrates that were being used for haemophiliacs?

A. In 1975?

Q. Yes.

A. I didn't see it, no.

Q. You didn't see it.

In paragraph 26 of your witness statement, you said that you knew that commercial donation was the norm in US products, but you had no idea of the low standard of screening donors. So the use of paid commercial donations which resulted in what's sometimes referred to in contemporaneous documents as people from skid row, intravenous drug users and so on, donating blood for money. That was something that you were unaware of?

A. I didn't know that that was how they obtained their plasma. They certainly didn't admit it or ... in their literature about what they sourced their product from. We just didn't know.

Q. So you've said your perception of the type of donor recruited in the US was optimistic, to say the least?

A. Absolutely. I just assumed that they had standards of -- similar to what we would have applied to people donating plasma in the UK.

Q. I have, with a number of the other clinical witnesses, looked with them at some of the materials from the mid-1970s about non-A, non-B hepatitis, but given that you arrived at the Royal Free in 1978, I wondered if we could just look at the state of knowledge in 1978 with you.

You described in your statement steps being taken at the Royal Free in terms of liver biopsies.

A. Mm.

Q. Again, I think that's paragraph 24. And you've referred to -- picking it up in 1978 and being at the Royal Free -- an awareness of chronic hepatitis, monitoring of the severity of the complication, and then liver biopsies being undertaken in the -- with advice from the unit established by Sheila Sherlock who was at the Royal Free --

A. Yes.

Q. -- until there was, I think, an incident where a -- one particular patient, after a liver biopsy, died. You go on to say:

"It was clear that the chronic inflammation associated with non-A, non-B hepatitis was causing fibrosis and declining function in some patients."

So is it fair to say that, whatever your state of knowledge in the earlier part of the '70s might have been, by 1978, you were aware, and your colleague Dr Kernoff certainly would have been aware because hepatitis was his particular interest, that non-A, non-B hepatitis was a clinically significant condition with potentially serious long-term consequences?

A. Yes. Although, as I say, the -- our understanding of the longer-term consequences evolved over time.

Q. Yes. I think, rather than take up your time with lots of documents, I'll just ask you to look at one with me, because it's something authored by Dr Kernoff.

Henry, it's BART0002487. You'll see this is a letter dated 27 April 1979. It's sent by Dr Kernoff to Dr Colvin. And we just go to the second page. If you zoom in, Henry, on paragraph 2, "Types of therapeutic material available", we can see -- it's about two-thirds of the way through that long

paragraph -- Dr Kernoff describes non-A, non-B hepatitis in these terms:

"This is a serious disease with long-term consequences."

Then he goes on to talk about its possible prevalence in different parts of the world.

By '78/'79, although I appreciate entirely, Professor Tuddenham, there is still a lot more to learn about non-A, non-B hepatitis, it was understood that it was a serious condition.

A. Yes.

Q. HIV. I just wanted to ask you about your developing knowledge in relation to AIDS. Again, we've looked in the Inquiry at a number of documents in relation to this, so I'm just going to take you to two, rather than take you to all of the documents we've explored with others.

Henry, could we have PRSE0002410, please. This is an article that appears in the New England Journal of Medicine, January 1983, 13th January 1983, and it's an article by Jane Desforges. We can see it's "AIDS and preventative treatment in haemophilia".

She talks about cases -- so if we go down the page, please, Henry -- she talks, in the paragraph beginning "The risk":

"The risk associated with exposure to plasma from multiple donors, however, has long been a concern in the care of these patients, primarily because of evidence of virus-induced liver disease."

Then talks about hepatitis.

Then she goes on in the next paragraph to say:

"Now we're becoming aware that treating haemophiliacs with Factor VIII preparations may exact a high cost. Reports in the Centers for Disease Control include three haemophiliacs amongst cases of acquired immunodeficiency syndrome (AIDS)."

If we go over to the next page, please, Henry. We can pick it up in the last paragraph of the left-hand column. She says:

"The fact that haemophiliacs are at risk for AIDS is becoming clear."

Then if we look at the last sentence of that paragraph:

"Preventing the complications of the present treatment may have to take precedence over preventing the complications of haemophilia itself."

First of all, at this time, early 1983, would you expect to have been reading the New England Journal of Medicine as part of keeping up to date?

A. One would certainly wish to be up to date, and the New

England Journal of Medicine is a premier medical journal with the highest impact factor, then and now.

This particular opinion, editorial piece, is putting very starkly a balance between which takes precedence: complications of haemophilia, or complications of treatment, which would be a hard thing to do when not knowing the prevalence or -- of the appeared complication of AIDS. But it's prescient, and it certainly brings to attention that choice.

Q. And can you recall when you first became aware of the reports of an association between haemophiliacs receiving factor concentrates and AIDS?

A. Oh, as soon as it was reported by the Center for Disease Control.

Q. So that would have been --

A. It was immediately.

Q. So that would have been, I think, probably July 1982?

A. Yes.

Q. The second document I wanted to look at with you, Professor Tuddenham, is at PRSE0002647.

These are the notes of a meeting with Immuno at London Airport, 24 January 1983. It's not a meeting which you're recorded as having attended, but if we go to the last page, please, we can see who was present.

You'll see there a list of names, including the Reference Centre Directors -- I think all of them apart from you -- and Dr Kernoff there, presumably representing the Royal Free, and then others. We know that there were representatives of Immuno. We can see Professor Zuckerman was there and a number of directors of non-Reference Centres but of some of the more significant and larger other haemophilia centres.

A. Mm.

Q. This was a meeting that was discussing the possibility of hepatitis-reduced Factor VIII and Factor IX concentrates, discussing the possibility of trials in relation to that. But there's also a discussion about AIDS.

So if we just go to the page before this, please, Henry. We can see, under the heading "Acquired immunodeficiency syndrome", it's reported:

"This was discussed in the after-lunch period. Dr Craske summarised the current position."

And then if we go towards the last paragraph on that page, we can see that what the summary includes:

"Ten haemophiliacs have been in the US have been affected and five have died. The youngest was age 7. All cases have had prolonged treatment with Factor VIII. There's no specific implication of one

particular product or batch. Other cases involving blood and blood product transmission have included platelets transfused in three cases."

And then it gives examples of two of those cases:

"The second, a 20-month-old child ... who had received several units, including platelets known to have come from a homosexual donor. The child has developed autoimmune haemolytic anaemia and a possible AIDS state".

And that's the case referred to in some of the literature subsequently as the San Francisco baby case.

Over the page, we can see, fourth paragraph down, the attention of the meeting being expressly drawn to the New England Journal of Medicine from 13 January.

I'm conscious this is a meeting that you were not at, Professor Tuddenham, unlike all the Reference Centre Director meetings which you attended.

Do you have any recollection of this meeting being raised with you by Dr Kernoff?

A. Yes. We ... probably didn't have a long discussion about it because I can't recall it. I do recall the T4/T8 ratio being discussed, and the implication being that cryoprecipitate either had something that maintained a better ratio, and there was something in

the concentrates that changed it. But I don't recall a detailed discussion, no.

Q. Professor Lee told us yesterday that, whilst she didn't know anything about this meeting, that the question of AIDS was something that, in 1983 and 1984, was -- I'm paraphrasing, not directly quoting -- but something that was very much being discovered within the Centre?

A. Yes.

Q. Can you recall any particular discussions, concerns, views, being expressed, whether at the multi-disciplinary team meetings or otherwise, about AIDS and what the Centre's response should be?

A. We were looking out for it, and signs of it, in our patients. They were aware that it was entering the haemophilia community as a result of the treatment. And the first patients who showed clear signs would have been sometime during 1985, I think, at the Haemophilia Centre.

Q. In the Royal Free?

A. At the Royal Free, in our patient group. There'd been a patient earlier in Bristol, the first UK patient. But we had a man who died of chickenpox pneumonia, which is obviously highly atypical in an adult. And soon after that, another patient was developing

progressive neurological problems which ended. And so by the time I left at the end of 1985, we'd actually had two deaths.

We also, of course, knew, as soon as we tested everyone, which -- who was positive. But, yes, we were constantly talking about it.

Q. Am I right in understanding that you attended the World Federation of Haemophilia meeting in Stockholm in 1983?

A. Yes, I did. Yes.

Q. And I think we've got a copy of a paper you delivered. It was reproduced in the bulletin. So just to see whether I can prompt your memory if I need to, it's PRSE0000411, please.

And if we go -- this is edition number 2 of 1983. If we go, please, Henry, to page 12. We can see there a talk, "Innovative Alternatives to Human Factor VIII" by you. And if we go to the next page, it says -- this is at the very bottom:

"Abstract number 37 given at the World Federation of Haemophilia Stockholm, 1983."

So is this the text of the talk you gave at that Stockholm meeting?

A. Yes.

Q. If we go back to the previous page, please, Henry,

right-hand column, about a third of the way down -- actually, we'll just pick it up in the beginning because you talk about the process of preparation of concentrates in very stark terms. You say:

"Let me begin by describing a process for you, one that's very familiar and one carried out in all developed countries. A heterogenous natural product in liquid form derived from many individual citizens is pooled. Various substances are added and precipitation occurs [etc, etc]. The end product is then widely distributed. Now, what process do you think that might be? Production of Factor VIII concentrate?"

If we skip over the picture of you, we can see you say:

"No, actually I was describing a sewage plant. The basic principles of sludge separation closely resemble those of fractional precipitation."

Then you say:

"I submit to you that the technology of Factor VIII concentrate production has got stuck at a point reached by about 1970."

You then go on to talk about a number of matters that I don't need to ask you about, but if we look at the right-hand column -- thank you -- third paragraph

down, you say this:

"Now, who is to blame for this deplorable situation, the results of which are being discussed in the seminars on hepatitis and AIDS? Frankly, we're all in this together: doctors, patients, national blood centres, commercial fractionators. We must recognise the deficiency and take drastic steps to bring coagulation factor purification into the 1980s. I do not consider that heating and irradiating blood products to remove things that shouldn't be there in the first place is anything other than a temporary measure of desperation."

It would seem fairly clear from that that very much on the agenda of the World Federation of Haemophilia were the risks of hepatitis and AIDS.

A. Yes.

Q. Do you recall what in particular was being discussed or raised on either of those issues at that meeting?

A. I was using colourful language to emphasise the inherent risks of pooling blood from thousands of donors. My view, the biochemical one, of let's purify what we really want out of the blood, and eventually, as I say later, let's synthesize it, which we did achieve, but not for quite a long time -- well, not at three -- two years after that -- what was being

developed then was ways of inactivating viruses. The details of that didn't really get discussed. There was a lot of commercial secrecy around that. There was also a problem that the agents at most risk, as it turned out, of hepatitis C and HIV, human immunodeficiency virus, HTLV-III, hadn't been isolated and characterised at that point, let alone assayed. So it was sort of feeling in the dark, and there weren't good or a reasonable animal model to look at transmission, so you're back to clinical trials of products after you'd treated them in ways that you hoped would, in some way, inactivate what you weren't really sure was there in the first place.

So, I mean, we were really in the dark, and I was taking a kind of purist biochemical approach, which was: let's isolate the thing we want, and that will get rid of the virus per se. But, yes, everyone was well aware that there was a life-threatening problem with our best treatments, and people were trying to find ways to deal with it. I suggested the way that came to me, others were working on viral inactivation.

They got lucky with that because the viruses that they had to inactivate had this property that you could actually inactivate them by rather simple methods. But it took a while to perfect those; the

early shots at heat treatment weren't effective, and didn't finally become effective until 1986. And the sort of steps on that road weren't being widely publicised; they were being developed in commercial laboratories.

SIR BRIAN LANGSTAFF: Are we moving on from this paper now?

MS RICHARDS: Yes, we are.

SIR BRIAN LANGSTAFF: May I just ask you about two things which you say in the paper, which have struck me just listening to you. The first is that you make a case in your paper that the -- nothing much has happened with the technology of blood production since the early 1970s, and you're critical of that.

The second is that you observed, I suspect entirely rightly, that there was quite a degree of commercial secrecy as between the various commercial firms which were attempting to inactivate viruses.

One of the features of what I'm looking at is that three or four firms, the four major pharmaceutical producers of Factor VIII perhaps, in the United States, all, under their own forms of commercial secrecy -- so presumably not talking to each other, short of espionage -- were -- on exactly the same lines and about the same time produced similar

products. There were differences, but there -- as you'd expect.

So could that have been done earlier with a bit of will?

A. I believe so, yes. I do believe so.

The purification methods for mass separation of fractions from human plasma were developed during the Second World War by Cohn, and the so-called cold ethanol fractionation was in use as the major -- and parts of that method are still in use today, but they were -- sort of modifications of those methods were in use for the Factor VIII concentrates.

Further steps were then taken, very empirically, but a sort of mainstream biochemical approach to separating took a long time to find its way through. They had a product which they could sell, and they did. And the impetus to improve it came rather slowly, in my view.

I guess I'm taking a purist view of that.

SIR BRIAN LANGSTAFF: Well, it's your view that I was looking for, because of the two matters I've just raised with you. Thank you for that.

MS RICHARDS: Professor Tuddenham, I wanted to ask you about the Royal Free Centre's response to what, by this stage, in the early 80s is a known risk of non-A,

non-B hepatitis, and by 1983 is knowledge of, at the very least, a possible if not likely link between factor concentrates and AIDS.

Professor Lee's evidence, both to the Lindsay Tribunal and to this Inquiry, was that there was no change in the treatment policies at the Royal Free in response to those risks. So throughout the first part of the 1980s until the end of 1984, when heat-treated products became available, her understanding was that the policy of treating children with NHS concentrate was continued, but other than that, and other than that it was -- continued commercial concentrates in the same way as before.

I think that's effectively what your statement also accepts?

A. Yes, I am stating that.

Q. And we can see if we look at RFLT0000019 -- please, Henry -- we can see it's an application for an early application for ethics approval of research involving investigations on human subjects. It's submitted by Dr Kernoff in 1st December 1983, but your name and Dr Kernoff's is given as the head of section. I know you've seen this document very recently.

There are two parts of what Dr Kernoff was proposing to study here: the polyelectrolyte

fractionated porcine Factor VIII, which we've already discussed, and then the heat-treated human Factor VIII. And he goes on to say -- if we look under the heading "Background", he says:

"The incidence of acute non-A, non-B after a first exposure to routine human Factor VIII concentrates (either NHS or commercial) approaches 100% ... Of particular concern is the high risk of chronic hepatitis following an acute attack."

Then he goes on to say that the Royal Free has been offered two human commercial heat-treated products for clinical assessment, both of which have been granted clinical trials exemption. And he asks for approval for a piece of work. And we know from other documents that I needn't trouble you with that approval was forthcoming.

Do you know whether those trials of heat-treated products ever took place at the Centre?

A. No, No.

Q. As in you don't know?

A. No. Unless one can find a publication in which the result of the trial is included, I don't know.

Q. And your interest in this, as I understand it, was the porcine element of it. Would you have been involved in any clinical trial in relation to the patients

using the heat-treated concentrates if gone ahead?

A. No, no, but I was involved in the porcine.

Q. If we go to BART0000676, this now brings us to December 1984. It's a meeting of the Haemophilia Working Party of the North East Thames Region Association of Haematologists, and we can see that Dr Kernoff is there and you're there.

If we go to the bottom of the second page, we can see there's reference to "the possibility of BPL heat-treated concentrate ..."

And then there's an agreement in the meantime, if we look at (ii), that:

"Heat-treated material should be used whenever possible (with the exception of NHS [Factor] IX concentrate ...)"

It's said that:

"All new patients, and mild haemophiliacs with injuries requiring maintenance of high levels of [Factor] VIII should be treated with heat-treated NHS Factor ... concentrate or small pool Factor ... concentrate *pro tem* if treatment with cryoprecipitate or DDAVP is not possible."

Then if we go to the top of the next page and look at the second paragraph:

"Elective surgery should be delayed until the

position is clearer and the efficacy of heat treatment proven."

Now as far as one can tell from the documents and Professor Lee's evidence, December 1984 was the first time that the Royal Free effectively responded by changing its approach to treatment, and it did so then in two ways: the introduction of heat-treated concentrates and, at that point, December 1984, a decision to delay elective surgery. Is that correct, as far as you're aware?

A. Yes, yes.

Q. And then, if we go to CGRA0000560, please, Henry.

I just wanted to ask if you're able to assist with what this letter was concerned with. This is a letter, March 1985, addressed to you. Not entirely sure -- so, yes, it's in relation to Koate, and you're being offered unheated Koate to cover the requirements of the Fatimid Foundation. Is this anything to do with treatment at the Royal Free or is this to do with something else entirely?

A. It's not to do with treatment at the Royal Free. It's to do with treatment at a Haemophilia Centre in Karachi.

Q. Okay. Then Professor Lee's further evidence to the Lindsay Tribunal and to this Inquiry was that, having

got to this stage in December 1984, there was then a phased introduction of heat-treated concentrates over a three to six-month period.

And we can see a letter at BART0000819_ 002, please, Henry.

This a letter, 17th January 1985, so a month after the meeting we just looked at, from Dr Kernoff addressed to patients receiving treatment on Factor VIII and IX concentrates at the Haemophilia Centre.

The heading is "Heat-Treated Concentrates", and it's telling patients that:

"To reduce the risks of virus transmission, we have decided that all Factor VIII concentrates used at the [Royal Free] will be heat-treated products."

No change proposed currently in relation to Factor IX.

Then in the second paragraph it says:

"For many complex reasons, including the fact that there is at present no heat-treated NHS Factor VIII available, it will not be possible to change everybody ... to heat-treated products immediately, and not everybody will receive the same type of material. In general, patients routinely treated with commercial Factor VIII will be changed to commercial heat-treated

materials. Patients treated with NHS Factor VIII will either be changed to heat-treated ... products or kept on standard NHS Factor VIII for a few months longer, in the hope that small quantities of heat-treated NHS Factor VIII may soon become available.

"In the longer term, we hope that larger amounts of heat-treated NHS Factor VIII will be supplied."

So it would appear to be, in part at least, a supply issue, in terms of not enough heat-treated concentrates available to switch everyone immediately. Do you recall whether there was any discussion in the centre between you and Dr Kernoff or others about what to do in response to this particular problem, now that the dangers of unheated concentrates are explicitly recognised? Was there a discussion that took place at all?

A. No, I don't recall that at all. Reading this -- I mean, it's obvious that he was very much engaged with this issue, trying to source heat-treated, safer concentrates, though whether they would be safer from the point of view of HIV transmission was not going to be fully apparent for some time. But we didn't talk about it. And he -- I was very much engaged at that point with this race to pure Factor VIII and its immediate sequelae, and we didn't talk about these

other issues. He kept these to himself.

Q. If we just look a couple of paragraphs down, it says first of all:

"The overall objective of our policy is to give the safest possible treatment to an individual."

Then it says this:

"Home treatment patients should continue to use their current stocks until they are almost finished, as at present, then call in personally ... to collect new supplies."

Now, the effect of that, presumably, is that patients who have unheated products capable -- it's believed, and understood at this time to be capable of transmitting HIV/AIDS, are going to just use up their supply rather than any step being taken to ask them to immediately change. Does that cause you concern, seeing that there?

A. Yes, it is obviously illogical. If there's a risk, it should be met by immediately stopping using the at-risk product. However, at that point you've then go to replace it with something else, because the risk of bleeding continues.

Q. And given that at this point in time, whatever the arguments might have been earlier, you're talking about treatment for a relatively short period of time,

a matter of months, it's going to be, or, in terms of supplies, weeks.

A. Mmm.

Q. Wouldn't cryoprecipitate, for example, have been, at least as a temporary measure, an obvious alternative?

A. It would have been, and I know that some directors took that decision, and some patients.

Q. If we just look, please, at your statement, paragraph 205 I think. I'll just put it on screen so others can follow.

It's WITN3435002, please, Henry.

And if we can go to page 16, please. At the top of the page, paragraph 25, you say this:

"I am not aware of any formal decision-making structure in place at KDHC during the period 1978 to 1986. If there was one it was in the knowledge and judgement of my colleagues, especially Peter Kernoff. He was certainly as well informed as anyone about these risks through his work on [non-A, non-B]."

Is it fair to understand from that that these were essentially judgments, decisions that were being left to the decision-making process of Dr Kernoff on his own, essentially?

A. Yes, that's my inference from all that happened, and the documents you've brought to my attention.

Q. You go on to say this:

"That may have had an inherent misleading bias when applied to Hepatitis C as contrasted to HIV ..."

And I just wanted to ask you what you meant by that.

A. Well, he would have formed a view about risk based on his experience with hepatitis C. And as he demonstrated, and as we saw earlier, all concentrates containing plasma sourced from more than 100 individuals -- well, certainly more than couple of hundred individuals, a biostatistical necessity -- will be transmitting hepatitis C. How much safer it was in relation to HIV would only emerge when the understanding of that virus and means to test it were available.

So I'm speculating, of course, about his thinking process, and it probably seemed to him likely at that time that the relative greater safety of NHS concentrate might not be that much better than the concentrates from elsewhere.

Q. And then in paragraph 27, just so that what you say there can be understood, the question that you were there answering, if I can find the question ...

Well, I can find it -- but I can paraphrase it. The question you were being asked, and you answer

there, is about whether there were any decisions or actions taken by the Centre to minimise or reduce the risk of infection. And your answer is:

"Other than only giving treatment when it was necessary to stop bleeding, none that I can recall."

And then you say this:

"The principle was, 'if in doubt as to whether signs and symptoms were due to bleeding or not, treat anyway'."

Can you just explain what you mean by that principle.

A. It's a general principle in haemophilia care that if you have reason to suspect there may be bleeding, give the treatment that will stop the bleeding and then you've taken care of that as a possible explanation for whatever symptoms you're observing. So it was: if in doubt, treat. But it's a safety principle in caring for people who were always at risk of life or limb-threatening bleeding. But of course that comes into this difficult area of doubt, whether treatment you're giving has its own inherent risks, which the whole subject of this Inquiry.

Q. Professor Tuddenham, I want to come on and ask you about UKHCDO and its role in response in particular to the AIDS crisis. And although, as you've explained,

your interest by this time was essentially research-based, rather than much by way of clinical decision-making, you're one of the few Reference Centre Directors who will be giving evidence, and so these are issues which it's important to just ask you about.

Before we look at any individual document, what, if anything, can you tell us about the way in which the UKHCDO operated, and its hierarchy, and the role of the Reference Centre Directors in that period '78 to '85?

A. We were a group of colleagues who were gathered together under the common objective of organising and improving the management of haemophilia, which was and is still very advanced in comparison to what was available in most other even developed countries. There's other sort of shining examples like some of the Scandinavian countries, but we prided ourselves on being the group that was best able to monitor, manage and progress how we managed this group of severe congenital disorders.

So we were gathered together to optimise the monitoring of standard of care, gathering data, making representation to the Department of Health for ways to improve. And as problems arose, as they indeed did in

the way we're here to discuss, they were dealt with. It wasn't very highly hierarchical. We were a group of colleagues who respected each other. People would volunteer to take on the roles within the organisation as they do today, and it wasn't often that there was a contentious issue that would give rise to a vote. I mean, agreements were reached over a course of discussion, and people used best efforts to come up with policies over the sort of new problems as and when they arose.

So it wasn't a sort of fierce debating society; it was a collegial effort to gather our thoughts and propose solutions as best we could in, as it was then, a rapidly evolving and difficult -- very difficult situation.

Q. And the Reference Centre Directors certainly seemed to meet annually. Was that the normal pattern, or was it more frequent than that? There were certainly special meetings we see.

A. I don't remember. I think you're right: it was this -- we were meeting quite more frequently as the need arose.

The meetings tended to take place quite often at the Royal Free, which was convenient for me, and sometimes in Oxford. The agenda was devised by

whoever the lead clinician of the day was. And people spoke as they felt moved, according to their experience.

We have a system of having committees that would address particular topics, as I think I've answered questions later on, and they would report back after taking further advice from experts, and the reports were considered. The idea was that if there was a particular project, it would be dealt with in a time-limited way. And I would say that, given a kind of national emergency, really, which this situation gave rise to, we did the best we could, but the steps that were going to change the situation, which was developing the assays that enable you to identify exactly where the infection is and who's got it and what to do about it, and the improvement in the virus inactivation and better quality product, were not in our hands.

What we had an opportunity to do was choose between different products and policies, but we were left in this between a rock and a hard place, between the fact you have to treat immediate emergency of a bleed, but is the product you've got a safe, effective means of doing that?

So I'd say the overall influence that the UKHCDO

could have on this as being, to some extent just a gathering of colleagues and a talking shop, is not -- unless a very, very firm line were taken to pursue a particular policy, we didn't tend to impose views that necessarily would be just kind of opinions, really, educated opinions, on the rest of our colleagues because we didn't have the executive power to do that.

We could make representation to Government. We could make recommendations to our colleagues. But we weren't in a position of being able to issue orders and dictats.

Q. Would the task of the Reference Centre Directors, in responding to this national emergency, have been assisted by guidance or advice or intervention at a national level by the Chief Medical Officer, for example, or the Department of Health?

A. I can only say that, to my recall, they weren't.

Well, committees began to be got together of virus experts, but the UK didn't have a sort of -- well, we had the fractionators at Oxford, but they weren't major players, and they weren't running large research groups, and they weren't, to my knowledge, collaborating closely with virologists and biochemists. I mean, it was all a bit semi-amateur,

slightly ad hoc. That's a harsh statement.

I mean, looking back, what were they doing? They were doing their best to produce good quality products for us to use. They were clearly underfunded in the ambition to be self-sufficient. Could have used a lot more funding and a lot more push to do that. Although it had been declared an ambition, it didn't come to pass ever. So we were left trying to do the best with the limited resources that we had, as you can see, and it was somewhat frustrating, as Peter Kernoff's letters illustrate.

And we were left trying to make the best of what was certainly, in retrospect and even apparently at the time, a pretty difficult and unsatisfactory situation, in regard to supply, resources, and assays. We -- all those things eventually emerged, but one could only wish that they would have emerged sooner with the benefit of the hindsight we now have. At the time, we were doing the best we could, I think, is all I could really say about that.

Q. Okay. We'll look at some documents with you but, it's just gone one o'clock, sir, so perhaps I can pick that up too?

SIR BRIAN LANGSTAFF: Yes. We'll take a break now until two o'clock, if you please, and then we come back.

(1.02 pm)

(Luncheon Adjournment)

(1.58 pm)

MS RICHARDS: Professor Tuddenham, I'm going to ask you to look with me at some documents which show the response of UKHCDO to the AIDS crisis in 1983 and 1984. We won't look at absolutely everything, but just to put it in its chronological context, the first reference to AIDS in a Reference Centre Directors meeting was September 1982, and the request was made at that point to Dr Craske to look into the matter and report back to the AGM that was taking place a week later.

So I'm not going to show you those but I'm going to pick matters up in 1983.

Could we have HCDO0000411, please, Henry. If we go to the next page we can see it's the minutes of the Reference Centre Directors meeting held at the Royal Free on 4th February 1983, and we can see you and Dr Kernoff are both in attendance.

Henry, if we could go to page 4, please -- sorry, the next page, my apologies.

You'll see there, Professor Tuddenham, under the paragraph headed "The AIDS Syndrome", Professor Bloom referred to the Stockholm meeting, there's an update that the -- reports from the US suggest that the

incidence of AIDS was higher than first thought. There's an expression of concern that the haemophiliac population of the UK who'd received American concentrates might be at risk. Dr Craske then summarised latest information: approximately ten cases thought to have occurred in non-haemophiliacs now in the UK.

Then there's a reference --

SIR BRIAN LANGSTAFF: I think it may be 12, might it? Ten in London.

MS RICHARDS: Oh, yes, I'm sorry, sir, you're absolutely right. Yes. Ten cases thought to have occurred in London, one in Glasgow, one -- it may be -- maybe that's right.

Then -- in any event, those are non-haemophiliac cases.

Then we see Dr Craske had drawn up a draft form, there's a lengthy discussion about it, and the agreement is that Dr Craske will draw up a new form for the reporting of cases and arrange for it to be circulated to Haemophilia Centre Directors.

Then there's a suggestion of inviting an immunologist to join the Hepatitis Working Party.

First of all, do you have any recollection of that particular meeting and the discussions about AIDS in

February 1983?
A. Yes, yes, of course. We were on full alert. Anxious, worried and, like everyone else, still highly puzzled as to what could be causing this syndrome, presumed by now to be transmissible by direct contact means and therefore likely to be a virus, and looking for advice on how to move forward, given that it was clear by then that the haemophilia population was at risk.
Q. And the action that was agreed at this stage didn't involve any recommendations about any change of approach to treatment; it's a plan to prepare a form so that cases could be reported to the Reference Centre Directors?
A. Yes, just observation.
Q. And then we can see what Dr Craske drew up and what was sent out if we look at RFLT0000021, this is the copy that came to Dr Kernoff but we have -- there were copies that went to, we assume, all the Haemophilia Centre Directors.
So it's dated 22nd March 1983, and you'll see it refers in the second line to:
"... a recent meeting of the Reference Centre Directors ... prompted us to circulate the enclosed paper so that a system for the reporting of possible cases of [AIDS] can be quickly set up ..."

Then, if we go to -- sorry, in fairness, if I go to the third paragraph, we can see that Dr Craske, Dr Rizza and Professor Bloom say:
"We do strongly urge you [ie, Directors] to collaborate in reporting cases of this syndrome ..."
There were two documents enclosed with this. We will just look briefly at one of them, Professor Tuddenham.
HCDO0000517_002, I think.
So this was one of the documents sent out to all Directors, and presumably you would have seen it?
A. Yes.
Q. It's authored by Dr Craske. This one is dated 1st March 1983. There are earlier iterations of it that were shared with Reference Centre Directors in the autumn of '82. But we can see, if we look towards the bottom of this page, here we see the first of two features noted. Here, in the last paragraph, the delay between the occurrence of initial symptoms and diagnosis and an observation that the signs and symptoms were mostly insidious and non-specific.
And then we go over the page, we can see underneath the list of symptoms, there's a paragraph that begins "The overall mortality was highest in those with patients with [PCP]", and you'll see there

the mortality rates, which are obviously very high.
If we go on to page 3, we can see then under the heading "Aetiology", towards the bottom of the page, Dr Craske advances three theories. The first is about the possibility of the effect of drugs. Would you agree with me he's then discounting that? He says:
"This is not a factor as the disease has been described in patients who do not use the drug."
Then he talks about the immunosuppressive effect of cytomegalovirus virus infection and says this seems unlikely.
Those two theories are put forward but effectively put to one side; would you accept that? For the transcript, Professor Tuddenham, if you wouldn't mind saying "yes" or "no" rather than nodding.
A. Yes.
Q. Thank you.
Then over on to the next page, he says here then, his third cause is the suggestion of an infectious agent with a similar epidemiology to that of hepatitis B, and then he goes on to say:
"If (3) is the most likely cause, then it is possible that such an agent might be present in the plasma pools used to prepare commercial Factor VIII and IX concentrate manufactured from donor plasma

collected in the USA."
He then goes on to discuss the three cases where the likeliest mode of transmission has been blood or platelet transfusion, and explains at least ten haemophiliacs -- this is in the States -- have been reported with clinical features of the syndrome. Five have died.
Then if we go to the next page, second paragraph, he says:
"It is thought likely that batches of Factor VIII concentrate which might contain the AIDS agent came into use since January 1st 1980 in the USA."
Now I've obviously not gone through the entirety of the paper with you, Professor Tuddenham, but would you agree that what emerges from that is, although there is still much that is not yet known, it's likely that the route of admission for haemophiliacs is blood products?
A. Yes.
Q. And this is a disease understood to have a high mortality rate?
A. Yes.
Q. So that's March 1983.
We then come on, in terms of the next step taken by UKHCDO, by the Reference Centre Directors, to a

meeting on 13th May of 1983. Now this is one of the few meetings you didn't attend but for the sake of completeness we'll look at it.

It's HCDO0000003_008, I think, Henry.

So we can see this is a meeting at St Thomas' 13th May 1983. You're not there for this meeting, Dr Kernoff is, and it's a special meeting that's been called.

If we go to the second page, we can see a discussion in the last paragraph as follows:

"With regard to general policy to be followed in the use of Factor VIII concentrates, it was noted that many directors have up until now reserved a supplies of [NHS] concentrates for children and mildly affected haemophiliacs and it was considered that it would be circumspect to continue with that policy. It was also agreed that there was, as yet, insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy. The situation shall be kept under constant review."

So this would appear to be the first discussion of whether anything should be done in terms of changing the approach to treatment, but would you agree there is no specific recommendation of any change of

approach, it's just circumspect to continue with an existing policy if that is your existing policy; is that a fair characterisation?

A. Yes.

Q. Then we'll see the document that was then sent out in light of that meeting.

HCDO0000270_004 please, Henry.

So this is the letter of 24th June 1983. This is a blank version but we understand, again, it was sent out to Haemophilia Centre Directors.

It refers to the special meeting that we've just looked at and says this:

"So far one possible case has been reported to our organisation. This patient ... conforms to the definition published by the CDC in Atlanta ... but cannot be considered as a definite case. We are not aware of any other definable patients amongst the UK haemophiliac population."

Pausing there for a moment, Professor Tuddenham, we understand that to be a reference to a case in Cardiff of a patient who was under Professor Bloom's care. Do you recall -- and I know in particular Professor Bloom had been -- you described him, I think, as something of a mentor to you -- did you ever discuss that case, that first AIDS case of

a haemophiliac with him at the time?

A. No, I wasn't in frequent contact with Arthur then, other than at the Reference Centre Directors meetings. The first confirmed case was in Bristol.

Q. That was the first death, we think.

A. The first death, yes. If Arthur had a case he suspected in Cardiff, I wasn't aware of it.

SIR BRIAN LANGSTAFF: Can I just clarify about the information that we have the Bristol case is that it hadn't been reported to the UKHCDO, and that was the subject of some concern later at a meeting in the autumn, because it had happened, it hadn't been reported so somehow the reporting systems missed it.

A. Yes, that's right, yes.

SIR BRIAN LANGSTAFF: That now rings a bell, I can see.

A. It does, yes, yes. It came out of the blue. It was a bit of a shock. I think the then director of the Bristol Centre wasn't kind of prominent at national meetings.

MS RICHARDS: Was that Dr Daly?

A. Yes.

Q. Yes. Then we can see the two recommendations here given on -- are:

"1. For mildly affected patients with haemophilia A or von Willebrand's ... and minor

lesions, treatment with DDAVP should be considered. Because of the increased risk of transmitting hepatitis by means of large pool concentrates in such patients, this is in any case the usual practice of many Directors."

Then:

"2. The treatment of children and mildly affected patients or patients unexposed to imported concentrates, many Directors already reserved supplies of NHS concentrates (cryoprecipitate or freeze-dried) and it will be circumspect to continue this policy."

So, again, what this would appear to be is a recommendation for directors to continue with existing policies if they have them in relation to children and mildly affected patients, or previously untreated patients, and a recommendation to consider the use of DDAVP from the categories of patients there identified.

It's quite tentative, isn't it? It falls short of any kind of firm steer or recommendation?

A. Yes, it's just a polite suggestion, with evidence and reasons given, but it's by no means an order and, as I mentioned earlier, we (the UKHCDO) weren't actually in a position to issue orders, just recommendations.

Q. Yes, no, I accept not in a position to issue orders.

There could be this kind of polite suggestion, as you characterise it, at one end of a spectrum, an instruction at the other, and in between there could be much firmer advice or recommendations than this; would you accept that?

A. I accept that. There can be firmer or there can be ... clinical advice is usually couched in very polite terms.

Q. Yes, and we'll see later, when we finally get to December 1984, that there were recommendations that were put in different terms.

So this was June 1983 arising out of the 13th May 1983 meeting. I just want to show you a document from around this time which is CBLA0000043_040.

I this is a letter dated 9th May 1983, and it's written by Dr Spence Galbraith, who was at the Communicable Disease Surveillance Centre in London. He's addressing it to the Department of Health.

You'll see in the first paragraph he talks about the case in Cardiff, he actually identifies it as being a Cardiff case, and explains that it fits the recognised criteria for the diagnosis of AIDS, and then refers to some other reports in The Lancet and other cases.

Then we can see his recommendation in the second paragraph is:

"I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be with withdrawn from use until the risk of AIDS transmission by these products has been clarified."

So Dr Spence Galbraith with, presumably, the same or similar information available to him as would have been available to the Reference Centre Directors, came up with a very different recommendation.

Do you recall whether this came to the attention of the Reference Centre Directors at this time?

A. I don't recall it. Until you brought it to my attention, I've never seen this letter or was aware of this view having been promoted. Did you say it was Kenneth Galbraith?

Q. Dr Spence Galbraith.

A. Spence Galbraith.

Q. Who was -- well, public health was his area of specialty. He was based at the Communicable Disease Surveillance Centre, so the cases were supposed to be reported to him.

A. In the UK?

Q. In the UK.

A. Wow. Well, it's -- then it's quite an authoritative opinion.

Q. I don't say this, certainly, as a criticism of you, Professor Tuddenham, or necessarily of any of the Reference Centre Directors, but this is the kind of opinion that should have been shared, should it not, with the Reference Centre Directors by somebody?

A. Somebody. He, himself, might have considered doing that, but I don't have any recall of it being proposed. It's a radical proposal, but it didn't make its way on to my desk.

Q. No. If we go to the next page, he sets out a number of reasons, and I just wanted to go through the reasons with you.

So the reasons for his recommendations: one, the AIDS epidemic in the USA is probably due to a transmissible agent. Would you agree with that?

A. Yes.

Q. Based upon the knowledge at the time.

A. Yes.

Q. Two, the agent is probably transmitted by blood and blood products. Would you agree?

A. Yes.

Q. Three, and this may be where his public health hat was significant, he said this:

"Although this number of cases of AIDS associated with the administration of Factor VIII concentrate is very small in relation to the number of individuals receiving the product, this may not indicate that the risk is small ..." and he goes on to explain why that is.

Would you accept that as a proposition that could and should have been understood at the time? That the number of currently reported cases was not necessarily the guide to what the true extent of the risk was.

A. I agree.

Q. And then if we go over the page, please --

A. It's a fundamental principle of epidemiology.

Q. If we go over the page, please, to point four:

"Factor VIII concentrate (and pooled products) would appear to have a high risk of being contaminated with AIDS agent."

And he explains that's because of the donor pool. Would you agree with that?

A. There's a slightly surprising suggestion there that homosexuals are more frequent blood donors than others.

Q. I think there may have been some evidence available -- that may have been available to Dr Spence Galbraith -- about certain practices and locations in which bloods

were collected for donations in the States, so maybe it's a reference to that.
A. Interesting.
Q. But in terms of the donor pool giving rise to a high risk of contamination, you would accept that as a statement, as at 1983?
A. Yes.
Q. And then:
"5. Apparently no known means of ensuring that blood or blood products are free of the AIDS agent."
That was correct at the time?
A. Of course, yes.
Q. And then point 6 is the high mortality rate which was also known at the time.
A. Yes.
Q. So we have the polite suggestion from the Reference Centre Directors, and then the rather bolder suggestion here. We then come on, in terms of the next Reference Centre Director consideration, to 19 September of this year --
A. Excuse me. Could I just ask a question again about --
Q. Of course.
A. -- Dr Galbraith's letter? Was this published anywhere, or was this is an internal communication?
Q. The letter was addressed to an official within the

Department of Health.
A. Right.
Q. So it was not, at least at that stage, published. Whether it was ever published, I'm afraid I don't know the answer.
A. All right. With hindsight, again, appreciate your comment in the context, but if it had had wider exposure, I'm sure it would have had some effect.
Q. And then if we go to HCDO0000413, please, Henry.
So we can see this is the next meeting of Reference Centre Directors. It's now 19 September 1983, and you and Dr Kernoff are both in attendance at this meeting. If we go to page 3, we can see "current situation regarding AIDS":
"Dr Craske presented a paper ... updating the current situation."
You'll see there reference to the patient who died in Bristol about six lines down, Professor Tuddenham. So I think there was evidence to suggest that death occurred in August 1983.
And then if we look at what was then discussed, we can see a little further down -- if we go to "It was agreed". Dr Craske, having given that update, the first thing that was agreed was a point about discouraging manufacturers of concentrates to sell

material to non-haemophilia centres.
So that may or may not have been an issue of some importance, but would you agree that's not really dealing with the public health issue and the risk of AIDS to haemophiliacs?
A. No, it isn't. There was some debate still at that time as between treatment or management of haemophiliacs at hospitals by individual doctors that weren't part of a registered Haemophilia Centre or Reference Centre, and that did continue for some time. And I think partly it's referring to that possibility, this kind of unacknowledged, recorded, or regulated use of those products.
Q. Yes. And then we can see there's then a discussion about blood products being supplied via regional transfusion centres (and that's the issue that we saw Dr Kernoff's strong views on this morning) and we can see, four lines up from the bottom, the Reference Centre Directors expressing grave misgivings about that.
Again, that's not really dealing with response to AIDS, is it?
A. No.
Q. Then if we go to the next page, we can see here -- and it touches on some observations you've just made,

Professor Tuddenham, about the Galbraith letter:
"The position regarding the collaboration of the Haemophilia Centre Directors, Dr Craske, and the Communicable Disease Surveillance Centre was raised. Professor Bloom said Dr Galbraith, director of the CDSC, was somewhat concerned he hadn't heard about the Bristol case until after the patient's death."
You'll see that there were some interactions between Dr Galbraith and Dr Craske, and possibly Professor Bloom. We don't know the full extent of them.
Then the issue that's there discussed. You'll see from that paragraph there's an issue about reporting of cases and whether it should go via Dr Craske or directly to CDSC. And if we look down the page, we'll see the agreement, the underlined bit:
"After discussion, it was agreed by a majority that reporting to CDSC should be through Dr Craske."
And then the discussion moves on to the collection of epidemiological data.
So would you accept that there are no substantive recommendations here about changes in policy or different ways of treating patients?
A. Yes, that's -- that is the case.
Q. Then the next meeting is 17 October 1983. This is not

of Reference Centre Directors alone; this is all Directors. It's PRSE0004440, please, Henry.

We can see it's 17 October 1983. It's a long list of attendees, and they include you, Professor Tuddenham. And if we go, please, Henry, to page 10, we can see an issue being raised under the heading "Any other business":

"Dr Chisholm [who was director in Southampton] raised the problem of patients refusing to take up commercial Factor VIII. She wondered, in view of the worry of patients whether Directors could revert to using cryoprecipitate for home therapy. Professor Bloom replied that he felt there was no need for patients to stop using the commercial concentrates because at present there was no proof that commercial concentrates were the cause of AIDS. Dr Chisholm pointed out there was a further problem in her region because of problems in getting large amounts of commercial concentrates, whereas she could get unlimited supplies of cryoprecipitate. Other Directors reported they had the same problems. After discussion, it was agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way."

Do you have any recollection of that meeting or that debate, Professor Tuddenham?

A. I don't remember Dr Chisholm raising this point. It's kind of poignant, looking back on it. There was all this cryoprecipitate, and why not use it for home treatment?

As we discussed earlier, there was a feeling that that was a step -- well, there was a reason to say that that was a step back, but then as the threat of AIDS from commercial concentrate rises and rises, alternative views are being expressed by the patients, as well as the centre directors.

Q. Can I invite you to consider in particular what's recorded here as Professor Bloom's statement. He says:

"There's no need for patients to stop using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS."

Does that surprise you as a statement, as at October 1983, that it's being looked at in that way?

A. Yes, it depends what your standard of proof is ... where, I would say, there's very strong circumstantial evidence that they are transmitting AIDS. Very strong indeed.

Q. Then we can see, in terms of any action to be taken, on the next page, we see "Current situation regarding AIDS". There's a presentation by Dr Craske. There's discussion about cases, and there's a suggestion that Dr Craske will send out details about proposals with regard to recommendations for the handling of samples.

So it's very clear that, in October 1983, directors are not being given any -- they've not themselves reached any shared view that there should not be any change at all in the course of treatment.

A. That's correct.

Q. We then move on almost a year before there's another meeting of Reference Centre Directors. So if we could have up on screen, please, Henry, HCDO0000416.

We can see it's now 10 September 1984. This is a meeting at St Thomas'. You and Dr Kernoff, amongst others, are present. And if we go to page 8, please, Henry, we can see under the heading "Current situation regarding AIDS", there's a presentation of more information by Dr Craske. He talks about -- he presents some graphs. He refers to a paper in The Lancet. He explains that a further 20 patients with AIDS-related symptoms have been notified to him. Then there's a discussion about testing and reference, towards the bottom of the page, to the possibility of

arrangements for HTLV-III testing now being made.

A. Yes.

Q. Again, I don't know whether you have any recollection of that meeting?

A. Yes, because by then we'd heard about HTLV-III, and it was apparent that the most likely causative agent had been identified, and we could test for it. So it was trying to consider moving forward.

Q. Other than testing, which obviously is a substantive step, there's still, however, no recommendation to directors to do anything different in terms of treatment, would you accept --

A. No, there wasn't.

Q. Then we come finally to the meeting at which that was discussed, which is 10th December of 1984.

The reference is HCDO0000394_117, please.

We can see this is effectively a special meeting, it's not the normal Reference Centre Directors meeting. You weren't, in fact, in attendance, this is 10 December 1984, but Dr Kernoff was, and a number of others as listed there.

And if we go, please, Henry, to --

Well, I'll just -- it results in recommendations and I'll show you the recommendations document rather than pore over the minutes, but there are just two

parts of the meeting where Dr Kernoff makes a comment that I wanted to ask you about.

Page 5, please.

You'll see, about four paragraphs down -- this in the context of a discussion about testing:

"Dr Kernoff commented that as some 70% of haemophiliacs are now [positive], it may be considered irrelevant if one tells or doesn't tell the results of testing."

That seems, at first blush, a somewhat surprising statement. Is that something you ever discussed with him?

A. When I read this, I was very surprised.

At the time I wasn't at the meeting, and so I wasn't aware of it, and I didn't discuss it with him. In the event, as you may be coming to, when we did test all the staff and patients of the Royal Free Haemophilia Centre, we conveyed the results pretty much straight away.

Q. Yes. Well, I will come on to that. We'll just look at the next paragraph which says:

"The Chairman summarised by saying that testing should be instituted as soon as possible, and that information on the test results, should not be given automatically but if asked for."

So it appears to be the view expressed there by Professor Bloom as chair also that, rather than a system of telling patients the results, it will be you'll tell them the results if they ask for them.

Would you agree that, amongst other things, a patient's got to know they'd been tested in order to be able to ask for the result, as a matter of logic?

A. Indeed. There's this range of opinion here, kind of extreme, everybody gets tested and told the result, over to what we would do now, which is proper counselling before you even take the sample, in most cases.

Q. Then if we go to the document that emerged from this meeting, which is HCDO0000270_007, please.

So this is the -- called "AIDS Advisory Document" drawn up after that meeting.

If we go to the second page, we can see towards the bottom of the page, under the heading "Options in probable decreasing order of safety from AIDS for Haemophilia A", there is a list in order of safety, and then a series of recommendations expressed in firmer terms than the earlier material we looked at, so for example:

"Use DDAVP in mild Haemophilia A and [von Willebrand's] if possible."

Then go over to the next page, we can see at the top, recommendations for haemophilia A, different categories, and recommendations for haemophilia B.

Then if we look at the text just under that, it says:

"In individual patients there may need to be a choice. In general heated concentrate appears to be the recommendation of virologists consulted but individual Directors may wish to make up their own minds. This is particularly true of unheated NHS material."

So even at this stage, when there are recommendations, Directors are still being told it's a matter ultimately for their individual judgment?

A. Yes.

Q. But did that surprise you at that stage, that it's put in those terms?

A. Not really. There's still some uncertainty as to efficacy of inactivation of the heat treatment. We can see here that it's considered that the heat treatment has inactivated the AIDS agent, HTLV-III as we were calling it then, and -- but not the NANB agent, which it took quite a while to finally isolate as hepatitis C.

So there's a range of risk, and the choice is left

to the individual director.

Q. This is, as I say, December 1984, so that's roughly two-and-a-half years after the first reports from the CDC in the States of cases in haemophiliacs. It's two years from the report of the San Francisco baby case, it's nearly two years from that Immuno London Airport meeting at which the available information was discussed.

Looking at that, do you think, Professor Tuddenham, that that was a good enough response by the Reference Centre Directors, that it took that long to produce any kind of recommendations to Directors?

A. It seems very gradual and cautious, viewed from here. How good was the evidence for each of the different choices? Um ...

It's accepted and was correct that UK-sourced material is lower risk; it's not no risk. And we have a treatment that may well be effective against HTLV-III, and a particular recommendation for patients not previously exposed, that they should have the lowest risk material.

Although at that point, it's -- well, cryo isn't zero risk, it's low risk. Heated NHS Factor VIII, low risk. There's a dosage phenomenon you have to look at

when you're doing an inactivation, how many logs of inactivation versus how many infectious particles are present, and those are variable.

So they're pretty -- I've got to agree that it's taken a while to get to this point and still the advice is pretty vague.

Q. I want to then move to deal shortly with some questions relating to what happened thereafter at the Royal Free. We've got some documentary evidence, we've heard from Professor Lee, so I think I can take it fairly quickly.

The evidence we had from Professor Lee suggested that patients were tested at the Royal Free using the stored samples that Dr Kernoff had started collecting in 1978 and so patients were tested for HTLV-III without knowing they were being tested. Was that something you knew at the time, or was discussed at the time?

A. It wasn't discussed at the time and -- do you know, I don't think I even queried it at the time. We just -- "Yes, we're going to test everyone", and it happened. I didn't take that decision and I wasn't asked about it before it happened. I was asked if I'd give a sample to be tested, and I did. As did all the nursing and other staff.

Q. In terms of patients then being told their test results, Professor Lee had moved on at that stage. Her understanding was that that was something done by Dr Goldman and Riva Miller. Do you know what the arrangements were for patients to be told that they had tested positive for HTLV-III?

A. Yes, I did know that Eleanor and Riva were going to do that in the context of their sort of family approach to counselling.

Q. Do you know whether patients were called in for special appointments for whether it was just something that was shared with them at the next scheduled appointment?

A. I don't actually know which it was. I would think they were pretty much called in, starting with the positives.

Q. And do you know whether any advance information was given to patients or whether they effectively just turned up, not knowing that they'd been tested, but told by Dr Goldman that they were HTLV-III positive?

A. I don't know that. But I should think there's a few people around who do remember it pretty well. Well, a lot of people.

Q. In terms of the staff who were present -- I meant to ask you this earlier, Professor Tuddenham -- the staff

who were working at the centre by then. We know that Dr Goldman was and obviously Riva Miller, the latter being deceased. Dr Kernoff.

What other doctors were working in day-to-day clinical work at the centre in 1984/85?

A. We'd have had rotating trainees, what we then called senior registrars and registrars who were trainee haematologists. Permanent staff, permanent medical staff, other than myself, Dr Kernoff, Dr Lee, Dr Goldman, no, I don't remember if there were any others.

Q. Okay.

Then, if we could have, please, BART0000675.

This is a meeting of the Haemophilia Working Party of the North East Thames Region Association of Haematologists, 22nd May 1985. You're not in attendance at this meeting, Dr Kernoff is. Can I ask you to look at the second page, please. It's the top of the page where it said this:

"Concern was expressed about the confidentiality of personal details of HTLV-III Ab positive patients. No lists are circulated ..."

Then it says this:

"All patients will be informed of the result of their HTLV-III antibody test on request and counselled

on the implications of a positive result to themselves and their families."

Now, that would suggest that as at May 1985 there are patients who have not been given their results, and that they're to request the result in order to get it. Do you know anything about that?

A. No, I -- that would be other centres than the Royal Free.

Q. Okay.

A. Since, as we've said, I think all the patients at the Royal Free were informed.

Q. Can I then ask you a little bit about what you say in your statement about research and some of the ethical principles regarding research.

Can we have Professor Tuddenham's statement back on the screen, please, Henry. It is WITN3435002. If we go to paragraph 93, page 48.

You say this in paragraph 93, at the top of the page:

"The first ethical principle of research involving humans is the one we inherit from Hippocrates 'First do no harm'. The second principle is that consent to take part in research must be a voluntary choice of the participant after a full explanation of the risks. These and other principles are well described in the

Helsinki declaration of 1964."

Then you say this:

"It took several decades for a full implementation of these principles to be instituted through a formal network of ethics committees and establishment of local research departments tasked with monitoring the clinical research undertaken in host institutions."

And you observe that at the beginning of your career in medical research, no formal procedures had been established to demonstrate informed consent or ethical approval.

Why did it take several decades for those principles that you rightly identify stemming -- or being set out in 1964, to filter through and be implemented in the United Kingdom?

A. Yes, I've looked at the history of this, including the documents you've kindly sent me. As a medical student I was very impressed by a book produced by Dr Pappworth, titled "Human Guinea Pigs", which was blowing the whistle on the kind of research and the low standards of ethics going on at the Hammersmith Hospital and at the Royal Free Hospital. Those were the examples he gave.

It certainly got my attention. There was, up to that point, a kind of old boys' and old girls' network

idea that doctors were all, rather paternalistically, able to decide what was best for their patients, and that they wouldn't -- they would follow the Hippocratic Oath, and they wouldn't carry out research on patients that didn't meet the standards implied in that, and in the general contract between doctors and their patients that the doctors know what best and the patients trust their doctors.

And to a very considerable extent, that did work, but it didn't really begin to take hold, and to be formally instituted by the setting up of research ethics committees in local hospitals until the National Institute of Health in the US said that they weren't going to fund research, clinical research, that didn't meet fully ethical standards as monitored by local committees. And then in the UK, a note was taken of that, and the Royal College of Physicians and the Department of Health began to work towards the establishment of those local research ethics committees. But it wasn't sort of fully and widely adopted and constituted in that form until the sort of 1970s.

So yes, there was a delay, and these things do take a while to evolve, and now of course we have a very elaborate and well-managed and fully applied

standards for clinical research. But it was just kind of developed in a rather ad hoc kind of way, as I've mentioned.

So expressing principles in an international declaration doesn't immediately translate into activity on the ground, and one could wish that it had taken place more quickly, but -- so there was a kind of a period when it was not even clear that it was necessary to undergo ethical approval for a trial of a new drug. Which seems surprising now, but that was the thinking at the time: that if the patient -- if a doctor had spoken to the patient and the patient had just agreed to undergo the trial, there was no need for anything to be formally recorded.

Q. You've given in your statement a long list of the research projects you were involved with. I'm not going to ask you about the specifics of any of them, but you talk in some of them, particularly the earlier ones, about proceeding upon the basis of a concept of informed consent -- sorry, implied consent.

A. Yes.

Q. And what was the way in which that was approached by yourself and others at the time?

A. Okay, so there was only two clinical trial projects involving administration of new drug, blood product

agents. One was the trial of the Hyate:C porcine Factor VIII polyelectrolyte purified. The report on that doesn't even contain any reference to ethical approval. We did discuss with the patients what the new product was. It had undergone testing for efficacy and safety in pre-clinical studies in animals, and we just discussed it with the patients, told them why we wanted to give it to them, and if they agreed, we went ahead. That was the standard at the time.

The other one was where I treated four patients, three with severe haemophilia A and one with severe von Willebrand disease, with the human Factor VIII prepared with polyelectrolyte that Dr Lane had made at Elstree and, again, we just explained to the patients why we wanted to do it and they had the infusion.

It was made -- it was high purity, very high purity, it was made from UK voluntary donor plasma, so I would say it was low risk. They were all patients who'd had multiple infusions of multiple donor concentrates, and again, we just explained why we wanted to do it, and discussed it, and they had the infusions and we reported it. And it was the first formal proof that von Willebrand factor supports Factor VIII in the circulation, but it was the only

time that that type of concentrate was used, and it didn't become part of the way that Factor VIII was purified at Elstree. But, as I say, those are the only two clinical research trials involving factor concentrate I was involved with at the Royal Free during my first period there.

Q. The practice of building up a bank of stored samples that we know took place at the Royal Free, was that Dr Kernoff's idea?

A. Yes, it was his idea and it was innovative, forward-looking, and proved to be a resource for very important research studies.

Q. Do you know what, if anything, was said to patients about that, or about the purposes for which any samples would be stored and used?

A. No. I mean, Peter told me straight off from the start why he was doing it.

Q. Which was?

A. That it was to track the potential effects of transmissible agents given to our patients. Because he also stored a sample bottle from every batch of concentrate that we used.

Q. Do you ever use those stored samples for any of your research?

A. On a couple of occasions we were contacted by patients

or their relatives -- and I'm talking about the later period of my time at the Royal Free, from 2006 onwards -- wanted to know if we could get the sample back out and check when they seroconverted for hepatitis C and/or HIV. And we'd get requests from time to time, they were useful in -- usually in cases of litigation.

So those were the only occasions on which I did use those samples. I don't know if you're coming to it, but there was a question of using them in relation to the most recent threat that's been identified in the blood supply, which is from Prion disease, variant CJD.

Q. I was going to ask you about that this afternoon, absolutely we can come to it now. Professor Lee referred to it yesterday and we looked at a newspaper report. You've dealt with the position in your statement in more detail so could you perhaps explain to us your involvement in that issue.

A. Yes, when it became apparent that at least one patient with haemophilia had been found post-mortem -- he'd died of other complications of haemophilia -- that the prion agent was detectable in tissue -- certainly we'd realised there was a theoretical, more than theoretical, risk of blood transmission of the protein

agent that causes CJD and which caused spongiform encephalopathy in the UK cattle herd, to which the whole population was then subjected, and with some, fortunately, low level of transmission. When we, as I say, became aware that blood products could transmit prion agent, we -- the haemophilia community took this very seriously and we started looking over all of our patients who'd received a blood product from an individual who later developed new variant CJD.

And it turned out that the most -- the largest group of our patients who had received such a product were in fact patients with Factor XI deficiency, of which we had the largest number of patients in the UK, because of the prevalence in the Ashkenazi Jewish population and our location in North London. And so we then had to advise those patients that they were considered at risk for new variant CJD.

By the way, the entire population of the UK is so considered at risk, and our blood is not -- our plasma is not used for plasma product preparation if we were eating beef in the relevant period. But we -- so there was great interest in the -- and concern about the extent to which haemophilia, our patients, may have been exposed to these prion agents from UK blood products, UK-sourced blood products. It's not

considered that blood products made in other countries were also so at risk. So the stored plasma bank was of interest, and I was thinking of things to do with it, just in general terms, being a research-oriented clinician, and I got talking to the people at the prion disease unit here in London, and asked them if they thought this bank could be of use in their researches.

Now at that point there was no established test on plasma to find prion. The only test we had then was to look in tissue, and stain for the material that accumulates, the prion protein. And -- but there was a hope that such a test could be developed to look in blood and the conversation had got just about that far when one of the researchers from the prion disease unit was at an international meeting and mentioned that there was a source of stored samples which would be of interest to look at and so, very prematurely from my point of view, this became public.

I hadn't got to the point of any arrangements, much less talking to our patients, which of course would be essential to do, before starting under -- you know, now -- by now we're talking 2010, I think -- we certainly would not proceed to do any tests on that material without consulting with the people from whom

it was taken.

So I acknowledged that there was an unfortunate leakage of early stage discussions at that point, and apologise for any concern or worry that may have caused.

Q. And just whilst we're on the subject of vCJD, I wanted to ask you to look at a letter you wrote. It's HCDO0000835_001. It's a letter from you and from the clinical haemophilia nurse specialist at the Royal Free in December of 2006, addressed to Dr Hill and to Dr Hay, in their capacity at UKHCDO. "Variant CJD and cost of endoscopes". Won't go through the entirety of it, but we can see from the first sentence, you say:

"This is an ongoing problem for us ... we have several patients whose treatment has been considerably influenced by the fact that they are on the at 'risk' register because they had concentrate during the relevant period."

Then you go on to give details of the first patient and, picking it up about five lines from the bottom of that paragraph:

"Our gastroenterologists were very reluctant to proceed with an endoscopic approach and although they claimed this was not because of the inevitable fact

that the instrument would be quarantined, we don't doubt that it entered the decision. He is under consideration for a double balloon push endoscopy at St. Mark's, but the instrument costs £25,000, and one would have to be bought for him."

So that was a case of an individual whose treatment was effectively being deferred, or there was a risk it might not take place at all, because of the cost of having to buy the endoscopy specifically for his surgery.

A. Yes.

Q. And then the second patient you gave an example of, and this was a Factor XI case:

"... not received one of the batches that contained a contribution from a vCJD patient, but is nevertheless on the at 'risk' register."

And you're saying you may have to purchase a colonoscope for that purpose. You've assured the patient that the Department of Health have stated no patient's health will suffer.

But there was going to be delay, rather than something that could have been done in one procedure. And if we go over the page, in the second paragraph you say:

"These are only two out of a large number of

patients potentially affected by the decision" --

SIR BRIAN LANGSTAFF: Are the -- what's on the screen isn't the second page at the moment. There it is. Thank you.

MS RICHARDS: Yes.

"These are only two out of a large number of patients potentially affected by the decision of the Health Protection Agency and this is a problem that is going to increase steadily, as the large number of patients affected age and increasingly require various kinds of instrumental intervention for diagnostic or therapeutic purposes."

So you were raising this concern, and indeed it's been raised by a number of individuals in their evidence to the Inquiry. How, if at all, has it -- or was it resolved during the time that you were at the Royal Free from 2006 to 2011?

A. Not definitively. We did our best for each patient in each circumstance; found a way around if we couldn't find anyone to use an endoscope. Eventually, endoscopes were purchased, and there's a large store of such endoscopes, each one assigned to one patient, that we have at the Royal Free for our patients. I think time only will eventually resolve this. Happily, the transmissibility appears to be pretty low

with blood product with prion agent, spongiform encephalopathy.

We haven't had any more cases, that I'm aware of, but it's an example of how you never know what's going to turn up next in blood, as new agents appear.

MS RICHARDS: I was going to turn to another topic. Would you like to take the break now?

SIR BRIAN LANGSTAFF: Yes, that might be a good idea. How long do you think you need?

MS RICHARDS: I've got a few more questions for Professor Tuddenham of my own; not a huge number, but there needs to be sufficient time for recognised legal representatives to suggest any further questions to me that they want.

SIR BRIAN LANGSTAFF: How long is that?

MS RICHARDS: I'm going to suggest 40 minutes, perhaps.

SIR BRIAN LANGSTAFF: That founds fine. So quarter to four.

(3.04 pm)

(A short break)

(3.45 pm)

MS RICHARDS: Professor Tuddenham, I just wanted to pick up on the theme of paternalism. You mentioned that earlier in context of the doctor's attitude towards consent in the context of research. I just wanted to

ask you to think about that principle or that concept when one is talking about treatment decisions.

Would you accept, as a matter of principle, that patients should have been told about the risks of non-A, non-B hepatitis?

A. Yes.

Q. And would you accept again, as a matter of principle, that they should have been told about the risks of AIDS?

A. Yes.

Q. Would you agree that one of the reasons at least why that's important is because if you've got a balance of risks, ultimately the judgment as to whether you run one risk or the other, and expose yourself to that, it's got to be for the patient?

A. In most circumstances, yes.

Q. Yes. So there may be firm advice and a firm view a doctor holds that they can impart to the patient?

A. Indeed, they can refuse. If they're Jehovah's Witnesses, they will have refused completely to have any blood product at all in that era.

Q. Do you know, as a matter of fact, what information was given by Dr Kernoff or your colleagues to patients in the 1978 to '85 period about the risks of non-A, non-B hepatitis or AIDS?

A. No. Conversations with patients that I can recall, on the occasions when that arose, they were clearly aware that -- to anyone who was reading the newspapers, it was, you know, these things circulated, and the patient community were -- it's not like today with the era, of course, of social media, but back then, people were in touch with each other and the news circulated. But I'm not -- I wouldn't know what was said during annual review consultations.

Q. Can I then just come to the question of pharmaceutical companies and their role, briefly.

You have described for us in your statement your relationship with Speywood and then later on other pharmaceutical companies. Can I ask you to look at a paragraph in your witness statement, paragraph 46 -- again, could we have it on screen, Henry, it's WITN3435002. If we go to page 20, please.

It's towards -- in paragraph 46, about last three lines of the page after you refer to there being a full sense of the risk benefit ratio, you say this:

"Once the demand for factor concentrate accelerated with more home treatment and some prophylaxis the commercial incentive to make more and sell more seems to have overwhelmed the safety issues."

Are you able to expand upon that observation?

A. I did slightly couch that in probable terms by putting "seems" in the middle of the sentence. There was clearly money to be made by producing factor concentrate, as more was being used to improve management of bleeding. Even by today's standards, it's still not very high, now that we have prophylaxis aiming at trough levels which eliminate bleeding. But there was a steady rise in consumption per capita, per patient.

And it's a valuable drug that sells at a high price. Currently there's a $10 billion industry making Factor VIII. And back then it was smaller, but there was a demand, and a commercial incentive.

Did it overwhelm the safety issues? Well, when one looks at the sort of headlong rush to make more Factor VIII, getting the plasma from wherever or whoever, in those days of the late 70s, early 80s, I think it's fair to say that a commercial incentive did overwhelm the safety issues, yes.

Q. And I just want to refer you to the transcript of an interview you gave in 2016.

It's JEVA0000011, I think.

So this is an interview you gave on 29th September 2016. You watched a film,

Bad Blood: A Cautionary Tale, and you were giving reflections on that. And then I wanted to ask you to look at some of the observations or comments you made about the pharmaceutical industry.

So -- if we go to the second page, please, Henry -- you say this, picking it up at line 13, you refer to the film and say:

"I think it's a film that should be required viewing for drug company executives in the field of blood products ... it's a very important message to bear that, as doctors, whilst trying to do our best for patients with our new technologies, there are increased risks and it should not be forgotten; and this thing will happen again, but we need to be alert to the possibility that we're making a mistake and be ever-vigilant and take the most measures that we possibly can to be aware of new threats and to keep safety at the forefront."

Then you go on to say at line 24:

"I think the commercial interests clearly outweighed best practice in safety."

Which I think is essentially the point you've just made.

Then if we go to the next page, please -- if we go to line 15, please, Henry -- you say this:

"It is very difficult to be a paid consultant to a particular drug company and still keep completely independent in your thought. I know that because I have done consulting and in many -- in the industry and the standards now are certainly better for declaring interest than they used to be. You have to be completely transparent with the total amount of money that you receive and the fact that you're on consultation boards ... it would be unusual for a very prominent researcher/medical doctor in the field not to be engaged with the companies who are making the treatment that we use, even only in an advisory capacity."

Then you say this:

"So, yes, there can be conscious and unconscious bias."

Just pausing there before we come on to the next part, conscious bias is pretty self-evident. What were you meaning when you talked about there might be unconscious bias on the part of a clinician?

A. I think that the evidence for that comes out of the amount of money that was being spent by the companies and on lavish entertainment.

Q. And you go on to talk about that as being at the bottom of the page:

"... it was overwhelmingly lavish at -- at various stages that I can recall."

And then you say that you weren't so exposed to it because you took a very academic route:

"... but I can see how it could influence people ..."

Then you say this:

"... why were they spending that money?"

You mean there the pharmaceutical companies, I take it, Professor Tuddenham? The answer:

"Because they could gain influence with it."

And that's the purpose, presumably, of the interactions, the visits from the sales reps, whether it's the mugs, the funding of booklets or whatever, pharmaceutical companies want doctors or hospitals to buy their product.

A. Yes.

Q. And then you talk about some examples of lavish hospitality:

"... you would be going to the best -- to a conference on haemophilia, there would be the very best restaurants, the river cruises, the -- all the paraphernalia of marketing products. It didn't go quite to the heights that it got in some areas with a bigger turnover like the, let's say, cardiology and

gastrointestinal diseases where people would go on cruises for so-called -- for educational purposes, and make hundreds of thousands of pounds out of it, but it was -- it was remarkably lavish."

That's from your direct knowledge from the way in which pharmaceutical companies acted, is it?

A. Yes.

Q. Then there's a number of specific questions raised by core participants, Professor Tuddenham, on a sort of range of miscellaneous but important issues.

You told us about the stored samples of sera and the fact that Dr Kernoff also stored samples of concentrate. Two questions -- sorry, three questions arising out of that.

Have those concentrates, to your knowledge, ever been tested?

A. I don't know. And there was boxes and boxes of bottles of concentrate that came from each batch sitting in a cold room at the Royal Free when I got back there in 2006, as were all the plasma and serum samples sitting in minus 80 refrigerators which kept breaking down. They were the old ones.

And at a certain point, when we'd had yet another meltdown of the minus 80 fridges over a long weekend and they were beginning to smell bad, we destroyed all

the plasma and sera samples because they weren't any use anymore and they'd become a biohazard.

And I think the concentrate bottles went out at the same time, and I'm not aware that they had been tested. They may have been, I just don't know.

Q. Did Dr Kernoff store, as well as the samples of concentrate, any samples of cryoprecipitate that had been used?

A. No.

Q. And do you know whether those -- the samples of plasma, whether they were ever accessed by others, so not doctors within the Royal Free, but third parties, other organisations, other clinicians?

A. If so, it would only have been done with consent of an individual. As I mentioned previously, sometimes we were asked to do a look-back and test samples, and I suppose that may have been sent out or supplied to somebody else. Not -- during my time there, if we were asked to check back, we did the testing.

Q. Okay. You have described in your statement your work with Speywood and we've got various documents, I'm not going to ask you for the details of that.

Did Speywood products, were they used at the Royal Free?

A. Yes, indeed. The Hyate:C, the high purity pig

Factor VIII, was used in our inhibitor patients for many years. In fact the very last batch was used on the patient who'd been treated back in 1986 sometime in 2010 to cover a hip replacement I think, yes.

Q. And I think we know from the ethical approval document we looked at earlier, there was, or there was intended to be a trial of Hyate:C -- sorry -- yes, of the porcine product.

A. Yes.

Q. And were you directly involved with that?

A. Yes. Yes.

Q. Did you perceive there to be any conflict of interest as between the use of the product at the centre for patients and your own consultancy with the firm?

A. No, it was a unique product, and if a patient had had anti-human Factor VIII but didn't have anti-porcine, they were automatically highly suited for that product.

My other involvement with Speywood was in the project to purify human Factor VIII for analysis and cloning and so on, yes.

Q. Then going back to the treatment policy in the late 1970s/early 1980s introduced by Dr Kernoff, do you agree that there was a conscious decision to switch patients to concentrates from cryoprecipitate?

A. Yes.

Q. That that switch to concentrates included patients with mild or moderate, as well as severe haemophilia?

A. Moderate, yes. If a mild patient was given a concentrate when there was an alternative -- DDAVP, cryo -- it should have been a conscious decision that there was a reason to do that, that the others would not have been appropriate, after we'd realised the risks and the advice had come out. But again, as always, there's a kind of grey period when the risk wasn't fully appreciated, and somebody might have just thought, well, in this particular circumstance, let's give the concentrate.

And there is one case of that which I've given evidence on to an earlier phase of the Inquiry, where a patient had particularly resistant bleed and was given concentrate. But -- so there would be a decision, and it should, in all instances, have been considered.

In clinical medicine, things happen at weekends when people are on call, and who might not be familiar with the case, and you might get mistakes and I guess there is going to be such instances. But as a general principle, by the time it was the case that we knew that there was more risk with concentrate to patients,

such as mild patients who hadn't previously been exposed, then there should always have been a conscious decision and a good reason to give the concentrate.

Q. And would you accept that the risk of transmission of hepatitis, of non-A, non-B hepatitis, was known, whatever might have been the view of the precise severity of it or its long-term consequences, that concentrates were highly likely if not certain to transmit non-A, non-B hepatitis was known by the late 1970s?

A. Yes.

Q. And would you agree that it's reasonable to infer, therefore, that Dr Kernoff must have been willing to take that risk?

A. Yes.

Q. Just on DDAVP, were there ever any problems with supply of DDAVP that you're aware of?

A. Not that I'm aware of.

Q. You mentioned in your statement some involvement in the Penrose Inquiry.

A. Yes.

Q. We've not currently been able to track down any documentation about that, and you didn't, I think, give oral evidence in any of the formal sessions.

Could you just summarise what your involvement was, how it came about, and what you did?

A. I gave a response to their questions during the course of several hours. General questions about how we reached decisions to give particular treatments during the critical period, late '70s to mid-'80s.

If my evidence was not included in the report, which I think is what you're saying, then I'm not sure why not, but because I wasn't involved with the situation in Scotland, I was giving general background information, I guess, perhaps not of a sufficiently specific character to merit inclusion in their report.

Q. And did you produce anything in writing, a report or statement, or was it a question of having a meeting and answering questions in person?

A. It was the latter.

Q. You mentioned the 'If in doubt, treat' principle.

A. (Nods).

Q. How would that apply to patients who were previously untreated patients -- PUPs; virgin haemophiliacs -- or those who had only received very minimal or infrequent treatment?

A. It would apply in the same way, but perhaps with a slightly higher bar on whether this was really likely to be a bleed, given that in mild and moderate

patients, bleeding is less frequent and usually only happens after significant trauma.

Somebody with mild haemophilia falls two floors down on to concrete and has a headache, you're going to treat them -- I mean, I'm thinking of a specific case -- and he'd gone to the local casualty and been refused treatment, and his mother fortunately made him come to see us, and we treated him. But, you know, without any hesitation. Just like all clinical decisions, you've got to take account of all the circumstances.

Q. Then two final matters, I think, Professor Tuddenham.

Could we have HSOC0029583, please.

This is an opinion you gave to the Haemophilia Society March 1987, and you were, I think, commenting in response to a request by Mr Watters of the Haemophilia Society on a -- was it on the general litigation or on a specific individual's case? Can you recall?

A. Yes.

Q. Was it general? A general observation about the litigation, or were you commenting on a specific individual?

A. Ah. It's a general observation.

Q. And then you pose a number of questions. You say:

"Was the Government negligent in not accelerating self-sufficiency of home produced Factor VIII?"

And you set out your opinion:

"[You] believe the Government was negligent in that regard but, as pointed out this falls within the area of 'discretion' and alternative supplies were procured.

And by "alternative supplies were procured", you mean commercial concentrates, presumably?

A. Yes.

Q. And then:

"Would be provision of home produced concentrate have reduced the number of HIV infected patients? The answer here must very clearly be 'yes' despite the over-cautious remarks of Professor Bloom in his Lancet editorial of 1984. He would himself now I am sure agree that we would have half or less of the antibody positive cases that we have now had UK Factor VIII sufficiency been reached in 1977 as promised by the Government of the day. This means that the bureaucratic discretion of the Government is responsible for at least half of our antibody positive cases."

Does that remain your view?

A. Yes.

Q. And then you pose a question about do individual patients have a prospect of proving negligence? And you say that might depend upon individual cases.

And then if we go further down, I don't think I need to ask you about your comment at the end about legal aid or being able to afford court costs.

Did you have any other involvement in the litigation that took place in the late 80s, beginning of the 1990s?

A. No, I didn't.

Q. And then, if we could go, please, to RLIT0000022.

Could we go to page 76. So this is the witness seminar we looked at this morning.

If we could go 10 pages further on and if we could just go to the previous page to check that this is you speaking. Sorry, previous page still. I think it's fairly obvious it's you but I just want to put it in context. If we keep going back. It's obviously a long intervention of yours. We've gone too far back now.

SIR BRIAN LANGSTAFF: It has all the details which would --

MS RICHARDS: It does. We'll move forward to 76. It talks about Speywood, so I'm fairly confident it's you, Professor Tuddenham.

You say this in the first -- in the second paragraph, third line:

"Everything that we give to a patient has ... to be subjected to the most intense scrutiny ..."

And that's the principle that you then go on to discuss in the context of recombinant.

Would you agree that that should always be, and have been, a guiding principle when dealing with blood products, whether now or in the 1970s and 1980s?

A. Yes, I would. Yes.

MS RICHARDS: Professor Tuddenham, those are the questions I have for you.

Sir, I don't know whether -- before I ask Professor Tuddenham if there's anything he wants to add, whether there's any questions you have.

Questioned by SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: Yes, I do.

At the end of this Inquiry, I shall have to consider making recommendations. That's recommendations as to what happens in the future.

You have said in your evidence -- you may well be right -- that we just don't know what may be carried by blood in the future when that blood is transferred from one person to another person. And you've said that we ought to assure the safety of it. How would

you suggest that were best achieved?
A. Firstly, by continuing careful and, where possible, intense surveillance of the response to existing and future products in people who receive them.
We do have good systems for recording issue and tracing recipients of given blood donations, and that performed well in the more recent context of the prion disease where it was possible to track everybody who'd received particular batches or products even down to the individual level. That must be continued where we use blood products.
And in my view, to the extent that we can, we should find ways to replace blood products with synthetic alternatives. The biotechnology industry has developed and advanced to the point where that can almost universally be applied. There's still a few examples where it has yet to be so applied, but there are occasions when there's nothing quite as good as the blood product itself because it's full of so many different agents. But we will never know what's coming along in the way of a future infective agent, so we have to preserve vigilance but replace, where we can, with the products of the ingenuity of biotechnology.
There are some blood products that currently are

not replaceable: red cells, platelets. These are produced in a phenomenally complex way within our bone marrows; ways we've only latterly understood and are certainly not yet in a position to replace. So there will be a continuing need for such blood products, but our best way to guard against future risks and -- is to maintain vigilance.
SIR BRIAN LANGSTAFF: Thank you very much.
MS RICHARDS: Is there anything that you would wish to add, Professor Tuddenham?
PROFESSOR TUDDENHAM: Only my great regret that during that period our best efforts to improve the management of haemophilia should have resulted in this disaster, and to hope that we do learn from it, to guard against any similar such catastrophic consequences by, as I've said, continuing vigilance and always being aware that we don't know it all and never will know it all, but we have to keep learning.
MS RICHARDS: Thank you.
SIR BRIAN LANGSTAFF: Can I thank you very much for the, if I may say so, clear, considered, thoughtful and balanced way that you have given your evidence. You've -- I have to say, you've given me the impression that you come with no particular agenda to pursue, other than helping the Inquiry to the best of

your ability, and I would like to pay testament to that and thank you very much for coming to give your evidence, and I suspect you probably regard it as your duty to do so. You've achieved it, and it may well be that, as I think your counsel may be aware, there may be some further questions to be addressed in writing in due course. I hope that you'll help us with that too.
PROFESSOR TUDDENHAM: Yes.
SIR BRIAN LANGSTAFF: Thank you.
MS RICHARDS: So that's it for hearings this week, and then we reconvene on Tuesday to look at Birmingham, there will be a presentation in relation to Birmingham Children's Hospital, then we'll hear evidence from Professor Franklin on Tuesday, probably running into Wednesday, then from Dr Wilde, so still Birmingham, and then on Thursday from Dr Parapia, Bradford.
SIR BRIAN LANGSTAFF: Yes, so ten o'clock on Tuesday for those of you who are coming back next week.
Stay safe.
(4.15 pm)
(The hearing adjourned until 10.00 am on Tuesday, 27th October 2020)

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