Thursday, 1 October 2020

(10.00 am)

SIR BRIAN LANGSTAFF: We have Dr Winter this morning. Shall we have -- Dr Winter, would you come forward, please.

DR MARK WINTER (affirmed)

SIR BRIAN LANGSTAFF: Dr Winter, I understand that you don't always find it very easy to hear.

A. I'm very deaf, if that's what you mean.

SIR BRIAN LANGSTAFF: That's a better way of putting it. I was being polite. We'll do what we can to help. I'm raising it now so that everyone understands that council will speak slowly, and that if you have any difficulty in hearing, please indicate, and one way or the other, we hope that you will hear everything. If you don't, please let us know.

A. I've managed through my hearing aids to get on to your loop-system, so you are very clear at the moment.

SIR BRIAN LANGSTAFF: I hope it continues that way, and I hope the same is true for counsel, so thank you for that.

Questioned by MS RICHARDS

Q. Dr Winter, I'm just going to ask you, first of all, to give us an overview of your career. My understanding is that you studied at medical school at Guy's

Hospital between 1968 and 1973?

A. Correct.

Q. You then undertook, over the following three years, various roles in general medicine?

A. Yes.

Q. Then between 1976 and 1979, you were a lecturer and honorary senior registrar at the Middlesex Hospital.

A. *(Nodded)*

Q. Is that where you undertook your haematology training?

A. That's where I started, and then after four years, I transferred sideways to a similar post at Guy's Hospital where my training was completed in 1983.

Q. Whilst you were at the Middlesex Hospital, I gather that you were seconded for six months to the Edgware Regional Blood Transfusion Centre?

A. Yes. It was part of standard haematology training that all trainees had to spend six months at a regional blood transfusion centre to give them experience of the way in which transfusion centres work.

Q. What were your duties, in outline, at the transfusion centre?

A. Nothing of any great significance, to be honest. It was really observatory. I mean, you sat in. You went

around the whole experience of one day, you went out on the vans and helped blood to be collected. You spent some time in the laboratory. You spent some time seeing how the fractionation, such as it was, happened before it went off to Elstree and, you know, the day-to-day workings of a blood transfusion service.

Q. So you transferred, as you just referred, in 1979 to Guy's Hospital as lecturer and honorary senior registrar?

A. Yes.

Q. That was in the Haematology Department at Guy's?

A. It was.

Q. Then you remained there until late 1983, and on 1 December, you took up a consultant post at Thanet General Hospital in Margate?

A. Yes. It was -- the post was -- the health authority in those days was Canterbury and Thanet, and there was a haemophilia centre there which, for historical reasons, covered nearly all of the county of Kent and was the sort of the biggest in the south-east outside of London. So it was a curious arrangement because of its geographical position.

Q. Then that centre relocated to Canterbury in the mid-1990s and became a comprehensive haemophilia care

centre?

A. Yes. For the -- really because the centre had grown so much and because the geographical access was so poor and the facilities were not very good that the service was put out to tender by the local health authority and was eventually relocated into very good facilities on the Canterbury site. So that was a big step forward. Then shortly after that, we managed to get accreditation as a comprehensive care centre.

Q. You retired from that post in 2011.

A. Yes.

Q. Then, in terms of your membership of or involvement with other relevant organisations, you were a member of the United Kingdom Haemophilia Centre Directors Organisation from late 1983 until 2011?

A. Yes, as are all Haemophilia Centre doctors.

Q. I think, during that time, you were at various stages on UKHCDO working parties of one kind or another?

A. I was.

Q. You became a designated HIV physician for the area -- was it the whole of Kent, or the Margate area?

A. It was for the health authority. This was really an unusual step. As we'll doubtless discuss, we had a particularly significant HIV problem, and the AIDS Control Act, which I think was 1985, stipulated every

HIV -- every health authority had to have a nominated HIV physician. So they said to me, how would I like to be that person, as I seemed to be the only one who had any HIV expertise. So from that moment on, I only did haemophilia and HIV.

But that, I think, gave me different insights, because I think I was the only haemophilia doctor who was an HIV physician, so I had people with haemophilia and HIV, and some people with HIV who did not have haemophilia.

Q. You're right. We'll come on to that in more detail later.

You were a medical trustee appointed by the Department of Health for the Macfarlane and Eileen Trusts from 1996 to 2009?

A. Yes. I think that came out of the -- you know, the rather unique HIV situation. I was a choice to be the trustee which -- the dates you say.

Q. Again, I'll ask you some more about that at a later stage.

You had some involvement with The Haemophilia Society. As I understand it, you were on their treatment and care committee -- and I'm taking these dates from your CV -- from 1987 to 1991. You were on their General Services Committee from 1992 to 1996,

and their Medical Advisory Panel from 1999 to 2005?

A. I was. I was particularly involved with them when we were trying to pressurise the Government to set up what became the Macfarlane Trust. So I acted with them as a sort of media liaison and medical support, and we went around -- we went to the House of Commons a few times and made presentations and lobbied politicians. So, yes, I was actively involved with the Society.

Q. Then you were one of the founders of an organisation called the Haemophilia Alliance. Again, I'll ask you a little more about that later. That was established in 1999?

A. It was.

Q. Now, you also have given evidence to both the Archer Inquiry and the Penrose Inquiry?

A. I did.

Q. I'm going to take your evidence to those inquiries as read, Dr Winter. I'm not going to go through it. Although, inevitably, my questions will cover some of the same ground, and we may look at a handful of extracts from your evidence.

I want to start, if I may, by asking you about the four years or so that you were at Guy's Hospital, so from 1979 to 1984.

Guy's was an accredited haemophilia centre, but a small one; is that right?

A. Well, it was because it was only barely a mile from St Thomas' which was a major centre. So, in a way, it was quite curious that it was seeing people with haemophilia at all, but there were some haemophiliacs who historically had gone there and chose to stay there. Neither of the consultants had an interest or expertise in haemophilia; so, together with another senior registrar, I started to get involved and that would be the first time really that I got involved with haemophilia patients.

Q. Roughly how many patients were registered with Guy's -- haemophilia patients -- during that period?

A. Well, there probably was sort of 30 or 40 registered, but there was a hardcore of sort of ten to 15 severely affected patients of all ages.

Q. I think your statement suggests mostly adults, but there were a small number of children.

A. There were.

Q. The director of the Haemophilia Centre was Dr Percy Barkhan?

A. He was an expert in vitamin K metabolism.

Q. Yes. You have said in your statement, in practice, the haemophilia patients were managed by the senior

registrars. I think one of the other registrars would have been Dr Clarke; is that right?

A. No. He was the other consultant. He was also not an expert in haemophilia.

Q. Can you recall who the other registrars were?

A. I can. They were a husband and wife team, Dr Hugh and Yvonne Williams.

Q. Now, your statement explains that, as a registrar at Guy's, you weren't involved in the procurement of blood products.

Can you help us with whose decision it was as to what products to source and use at Guy's? Was it Dr Barkhan's?

A. Well, I was certainly not part, in any way, of the procurement, as you say, because I had no role in sort of day-to-day managerial functions as, effectively, a trainee. My recollection was that we received from a transfusion centre supplies of such NHS-derived Factor VIII concentrate as was available, and that almost certainly was never enough. So to top that up -- I'm sure they supplied to nearly all centres -- we had to purchase some commercial concentrate to meet needs.

There was a particular issue in the south. Every health authority was supposed to have its own

Blood Transfusion Service, but for reasons that were never clear, the south-east Thames did not have its own Blood Transfusion Service. So the Tooting centre, the Tooting Blood Transfusion Unit, covered two very, very large regional health authorities. It covered the south-east, and it covered the whole of the south-west, and that really led to a lot of problems because that service was inevitably under a great deal of pressure, in terms of clinical demand.

I don't recall, I think, that some -- you know, we went to the pharmacy and said, you know, we're not receiving enough Factor VIII concentrate that is NHS-derived. We're going to need to buy some commercial concentrate. I can't remember which one we used, and, as I say, I was not part of the contractual arrangement.

Q. The way you've put it in your statement is your recollection that you received an allocation of NHS concentrate, and then a shortfall was covered by the usage of commercial concentrates?

A. Yes.

Q. I'm going to ask you more about cryoprecipitate in a while, but just dealing with the use of it as a matter of fact, your statement says that at Guy's, cryoprecipitate was not used, although it was

available.

A. It was used on occasions. If we had, for instance, a patient with mild haemophilia or von Willebrand's disease -- already, you know, late 1970s -- we'll be talking more about this, doubtless. But we're already aware of the evolving data about abnormal liver function, suggestive of hepatitis. We were trying to limit the exposure of patients to Factor VIII concentrates if they were not regularly treated patients.

So I think, occasionally, if they were children, if it was a rarely treated child, particularly if they were adults, maybe on occasions if the products were in short supply, we certainly did use occasional cryoprecipitate. Cryoprecipitate is so laborious to give up you don't forget giving it and, you know, I can remember days when we sat there drawing it up and giving it to patients, but there weren't very many of those days.

Q. Maybe you don't know the answer to this, but do you know whose decision it was at Guy's to make only limited use of cryoprecipitate? Was that Dr Barkhan's?

A. No. Everything -- all those clinical decisions were left to the two registrars running the programme.

Q. So that was effectively your decision and the decision of the colleagues you've mentioned?

A. Yes.

Q. I'll come on later to the pros and cons of cryoprecipitate, Dr Winter.

You also said in your statement that when you started at Guy's there was no home treatment programme, but you established one. Can you just explain a little more how you went about it, what discussions took place?

A. Well, it's only, as we've said, a pretty small number of patients. But, you know, factor VIII concentrates came in, what, '73/'74, and they instantly and immediately revolutionised the quality of life for people with haemophilia, and by the mid-1970s, most centres had established this package of comprehensive care which included the home treatment programme. So this wasn't anything controversial. It was surprising that Guy's, you know, for patients with severe haemophilia, didn't have such a programme established.

So I spoke to Dr Barkhan, and he thought, you know -- I mean, his attitude was he wasn't going to get involved with the management of haemophilia care, even though they were a designated haemophilia centre, and he was very happy for us to take the matter

forward. It didn't involve very much in the way of financial input. It was really logistics. It was training patients how to give their own injections, training parents how to give injections, getting transport arranged so we could get Factor VIII to the home setting. There wasn't a great deal of expense involved. It was really quite a straightforward undertaking.

Q. Was any consideration given as to whether setting up a home treatment programme would increase the demand for concentrates and, therefore, potentially increase the need for commercial concentrates to be used?

A. Well, I think there's data that the use of Factor VIII was already increasing at that time, and, in particular, people were beginning to start to use prophylaxis; that's to say, Factor VIII given not to treat a bleed but to prevent a bleed. People with haemophilia, once they were established on home therapy, which was such an enormous advantage, they could take Factor VIII to their school or to their work and inject it in the place where they were. You know, their life didn't revolve around haemophilia centres any longer. It just gave them, you know, complete independence. They then began to look at their lives and say, "Every Tuesday evening I play

tennis and it seems to me sensible because it's a risk activity but one that I very much enjoy, I'm going to talk to the doctors about whether I might give myself an injection to target that period of activity".

So prophylaxis was, you know, pioneered by the Swedish, really, that were starting to be there as part of haemophilia management and something that most particularly for children, later for adults, was something that was really effective.

So Factor VIII was growing in usage from the mid-1970s onwards.

Q. What information or advice did you or your fellow registrar colleagues give to patients or parents of patients in relation to home treatment and the use of Factor VIII?

A. Well, I mean, there were criteria that you had to jump through to be able to get onto the programme. You'd be able to do your own injections if you were an adult. If it was a child, we needed to be satisfied that the parents had the ability to recognise a bleed and then to implement the Factor VIII therapy promptly. To keep records. So there were a number of hoops the patients had to jump through from our point of view, and then we obviously informed them as to, you know, the nature of concentrate, to look out for

any side effects, even though the side effects were much less than with cryoprecipitate, which really did quite commonly cause significant side effects.

I can't remember whether we gave them, at that stage, any written publications. It's more than 40 years ago. I can't remember -- I can't remember whether we said anything to them about the evolving evidence about non-A, non-B.

We certainly would have spoken about hepatitis viruses because part of being on a comprehensive care programme, including home therapy, is to come in every two or three months and have a full clinical review, and that included blood tests which included hepatitis markers. So the patients certainly were aware that they were being screened every three months or so. We didn't have hepatitis B vaccine at that stage, but they were aware that part of the package of care they were getting was a range of blood tests which have to be carried out on people with haemophilia. Most especially for trying to see whether they had developed what we call an inhibitor. About 10 per cent of people with haemophilia develop an antibody which recognises the Factor VIII and destroys it, and that's a very significant clinical development because it makes future treatment with Factor VIII

really difficult. So people with haemophilia need regular blood checks anyway as well as wellness checks, and part of that package of blood tests was to do hepatitis markers.

I was certainly aware of the evolving data around non-A, non-B. I can remember us talking about it. I can't recall at this distance of time whether we spoke to the patients about our concerns.

Q. I'll ask you a little more about that at a later stage but, again, just dealing with what, as a matter of fact, was established at Guy's, what you've said in your statement is, in terms of the treatments that were used for patients, with severe haemophiliac adults you would use either the BPL, Elstree product or commercial depending upon supplies.

Do you have any sense or recollection as to how often it was that you had to use commercial products because there wasn't enough Elstree material available?

A. No, but it was such a recurrent thing for the next seven or eight years really, extending into my consultancy. Factor VIII was always in short supply nationally, as we all know, but it was in especially short supply in these two health authorities because it was being served by one transfusion centre, who

were working flat out and who just couldn't cope with demand. So it was a very regular feature that you would have to top up with commercial.

Q. Do you know or recollect whether anything was said, for example, by you or your colleagues or Dr Barkhan or others about this shortage and this particular problem of having to depend on Tooting, which was covering these two large Thames Regional Health Authority areas? Was that problem raised with the Blood Transfusion Service; do you know?

A. Well, not to my knowledge. As I say, I wasn't a consultant. I was a doctor in training so I had no sort of managerial/administrative roles, and although it was a designated centre, you'll see, one of the papers you sent me of a UKHCDO meeting, I represented Dr Barkhan, and I can remember Dr Barkhan didn't ever go to haemophilia meetings. He used to ask me to represent him, which I was happy to do. But I had no sort of managerial responsibilities in doing that.

Q. Then in relation to moderate haemophiliacs, so again this is still at Guy's, your statement says that you would use DDAVP or, wherever possible, BPL concentrate?

A. Yes, moderate haemophiliacs, some do respond to DDAVP, some don't, so you would have to assess the situation.

If they did respond, fine, you would use that, depending on what was the need for Factor VIII. If they were about to have major surgery, the DDAVP wouldn't be enough.

Q. Where you say "wherever possible, BPL concentrate", does that mean that, in all probability, some moderate haemophiliacs would have received commercial concentrate because of the shortfall?

A. Yes. I mean, all these deliberations were based on an evolving understanding that you really did not want to use commercial concentrates if at all possible, as set out so unforgettably in the World in Action documentary which we had seen.

So this was something that we didn't really ever want to do. You know, if you had said to us, "What sort of Factor VIII would you want?", we would have said, "We want BPL Factor VIII for our patients and we don't want to use anything else". But the reality was there just weren't the supplies to do that, so it was with reluctance, great reluctance, that we used commercial product.

Then we obviously, as recommended by UKHCDO, started to say, "Well, who should we prioritise to give the BPL product to?" It was obviously children, mildly affected patients, patients that weren't having

Factor VIII very often, because we were especially sensitive to the possibility of giving them viruses if they were only going to have a few life-time treatments.

Q. With mild haemophiliacs and those with von Willebrand disease, your statement suggests that the first treatment of choice would have been DDAVP.

A. Yes, we would have assessed them to see whether the DDAVP -- response to DDAVP is variable, you have to assess it, but we would have assessed them. I mean, von Willebrand's is a particular case because, in fact, Factor VIII is usually not an appropriate treatment. So all von Willebrand's we would have expected to treat with DDAVP, and mild haemophilia we would have expected to but it would have depended on how much rise in Factor VIII could the DDAVP treatment lead to.

Q. With mild haemophiliacs, if you couldn't use DDAVP, is it possible that at Guy's, because of the shortfall that you have explained, mild haemophiliacs might have been treated with commercial concentrates?

A. It is possible. It very much depended on the clinical context. If it was a mild haemophiliac and if DDAVP wasn't going to work -- which was unusual for mild but something that happened -- then you were in

a different situation. Then it really depended on the answer to the question: why does this person need Factor VIII? If the answer was because they are having a hernia, which is a minor surgical procedure, you might say, "I really don't -- you know, this might be the only time in their life this patient gets Factor VIII, I might do a wait and see policy here. I might not give Factor VIII and see if we can get away with it, with local measures."

But if on the other hand they were having open heart surgery, I they would -- you would say, "Well, DDAVP doesn't work. This patient will have to have Factor VIII."

Q. You would give Elstree if it was available but if it was not available and you felt you had to use Factor VIII, for the reasons you have given, it could be commercial?

A. Correct.

Q. Then you have alluded to the position of children already but your statement says, as you've confirmed, children were prioritised to receive treatment with BPL supplies, if available effectively. So again, with children, is it possible/probable that, on some occasions at least, they may have had to be treated with Factor VIII concentrates that were commercial

concentrates because you didn't have enough Elstree product?

A. Well, we had -- each month there was a supply, and the particular dynamic was, as I recall, the policy was Elstree sent out, in terms of Factor VIII -- there was a formula related to the amount of plasma that had gone in from the local Blood Transfusion Service. So how much Factor VIII came to your region was related to how much plasma Tooting had sent to Elstree. There was this formula.

But we did every month -- it was monthly, as I recall -- get a supply which came into pharmacy. Now, children would have been our priority, and of course they need less Factor VIII than adults. So my recollection is that I don't -- you know, this would have been the first choice, that a child always got BPL. I can't remember giving a child commercial but I couldn't be absolutely sure.

Q. The formula that you've mentioned, that the amount provided by way of BPL Factor VIII concentrate was related to the amount of plasma supplied, did that make it difficult to plan, because you would have no control and presumably no knowledge of how much plasma had been supplied by the transfusion centre to Elstree?

A. It was a very long-running and thoroughly unsatisfactory difficulty and, of course, there was then this great variability of financial need. You know, haemophilia doctors all round the region didn't know whether they were going to need to top up or not. The finance departments hated this sudden appearance of a haemophilia doctor saying, "We didn't get as much BPL Factor VIII this month as we expected, I'm going to need to spend another £50,000 topping up." They hated things like that. So it was a recurrent difficulty. When we talk in a minute about the future, I remember in particular that Dr Savidge at St Thomas', and when I was at Canterbury, because we had -- we had contracts set up with our pharmacies, we had close contact with our pharmacy divisions, I remember for some years we directed the BPL product to the smaller centres because the doctors there didn't have -- you know, they didn't have resource to go and order commercial, they didn't have designated budgets, they were essentially leukaemia doctors.

Of course if we had that policy, St Thomas' and the Canterbury centre were buying in bulk, so it was much better for the NHS because we could drive down the price because we were buying such large amounts. But I remember for several years the smaller centres

got the priority of BPL, which was never enough for the two regions, and then we, the two major centres, in with two -- South West Thames, South East Thames, topped up with commercial.

Q. Now, can I just go back to the question of prophylaxis at Guy's. What you've said in your witness statement is that for adults there wasn't, at that stage, a programme of prophylactic treatment unless it was short-term for target joints or surgery.

A. Yes. Prophylactic treatment for adults didn't really take off until later than that, although it was begun to be talked about. But there was a couple of clear indications which is really, as you say, if somebody had had surgery they would need Factor VIII for a couple of weeks to make sure that the wound didn't break down and that they would re-bleed.

The other particular indication is that one of the major clinical problems in haemophilia is that if you, in those days, started to talk to, say, a ten year old boy with haemophilia and say, "How are your joints?" They would very often say, "I have one particular problem." So the major clinical event in haemophilia is a bleeding into a joint, the joint is damaged, and because it's damaged it's then more likely to bleed. So you get into a cycle of bleeding

causes joint damage causes bleeding. So a very common finding was that patients would have one joint in particular that was a bad one because they'd got into this cycle.

So these were called target joints and there would be occasions where they would, you know, get a lot of bleeds. We'd see them for review and they would say, "Well, I've had three bleeds into my right knee in the last month", and we would say, "Well, we want to calm this down by giving prophylaxis rather than waiting for the knee to bleed again. So for the next month we'd like you to inject yourself three times a week at home" and that would calm the whole thing down.

So those were the two very clear-cut indications for prophylaxis in adults at that time. Years later it changed very significantly.

Q. Would those adults falling within either of those two categories, would those generally tend to be severe haemophiliacs rather than mild or moderate?

A. Oh, yes. These features I'm discussing were only for severe haemophiliacs. In mild and moderate haemophilia you don't get that degree of bleeding.

Q. Then in relation to children, again we're still at Guy's here, you say in your statement that children

were treated with prophylaxis if deemed appropriate. Can you expand upon that, please.

A. Yes, I've covered some of that already. So it's quite an undertaking and, you know, you are using very expensive material. It needs to be given into a vein. It needs to be given promptly by parents who recognise a bleed. So there's a number of hoops that parents needed to jump through to be able to do home treatment.

Firstly, which wasn't always the case, the child needed to have good veins. Realistically, you don't get prophylaxis going until the child's about three years old. When the children were about three we would start teaching the parents how to administer Factor VIII. But that was the hurdle number one. Some, I would say about 10 per cent of children, their veins were too poor, and on those circumstances, if the child was severely infected, we would insert central venous devices called portacaths. So they would have to be put in under a surgical procedure, and it would be like a little disk, like an old half crown, which you could feel underneath the skin, and then the parents were taught to inject straight through the disk, and that would take into a -- straight into a blood vessel. But those could get

infected so we were reluctant to do that. You had to be scrupulous with hygiene. But that was the first hurdle.

Secondly, you know, it's a big commitment. So we needed to be convinced that the parents were taking this seriously. If it was from, you know, a family with social difficulties, single-parent family, if we weren't confident that the mother was going to be able to do this, then we would discuss with her whether it was actually -- whether she felt able to do this. They had to be trained how to spot a bleed -- you know, which was done by the nurses. The nurses would go and visit the home. That was a key part of it. They would go and see the facilities. Sometimes the nurse would come back and say, "I really don't think this is going to work, you know, the social arrangements are so poor." So those were more criteria. They had to be able to communicate. You know, we absolutely needed to know if a child was having problems. If a -- you know, we didn't want a mother to come in and say, "Three weeks ago I gave a treatment every day for a week because there was a bad bleed", we'd say, "Why didn't you ring us?" We absolutely wanted to know if there was a problem.

So these were the sort of things we addressed.

Having said that, it was pretty unusual if we said, "I don't think this is going to work", but it did happen in a few families.

Q. So the children who went on to prophylactic treatment would all have been severe haemophiliacs?

A. Severe.

Q. Was the product that was given to their families for them to use at home on a prophylactic basis always NHS product or was it --

A. By choice, yes, very much so.

Q. To what extent at Guy's were patients given a say or a choice in the type of treatment that they had?

A. None, I would say, because in those days -- I mean, I don't think the doctors were given a choice in terms of what sort of commercial concentrate. I think that -- you know, there was a manager in the centre. I would go and say there was a BPL shortfall and the manager would go and order some commercial concentrate from the pharmacy, who didn't really know a great deal about Factor VIII concentrates as it's not a drug, it's a blood product, but they would come to some arrangement with the commercial company for the supply to come in. So we would certainly be talking to patients about the types of concentrate and that we had hoped to get them BPL concentrate, but that they

might notice on some months, when the supplies -- we would have a van that would send out the supplies to the parents' homes or, sometimes, if the patients were coming in for review, they would pick up supplies and goes home with supplies -- they were certainly aware that concentrates came in two different generic types. There was the British type and the American type and the patients were understandably very keen and anxious to have the British Factor VIII. You know, they used to say to you, "You are going to give me British Factor VIII this month, aren't you?"

If they had to have commercial Factor VIII, there wouldn't have been any sort of conversation about which particular product it was. I think it was perceived, at that time in any case, there wasn't any clinical difference in efficacy across the different commercial concentrates, and we had no evidence there was any difference in risk of infection across the commercial concentrate. So as doctors we didn't have any sort of impetus to start making noises with the powers that be to say, "We don't really like giving commercial concentrate but we understand why -- there isn't enough BPL -- but we really want to have a say as to what sort of commercial concentrate". That sort of conversation didn't take place.

Q. You have said that patients would express a preference for British concentrate. What was your understanding of the reasons for that preference?

A. Well, haemophilia is a small and close-knit community. All patients are encouraged to join The Haemophilia Society. The Haemophilia Society used to produce lots of written information for them and we used to have these residential seminars. Once or twice a year, there would be a national seminar and we very much encouraged our patients to go. The weekends were free and they were of great benefit to the patients. They could be given lectures by doctors or nurses about matters of interest. There would be little workshops they could go and attend. There would be a dinner and a few drinks on the Saturday night. They could meet other parents. It was something that was terribly valuable. And this sort of very strong feeling, which we'll talk about later on, in terms of the critical times coming five years later, there was this very, very strong feeling amongst the British Haemophilia Society population of -- I previously described it as a sort of Tarzan-oid philosophy, you know: "British good, American bad. I don't want to have American Factor VIII."

A lot of that came from publications from The

Haemophilia Society, or it came from these residential weekends and meeting other patients. Of course no internet in those days.

Q. Do you recall whether, during the years you were at Guy's, you had conversations with patients about the pros and cons of British concentrate versus commercial concentrate?

A. Yes. I mean, we had conversations with them, and The Haemophilia Society publications were saying that the commercial concentrates theoretically carry more risk and we're not happy about that and, as you know, by this time UKHCDO were beginning to have dialogues with Elstree and the transfusion services and there was Dr David Owen's initiative, et cetera. So the patients were well aware of the theoretical differences. Which is where this philosophy came from, which you have to completely understand. They very much wanted to have British Factor VIII because it was perceived as being less likely to transmit viruses.

Of course at that time that phrase meant "hepatitis" -- nothing known about AIDS.

Q. What about concentrates versus cryoprecipitate? Again, I'm going to come in more detail to what you say in your statement about disadvantages of

cryoprecipitate but, as a matter of fact, do you recall whether you had conversations with your patients at Guy's explaining to them that there was this other treatment, cryoprecipitate? Many of them would presumably have known that from earlier in the '70s. Did you explain to them your views of the relative merits of cryoprecipitate versus concentrates?

A. Well, these are patients who, unless they were a child, would previously have been treated with cryoprecipitate, which was available in the late 1960s. So all of these patients, apart from children, knew about cryoprecipitate because it was their previous treatment before the concentrates came in and then they didn't need any persuading at all. As you've seen from the various documentaries that have been on recently, it was such a sea change, to move from cryoprecipitate -- which was the first treatment, but it really was not, by any measure, a good treatment, which we will talk about -- to suddenly this treatment, which is what everybody, doctor, nurse, patient had wanted, which was small volume, kept in a domestic fridge, you knew the amount of Factor VIII on the bottle, didn't have to be in a deep freeze, reasonable supply, easy to draw up, quick to

give. From every perspective, the concentrate was so much better and it was a much more effective treatment. You know, cryo was not a very effective treatment at stopping bleeding. You couldn't use it for prophylaxis.

So the patients were fully signed up to concentrate. No patient ever said to us, "Can I go back onto cryoprecipitate?" They would have had to come off home therapy.

Q. Did you explain to patients the relative degree of viral infection risks of cryoprecipitate versus concentrate; in other words, that there was a greater risk with concentrate because of pooling?

A. Well, I didn't know for certain that that was the case. I mean, in theory, because cryo might come from ten donors and the concentrates come from 20,000, there were these theoretical risks. But, again, I think the patients were well-informed as to how concentrate was made, and I don't think they had any reservations at all. No patient ever said to me, "I'm really not happy about being on concentrate because of this number of donors that the concentrates are derived from. I want to go back to having cryoprecipitate." It was known about. People maybe didn't feel very comfortable about it. The doctors

didn't feel comfortable about it. It was recognised as being an Achilles heel of a treatment that was otherwise spectacularly successful.

Q. You left Guy's in late 1983. Did you ever find out how many of the patients you cared for at Guy's were infected with HIV?

A. No. There were one or two that moved down to Kent and came under my care who obviously I did know what happened to but the rest of them at Guy's I didn't. I say, these weren't very large numbers. There were probably, as far as I can recollect, ten to fifteen patients on home therapy.

Q. I want to turn now, please, in more detail to some of the matters you have alluded to about the developing knowledge of risk from concentrates.

Can I start by asking you what you were taught as part of both, first, your general medical training, and then your specific haematology training, about the risks of viral transmission from blood and blood products.

A. Well ...

Q. I know I'm asking you to think back a long time, Dr Winter --

A. A very long time.

Q. -- as best you can.

A. I don't recall in my medical training anything about that, but then I qualified in 1973. I now know that there was data from the late 1960s about hepatitis transmission. Of course then, once I'd entered haematology training, I was working both at the Middlesex and Guy's for doctors who were not haemophilia specialists, so they didn't teach me anything about that either because they didn't know anything about it. So the answer is, no, I didn't get any teaching, but then I wasn't expecting it because there wasn't anybody, when I was in training, as it were, to be teaching me about haemophilia. I got my information from other sources, by reading and by going to meetings.

Q. Just in terms of reading material, written material, what journals or periodicals would you typically have read in the late 1970s/early 1980s?

A. I think there was a staple diet really. Everybody read the British Journal of Haematology, so you were a member of the British Society of Haematology. That was -- you know, it wasn't much haemophilia in that, but you read it. Everybody, as members of the BMA, had the British Medical Journal. There wasn't much haemophilia in that. There was The Lancet, probably the most important medical journal in Britain, and

there was the New England Journal of Medicine. Those were your two main sources, because they would carry important articles about haemophilia. Both at the Middlesex and Guy's we had a weekly journal club, I remember. So the registrars were told by the professors to make a presentation each week on an article of interest from one of those journals.

Q. Then what other sources did you have of information? Leaving aside for a moment UKHCDO as a potential source, which I'll come on to in a moment, what other kind of conversations or meetings would you attend in the late '70s or early '80s where you would receive information about matters such as infection risks or other hazards?

A. Well, very little really. I mean, there's -- when you're training in haematology, you have already been through one postgraduate examination, which is the membership of the Royal College of physicians. So the later doctors, like of my generation, went into general medicine, did another exam to get what's called the MRCP. Then to be accredited, you had to pass yet another exam, the membership of the Royal College of Pathologists. So there were training programmes for that, as I reflect on your question. I remember going over London on one afternoon a week

to a series of seminars that were put on by the Hammersmith Hospital by the Medical Research Council.

So there were MRC path training programmes. They were mainly general haematology, but they were for registrars in training who were building up to this really quite substantial examination which took three days, including practicals, which you had to pass in order to be accredited and to become a consultant.

A very small fraction of those meetings, if you were lucky, might be about haemostasis and thrombosis.

Q. Do you recall whether any of those meetings would have covered viral risks from the use of blood or blood products?

A. No. I mean, as we're having this conversation, I'm getting these memories. The predecessor of Dr Savidge at St Thomas' was Professor Ilsley Ingram, who I came to know socially and he I remember going to listen to. He was one of the tutors on that course. So he was professor of haemophilia at St Thomas'. He must have spoken to us about haemophilia. I think in his department was Professor Mannucci as a trainee, and that's when DDAVP was discovered by Dr Mannucci when he was a registrar working for Professor Ingram. That would be 1970s. So I'm pretty sure that

Professor Ingram would have spoken to us about the work that Dr Mannucci was doing with DDAVP. I don't remember anything, even though I'm -- suddenly, you have taken me back to a sort of thing I haven't thought about. I don't remember anybody discussing with us, if you like, the word non-A, non-B. That was a concept that was only circulating in haemophilia centres that was beginning to evolve sort of mid-1970s onwards.

Q. Then Dr Barkhan was an infrequent but occasional attender at UKHCDO meetings. There are a very small number we tracked down that he went to. Did he ever come back from UKHCDO meetings and share any of the information he'd gleaned with you?

A. No. I think he saw it as a managerial event.

Q. Again, in this period when you're either at the Middlesex or at Guy's, so before you take up your consultant post, did you ever see UKHCDO minutes, either of the Reference Centre Directors meetings, which was the meetings attended by ten or so, or the bigger meetings attended by all directors, or to which all directors were invited?

A. My recollection is we wouldn't have seen the AGM minutes which happened just once a year, but I think, as I've already said to you, we were aware of the

recommendations about minimising concentrate exposure in non-severe patients. So I think we would have seen the advice given by the smaller working groups of UKHCDO to be aware of that.

Q. You mention having become aware of publications or information from the late 1960s about risks of hepatitis. The Inquiry has seen evidence dating back certainly to the 1940s to suggest that the risk of hepatitis -- then referred to usually as serum hepatitis, sometimes post-transfusion hepatitis -- was known to be the major risk from blood transfusion and had been known for decades.

First of all, do you accept that as correct?

A. Yes.

Q. Do you recall when you were first to become aware of that?

A. Well, I can -- although we've just spoken about when I was a student, I was aware that there were two types of hepatitis, and that they were different, and that hepatitis A was not usually transmitted by blood, but hepatitis B was and we knew all about Australia antigen, and it was, indeed, even called "serum hepatitis". So, exactly as you say, by the end of the 1960s at the very latest, it was very well established that, of the two known types of hepatitis, one of them

could be transmitted by blood.

Q. You were I think aware, from what you've already said, that commercial concentrates were made using large pools of material from paid donors?

A. Yes.

Q. I think you may have already referred to this, Dr Winter, but do you recall watching the 1975 World in Action programme at the time in 1975?

A. Not at the time, but I've seen it, and I know it very well because I've seen it so many times since.

Q. Do you recall whether, although you didn't watch it at the time, you became aware of it? Was it a topic of discussion after its broadcast in late 1975 in haemophilia circles?

A. No. I have no recollection of that.

Q. I'm just going to ask to play a short extract from an interview you gave in 1988, so you are going to see your younger self on the screen in a moment, Dr Winter. It's MDIA0000111. It is the first of the two clips, please, Henry.

(video played).

I think you have seen that this morning, and you accept that as an accurate account of your knowledge at the time?

A. I don't think I regret any of that, is my immediate

reaction.

Q. Now, your witness statement says that you knew, or clinicians knew by 1979 that commercial Factor VIII was contaminated with non-A, non-B hepatitis and that this caused cirrhosis in regularly treated patients. I want to take that in two stages.

First of all, the existence of non-A, non-B hepatitis. Can you recall, roughly at least, when you became aware of the existence of this third type of hepatitis?

A. So the easiest way to deal with this is to do a timeline. Let's say 1973, concentrates are coming in; you're setting up a comprehensive care programme with home therapy; you're working out which blood tests to do; and, as we've just been discussing, you're going to monitor the patient for known hepatitis viruses, for hepatitis A and hepatitis B. So that's already established in 1973 and 1974.

There's this revolution. The patients are all saying to you, my life is totally, utterly changed. This is wonderful. We've always called this the golden interval, a little two-year gap, about 1974 to about 1976, where suddenly, after years of darkness, disability, pain, inability to work properly, have to go to a special boarding school, suddenly there's the

land of milk and honey, home therapy concentrates, everything is wonderful, people are feeling really good, their joints are good, started to do sports again. Everything is really, really coming along well. Then 1975, I recall -- again, we were just talking about him. Professor Mannucci had gone on to be head of the very large centre in Milan and he, amongst several other people, produced data that showed about 45 per cent, I think, in his paper of regularly treated patients had abnormal liver function tests of a hepatitic pattern. They didn't have hepatitis A, and hardly any of them had hepatitis B. So this was the very start, as far as I'm concerned, of this theoretical concept of, we think we're dealing with a third virus.

This term non-A, non-B came from the haemophilia doctors. You know, we started to realise something else is going on in here. It looks like many of our patients have been exposed to it.

However, they are not -- the pattern of the test results is not changing very much. Obviously every three months they came in and had the results checked. The results weren't changing very much. There were no signs of patients getting any clinical liver disorders. The patients kept saying to us, "I've

never felt as well as this, I never want to change, this is the treatment I've always wanted". So I think there was a feeling across the haemophilia doctors that we've noted this. It looks like there's a third virus, you've to speculate. If it is, it doesn't seem to be doing any harm. You know, viruses are variable. Maybe -- you see, cytomegalovirus can affect the liver. It doesn't do a lot of symptomatology. Maybe this is something like CMV. It's just causing a little bit of mild inflammation. The massive benefits of the new therapy are there for all to see. We're just going to keep an eye on this. So this was the first phase of what's going to change in a minute.

All of that changed radically around about 1978/79, again, of various studies. You are going to be talking to Professor Preston. The Sheffield group, in particular, did a study where they bravely did liver biopsies on patients with haemophilia who had abnormal liver function tests, and what their results from that study blew out of the water instantly the idea that this was nothing to worry about because their study showed, as did other studies, that most of these patients had very significant chronic liver disease biopsy. They had chronic active -- there's a range of different histological stages, ranging from

chronic active hepatitis to cirrhosis. Most of these patients were along that pathway.

So this was a dramatic finding and this changed haemophilia doctors completely to believe this is not something that we can just relax about and just keep a look at and ignore -- not "ignore" but not get excited about. This is a really serious evolving clinical problem and we really have to look very hard at, you know, how can we minimise exposure to this third virus (non-A, non-B as we still called it), what steps can we take to minimise further exposure to the patients already seen to have it and what steps can we take to minimise exposure to those patients who never received the concentrate?

Q. Dr Winter, there's a handful of publications in the 1970s I want to look at with you but, sir, noting the time I'd rather do that in one go and then ask you about them, Dr Winter, than split it over the break. Should we take the break now, sir?

SIR BRIAN LANGSTAFF: Yes. What we do, doctor, at breaks is we take 45 minutes because it allows those who are here to go and be served with their drinks and keep socially distant. It takes a while. So 45 minutes. We will come back at 11.45.

(11.03 am)

(A short break)

(11. 45 am)

MS RICHARDS: Dr Winter, I want to ask you a little more about your view that the sea change in the understanding of non-A, non-B hepatitis and its seriousness came with Professor Preston's publication in 1978.

I want to show you a handful of materials from 1974 through to 1977 and then ask you about them. I'm conscious they may not have been materials you would have seen at the time, not least because for part of that time you were still in general medicine, so that is understood.

Before we look at the first document, can I ask you this: would you agree that, at all the times we're talking about in the 1970s, hepatitis B was known to be a serious condition with potential long-term consequences?

THE WITNESS: Yes, and there were indeed occasional outbreaks of haemophilia B amongst treated haemophiliacs. There was one in Bournemouth, I think. So, yes, it was accepted that, whilst it didn't appear to be the most predominant type of hepatitis, it was a very significant virus and something that needed to be monitored, and people need to be vaccinated if they

hadn't been exposed.

Q. So, given that knowledge of hepatitis B, why would one expect non-A, non-B hepatitis to take a significantly different course?

A. Because, as I've said, different viruses have different effects on the liver. You see, if you have glandular fever, that usually -- if you measured somebody's liver function tests, you would find that part of a glandular fever episode that those tests were not normal. So viruses cause a whole spectrum of degrees of inflammation in the liver. Cytomegalovirus is another one where the degree of liver inflammation is relatively modest. I am sort of listening to myself saying this to you. I'm not a liver expert, but that's my understanding.

So viruses have different pathogenic effects on the liver and the point I was trying to make before the break was that we originally thought that non-A, non-B might be just a mild virus and nothing to worry about, and then things changed radically with these studies that we're about to talk about.

Q. If we have up on screen, please, Henry, PRSE0001431.

This is an article published in The Lancet in August of 1974 by Prince and others. We can see it's entitled:

"Long-Incubation Post-Transfusion Hepatitis without Serological Evidence of Exposure to Hepatitis B Virus."

There are just two passages I'm going to ask you to look at, Dr Winter. The first is just the summary:

"An agent other than hepatitis B virus seemed to be the cause of 36, 71 per cent, of 51 cases of post-transfusion hepatitis identified during prospective biweekly serological follow up of 204 cardiovascular surgery patients. The sera of the 36 cases showed no evidence of the antigen or antibody response expected to accompany infection by HB virus and to be detectable by the sensitive assays used. Incubation periods and clinical and epidemiological features were inconsistent with hepatitis A. Cytomegalovirus-associated seroconversion was no more common among the HB-negative cases than among the HB-positive cases or among patients who did not develop hepatitis. The data suggest that a large proportion of long-incubation post-transfusion hepatitis is unrelated to hepatitis B and that control of the post-transfusion hepatitis will require identification of a hepatitis virus(es) type C."

Then, Henry, could we go to the last page of this, and we'll just pick up one more passage,

Dr Winter. If you could zoom in on the top left-hand column, please, Henry, picking up the third line down:

"The fact that non-B hepatitis cases are less frequently associated with serious acute illness does not imply that such cases are of lesser importance. Long-term complications of acute hepatitis B infection, such as chronic hepatitis, cirrhosis, and hepatoma, have been reported to follow mild anicteric infections more frequently than severe icteric cases; consideration must thus also be given to the possibility that non-B hepatitis may play a role in the aetiology of some forms of chronic liver disease."

So that's the first one. I'm going to show you four and then ask you some questions. As a matter of fact, do you think you would have read that at the time? It's The Lancet, but you were still in general medicine.

A. I may well have done. I mean, it does bring -- we're going to talk later about this, are we?

Q. I am going to show you four, I think, and then ask you to discuss them. So that's the first.

So you might have seen it, but you can't say one way or another?

A. I cannot remember papers I read 45 years ago.

Q. That's understandable.

The second document -- Henry, could we have PRSE0000381. This is a publication in the Yale Journal of Biology and Medicine in 1976. "Non-A, non-B hepatitis". Purcell, Alter and Dienstag.

If we could go, please, Henry, to the fourth page, and if we could zoom in on the paragraph beginning "Although type non-A, non-B". That's the one there. Thank you. So this is now 1976, and this particular paper says:

"Although type non-A, non-B hepatitis is associated with less severe acute illness than type B disease, as judged by frequency of jaundice and magnitude of SGPT elevations, the long-term prognosis for the two diseases may be similar. Thus, elevation of transaminase values persisting for six or more months has been observed more frequently following non-A, non-B disease than following type B hepatitis. Others have reported similar results. Transaminase elevations have been documented for several years in some patients. Three such patients at the NIH underwent liver biopsy; two had histopathologic changes in the liver compatible with chronic active hepatitis, and the other was diagnosed as having chronic persistent hepatitis. Thus, chronic non-A, non-B hepatitis is not necessarily a benign infection

and may be the cause of a significant proportion of chronic hepatitis not identifiable as type B disease."

Again, I'll come back to the content. As a matter of fact, do you think it's likely that you would have read in 1976 this, which is the Yale Journal of Biology and Medicine?

A. No.

Q. Then the third one, Henry. Could we have NHBT0000092_002. This is the report in -- of an international forum in Vox Sang, 1977. You will see the title is:

"How Frequent is Post-Transfusion Hepatitis After the Introduction of Third Generation Donor Screening for Hepatitis B? What is Its Probable Nature?"

It appears to be the text of a speech delivered by Harvey Alter in the international forum, or a publication for that purpose.

If we could just go to the second page, please, Henry. The last paragraph of the article. If you could zoom in on that:

"Although non-A, non-B hepatitis is, on the average, less acutely severe than type B hepatitis, it can cause severe acute disease and, more disturbing, it appears to have considerable propensity to progress

to chronic hepatitis. The major thrust of post-transfusion hepatitis research must now be directed at developing detection methods for the non-A, non-B agents, or developing some reliable method of viral inactivation or removal which would be independent of testing."

Again, before we consider the content, this is now 1977, so you're, I think, undergoing your specialist training by then, but is this the kind of publication you would have seen at the time?

A. Which journal was this?

Q. It's Vox Sang?

A. Vox Sang was really a sort of blood transfusion journal. I wouldn't have read that routinely.

Q. Then the fourth document, Henry, is RLIT0000228. This is another publication from 1977. It's by Hoofnagle and others. The publication, Dr Winter, is Annals of Internal Medicine. Could we go to the last page but one, Henry. It should be the sixth page. Could we zoom in on the right-hand column. It's quite a long passage, Dr Winter. I am going to read it, as much as anything, for the benefit of those listening:

"Several clinical and epidemiologic features of non-A, non-B hepatitis have become clear from studies such as the present one. First, non-A, non-B

hepatitis closely resembles type B hepatitis. The incubation period, the clinical symptoms and signs, and the potential for chronicity appear to be similar to type B hepatitis. Undoubtedly, what was once referred to as serum hepatitis included both type B and non-A, non-B hepatitis. Second, non-A, non-B hepatitis appears to be spread predominantly by the parenteral route. Most cases have been described in association with transfusion, intravenous drug use or serum inoculation."

Then if we skip down to his third point:

"Third, non-A, non-B hepatitis appears to be associated with a chronic carrier state and chronic liver disease. In this study, sero taken from HB negative donors 149 to 385 days after an implicated transfusion were found to be infectious. These implicated blood donors were, for the most part, asymptomatic, although liver function tests and liver biopsy examinations frequently showed evidence of underlying chronic hepatitis. Finally, non-A, non-B hepatitis appears to be common. Three of the five infectious donor studied here transmitted this non-A, non-B hepatitis."

Can we scroll down a bit further, Henry. Then it goes on to suggest that more than 90 per cent of

post-transfusion hepatitis may be due to non-A, non-B hepatitis.

That's 1977 Annals of Internal Medicine. Is that a journal that you would have read at the time?

A. That was on my reading list at that time.

Q. Now, we then get, obviously, to 1978 and Professor Preston's publication which you've referred to and which you recall and you have already described. Just looking at those materials, and Dr Winter, I accept that you were in training at this time or, indeed, in general medicine at the first time, but looking at that material now, would you accept that if clinicians in the mid-'70s had formed the view that non-A, non-B hepatitis was a mild or not clinically significant condition, they were wrong to do so at that time?

A. One of the major problems of all this is we did not know what we were dealing with. The term "non-A, non-B", there was talk very often this might be several viruses. This might be hepatitis C, D and E. It might not even be a hepatitis virus at all. Somebody getting non A non-B after a blood transfusion, 1 pint, how does that compare with someone getting non-A, non-B after being exposed to Factor VIII concentrate from 20,000 blood -- 20,000

donors?

So I think those were all difficulties in interpretation really. I mean, as I recall, I don't think that haemophilia doctors dismissed the abnormal liver function tests. The major dynamic I can only stress to you because I remember it so clearly was, if you like, there was a sort of unwillingness to think it might be a problem because this new treatment had brought such spectacular benefits and because the patients were so enthusiastic about it that I think that people were reluctant, if you like, to say this is a serious problem.

There is a point here that we should have made a few minutes ago. When you get non-A, non-B, most but not all patients are asymptomatic. Some people do have symptoms. If you get Hep B, most people are symptomatic. When, 1991, whatever it was, I got Hep C testing, and I told all my positive patients, most of them said, I've never had any symptoms of jaundice. I don't recall an acute attack. Nobody ever said to me I was yellow. You know, this is a surprise to me because I've never felt unwell. Other patients very much did. So there are differences there.

I think it was just -- I do think the fact that it was linked into such an obviously tangible therapy

was one aspect of this, but I don't think it's true to say that haemophilia doctors dismissed it. We just maybe -- you know, if we'd known then what we were to know five years later, we might have done things differently, maybe in terms even of doing liver biopsies.

I mean, one of the major features that we learnt subsequently, which is a very important observation, is that when you take a blood test and look at somebody's liver function tests, you know, the levels might be twice the normal range or four times or six times. It turned out there was very little link between the degree of abnormality and what their liver biopsy looked like. So that's very important. It was totally invalid to say to somebody, oh, your liver's less inflamed than three months ago because your AST level was 140, and now it's only 80, so that's good, isn't it? All that was completely not right.

This, again, of course, was another major difficulty about monitoring the state of non-A, non-B. We came to realise, just to do somebody's liver function tests didn't actually tell you anything informative, and the only real way to see what clinical effect the hepatitis was having was to do a liver biopsy, and nobody wanted to do a liver biopsy

on someone with haemophilia. There was a patient who died after having a liver biopsy. You know, these people have the most profound bleeding tendency known to medical science. You're probably spending £5,000 worth of Factor VIII beforehand and afterwards to make sure they don't bleed. You really need a jolly good reason to want to do that.

Q. I understand that there were uncertainties. Again, just looking at this mid-70s period. I understand, and the materials we've just looked at show this, that there were differences observed in the acute stage of the illness as between hepatitis B and what was becoming known as non-A, non-B hepatitis.

What I'm really trying to do is try to understand -- and in some respect, Dr Winter, you're the vehicle for doing so -- try to understand why clinicians worked or seemed to have worked, to some extent at least, on the assumption that the long-term consequences, beyond the acute stage into the chronic stage, of non-A, non-B hepatitis was going to be less severe than hepatitis B.

You have given us -- you've pointed to uncertainty, you've pointed to what might have been an unconscious unwillingness or even a conscious unwillingness to look beneath this golden therapy.

Are there any other reasons that you can think of why clinicians don't appear to have fully grasped that non-A, non-B hepatitis in its chronic stage could be very serious, until Professor Preston's publication?

A. Well, I think the initial symptomatology is another part of it. I mean, if you've got somebody with hepatitis B who's really sick at presentation, then the patient will never forget that, and that's an important part of the history that comes with the patient.

I think part of it also were these patients were not only well, they'd always been well. They hadn't sort of come in with diagnoses of acute clinical jaundice. So I think that's another feature.

I mean, subsequently, the UKHCDO always had a liver disease working group, and it seems to me, looking back now to this time, in view of all the uncertainties that you're perfectly reasonably raising, I wonder why, unless -- you know, why didn't they constitute a liver working party at that time and ask some liver specialists to get on board?

I mean, you're asking me all these questions about the way in which haemophilia doctors thought. Haemophilia doctors are not liver specialists, and,

you know, we don't have specialist expertise in matters of hepatitis.

So I don't know the answer to your questions but it seems to me, in retrospect, I wonder whether anybody had thought of forming a hepatitis working party with some liver specialists on board. Because that's certainly what happened in the 1980s. I don't think I was ever on one but I remember such working parties existing and there were liver specialists from the Royal Free in particular, I remember, who gave very valuable advice about the management of hepatitis.

Q. There was, as a matter of fact, and there's no reason why you would have personally known this at the time, Dr Winter, there was a Hepatitis Working Party established by UKHCDO in the 1970s -- I can't remember off the top of my head the precise date -- with Dr Joan Trowell, who was a liver specialist part of it.

Before you joined Guy's and you were at Middlesex, is it right that Professor Stewart was the director there?

A. Professor Stewart.

Q. Did Professor Stewart ever report back to his registrars information he'd gleaned from UKHCDO

meetings about non-A, non-B hepatitis or liver disease?

A. No, it was a very small centre and a major haematology centre. So haemophilia was a very -- you know, it was a very small part of the workload as far as Professor Stewart was concerned.

Q. Lest you wonder me why I ask that, there was a presentation by Dr Craske of the Hepatitis Working Party in 1978 at the UKHCDO AGM which was attended by both Professor Stewart and Dr Barkhan. But, in any event, whatever they may have learnt from that was not shared with you at that time?

A. No.

Q. You've already mentioned Professor Preston's research which was published in The Lancet in 1978. That appears on any view to you to have been a very significant development, from the evidence that you were giving before the break.

Would you accept that, at least from 1978 onwards, haemophilia clinicians should have worked on the basis that non-A, non-B hepatitis was potentially a very serious condition?

A. I mean, Professor Preston's was not the only study, as I recall. This -- you know, doctors always -- not -- cynical's the wrong word, but you read a paper from

a particular group that puts as -- a new observation, you want to see it confirmed by somebody else from another centre and these observations were. So there didn't seem any doubt at all for -- you know, any reason why a doctor should look at this data and say, "Well, I'm not sure I believe that". Sometimes doctors do read papers and say, "I don't think I believe that". The evidence seemed to be very strong.

So, for me, this is one of the sort of key moments -- in the whole of the viral epidemic amongst haemophilia patients of contamination, this was an absolutely key moment, where any haemophilia doctor should have switched from a viewpoint which was "I've noted the abnormal liver function tests of my patients but they are very well and I'm just keeping an eye on it and they have probably got a mild form of a virus" to "I'm very concerned about what appears to be liver biopsy demonstrable significant damage of a range of abnormalities, from chronic active hepatitis to cirrhosis, in these patients which doesn't seem to bear any relationship to the state of their liver function test, so I'm not going to be able to monitor this accurately, I can't tell whether it's getting worse or better except by doing a liver biopsy and

I absolutely don't want to do that on somebody with severe haemophilia."

So we've used the word "sea change". This is one of the great sea change moments in the history, and I would have expected every haemophilia doctor to say all the rules have changed on this one and chronic liver disease is a major clinical problem in haemophilia.

Spilling out from that, more activity around the question of self-sufficiency. You know, Dr Owen's initiative has been and gone, things have gone into not much in the way of progress '77/'78. We're still importing significant amounts of imported blood. Elstree's about to be closed down, I think, because of the unsatisfactory state of the building.

You would think the other thing that would have come out of this would have been increased political pressure from the UKHCDO on the Department of Health to say look at this data, you know, this is a really different way of looking at this problem. It now really does seem to be severe -- nothing known about AIDS -- and it underscores what we've been saying for the last few years about the importance of becoming self-sufficient.

Q. Before I ask the question, let me show you a document.

This is March 1979, The Lancet, so it's one you may have seen. It's PRSE0004067.

So this is The Lancet, March 1979, "Transmission of non-A non-B hepatitis to chimpanzees by Factor IX concentrates after fatal complications in patients with chronic liver disease". It's a number of authors, including, as you will see, Professor Zuckerman.

Could we just go, Henry, please, to the last page, last paragraph. No, that's not it. I'm sorry, the last paragraph of this article. So it's the left-hand column, Henry, my apologies. Beginning "Until blood donors". No, not that bit, the paragraph above.

So this was the view expressed by Professor Zuckerman and others:

"Until blood-donors can be screened for the non-A non-B hepatitis agent, it would seem wise to restrict the use of both commercial and non-commercial concentrates to life-threatening situations."

Then they go on to say that:

"In particular, their use in patients with chronic liver disease should be avoided ..."

Do you think it likely that you would have seen this article in The Lancet in '79?

A. I probably would. I mean, there are two obvious problems with this paper, talking about doctors looking at papers and raising their eyebrow.

Firstly, we came to have no faith at all in chimpanzees, anything to do with a chimpanzee. There was a very famous study evaluating a new form of Factor VIII which was given to chimpanzees and they were absolutely fine and it was then introduced into clinical practice, and several patients got hepatitis. So it became clear that chimpanzees were a totally unreliable model for looking at hepatitis. So, as a doctor reading that, I wouldn't have been very impressed about -- just because it's involving chimpanzees.

The second thing, I mean, these people are not blood specialists. They want to restrict the use of concentrates to life-threatening situations. Haemophilia is a life-threatening situation. There's a very high incidence of very serious bleeding. So I couldn't accept that bit. I could accept about restricting the use of commercial concentrates wherever possible. Doubtless we'll talk at some stage, today or tomorrow, about haemophiliacs not having treatment and maybe avoiding the risk of virus infections. It's a very -- well, it is the most

severe bleeding tendency known to medical science. So the idea of not treating it, to a clinician like me, is not acceptable.

Q. I will come back to that, Dr Winter, but do you recall whether there was any discussion about this recommendation? Were you at Guy's by then?

A. No, it wouldn't. I can say for sure that it would not have got off the ground if it had been presented at a haemophilia meeting. The haemophilia clinicians were completely signing up to the principle of continuing to give treatment, as were the patients, and, of course, including The Haemophilia Society, who wrote a letter to the DOH imploring them not to stop importing commercial concentrate. So this wasn't just the doctors who wanted to carry on the treatment, it was the patients' organisations as well.

Q. Do you accept that, given what you have said about the change following Professor Preston's work, that patients should have had that explained to them, spelt out to them, that there was now a risk that they might get non-A, non-B hepatitis which was now understood to be potentially more serious than had previously been thought?

A. I mean, patients already knew they had presumptive non-A, non-B because, you know, they were told -- at

least in our centre and I'm sure in, you know, other centres -- that, you know, one of the things that happened at a comprehensive care review was review of the previous visits' blood tests, and doctors like me would sit down and say, "You know, you've done your blood tests again and, as you know, you've got this abnormal pattern of liver function, but it doesn't seem to be changing". As I've said to you, we now know it wasn't a valid statement as to in any way predicting what their liver inflammation was going to be in vivo, as it were, and patients were aware that we were trying to, as a country, move over to a situation of self-sufficiency, and they were supportive of that. Very, very strongly. As I said to you, they really did not want to have American concentrate if at all possible.

Q. I understand your evidence that patients may have been aware of non-A, non-B hepatitis as a concept -- at least you say your patients would have been aware of that -- but given that you have told us that clinicians, until 1978, or some clinicians at least, in the world of haemophilia didn't think it to be necessarily a particularly serious condition until 1978, when the risk of chronic liver disease became apparent, unless the haemophilia clinicians

tell the patients that it's now known that there's a risk of chronic liver disease, patients aren't going to know that, are they, because they are not going to be reading Professor Preston's publication in The Lancet?

So would you accept that patients should have been told in or after 1978 of this new understanding of the seriousness of non-A, non-B?

A. I mean, they were getting -- already getting advice about healthy lifestyle. So they would have been told how to minimise the chances of their liver problems progressing. So, you know, eat a healthy diet, not too much fats, particularly obviously about alcohol usage.

So we get into quite an interesting area here. Let's just walk through. I'm a doctor dealing with a patient like that. I now believe that the liver disease might be more significant than previously. I'm already following the patient. I'm monitoring him. Should I say to the patient, "There's a recent paper that says that people like you actually might get cirrhosis, and I'm just telling you this even though I've got no way of monitoring you and no way of treating you"? We get into quite philosophical territories here about -- this is actually something

we'll talk about with variant CJD as well, which is similar. I worked as a doctor by believing that the patient should have the truth, but does that go down to being every single paper that said the following things might happen to you even -- you know, how much can you and should you tell a patient? You obviously must tell them the core things about their illness. I can't remember, 40 years later, whether I discussed these papers with the patients. I wasn't even a consultant. I can't remember.

I think it's very important that the patients were aware that their liver function tests were abnormal because they needed to follow the instructions I've just outlined to you. I don't -- I can't express a view as to whether they should have been told about what Professor Preston's papers had shown.

Q. I understand that you might not descend to the detail of specific papers with patients, Dr Winter, and I understand also the difficulty of being asked to recall what your advice would have been in the late 1970s. But you've posed the philosophical question; I am going to pressure you to answer it.

Do you accept that in 1979 the patients should have been told that there was a possible risk of

chronic liver disease from the treatment they were receiving?

A. I really do accept that, yes. And I think because it would help to reinforce the point (which for some patients, you'll understand, they were reluctant to follow) that they really needed to take this issue seriously and, for some of them in particular, that really did mean moderating their alcohol intake.

So I think as a sort of lever for patient compliance as well as a process of giving the patient information, I do accept that patients should have been aware that not only did they have a form of abnormal liver function, which I'm sure they all knew, but that there was evidence that it could have been -- you know, this matter might be more serious than had been thought previously.

Q. You said in your statement that the information that would have been given to patients -- this isn't specifically as at 1979, but would have been strongly in favour of the expectation of a positive improvement in lifestyle.

I think what I'm suggesting, and I think you probably agreed with this, is that that's one side of the coin, that's the great advantage of the concentrate treatment, and the other side of the coin

is the potential risks and patients would need to know both, not least because, as you've said, they would need to take seriously the lifestyle and other advice that clinicians would be giving them.

A. Yes. I mean, I can't stress to you enough the difference that the concentrate made. In the documentary, you know, one of the mothers said, "You know, my son went to hospital 79 times last year and missed 35 days off school on cryoprecipitate."

It was not at all a good treatment. It was a treatment.

I think there was an element, too, you've quite rightly got these two sort of scales: benefit and risk. We were so full of benefit. This was the first time -- haemophilia was around in biblical times. In 2,000 years of early death from bleeding at the age of about 20 on average, for the first time there's a decent treatment. The boarding school is closed, people can work, people can play sport, people got their lives back and, if you like, they didn't want to see the risk. And I think that applies to not only the patients, it very much applied to the doctors.

And I -- you know, there are ways in which doctors and patients look at illnesses, and I think I accept the point maybe it was understated at the

time. It's so difficult 40 years later. I don't think the patients wanted to hear about risk and I think the doctors, you know, didn't want to hear about risk. That's the way the brain works. They -- everybody was so full of "this is incredible, the change".

You know, to see a patient with haemophilia brought up before concentrate, or who'd never had Factor VIII concentrate in their life, if you went to a World Federation of Haemophilia you'd see these poor people with, like, the worst arthritis you have ever seen in their life. They'd be just shuffling along. None of their joints moved. If you watch television footage, there is some, of the tsarevich in Russia, he's 13 years old, before his murder. He's being carried. He is being carried by a sailor. He can't walk.

So this is what life was like for people with haemophilia. Even on cryo. Cryo was a treatment, but it wasn't a good treatment.

So suddenly, for the first time ever for this dreadful disorder, there is a decent treatment. People don't want to hear, oh, there might be a problem. I'm just making a point about the way the illness was looked at.

I accept the points you make but that's the way it was perceived. I fully accept -- because it was difficult to get patients to comply, some patients, because some human beings like to drink and some people obviously felt, "You don't want me to have alcohol" -- that's the ideal -- "I've got this hepatitis", and to be able to say -- or you've got to say to them, you know, "There's recent evidence that this thing might be more serious than we had originally thought", that should have been made clear to them. Of course I accept that.

Q. I know it's hard to remember what you did, as a matter of fact, say, over four decades ago or four decades ago. Do you think, however, it's more likely than not that in your personal case -- not talking about other clinicians -- that you advised your patients about this change in understanding, albeit potentially in an understated way?

A. I just can't remember. They would certainly have been told their liver function tests. They would have been given information from me and written information about diet and alcohol avoidance. I just can't remember as to whether I spoke about Professor Preston's paper.

Q. Before we turn to consider HIV, just a more general

question, again, thinking about the 1970s in general, rather than any specific year within that.

Would you have consciously understood and thought about the risk that pooled products, whether they were imported or domestic, might contain viruses not yet known to medical science? Is that something that clinicians would have had in mind, that possibility that there could be something there just not yet known about?

A. Very much so. A central mantra for all the time that I was working was, it wasn't the virus you knew about; it was the virus that you didn't know about. If you looked at the history of blood products, every few years you would come -- there would be a new virus apparent and, most importantly, it would then become apparent (as we'll discuss with HIV and obviously with hepatitis C) that it had been there for some time. So we used to have a system in the hospital where we were told to bag up high risk. Somebody had hepatitis; they had to go in a special blood sample. And I vehemently opposed that because I said to the microbiologist, but all blood is -- all blood and blood products are risky because, you know, how do you know what we're about to discover in three years?

What's built up from that is, when you are

trying to get Factor VIII for your patients, there were two aspects to that safety. There's the viruses you know about, but there's also the purity of the concentrate. I had great difficulty trying to persuade or to get enough finance to enable me to get a treatment that was not only very safe, away from the viruses we knew about, but was very pure. Concentrates contain proteins. Even recombinant contain proteins. So I felt that the more pure the product was, it was more likely, too, to be getting rid of any viruses you hadn't yet encountered.

So your points, actually, are really important. At all times, we were wary of the possibility of new viruses coming through, and, you know, that hadn't yet been discovered. There was this work going on for self-sufficiency. It wasn't just to combat the viruses we knew about and the theoretical ones -- non-A, non-B -- that we were -- you know, when we spoke about non-A, non-B in the mid-1970s, we were right. There was a non-A, non-B, and 15 years later, we were proved to be correct. So there were a lot of conversations about, you know, what if? What if there are other viruses? So that was a very central part of the thinking.

Q. That leads us on to HIV.

SIR BRIAN LANGSTAFF: Just before we go there, if I may, may I just ask you this, doctor: you have described the unwillingness of colleagues, others in jobs such as yours, to accept that the factor concentrate that they were having might have this dangerous virus we now know as hepatitis C, then non-A, non-B.

Why do you think -- what do you think was the consequence of accepting that it did that they feared?

A. Well, I hope we haven't been at a misunderstanding. I've not tried to say that haemophilia clinicians thought that their patients, the majority of regularly treated patients. Had some form of chronic hepatitis. I think everybody accepted that. The issue was: how serious was it? The point I tried to make was, for several years, particularly in tandem with the tangible benefits, it was accepted as being there, but the patients were well, so we'll just keep an eye on it. And then suddenly to this very profound change when these reports of abnormal liver biopsies started coming through. I think that's the major point I've been trying to get across, you know, throughout this conversation.

I don't think for a minute any haemophilia doctor denied that there were issues around the abnormal liver function in these patients who were

regularly treated.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Dr Winter, so turning to HIV, we'll look at, please, Henry, PRSE0000523. This is really just to give us a date to work with, Dr Winter. This is the MMWR for 16 July 1982 and the Centers for Disease Control reports of three cases of PCP pneumonia among patients with haemophilia A. That, obviously, is in the context, and I'm confident from your testimony to Lord Archer and to Lord Penrose that you know the pre-history of earlier reports from, in particular, through 1981 and the first part of 1982 of the increasing number of cases of what later became referred to as AIDS.

So this is a report of cases amongst patients with haemophilia. Would you have at the time seen MMWRs?

A. Yes. Very much so. So, if we may, let's just walk through that one year because it's so central to what happens next.

So all doctors would have been aware of, you know, 1981, these reports of the gay patients with a new disease. What's it due to? Well, the suggestion initially, for at least a year, was that these were clearly disorders that were only seen in

people whose immune systems were not working properly, either because they had an underlying medical disorder, or because they'd been on chemotherapy or something like that. So it was clear these people -- these were gay patients -- something had happened to their immune systems as if they had just had chemotherapy. So what could have been doing that? There was evidence that poppers, amyl nitrite that they were taking on social occasions, was suppressing the immune system.

That was the initial theory. There was no suggestion at all it was anything to do with blood or anything transmissible. And here's another major sea change moment in the whole of the epidemic is this report. I'm going to tell you, if you don't know this, the background as to how this happened.

When you have this pneumocystis, this unusual pneumonia that only happens in immunosuppressed patients, the treatment of choice is a drug called pentamidine (which is a very, very rarely used antibiotic) and it transpired that the only way you could get pentamidine in the US was to ring up the Center for Disease Control in Atlanta and speak to a doctor called Bruce Evatt, who became a very major figure in haemophilia. And in the space of one month,

he had three hospitals on the phone, these three patients saying, "I've got a patient with haemophilia, with pneumocystis. Could you please send me some pentamidine?" Bruce Evatt obviously said, "Well, why? Why are these patients with haemophilia getting the same immunosuppressed-type illness that the gay patients from last year" -- so this is an absolutely critical moment. Here is surely a sign that we are dealing with a transmissible agent of some description, followed shortly by this case in San Francisco of a baby who had a platelet transfusion from a donor who subsequently developed AIDS.

So in this period of six months, say, from July '82 to December '82, by the end of that period, as a haemophilia doctor, you would have to look at that data and say, I'm really concerned that this new disease is actually nothing to do with poppers or anything like that. This is something which is in blood. This must be a virus or something like that, and we urgently need more information to tell us who else might have this virus, if that's what it is, so we know how to respond to this apparent potentially very serious problem.

Q. I'm just going to ask you to look at the way you put it in your evidence to Lord Penrose. Henry, it's

PRSE0006016. This was your evidence in April 2011. Could we go to page 8, please, Henry.

We can see the way in which you put it, picking it up at line 10. This is part of your answer:

"So shall we say September 1982 there is uncertainty. There is this very small number of cases. We don't have an agent. What does it mean? There are other theories. Most of the patients are gay."

And then you say this, and I'm just going to read it aloud for the benefit of others as well:

"By December 1982 that theory is no longer tenable because you have now ten patients with haemophilia, but most particularly you have this case."

That was the San Francisco baby case I think you were referring to there, Dr Winter:

"Any clinician looking at this data would have to believe that AIDS was a transmissible disorder and that it could be transmitted by blood and by blood products. It was the only clinical interpretation of the data that was available. There was no other way that this child could have acquired this very unusual condition; very unusual for a baby to have these series of opportunistic infections. So it was very

highly likely that it must be AIDS and must have been caused by the blood transfusion from the donor who subsequently developed AIDS. So here is a really critical moment. Doctors everywhere now have to believe that AIDS is a transmissible disorder."

That is effectively the same answer that you have already given a few minutes ago, but would you -- does that remain your view?

A. Yes. So at this moment in time, we're now really believing that there are two major problems with concentrate therapy. Firstly is, the liver disease is much more significant than we thought. Secondly, we're at the start of something which we are really very concerned about. This sounds -- this new disease sounds like a transmissible disorder, and we very rapidly need identification of what the agent is, a test for it, and some understanding of how to respond to it. But it is underscoring -- set against the extraordinary benefits of concentrate therapy, it's really stressing the dangers of concentrate therapy.

Q. In addition, too, by December 1982, understanding as you explained there and have explained again that the likelihood that this is a -- something transmissible by blood, would you accept that it is also clear at

that stage, December 1982, that this is a condition with a very high mortality rate?

A. Well, that seemed to be the case. Obviously, you are dealing with very, very small numbers of cases.

Q. It was also evidence, by that stage, that there was potentially a significant lapse of time between the initial infection or transmission of the agent and symptoms presenting themselves.

A. Well, we didn't know that because we didn't know -- we didn't know when the gay patients had been infected if it was an infectious agent and we didn't know, similarly, with the haemophilia patients because they would have been multi-treated, and we didn't know which batch might have had the agent in it.

Q. You have already referred to the New England Journal of Medicine, and we'll just look at that. I know you are familiar with it, Dr Winter. It is PRSE0002410, please.

This is January 13, 1983. You see on the right-hand side, "AIDS and the preventative treatment in haemophilia". We will just look at the last paragraph of this article which is on the next page, Henry, bottom of the left-hand column. It says this:

"The fact that haemophiliacs are at risk for AIDS is becoming clear. If the use of cryoprecipitate

will minimise this risk, the current home infusion programme needs to be revised. The studies reported in this issue demonstrate in vitro abnormalities of immuno-regulation, but the numbers are too small for definitive comparison of the risks of different modes of treatment. Unfortunately, the data are consistent with a greater potential for AIDS in the population treated with concentrate. Physicians involved in the care of haemophiliacs must now be alert to this risk. Preventing the complications of the present treatment may have to take precedence over preventing the complications of haemophilia itself."

Now, I'm going to come back to or come on to in a while the question of the use of cryoprecipitate. But you recall, as I understand it, reading that article at the time?

A. I do.

Q. We're just going to play a second extract from that 1988 documentary, so be prepared for your younger self on the screen again, Dr Winter. MDIA0000111, and it's the second excerpt, please, Henry.

(Video played)

You would, I think, agree, given your evidence thus far, that this was a warning that haemophilia clinicians could not and should not ignore?

A. Well, however many alarm bells a human being has, they should all have been ringing at this stage.

Q. Now, you were still working at Guy's at this time, end of 1982, and indeed for most of 1983. Can you recall what discussions took place between you and your colleagues, your fellow registrars who are managing the haemophilia patients, or with either of the two consultants about this issue?

A. Well, what I recall is that UKHCDO had responded to the evolving situation, in terms of issuing recommendations to minimise risk. So we certainly implemented trying to avoid the use of concentrate where at all possible. So DDAVP, obviously, for mildly affected patients with haemophilia where at all possible; could surgery be postponed if it was a cold surgery and the patient didn't need to have the surgery too quickly; the use of cryoprecipitate maybe in children very reluctantly. These were the sort of factors that UKHCDO were recommending as a sort of holding measure that haemophilia centres introduce.

There was no recommendation that concentrate should be withheld or withdrawn. As I've said to you, the patients wanted to go on with treatment. The Haemophilia Society wanted to go on with treatment. That was really the sort of only interventions we

could do, or modifications if you like, of the current programme to minimise risk.

Parallel with this, one would like to know, if it hasn't, you know, come out in the Inquiry already, why were all the alarm bells not ringing at the Department of Health, you know, in terms of accelerating a process of redeveloping our blood fractionation plants so that this country could be self-sufficient in blood products, as other countries had achieved. So this alarm bells question, of course, isn't just for clinicians; it's for politicians and people who plan the supplies of the concentrates that we were using.

Q. We will certainly be looking at that.

The UKHCDO advice -- it was June 1983, but I just want to -- and, again, I know I'm asking you about events a long time ago, but I just want to go back to the beginning of 1983. So for the first half of 1983, there's no published advice from UKHCDO. Do you recall whether you began to make the adjustments you have described at the beginning of 1983, or was that only after the UKHCDO recommendations from June of 1983?

A. I can't remember. I mean, I certainly read the Deforge paper, and we were aware of it, and we had

taken what steps we could. So I'd like to be able to say we introduced those changes that UKHCDO recommended a few months later at that time, but in all honesty, I can't remember whether we did or didn't.

Q. You have said in your statement that, in relation to children, BPL product was prioritised. You already were prioritising it, so is it right to say it became a greater priority?

A. Well, we already were. We would have been extremely -- it already was the first priority, and we had enough BPL supplies coming in to treat children because, obviously, the amount you needed for the children was less than adults, and there weren't in any case many children. So I'm sure that we went on treating these children with BPL product. But we very much sort of concentrated things around when the concentrate was actually needed. I mean, it's possible that we might have suspended prophylaxis programmes. I just can't remember. But we certainly -- to senior registrars, we would have said to each other -- the key message was, do not give concentrate unless the patient absolutely needs it.

Q. What would the criteria have been for absolutely needing it, then?

A. Well, a patient with a significant bleed, which is normally meaning joints and muscles. Obviously, any period of internal bleeding, most especially cerebral or gastrointestinal. Patients who had had trauma, significant trauma, that wasn't settling down with conservative measures, and patients who needed major surgery which could not be postponed because they had cancer or something like that. Those would be the sort of major indications.

Q. So the aim would have been to use concentrates only in those kind of occasions, and would that only have been for severe haemophiliacs by then?

A. Mainly, but if you had a mild haemophiliac who had bowel cancer and needed major bowel surgery, you would have to give them Factor VIII.

Q. Do you recall whether given this, as you say, this second new risk, were any attempts made to get more BPL product to reduce the size of the shortfall through discussions with Tooting or elsewhere?

A. Certainly not by the consultants who I worked for who had really devolved haemophilia care to us and, in any case, it was a long-running issue (the shortfall of BPL, as I've described to you) in these two Thames regions. It was a very long-running and unsatisfactory saga and there was nothing, as

registrars, that we could do to increase the supply. Everybody wanted more supplies from BPL and the reply was always the same: you're only getting so much because Tooting are only sending so much to Elstree.

Q. Then the next question, Dr Winter, is, given what you say should have dawned on haemophilia clinicians by the end of 1982, do you accept that this is information that should have been shared with patients?

A. About what in particular?

Q. About the view, as described by you to Lord Penrose and in your evidence here today, that the AIDS was in all likelihood caused by blood or blood products and haemophiliacs might be at risk?

A. Oh, yes. Because, you know, it really was a significant concern. There was a clear policy of moderating concentrate usage. So we would have said to patients, "You know, we want you to go on using concentrate for occasions when it really is needed" -- and we would have outlined that -- "but, you know, we want you to be absolutely sure in the home setting that you give it for a good reason."

I mean, the reality of haemophilia life is that patients didn't always give Factor VIII for a good reason in the home setting, and we wanted to make sure

that they were only using it under the sort of clinical indications that I've just given to you.

Q. To ensure that, do you accept, first of all, that patients should have been told of the possible risk of AIDS?

A. I do.

Q. Do you recall that that was information that you yourself gave to the patients at Guy's at the time?

A. I do. In any case, around this time there are communications from The Haemophilia Society to patients, are there not, about this new disease I think?

Q. There are.

A. You are going to know the answer to this better than me.

Q. There are. Whether those are communications which correctly conveyed the risk is another matter which the chair will be considering in due course.

A. Yes. But suffice it to say that the new disease, if we call it that, was being widely discussed throughout the wider haemophilia community, in terms of Haemophilia Society meetings, seminars, the bulletins that went out to each of the patients, in addition to the information that patients were getting from their own centres.

Q. Now I want to move to ask you some questions about cryoprecipitate. In your witness statement -- and it may assist if you have your witness statement before you, I think you've got a hard copy of that?

A. I haven't got one. It's in the other room.

Q. In that case we can always rectify that after lunch because it will probably take longer than seven or eight minutes. But in your witness statement at paragraph 35.3 --

(Handed)

A. Thank you.

Q. So if you turn, Dr Winter, to paragraph 35.3.

A. 35?

Q. Yes, 35.3. So it's on page 6 of 25. Under the heading "Cryoprecipitate", you have identified there, and over the page, seven disadvantages of cryoprecipitate, and I want to ask you about those.

The second disadvantage you have identified is it wasn't effective in Factor IX deficiency. I am going to ask you to leave that to one side because that might be relevant, obviously, to treatment decisions in relation to treatments with haemophilia B but wouldn't be relevant to treatment of patients with haemophilia A.

So could we start then with the view there set

out that cryoprecipitate which was much less effective clinically than Factor VIII concentrate.

First of all, can I ask you to explain what you meant by that.

A. So let's just walk through this. I'm picking this up as a demonstration as this is actually the size of a bag of cryoprecipitate roughly. *(Indicated)*

So these had to be deep frozen and to give somebody cryoprecipitate, you would go to the deep freeze -- hospital treatment only, people didn't have domestic deep freezers, there was no home therapy -- and two doctors or transfusion technicians would take out 20 of these bags and throw them into a water bath, where they had to be left for about half-an-hour to thaw, and you would then be left with a sort of yellow sludge that looked rather like Lucozade, if anybody is old enough to remember Lucozade.

You then, the two of you, rolled them up into a big master bag, almost the size of this console, which you agitated until you were confident that all of the cryo had gone into it. You then had to inject something, as I recall, to wash out the last few bits, which then went into the master bag. So by the time that you had done all that, the two of you, it had taken probably at least an hour to do that while the

patient was waiting for their treatment, with a bleed, which was probably a painful one.

Once you had done that with the 20 bags, you still didn't end up with much in the way of Factor VIII. So in terms of efficacy, which was your question, it was nothing like as efficacious as concentrate. It didn't have as much Factor VIII in it. So point number 1: it was not as clinically effective.

Then I go on to describe here the other problems with it. It was, as I've described to you, difficult and laborious and it had to be deep frozen. It caused side effects. So a very common thing was that during the infusion, which was slow, you had to put up a drip -- whereas concentrate took five minutes, cryoprecipitate might take an hour to get it all in -- very often the patient, in a hospital bed, if you could find one, or a corner of the casualty department, often got the chills and the shakes and the shivers, which weren't very pleasant, and then they had to be monitored afterwards, "You can't go home yet, I'm just going to make sure you're okay."

So for all these reasons, you know, it wasn't good as concentrate. It wasn't as good for the people who had to draw it up. It caused side effects.

Now, another final particular issue is if you had a young child you ended up with a bag where you had 500mls, maybe, of cryo to give them, there are real issues, obviously, about giving young children high volumes of an infusion. So there were also particular issues about using cryoprecipitate in the treatment of young children with haemophilia.

So, for all those reasons, whilst it was the first treatment ever, in 2,000 years, for people with haemophilia, it undoubtedly saved lives, but it was a very primitive, I think is a good word to use, treatment. It was so unsophisticated in every regard compared with the concentrate, which was everything that the cryo wasn't: it was easily made up; took five minutes; suitable for home freezers; didn't cause side effects; it said on the bottle how much Factor VIII there was in each bottle, how many electrolytes -- here's another factor. You didn't know how much sodium or potassium and things was in the cryo.

So the concentrate had everything that the cryo didn't. So the idea of going from concentrate, with all its massive advantages, particularly, frankly, giving people their lives back -- you know, as we've been stressing, to move from a hospital-based

existence with haemophilia -- many of my patients never went on holiday. They said, "I can't go on holiday, I need to be near my haemophilia centre". You know, certainly there was liberty. They could go and have a more or less -- it wasn't a completely normal existence, we didn't let people do high contact sports like rugby or karate or boxing, but virtually everything else about their lives became normal for the first time ever.

So there was this extreme reluctance of patients to change and for doctors to change. So the idea of moving, it was very difficult, in a time when we've now got two major problems we're really, really worried about, firstly, nobody wanted to go back to cryo for all the reasons I've said.

Now, finally, a very important point, this was raised at various bodies. The Committee on Safety of Medicine said, well, you can't in any case, because there's no supply. Because, you know, the production of cryo had been diminishing greatly, because it was being sent to -- plasma was being sent to Elstree to turn into Factor VIII concentrate.

So even if we'd wanted to switch to cryo, which we certainly didn't, there wasn't the supply anyway. So it was a non-starter.

Q. I am going to try and unpick a number of those, which I'll largely do after lunch looking at the time. There's just one factual question I wanted to ask you first about supply.

Let's leave aside for the moment the question of supply on a national scale and what the Committee on Safety of Medicines may have been advised or understood.

Your witness statement says that cryoprecipitate -- this was talking about it when you were at Guy's -- wasn't used but was available. Was there a particular supply problem with cryoprecipitate local to your area, to Tooting? Because we know, not least, for example, from what Dr Chisholm raised at a UKHCDO meeting in the autumn of 1983, she had no difficulty in her area getting cryoprecipitate supplies, and the minutes record agreement by other directors that they are in the same position. So it may be a variable picture geographically.

What about your area, Dr Winter?

A. There was a problem with all supplies from Tooting. Blood, whole blood, fresh frozen plasma. This was a centre under enormous pressure because it was the only centre serving two regions. Not only that, the regions were London regions, with enormous -- some of

the biggest hospitals in Britain. So nobody got what they wanted from Tooting.

Q. Did anyone from Guy's or, to your knowledge, any of the other haemophilia centres served by Tooting approach Tooting at this point in time and say, "Well, what we actually need now is some more cryoprecipitate because of the risks of Factor VIII concentrates"?

A. No, because nobody -- I don't think anybody considered -- apart from the subgroups I've mentioned to you, which were few and far between, nobody was considering, for all the reasons I've said, switching the therapy of a patient with severe haemophilia back to cryoprecipitate.

MS RICHARDS: Sir, I note the time. There's quite a lot I need to discuss and ask Dr Winter on this issue. Shall we do that after lunch?

SIR BRIAN LANGSTAFF: Yes.

Well, as before, Doctor, don't talk about your evidence to anyone, whatever else you may wish to talk about, and we'll meet back at 2.00, shall we.

2 o'clock.

(1.02 pm)

(Luncheon Adjournment)

(2.00 pm)

SIR BRIAN LANGSTAFF: There's no need to stand when I come

in if you are more comfortable sitting. It's entirely a matter for you.

A. Okay.

MS RICHARDS: Can you hear okay?

A. No. I've changed my battery.

SIR BRIAN LANGSTAFF: Can you hear me now?

A. Not as well as I could this morning.

MS RICHARDS: We won't start until we have sorted this out.

A. Something seems to have happened after he changed my battery. I can hear myself, but I'm not getting the loop.

MS RICHARDS: Don't worry, we will get our technical person in.

(Pause)

SIR BRIAN LANGSTAFF: All I was saying to you, so that there's no mystery about it, was there's no need, unless you want to do so, to stand up when I come in. Counsel will because she performs the role she has standing, but if you are more comfortable sitting, that's fine.

MS RICHARDS: Dr Winter, we were talking about cryoprecipitate. One of the observations you made was that it was not suitable for home treatment. Now, I should say the Inquiry has had evidence that

cryoprecipitate was used for home treatment at Great Ormond Street, at Birmingham Children's Hospital, and we know it was used by Katherine Dormandy at the Royal Free.

I can entirely see that it may have been -- or the concentrate home treatment might be more straightforward, less laborious and so on, but I think it is not right to say that it was impracticable or impossible to have cryoprecipitate as home treatment? Would you accept that?

A. But you have to have a deep freeze, and that was a problem.

Q. Certainly, Dr Dormandy at the Royal Free made those arrangements for her patients.

A. Right.

Q. Do you accept that cryoprecipitate posed a lower risk of infection for HIV and non-A, non-B hepatitis?

A. Yes, because it only came from -- you know, gave somebody 20 bags; that was exposure to 20 donors rather than to the 20,000 with an infusion of concentrate.

Q. You have explained why you thought cryoprecipitate was less clinically effective than concentrate, but would you agree that cryoprecipitate could be used, and indeed had been used, to raise Factor VIII levels, and

so it was clinically efficacious, even if it took longer or was a more laborious process than concentrate?

A. Yes. I've already stated that. It was just not as effective.

Q. Then, in terms of side effects, as I understand your evidence from before lunch, the side effects from cryoprecipitate that you were describing, the chills and shakes and need to be monitored, so, as you say, certainly not pleasant, but not long-term and serious side effects?

A. No. They were just transient, maybe lasting a few minutes, but they needed to be monitored.

Q. You also suggested that cryoprecipitate couldn't be used in children, although I think your answer was young children. As we'll come on to see, you have already made reference to, the UKHCDO recommendation that emerged in the middle of 1983 did actually include a recommendation to use cryoprecipitate for children. So it was, as a matter of fact, something that could be used for children, I think?

A. Yes. It just had practical problems if the child was young, as you say.

Q. So we come, essentially, to a number of practical issues in relation to cryoprecipitate -- it took

longer, you might need a deep freeze, but if in hospital you would have that facility, but it would take longer; it would need medical staff. So those are practical disadvantages, but would you accept that one has to set against that the fact that it was safer? Why would the practical disadvantages outweigh the safety of the product?

A. If you're moving towards why didn't we use cryo on everybody, I've already told you, there was just no supply. Secondly, there was massive -- there would have been massive antipathy from the patients, and there would have been great reluctance from the doctors. It was -- I don't ever recall any haemophilia doctor ever suggesting, in response at this critical moment, that we should switch all patients to cryoprecipitate. I have no recollection of any haemophilia doctor thinking that that was a possible way forward.

I think there was Dr Ratnoff in Cleveland I think he was. I think he was always remembered as the one doctor who kept his patients on cryoprecipitate, but it was just not considered as a realistic option in this country.

Q. Yes, and we may hear some evidence at least to the contrary, but I understand that to be your

understanding.

In terms of supply, if there wasn't enough available for an immediate switch of everybody from concentrate to cryoprecipitate, would there have been enough to ration it so that cryoprecipitate was used for children and previously untreated patients or mild haemophiliacs?

A. Well, that's what UKHCDO was recommending, wasn't it, and that's what happened at Guy's, to my recollection.

Q. Would you agree that if there was a switch from reverting to cryoprecipitate instead of concentrate, there may have been an ability to catch up, in terms of supply issues, because you could utilise the plasma that would previously have been required for concentrate to make cryoprecipitate?

A. That would only be the British plasma, obviously.

Q. Yes.

A. Of which there wasn't very much.

Q. What about the option of switching to cryoprecipitate for more patients on a temporary basis until more was known about the risk of AIDS, or more known about the possibility of viral inactivation? Was that an option?

A. Isn't that the same thing as we've just been discussing?

Q. I think we've discussed using cryoprecipitate for children and the other categories identified in the UKHCDO --

A. So we're 1983, aren't we?

Q. So we're 1983.

A. Yes.

Q. What about using cryoprecipitate for a wider range of patients, including adults who are severely affected, as a temporary option? Was supply the only reason?

A. Same answers, I think, you know. No supply. I mean, you know, there was very little cryo around, as far as I can recollect. At least the part of the world where I was working, it would have meant cessation of home therapy, patient reluctance, less efficacious, et cetera. I mean, safer. I'm not denying the importance of that, but it just didn't seem an option to it for all those reasons.

Q. Do you recall whether you had or your colleagues at Guy's at this time had any discussions with patients to offer them cryoprecipitate?

A. No.

Q. As in, no, you can't recall, or you didn't have --

A. No, I can't recall.

Q. I think you have already told us that no patient positively asked you to go back on -- asked if they

could go back on cryoprecipitate?

A. No.

Q. If they had -- this is a hypothetical question, but if they had, what would your response have been?

A. Well, I would have talked it through with them. I mean, if they were very, very concerned about going on with concentrate, if I could have got guaranteed supplies of cryoprecipitate, if they understood the implications of what that decision meant, in terms of having to come into hospital each time they had a bleed, which is quite a significant thing, then I would certainly have had an open discussion with them.

But our recommendation was, you know, as we've been discussing, to introduce these restrictions to these particular sort of subgroups of patients who we could get away from concentrate to, you know, express our anxiety about the situation and the lack of apparent progress towards self-sufficiency. I mean, of course, I am still a trainee at this time, so I don't have any managerial authority or anything, and that was really as far as we could go.

Q. You may or may not know the answer to this, Dr Winter, but in terms of cost, and leave aside for one moment the practical question that there may have been supply

issues in relation to the Tooting centre -- in terms of cost, do you know whether cryoprecipitate was, to the health authority, more expensive or cheaper than factor concentrates?

A. Oh, much cheaper.

Q. Then can I ask you just a little about commercial versus British concentrates?

SIR BRIAN LANGSTAFF: May I just ask this: did any patient later on, when you were a consultant -- did any of the patients whom you treated who were young -- that is children who were having cryoprecipitate in accordance with the guidelines, or mild, early affected, and having it in accordance with the guidelines, or first just newly diagnosed -- did any of them say to you, well, look, these other people we've come across, they get this factor concentrate to keep in their fridge at home. Can I have some of that?

A. No. No, they didn't. I mean, as I stressed, this was a very small centre with very small numbers of children only, but none of the patients approached me with that sort of conversation, and I can't recall at this distance of time -- I mean, I can remember using cryoprecipitate in a child, but I can't remember -- my recollection is that most of them we were able to secure BPL concentrate, and that's the way we treated

them, and we advised them to only use it for times when it was absolutely necessary. We didn't have prophylaxis programmes going in children, so we suspended prophylaxis, so it was only given for episodes of significant bleeding.

MS RICHARDS: Then the question of commercial versus British concentrates. Your statement says, and your evidence has been clear, that in terms of concentrates, BPL concentrate was your treatment of choice. Was the reason for that your understanding that it was, relatively speaking, safer than commercial concentrates?

A. Yes, because I'd been signed up for a long time -- well, really during all my time as a trainee -- to a firm belief that if you had Factor VIII that was derived from a pool of voluntary donors, it was -- wherever those donors lived, it was going to be much safer than if the concentrate was derived from a pool of paid donors, for obvious reasons. Because the voluntary donors were giving it through altruism, and the paid donors were doing it because they needed the money and were, therefore, much likely to have alcohol and drug problems and, therefore, much more likely to be carriers of viruses.

Q. Other than safety, were there any other advantages or

disadvantages of British product over commercial product?

A. No. I mean, we had obviously wished, as the situation was in Scotland, to be entirely self-sufficient in what would have been English Factor VIII. That's what we wanted. But that was the only consideration -- and we wanted that because it was safer.

Q. Were you aware at this time that in the United Kingdom there was still collection of blood from prisoners?

A. In the US?

Q. No, in the United Kingdom.

A. No.

Q. Can I ask you just to clarify one point in your witness statement, Dr Winter, before I move to a next topic. It's paragraph 23(c) of your witness statement if you just have the hard copy.

A. Could I ask you to get the audio person back. I'm still not picking you up.

MS RICHARDS: Certainly. We will just pause there.

(Pause)

I just wanted to check one point in your witness statement to see that I've correctly understood it. It's paragraph 23 of your witness statement, and at paragraph 23(c) you say:

"As I believed that all of the available

commercial concentrates were of equal clinical efficacy and safety my main responsibility was then to purchase coagulation factor concentrate at the most advantageous price."

As I understand that, you are not saying that commercial concentrates were of equal safety to British concentrate, you are saying that, as between the various different commercial concentrates, you weren't aware of anything to pick and choose between them. Is that right?

A. That's correct in terms of both efficacy and safety.

Q. Thank you.

Before we get to you being a consultant, which I promise we will get to, I just wanted to ask you a handful of questions about UKHCDO and its decisions and actions during this period.

So if we go first, please, Henry, to CBLA0001619.

We can see these are the minutes of a UKHCDO meeting on 13 September 1982. If we go to the bottom of the second page, please, Henry, we can see, towards the very bottom, that you're there in place of Dr Barkhan, and Dr Barkhan was represented by you and apologies had been received by him.

This was, I think, the first UKHCDO directors'

meeting that you attended, and you attended at this stage not as a director but still as a registrar?

A. That's correct.

Q. Then if we go, please, to page 10, Henry.

We can see that AIDS was discussed. It's the bottom of page 10. It's said that:

"The Reference Centre Directors had asked Dr Craske to look into the report from the United States of this syndrome mainly in homosexuals but including three haemophiliacs. It appeared that there was a remote possibility that commercial blood products had been involved. Dr Craske asked the Directors to let him know if they had any cases of the syndrome. The Working Party was considering the implications of the reports of the USA."

So that's the sum total of the discussion on AIDS as recorded in those minutes.

First of all, what, if anything, do you recall of that meeting?

A. Nothing. But I -- obviously, interestingly, you reading the words there, look at it. I mean, the phrase "remote possibility" doesn't seem the best of phrasing, does it? I certainly would not have used that phrase at all, because it seemed to me that, by this stage, you would have had to use a phrase like it

was considered a "significant possibility" that these patients had been infected by an agent in blood products.

Q. So that's September '82 when you're there. Now I'm going to go now to a meeting which I know you weren't at, Dr Winter. It's HCDO000003_008 please, Henry.

I will just get an alternative reference. Forgive me. We'll see if we can find a difference reference for that, Dr Winter. Let me tell you what it was. It was a meeting of Reference Centre Directors at St Thomas' on 13 May 1983 to discuss AIDS.

Could I ask you whether you have any reflection on the lapse of time between September 1982, the meeting we have just looked at, and there not being a special meeting to discuss this until May of 1983. Do you think that can -- showed sufficient urgency on the part of Reference Centre Directors?

A. Well, of course this was an organisation that I didn't belong to at that time. It seems to me that -- if my memory's correct, it was the end of 1982 that we had the San Francisco baby --

Q. Yes.

A. -- which was important sort of additional information, in addition to the three original American cases. We

would have had a small number of further American cases. We didn't get the first British case until May '83 I think, in Cardiff.

Q. It was publicly reported in May of '83. We've seen evidence to suggest that the patient presented to Professor Bloom in Cardiff in March of '83.

A. Yes. I mean, you know, looking back I just don't know what drove them to schedule the meetings in that way. I mean, the Haemophilia Directors, now known as Comprehensive Care, is a pretty small community, and we -- you know, outside of the meetings, we are all in touch with each other pretty closely, or most of each other. So for all I know there may have been quite a lot of telephone dialogue going on about the evolving situation, but I obviously don't know why they didn't meet again until May, which -- here's the document now in front of me.

Q. Yes. That's fair enough, Dr Winter.

Can we then look at the document that you did become aware of, which was the recommendation sent out after this meeting in June of 1983.

I'm hoping this is the right reference, Henry, HCDO0000270_004.

So after that meeting in May, this letter was sent by Professor Bloom and Dr Rizza. You will see

it's dated 24 June 1983. You can see, if we just scroll down a little, "general recommendations":

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

That reflected the practice at Guy's?

A. It did.

Q. Then:

"For treatment of children and mildly affected patients or patients unexposed to imported concentrates many Directors already reserve supplies of NHS concentrates (cryoprecipitate or freeze-dried) and it would be circumspect to continue this policy."

So the recommendation is cryoprecipitate or NHS factor concentrate for those categories?

A. Which is what were already implemented.

Q. At Guy's at this stage?

A. Yes.

Q. You may or may not have view on this, Dr Winter, but this is voiced as "general recommendations", and what we see in paragraphs 1 and 2 is, well, this is the

practice generally, "circumspect to continue" is the language of paragraph 2.

It falls short of being an instruction or firm advice. It's to some extent leaving it to clinical judgment; would you agree?

A. Yes, it's interesting to reflect on this. Medicine now is different to medicine then and there was a great stall then, the famous phrase "clinical freedom", the ability of a doctor to look at some guidelines and say, "I'm going to do something totally opposite to that because I have clinical freedom" -- a very dangerous concept.

I think, therefore, for some doctors at that time, these documents were seen as advisory but not binding. I think now the word "protocol", which is not mentioned here, we don't -- well, when I was working we didn't have advisory documents, we had protocols, and it was generally agreed that once the haemophilia directors had issued a protocol to the haemophilia -- to the UKHCDO members, they were on dangerous ground if they deviated from that and something went wrong with the patient. So this was, you know, this moved from being a guidance, which is advisory, over the course of the next 30 years to being essentially a strongly recommended protocol

which was produced by experts and you were expected to follow it. If you didn't follow it, then that might be a problem.

Q. Then we'll move from June 1983 to October 1983.

Henry, could we have PRSE0004440, please.

So we can see this is a meeting of the directors on 17 October 1983. If we go down we can see -- actually, if you leave it there, Henry, that's great.

I don't know whether you see, if you go down, in alphabetical order, the list of attendees. We have, I believe, Dr Chisholm, Dr KGA Clark, Guy's Hospital, London. That's the other consultant?

A. That is the case. He is not a haemophilia specialist.

Q. Then if we could go to page 10, please, Henry.

We can see under the heading "Any other business", bottom half of the page:

"Dr Chisholm raising the problem of patients refusing to take up commercial Factor VIII concentrate because of the AIDS scare. She wondered, in view of the worry of the patients whether the directors could revert to using cryoprecipitate for home therapy."

Then this is Professor Bloom's response:

"He felt that there was no need for patients to stop using the commercial concentrates because, at present, there was no proof that the commercial

concentrates were the cause of AIDS."

Would you agree with this, that to await proof before taking action in circumstances where the link, although not proven, is pretty clear, is the wrong course to take?

A. Well, we're only a few months away from the events of April and May 1984, which we'll talk about in a few minutes, where exactly that situation arose. And, together with some other doctors, I did have to make very radical changes to therapy on theoretical considerations alone.

Q. You have told us you were pretty satisfied, and as far as you are concerned, most haemophilia clinicians were pretty satisfied at the beginning of 1983 that blood, blood products, were the cause of -- or were the relevant transmissible agent. And yet here's Professor Bloom saying, well, there's no need to stop using concentrates, and the reason he gives is not supply or anything else. The reason he gives is no proof. Would you agree that's the wrong question for him to have been posing, or the wrong answer for him to be giving at that time?

A. When I've done these inquiries, one of the difficulties is being asked to explain why other doctors said and did something.

SIR BRIAN LANGSTAFF: You are right. I think this is a question, ultimately, for me to evaluate. What counsel is doing, I think, is finding out what the views were of different clinicians as to what the answer should be, although ultimately it's one which I will have to decide. So it's helpful. You have -- I think the background to this is you have just described the word "remote" possibility. The word "remote" used several months before this as being misplaced and significant would be better. You have indicated that you understood there is a real risk -- leave aside the question of certainty -- the question might be put this way: is a significant or real risk a proper ground for action? You've said it was, for yourself, a year later or a few months later when you had to consider what action to take in advance of there being definite proof of cause and effect.

A. I mean, of course, if I may say so, I stress, you know, this has been a very long conversation. You're talking now about what interactions I had with other haemophilia doctors. I didn't have any. I wasn't a consultant. I didn't -- I was not part of UKHCDO. I was not having regular dialogues with other haemophilia treaters around the country because I didn't know them because I was a trainee. So all this

will change in a minute when I eventually do get to be appointed as a consultant. But if I've been rather vague with my answers for this last couple of hours, it's because, you know, I was in a little bubble at Guy's Hospital working as a senior registrar, and I was not part of the UKHCDO network, and I can't tell what interactions they were having at their level, which was presumably by telephone and informal meetings.

MS RICHARDS: I understand that. Now, we know that the next document or set of recommendations issued by UKHCDO was in December of 1984, and I know you have got some observations you want to make about that document. What I'll do is come back to that when you've explained the decisions and actions you took in the course of 1984, so we can look at it in that context.

Can I just ask this, though: you talked about the status of UKHCDO recommendations. If -- and this is hypothetical -- but if the Chief Medical Officer had issued guidance (for example, guidance saying clinicians should no longer use imported concentrates, or clinicians should revert to using cryoprecipitate), would you have expected to follow guidance from the Chief Medical Officer?

A. I think that that's -- it became a very significant issue as we, over the next few years, dealing with all these very spectacular problems, the lack of very what you might call powerful, influential, centralised advice. I think we're going to talk about this when we talk about how to tell patients they've got HIV, how to test them, and so on, and so on. There were many of these issues. It was made a lot more difficult to cope with at local level as a consultant trying to respond to these spectacularly difficult problems that there was no central body that had published very clear, firm guidance or protocol, or call it what you will, to haemophilia doctors saying, this is what we think you should do in this situation. You know, this is why one of the key things for me in the whole academic is the variability word, and all these things we've already been speaking about of each doctor having the freedom to do what he wanted.

That was just one of the very, very major difficulties that emanated out of a very clear diktat -- let's use a proper word -- from somewhere powerful and central saying this is what you should do, and we really lacked that. Particularly when HIV broke, we were blood specialists, haemophilia doctors, not virologists dealing [on a] day-to-day basis with

the problems caused by a virus of which we were not specialists.

So I think that point you are raising is a really core one. We very much lacked firm, central guidance from whatever body; you know, a body set up for national virological advice, or the Chief Medical Officer or whatever.

Q. And you -- I infer from your answers -- would have welcomed such guidance, whether it was from the CMO or others?

A. Yes.

Q. Because what you have described is a situation in which you as a registrar with your fellow registrars in a centre in which the two consultants are not specialists in this field are having to take your own decisions?

A. Well, yes. We had the UKHCDO guideline, which we'd followed, about how to minimise concentrate usage. But apart from that, yes.

Q. Can I ask you one further question about UKHCDO, not at any one point in time, but in the knowledge that you are about to become a member, in the end of 1983, when you become a director in Kent.

Professor Savidge, who you obviously dealt with quite extensively over the following months and years,

in his evidence to the Archer Inquiry was very critical of UKHCDO. He said it was run pretty much as a club by the ten or so main players, and there was something of an information vacuum for directors in particular of smaller centres.

Would you agree with that, based upon your own experience once you became a director?

A. I don't agree with that. I think we should state UKHCDO was generally regarded by the other haemophilia societies and doctors and other countries as actually being a model of its kind. There isn't really any other country where haemophilia doctors came together and collaborated to such an extent that every patient with an inherited blood disease in the country was registered, we knew the number of patients with the condition, we knew the severity of the condition, we knew whether they had an inhibitor, we knew whether they were on home treatment, we knew whether they were alive or dead. No other country had information like this and every time you went to a World Federation meeting, people would say, you know, your system you have in the UK is light years of what we have in our country. We have nothing like it.

Then, in addition to that, as we've seen already, it was a very active organisation, in

addition to all the day-to-day work we were doing. At any one time, there would be six, seven, eight working parties in specialist areas. So I thought the UKHCDO was a very good thing. Of course, there were personalities involved, of which Professor Savidge was a large one.

Q. So we've finally, Dr Winter, reached December 1983 when you took up your appointment in Kent as the centre director and consultant haematologist.

Could you just describe what the services were when you arrived in Margate at the haemophilia centre.

A. Well, very unsatisfactory really. There were very -- although it was a centre and covering a very wide geographical area and with quite a good number of patients, there was no proper centre as such. It was just a haematology department.

There was a particularly unsatisfactory state of affairs in that the patients got Factor VIII on prescription from the general practitioner, and it wasn't clear to me how this completely inappropriate system had come about. But what that meant was when the patient needed Factor VIII, they went off to a GP who wrote a prescription -- please issue ten bottles of Factor VIII, and they went to a local pharmacy who had never heard of Factor VIII but looked it up and

found somebody who would sell it at an inflated price, doubtless. And the particular and very, very unsatisfactory aspect to all this was that, of course, no batch numbers were taken.

So when I took over, I had no information whatsoever as to what people had been receiving over the years and that became critical when, over the months to come as HIV broke, UKHCDO would start circulating to all haemophilia treaters details of contaminated batches. You would get a letter saying, "We now know that the following batches, a patient's got HIV. Please let us know if your patients have received that batch" and I couldn't tell them because I had absolutely no records at all.

So that was one of my top priorities, was to get rid of that completely inappropriate system.

Q. We'll just look at a couple of documents in relation to that, if we may, Dr Winter, just to illuminate that. HCDO0000174_009, please. We can see this is 7 February 1984, and it's a letter that you wrote to Miss Spooner at the Oxford Haemophilia Centre. You say that you recently replaced Dr Harold Sterndale as director. You enclose the annual returns and then you say this. You note:

"I have not been able to give you any

information about material used in the home treatment of our haemophiliac patients. I understand that there was a serious lack of local funding a few years ago, and for these reasons an arrangement was made whereby all haemophiliacs on home treatment received Factor VIII concentrate from their general practitioners on prescription."

Then you explain that you are extremely unhappy about that and taking every step you can to abolish it and issue Factor VIII directly. Then you are afraid you have no data on the type or amount of Factor VIII that was used by our haemophiliacs on home treatment.

If we just look at the returns.

A. Can we just point out that she is the secretary of UKHCDO which, at that time, was based in Oxford and subsequently moved to Manchester.

Q. Yes. We've seen that from other documents. Thank you.

Then if we could have, please, Henry, HCDO0000174_003. So we can see this is the annual return for 1983 for Margate. Your name is there. This is in relation to haemophilia B. Total number of patients treated during the year, three. Then we can see that you have been able to give a figure for the total used at hospital, whether in-patient or

out-patient, and that it's NHS Factor IX concentrate. No commercial Factor IX concentrate has been used at the hospital, but you are not able to give any figures for home treatment. It's nil because you don't have the data.

A. It's useful to see this because it gives everybody an idea of the way in which the Oxford returns -- every January or February, all haemophilia doctors would sit down and submit information about the previous year's treatment. These are patients with haemophilia B, not A.

Q. Yes, we will look at --

A. The haemophilia A would look very similar to that.

Q. Yes, and we've got that. Henry it is the same, but 004 at the end.

A. Then, in addition to this, each patient is registered with Oxford, has a unique identification code, so there would be a separate piece of paperwork to do where for every registered patient you would provide agreed information along the lines of had they had treatment, are they still alive, have they developed an inhibitor, et cetera.

Q. Yes. Then we can see again -- if we look at the column, we've got -- at the top, we've got total number of haemophilia A patients treated during the

year, 25, and then we can see for the haemophilia A patients, for in-patient or out-patient treatment, so treatment at the hospital, there's 48,750 units there of NHS Factor VIII. Then we can see the figure for commercial Factor VIII at 16,320 of Kryobulin. But in terms of home treatment you've put nil, and then you've put amount unknown, for the reason you've given because the home treatment system was being done through the GP and local pharmacies.

A. These are tiny amounts; less than 5 per cent of the usage, I would think. So nearly everything has gone through a general practitioner.

Q. So that system -- and I appreciate entirely it's not a system for which you were responsible, and it's a system which you were horrified by, but that meant that either a GP -- not a specialist -- or a pharmacist -- not a clinician -- was determining what actual product the haemophiliac patient had for their home treatment?

A. It was not the GP at all who had also not heard of Factor VIII. He wouldn't have known anything about Factor VIII or even if it came in different types. It was all down to the pharmacist who also had not heard of Factor VIII who went and looked it up in a book and found there were suppliers and, for whatever reason,

chose one of the suppliers and rang them up and said, how much is a bottle of Factor VIII? Whereas most haemophilia centres would have been ordering several hundred bottles at a go, they must have been highly amused at a commercial company to have a local pharmacist ring up and ask to buy ten bottles of Factor VIII. But that's what happened.

Q. Is this a correct inference to draw, that the patients who would have been receiving their Factor VIII in this way would have been receiving exclusively commercial concentrates because the pharmacist wouldn't have access to the regional transfusion centre supply?

A. That's correct. This is a reflection of what we've been talking about earlier; the great shortage of Elstree BPL in the south-west Thames and south-east Thames regions, and therefore the need to buy commercial.

Q. It's probably clear from the letter you wrote to Miss Spooner, but would you agree that this was a completely inappropriate way to manage the care of the patients at the centre?

A. Well, it wasn't any form of management at all. It was anti-management.

Q. You then arrived in December of 1983, and at that

point, as consultant, the decision as to which form of treatment to use or which particular product to use was yours. Your witness statement says that it's the ultimate responsibility of the local trust. Can I just ask what you mean by that; do you mean you are an employee of the health authority and, in that sense, it's the trust's responsibility?

A. Yes, I mean, the ultimate responsibility laid with me, really, as the clinician. It was solely my decision as to which type of concentrate a patient received. And that, for the first three or four months of my consultancy, until we move on in a minute to talk about heat treatment, was basically a situation where there was very little Elstree available. So I was also, of course, continuing to follow the same recommendations that we had been implementing at Guy's about moderating concentrate usage for this first three or four months in early 1984. Then for the other regular severely affected patients I was having to purchase commercial Factor VIII.

Q. The source of NHS concentrate for you in Margate, would it still have been Tooting?

A. Mmm.

Q. It was. You were now a consultant and therefore had a status you hadn't had at Guy's, and indeed

a responsibility that you perhaps hadn't had at Guy's. Did you raise the question of the shortfall or inadequate supply of NHS concentrate with anyone at the Tooting regional transfusion centre or in the Blood Transfusion Service?

A. I think something very influential happened. Dr Savidge, as he was then, rang me up very, very early in my consultancy and he said, "I think we need to meet and to talk", which was extremely helpful. I remember going to meet him at St Thomas' very, very shortly after I started, and we actually, rather than talking about shortage of BPL, what we spoke about at that meeting were the double problems, what we were going to do about the new disease, which seemed to be in the blood supply, what were we going to do about chronic liver disease and we actually immediately -- most our conversation was could we get heat treatment.

I know we're just about to come on to talk about that but he was extremely helpful and influential in persuading me as to the right way forward over the next few months and -- because, if you like, we were very hopeful of -- we'd accepted that Tooting was never going to be able to come up with any improvement. This had been a very long-running saga and, as I say, at really all aspects of their

operation.

You know, we'd have situations in the hospital where we would ring up Tooting at night for emergency supplies and be told, "Oh, we're very short". There was a chronic shortage of all blood and blood products from Tooting because of this situation where they were covering the two health authorities. So we didn't think there was any mileage in trying to get more supplies of Elstree. By January there was so much of concern that we were already at that stage talking, the two of us, asking ourselves: can we get inactivated Factor VIII? Because that's going to be the way forward.

Q. Now, in the period from December 1983 until May 1984, when you started to use the heat-treated product, are you able to give us any idea, on a very rough basis, what the percentage was of NHS versus commercial that you were using for your patients?

A. Well, as you've seen from the previous year, there was hardly any Elstree reaching Margate. The supplies were so limited. There was a feeling, of course, in the provinces, that it all went into central London and that we were an afterthought, but this -- I can only reflect that we had very, very little BPL, as the previous year's returns show.

Q. So is it fair to say that probably the majority of the treatment was commercial concentrates?
A. Yes -- nearly all of it.
Q. Where you were using factor concentrates --
A. For that three or four months when I was in post.
Q. You told the Penrose Inquiry that -- I can take you to it if need be but I will just summarise and if you don't remember and want to look at it, we will.

You told the Penrose Inquiry the patients didn't want to have American concentrate or some patients didn't want to, and you say it took quite a bit of work to persuade patients in some cases to continue to receive commercial concentrate. Do you want to look at the passage?
A. No. So this is really, now, one of the next of a number of absolute key points in the epidemic.
Q. I wanted to ask, that process you talk of, persuading patients to continue to receive commercial concentrate, are you talking there about the heat-treated concentrate?
A. Well, that's -- I wasn't sure whether you were talking about -- are you talking about -- before we switched to heat treatment, about carrying on with commercial?
Q. Yes, I really just wanted to know that that description of persuading patients in some cases to

continue to receive commercial concentrate, what time period does that relate to?
A. Well, in my experience, the whole history was, haemophilia patients, from the moment of their diagnosis and growing up and going to meetings, learnt that one of the sort of key things to follow was that you -- you know, people used to say to them in the Sunday morning meeting in a Haemophilia Society seminar in wherever, "You know, when you get back to your centre, you want to make sure that you get British Factor VIII. Don't ever get American Factor VIII". Very early on in the haemophilia experience the patient would have that message from somebody. It's a family illness; other people, a cousin or somebody, an auntie, might have said, "You make sure". All the patients knew.

You know, in my experience, whether it's this period, January '84 or at a time a few months later, when we're trying to persuade people to switch, people were very, very reluctant -- completely understandably, they were right -- to have Factor VIII from commercial donors.
Q. The reason -- I'm really just interested in your use of the verb "persuade". What was the reason you were trying to persuade patients to do so?

A. Well, before the switch, because it was the only Factor VIII I had, because I didn't have any Elstree, and as we've discussed I didn't want to go back to cryoprecipitate.
Q. Then for this first few months of your consultancy, was it the case that you were still trying to treat in accordance with the UKHCDO recommendation from the June of the previous year?
A. Yes.
Q. So for children, for newly diagnosed, for mildly affected patients, would you be trying to use NHS concentrate?
A. Try to use NHS, use DDAVP where appropriate, try and postpone surgery if it wasn't necessary, use BPL for children, maybe cryo for an older child if it was possible. Do all you can to restrict concentrate usage for children and mildly affected patients.
Q. Was there any prophylactic programme during these first few months --
A. No, not at that time.
Q. So just given that there had been this previous rather unsatisfactory situation of the GP and the pharmacist, could you just talk us briefly through what you then did. This is, again, before heat treatment. Did you call every patient in or invite every paint for an

appointment and explain that the situation was going to now be different?
A. Yes. I mean, when patients come in to a haemophilia centre and they get supplies, they get enough for a couple of months, say. On this very inappropriate system, the ten bottles they were given might only last them a week or something, so the patients were having to get prescriptions very regularly, so they ran out very quickly. So it was actually pretty easy to send for them to say, "I need to talk to you about what's going to happen in the future, I've got a better system, we're going to give you the Factor VIII from the hospital and you don't need to go to the GP anymore."
Q. Given that the time-frame we're talking about is end of 1983/early 1984, in the course of that conversation that you're having with your patients because you're changing the way in which they receive their treatment, did you tell your patients anything about the risks from commercial concentrates in terms of either AIDS or non-A, non-B hepatitis?
A. Well, I certainly, in a very major way, did, as we're coming on to talk about, in April and May. These patients had not been particularly well informed about haemophilia, really, let alone its treatment. I think

because I was already in a discussion with Dr Savidge, my priority -- I had a highly inappropriate, dangerous system. My priority was to get a proper haemophilia treatment programme going with dispensation -- that's the wrong word -- dispensing being done from the hospital rather than GP and a pharmacy.

So my priority was to get the patients onto, you know, a system where they collected from us, and I thought: let me do that first of all and then I can talk to the patient about a range of things.

There was hardly any home therapy I wanted to do, there was no prophylaxis I wanted to do. The major thing bubbling under was: are we about to switch to heat treatment?

Q. So in those first few months is it right to understand from your answer that you wouldn't have necessarily have been telling your patients as a matter of routine about the risks of AIDS and non-A, non-B hepatitis?

A. I didn't start until 12 December, so by the time -- you know, Christmas, and then most of these patients I'd never met and they were coming in for reviews once every couple of months or so, by which time I was well on the way to trying to switch.

Q. Then you've told us I think of some of the initiatives of trying to implement the UKHCDO recommendations, and

you mentioned possibly delaying surgery, not having prophylactic treatment until you can sort the situation out. Was the giving of advice about how to manage the condition, through lifestyle changes, through rest, was that ever part of the conversation at that point in time?

A. To be honest, it was -- I was starting from scratch there. I did not have a haemophilia nurse, I didn't have a physio, I didn't have a centre, I didn't have a finance manager, I didn't have a secretary, I didn't have a centre. All my patients were getting Factor VIII from a GP. I mean, you couldn't have started from a lower position.

So I started -- you know -- and also, as if that wasn't enough, I was immediately into a situation where I knew there were two really serious issues which was really also at the core of my thinking. So I had a whole range of really important priorities about, firstly, establishing, in effect, for quite a lot of patients, coming in from all over Kent, for the first time a proper centre. So -- and there were just me. So there were a whole range of priorities I had to do first. By then it's spring time, by then we're into heat treatment.

Q. Just in terms of the numbers of patients that we're

talking about, I think we saw a number on the return, your statement had estimated about 20 or so severe haemophiliacs, with haemophilia A?

A. I think that's right. We had a sort of hub and spokes. So I did also look after patients in adjacent centres. They would go for day-to-day treatment to Medway or Maidstone or places like that, and then they would come to me for reviews, as a haemophilia specialist. So, in all, I'm thinking about 35 patients with significant haemophilia and I say that because those were the patients who were coming on later in the year to get HIV tested.

Q. Then, if we just look at your witness statement again please, Dr Winter, at paragraph 35.4 you say this:

"At this highly critical time there were therefore only three options for haemophilia clinicians:

"... suspend treatment ..."

I'm sorry, I'll wait -- do you have that?

A. Yes.

Q. My apologies.

So your option 1 was "suspend treatment" completely?

A. Yes.

Q. Your option 2 was to "continue with BPL concentrate

only". Your option 3 was to "switch to heat-treated Factor VIII and IX".

Now, we know you opted for option 3, and we'll talk about that in a moment. I just wanted to ask whether the position was truly as stark as you there set out. Because presumably you wouldn't have to suspend all treatment; you could reduce the amount of treatment, suggest "try and use a little bit more cryoprecipitate", give advice about management and bed rest, on a temporary basis at least. Was it a more nuanced set of options than this perhaps suggests?

A. No. Nobody ever gave bed rest to a person with haemophilia. They're bleeding and they need to have the bleeding stopped.

With hepatitis C we know you almost certainly got hepatitis C the first time you had a treatment, so the viral risk from one treatment might have been the same as from 30 treatments. So where was the logic in trying to reduce treatment? You know, you were still going to give the treatment that had the virus, so there was no logic there.

So it really did seem, as a matter of sort of strategic principle, those were the three core choices that lay in front of us.

Q. So could you then talk us through your reasoning for taking what was -- I think, could fairly be characterised as a bold decision, in the spring of 1984, to use heat-treated products?

A. Yes. This is one of the absolute key moments in the history of the epidemic. We'll have heard on the documentary and other things there was a certain view retrospectively from some people with haemophilia: why did I have to continue to have Factor VIII, couldn't I have stopped? Haemophilia clinicians like me were very unhappy about that suggestion. Cerebral bleeding has always been the most common cause of death in haemophilia. I think in that year there had already been ten deaths from cerebral bleeding in haemophilia. These are things, of course, the patients don't see unless it happens to their family relative. It's the sort of thing that the doctors see.

If you look at the Birch report of the early 1930s, an American doctor I think, she looked at life expectancy of patients with severe haemophilia. Of course there was no treatment. Nearly all the patients were dead by the age of 21/22. The World Federation of Haemophilia have a twinning system and every two years at the World Federation a centre like ours, from the developed world, would get twinned with

a developing centre, and we became twinned with Islamabad, in Pakistan, who we went to see. They are a nuclear power but they had no Factor VIII at all, nothing. On the first day we did a clinic for about 50 children, all of whom got carried in by their fathers, unable to walk, and at the end of the day I said to the centre director from Islamabad, "Well, tomorrow presumably we can go and do a clinic at the adult centre", and he just looked at me and said, "There isn't one. We don't need one. All of these children will die of bleeding."

So the natural history of haemophilia, untreated, is to die of bleeding. So you'd never get a clinical doctor like me to sign up to a situation where I said to a patient, "Why don't you stop having Factor VIII for a bit?" Bleeding is a very, very serious issue. As I keep on saying, it's the most potent bleeding disorder known to man.

So that was the easiest of the three options. It was absolutely not an option not to treat. So that was the easy bit.

Now we come to the really hard bit. For years, I reflected on this very difficult time and thought it was the hardest decision I ever had to make as a doctor. So let me just try and walk you through

what the issues were.

Firstly, we have the patients', "British, good, American, bad". So the choice is: you can stay on British Factor VIII. It's from voluntary donated plasma: good. It's got a full product licence: good. It's cheap: good. The patients like it: good. But there's no inactivation step. Surely you have to believe that this new virus, which hadn't -- well, it had been identified by then, and we had better make the point. In mid-1983, the French and then the American groups had identified the virus that we now know as HIV. So we knew that we were dealing with a virus, we just didn't have a test for it.

So that was the big "but": did you believe, with increasing numbers of cases -- still not very many -- did you believe that the new virus would only be present in American Factor VIII or could it be possibly there also in British Factor VIII?

So that was the British choice.

Or did you say to yourself, "People with haemophilia are so vulnerable, the batches are from 20,000 donors, if one of those donors has a virus, the patient's likely to get it, they are incredibly vulnerable to any virus, therefore if I go for American, not liked by the patients, 50 per cent more

expensive, no licence, but it's heated"?

Now there was experimental evidence. The companies had started to bring in heat-treated Factor VIII to try and see if it inactivated hepatitis, before anything was known about AIDS. So the companies in the US had started to work on heat inactivation. In 1983 the Germans had a heat-treated product, Bering, but we were not able to get that. But -- so that was the choice.

You know, and I sat down with the patients and said, "I'm not happy about no treatment. This is a really, really difficult call, but ..."

Again, I stress, I owe a debt of gratitude to Dr Savidge, who was very, very clear and strong that he thought we ought to switch -- everybody -- to both Factor VIII and Factor IX.

By February 1984, one of the companies, Alpha, who had a plant in Norfolk, they are an American company, they had a licence in the US for the heat-treated product. That was a major step forward. Dr Savidge and I approached them together with the two other doctors in Britain and said: we're aware of this licence in the US, do you think you would be able to get supplies for us? Which we would have to give on a named patient basis. So, you understand, if a drug

doesn't have a licence, doctors in this country still have the ability to use a drug on a named patient basis. The answer was, "Yes, we can. It's going to be 50 per cent more expensive".

So we decided that was the route we really ought to go down, because we were so very concerned, for all the reasons we've discussed this morning, that HIV -- we now had a virus. We couldn't convince ourselves that it wasn't going to be in British Factor VIII as well as American because of the intrinsic vulnerability of the system.

There was very widespread disagreement with those views, and I'm never critical -- you can ask the other doctors who are coming who didn't go down that pathway. The arguments against were: some people believed, including Professor Bloom the Chairman, that this was a problem to do with commercial Factor VIII. The whole virus story, non-A, non-B, HIV, it was commercial. Terrible donor practices. It was not going to happen to Britain with altruistic voluntary donors. This was an American problem. That was view number one.

Secondly, the Germans always used huge amounts of Factor VIII, much higher than Britain, from German donors. They had -- apparently, they had had little

or no HIV. That was quoted.

Then, thirdly, there was a very understandable concern -- we've spoken about inhibitors. About 10 per cent of patients develop inhibitors which makes the future treatment with Factor VIII effectively impossible. Some doctors very reasonably said, I'm really worried about this because the heat treatment might alter the antigenic nature of Factor VIII in the bottle so that when it's injected into the patient, the antibodies, the patient's immune system might recognise the injection as being foreign for the first time and make an inhibitor. This was a very serious -- you know, it would have been a very serious development, and it was a perfectly -- it was perfectly reasonable to put up that as an argument.

Having said all that and had this incredibly -- I can't stress to you enough -- the difficulties and the -- plus all the implementation of it, I had to persuade the patients who were anti-American. I had to, in the middle of a financial year, increase the budget by 50 per cent. At some stage in the next day and a half, I would like to talk to you about the way finances were arranged in haemophilia and priorities and things because that's a particularly important thing. We had all the logistics of getting

un-heat-treated supplies in, getting heat-treated supplies out. So it was -- just in terms of logistics, once you'd done that, it was complicated, and you had other doctors saying to us at meetings, I don't know why you're doing this.

Anyway, finally, very poignantly, although for a long time I thought this was just the most unimaginably difficult decision, I now realise -- and this is quite a powerful thing to say -- actually, it was all probably irrelevant because I now realise that nearly all of the patients had already been infected. And at some stage, I'd like to talk to you about that data.

Q. Absolutely. We will come to that.

A. Anyway, that was the heat treatment dialogue.

Q. Can I just ask -- sorry. You mentioned two other doctors along with you and Professor Savidge. I think you've named Middlesex and Sheffield as the areas. Could you just let us know who the doctors were?

A. Yes. There was a Professor Eric Preston, who you are due to be seeing, and Professor Sam Machin from the Middlesex. They were -- his is quite a smaller centre.

Q. Did you consider heat-treated products other than Alpha? Were there other options available to you that

time?

A. No, that was the only one available, and we were very, very keen to get on with it as soon as possible. We were -- we made the decision. It seemed absolutely right but difficult, and we absolutely wanted to get it done, so we started May 1984. There were then some supply problems, but from June '84, all of those four centres were using only heat-treated Factor VIII and Factor IX, and they did not get any more viral infections in those centres after those dates, whilst other centres, as we will discuss, were going on using un-heat-treated material all the way through till September the following year, a period of about 15 months or so.

Q. Can I just ask before we break again, Dr Winter, in terms of the categories of patient who switched to heat-treated product in May of 1984, was that all of your patients, so those who had been on some form of NHS or cryoprecipitate? Presumably it wasn't those for whom DDAVP was the most appropriate treatment?

A. No, DDAVP is fine. For everybody else, we were making a core statement. Any concentrate is unsafe because of the nature of concentrate manufacture. You know, the vulnerability of a haemophiliac patient to get a virus is so strong with 20,000 whatever it is

donors, be it donor from voluntary donor or commercial donor. We'd convinced ourselves all -- at that moment in time, you were very, very unwise to continue to treat any patient with a concentrate that had not had a step to inactive a virus.

Q. If we leave aside von Willebrand's and mild haemophiliacs, for whom DDAVP was appropriate, all the rest of the patients, haemophilia A and haemophilia B --

A. And haemophilia B as well. Even though there were no patients with AIDS, we felt, as a principle, if it was in Factor VIII concentrate, why shouldn't it be in Factor IX as well? We wanted everybody to switch.

Q. I'll ask you a little about the process, but I note the time, sir. Is this a convenient moment for the afternoon break?

SIR BRIAN LANGSTAFF: Well, it will be after I have asked one further question, if I may.

You have described how difficult a decision it was. You've given credit to the arguments against that decision. Was there one factor in particular which made you decide the way you did or not? And if so, what was it?

A. Well, I think the combination of these particular factors -- I was totally sold up, and had been since

1982, to the idea that AIDS was due to a transmissible agent. I then knew, by the middle of '83, that that was the case because the virus had been identified. I knew then that that virus had been causing illness in a small number of American haemophiliacs and, by that stage, a British haemophiliac and I knew that the patients were incredibly vulnerable because they were receiving concentrate from thousands of donors. So if you added in all those little things, you had a pretty clear view. You had just lost confidence, if you ever had confidence, that concentrates were safe.

When historians in 50 years will write histories of haemophilia, they'll say concentrates brought unimaginable benefits to people with haemophilia for the first time: home therapy, schools, work, exercise, et cetera, a normal life with a huge but -- a huge but. The Achilles heel: it came from thousands of blood donors. If there was a virus in town in blood, the haemophiliacs would get it.

SIR BRIAN LANGSTAFF: Thank you very much. We will take a break until quarter to four. Half an hour, I hope, is okay for you. Quarter to four, doctor.

(3.15 pm)

(A short break)

(3.45 pm)

MS RICHARDS: Dr Winter, are you able to hear me okay?

A. I can.

Q. So you had been describing the switch of your patients to heat-treated product in May of 1984. You'd said that that was essentially for all your patients, other than those who could be treated as mild patients or von Willebrand's patients with DDAVP.

Was there any space left, as it were, for the treatment of cryoprecipitate? Did that continue at all for any category of patient, or was it, other than DDAVP, all now heat-treated concentrates?

A. No. As you'll gather from my remarks, cryo was really regarded as obsolete, and we didn't want to use it unless we absolutely had to. After an initial hiccup, we were able to get all the supplies of the heat-treated material that we needed from Alpha so we could get all the patients across, as I say, by the end of June '84.

Q. So the switch took place, I think, between May and June, or in the course of May and June 1984.

Can you just describe for us, please, the process in terms of your meetings with patients and the information that was provided to patients.

A. So I sat down -- we're probably talking about a switch of about -- you know, this is initially with the

regularly treated patients who were going to be switched as a priority, and there were probably about 30 of those, I suppose. So some of those had upcoming appointments. If they didn't, I sent for them.

I don't know about other centres, but my patients were well-read and knew of the issues and had obviously been talking about the possibility of getting treatment that had been virally inactivated. So I sat down with them, usually with their wife or partner, and said, "I really need to have a very significant discussion with you because we've got a big decision to make because I can now" -- I explained all about heat treatment. I explained all about why I was very worried about carrying on with any form of concentrate that hadn't been virally inactivated. And I said, you know, we've now got a choice, but I can get supplies of heat-treated Factor VIII, or Factor IX if they were a haemophilia B patient.

I mean, I wouldn't say I pushed them, but I said, you know, this is my recommendation. I really -- we thought about this very hard. I said St Thomas' are going to do the same thing, and I really think we should -- it's the best way forward for you. You know, as I'm the centre director looking

after you, this is going to be your choice, but my recommendation would be that we did change you over on to this different treatment.

Q. Did all the patients that you spoke to accept that recommendation?

A. Yes. I mean, the issue was the word "American", and we spoke through all that, about -- I said even if I could get them British unheated Factor VIII -- which I couldn't -- but if I could, you know, I still had significant concerns that although the virus load might be less than in American un-heat-treated, it was still significant. So for that reason -- this was the total reversal of everything they always wanted to hear, but I was saying, controversially, American heat-treated was safer than British unheated, even though the latter came from voluntary donors.

So it was a very dramatic switch, and for some of them, you know, they sort of needed an intake of a few moments to really think about what I was saying, and -- but, you know, this wasn't a surprise to them. It had been in the air. I may have been speaking about them in February, you know, earlier when -- for the first time I was thinking about trying to switch.

That's what happened, and they -- I mean, some were more enthusiastic than others, but nobody

disagreed, which made it easier because that would have been very messy logistically to have some patients on heat-treated and some on un-heat-treated. But we managed to get everybody to agree to switch, and that's what happened.

Q. What was the mechanism for the named patient basis? Was there any particular procedure that you had to go through?

A. Yes. That was another area. I can't remember the exact way it's done now, but it's all very formal, and you have forms to fill in for each patient that you might treat, not only the regular ones. So I had to do it for every patient in the centre who was likely to need clotting factor concentrate. So there was a lot of administration to be done. This would have been a national form for doctors to treat patients on a named patient basis. That must have been sent off to some national committee somewhere to be registered. So all that had to be done and approved. Doubtless, there was work with my Trust to get them to agree that I should start treating patients on a named patient basis. I would have had to go to the ethical committee, and then there was the finance. You know, this is what may -- I'm buying it -- well, the new financial year's just started in April, and NHS

budgets are not easy at the best of times. But to go -- you know, when the budgets have all been set early in the year and to go and see the finance people and say, I really want to change to using a different type of Factor VIII. It's 50 per cent more expensive. The reason I want to do this is theoretical. And they've got people coming in, the neurologists coming in saying there's a new drug for multiple sclerosis. The oncologists are coming in and saying there's a new drug for breast cancer. Haemophilia is low priority in the Health Service because it's a chronic disability. You've heard this. Priorities in the Health Service are: accident and emergency, cancer waiting times, surgery waiting times. Chronic disability is low, and haemophilia is especially unpopular. What finance people like are low cost, high volume, totally predictable. They want to go to a Trust and say, we're going to commission 20,000 hip replacements from you. Haemophilia was a complete nightmare because it was everything they hated: low volume, high cost, and totally unpredictable.

Every March, I used to sit down with them, and they used to say to me, "Dr Winter, how much are you going to spend on Factor VIII this year"? And I said, "You're asking me how often my patients are going to

bleed, and I don't know the answer to that". So haemophilia was a nightmare for finance.

Sorry, you've rather started me off on a long-winded theme, but I'm not quite sure how we manage to get the finance, given all those things, but I think there must have been a bit of press activity. In fact, I'm sure there was. I think there was a Sunday Times campaign or something. My local MP was Jonathan Aitken, and I got him to ask a question in the House of Commons. He was the first MP to ask a question about AIDS. So I think there was a bit of political activity going on which must have helped. Anyway, we somehow did manage to get the money.

Q. You may not know the answer to this, given what you've said a few moments ago, but the named patient forms, I've been going to ask you who you sent them to. You thought it was potentially some national committee or organisation?

A. Yes.

Q. But you don't at this stage recall that?

A. I cannot remember who it was, but there was definitely a mandatory process for each patient. You know, what was the name of the patient, the name of the drug, why you were doing it.

Q. Then how did you manage asking your patients to return

to you any stocks they had of unheated product?
A. So I think -- because we knew it was going to be a rolling period over a few weeks, most of the patients had upcoming appointments, so by that stage I had one or two haemophilia nurses appointed. They were responsible for home therapy administration. So they would have rung up the patients and said, you know, Dr Winter was talking to you about this switch. We're now in a position to do the switch, so the next time you come to the centre, we're going to give you the new supplies of the new treatment and show you how to draw it up and how it works. Please will you bring with your any unused bottles of the old concentrate. That was pretty straightforward.
Q. Now, that was May/June. The exclusive product, in terms of concentrate used from then onwards in the centre, was the heat-treated Alpha concentrate.
Did you -- and presumably that was used both in the hospital and for home therapy?
A. For all treatment.
Q. Did you initiate a prophylactic programme at that stage?
A. I did.
Q. For children or adults?
A. Just for children.

Q. You then -- in the summer of '84, testing for HIV started to become available.
Can you talk us through the process whereby you sent off or collected blood samples and sent them off for testing.
A. Yes. It was actually a bit later. It was October 1984. A viral test then known as HTLV-III -- it was an antibody test. Not for the virus but for antibody -- was available through the laboratory of Dr Richard Tedder who was a virologist at the Middlesex Hospital and it was not being advertised to any of the hospitals because everybody suddenly wanted this test. But the UKHCDO came to an arrangement with Dr Tedder that haemophilia centres could send him blood samples on their patients for that test to be done.
A range of things then happened, apparently, from centre to centre. In my centre -- I hadn't been there all that long -- there were no stored blood samples. So I had to speak to each patient by writing and say, you know about this new virus. I can now get you the blood test. Please will you come and see me on such and such a date so we can have this test done. That was the process that happened in my centre.
Q. So every patient who -- in respect of whom you sent

off a test was a patient who you had told why you were asking them for a blood sample?
A. Because they had to come to the hospital to have a blood test. But there was a whole diversity of practice, as you will gather, and it appears that in some centres blood tests were done on these patients without them being informed. I think that's clear. It seems that in some centres they had blood stored down which they sent off to Dr Tedder and it seems that in some centres they maybe, at that stage, didn't test at all but tested a bit later. So there was a whole range of things that happened in response to this announcement that the test was available. But anyway, that's what happened in our centre.
Q. All the patients who you invited to come to give a sample to be tested, did all of them agree?
A. They did, and they were very pleased about it because it had been such a major worry. They wanted to know what was going on.
Q. You have explained the process of conversation you had with your patient. One of the questions you were asked to consider in your statement was the question of pre-test counselling, and you said that wasn't a concept that was in practice at the time. What would you understand now about pre-test counselling

and how would that differ from the conversations that you did have?
A. So -- I think we did discuss this earlier -- the performance of blood testing was just seen as part of a comprehensive care package. You know, you came in every three months, you saw a doctor, a nurse for home therapy, a physio for review, a social worker or a counsellor, and you had your blood test and you picked up supplies and that was the deal. That was the package of what became known as comprehensive care. It was understood that the blood test had to be done because you needed to be screened for an inhibitor. These blood tests were very often -- the patient would say, "I'm due" -- you know, "I'm due Factor VIII today", so it wasn't even an extra venous injection because they were going to have Factor VIII anyway.
They knew that they were having their hepatitis status checked for the hepatitis A and B, they knew that they were having their liver function tests looked at because of the non-A, non-B situation, they knew that they were having, sort of, wellness blood tests and that was accepted as part of the things that haemophilia doctors did for patients.
So when the HIV test came along, it was assumed

that doctors would add this to their list. It was just yet another blood test to add to quite a long list.

Now, what happened then was particularly important. Not haemophiliacs, but outside of haemophilia, the test became more widely available. Members of the general public were having the test done maybe at the end of a relationship, "I just want to see if I'm okay", or starting a new relationship, they would have the test done, they would test negative, they would then get together with their new partner and apply for life insurance or a mortgage, the building society would say, "have you ever had an HIV test?" They would say, "Yes, but it was negative" and the building society or insurance company would load the premium on the basis that they felt you must have been in some sort of risk group to have had that test carried out.

So here for the first time in medical practice was a test which if you had it done, even if the result was negative, it could have significant implications for your life. So this is where the whole concept of pre-test counselling came from. It came from the AIDS test. It did not exist in medical practice beforehand.

We'll see I'm sure in a moment a document from UKHCDO telling haemophilia doctors to test the patients. It says nothing at all about counselling, pre-test advice. It says: test the patients.

Q. We will come to that. So you obtained your patients' consent to give blood samples for the HIV test, the HTLV-III test?

A. Yes.

Q. You sent those samples off to Dr Tedder?

A. Yes.

Q. 31 you say in your statement?

A. About that number, yes.

Q. You then had the results back, you've said again in your statement, by 26 October --

A. Around then.

Q. -- of that year. What was the outcome?

A. The outcome was all but one of them were positive for HTLV-III.

Q. And of that, about half were children?

A. About that. So maybe -- I think this is such another watershed moment. Maybe I could just make a couple of comments around that because it's such a turning point in the epidemic.

So if you think about the build-up to this test being available, we've got this nearly two years of

concern after the San Francisco baby, the American cases, it looks like there must be a virus. We're very concerned, we need to know what the cause is. Okay, it's -- now it's the middle of '83, it's a virus, now we need the test, we must have a test. And now we've got the test.

We've got some people in Britain, Professor Bloom, saying that this isn't going to be a problem. You know, there might be a small number of cases, I really don't think it's going to be a big problem. We've got some major American haemophilia treaters, huge numbers of patients, saying formally -- director of the New York centre, New England -- "This is not a big deal to the patients, just -- you don't need to get excited about this, there might be a few cases, this is not going to be anything to worry about."

So we're really relieved to have the test, and we've done these tests thinking, well, this is good, you know, maybe we're going to get 5 per cent, 10 per cent positivity and I can't tell you the sort of reaction of all of us when we saw the results.

I rang up Dr Savidge and said, "How do your tests look?" He said, "I've got the majority positive". He said, "I've just spoken to

Peter Kernoff at the Royal Free, he's got 100 positive results."

So this was a complete turning point. You knew from that moment, whatever part of the haemophilia community you were in, a doctor, a nurse, a patient, or a relative, life would never, ever be the same again. This was the start of something dreadful and you knew that immediately; you just saw and feared everything that was about to happen. And it was just all so unexpected, really.

Q. Some of those who tested positive would presumably have been moderate or mild haemophiliacs because you -- I think you've given a rough figure, you had about 20 severe haemophiliacs?

A. Yes. That's correct. The rest would have been moderate. I mean, we've tried very hard. One of the worst aspects of the whole epidemic was the people who got HIV and died who only had very, very, very occasional Factor VIII, either because they had mild haemophilia or they were a haemophilia carrier. Some girls got treated with Factor VIII and got HIV and died.

Even worse were the people with von Willebrand's, because nearly everybody with von Willebrand's, a related condition -- Factor VIII

is not actually the treatment of choice. They should have DDAVP. And through Macfarlane Trust, I became aware there were a number of patients with von Willebrand's who had been given Factor VIII. So firstly they had been given the wrong treatment and then been infected HIV and died. So this was some of the very worst aspects of the whole epidemic.

Q. Can you describe what you then did once you had received these test results of all but one positive. What did you do in relation to that information and telling patients?

A. Well, I think I had already given the patients' appointments for about six or eight weeks, knowing -- or hoping the results should be back. So they had scheduled appointments to come back and -- this would be the adults. I'm just talking adults firstly. So I knew they were coming to see me.

So I've sat down with them and told them the result was positive. Now, it was very difficult for doctors to know what a positive result meant. This was an antibody test so it meant they had been exposed. Some virus infections that you get, chicken pox, mumps, measles, if you have antibody it means you are immune. So one possible interpretation was these patients had been exposed, there was

a theory the virus might be dead because it had been fractionated in a laboratory. How could it have survived? So people said: oh, they've got antibody positive, that's just because they have been exposed to dead virus. They are not really infected. So that was one explanation.

The other explanation was they had antibody because they had been exposed to it and they were carriers of the virus, which sadly turned out to be the case. So the first thing I had to say to them, once I told them the test was positive, was to say I wasn't completely sure as a doctor what it meant, but it either meant one of those two things.

I then said I didn't know what the future would hold but we'd be following them really closely because we knew that the virus might or might not damage the immune system and we had these markers for immune system function which we could follow. So we would be following them more closely than we normally did and we'd want to know from them very urgently if they had any particular problems with infection. I think we issued antibiotics and gave them instructions to have that at home if they had a bug over the weekend and were having problems getting access.

In particular I said, "You know, I need to talk

to you" -- this is something haemophilia doctors have never had to do before, talk to them about sexual activity and possible transmission. There were no cases of sexual transmission at that stage. But I said, you know, we need to consider the possibility you might be able to transmit the virus by sexual activity.

There was a curious system, you could actually prescribe condoms on the NHS, I discovered. So we used to issue the patients with prescriptions for condoms and off they went and got supplies -- because we were, you know, concerned about that. A lot of people were in denial and it took a lot of reinforcing.

So I tried to keep the interview quite short and then followed it up a few weeks later with a follow-up. I'm sure I'd asked them to come with their partners, so it wasn't just them, there would be the patient and their wife as well, and then we'd follow it up a few weeks later. I didn't have any written information at that time.

Q. So that I understand the setting, as it were -- we've heard evidence of people being given their diagnosis in corridors, of being given their diagnosis in group meetings, in being given their diagnosis in the

presence of others. Were your communications your consultations with patients private consultations, with just the patient and their family member?

A. They were. But obviously one of the things I wanted to say to you when I came to talk to this Inquest*(sic)*, reflecting on everything, but particularly with the Macfarlane Trust's -- maybe we are going to talk more about that tomorrow, but for 12 years I interacted with every centre in the country and I became painfully aware of the way in which many people had been told of their diagnosis, and I wanted to state in this forum how I feel that many patients were badly let down by some centres.

Medicine was different then. We've heard all about this paternalism. When I was doing my general medicine, a patient would come in very sick and after a couple of days we'd established that they had cancer of the pancreas and I would say to the consultant, "This is the diagnosis". The consultant would say, "I'd like to see this patient's wife", and we would sit down with the wife and the consultant would say, "I'm very sorry to say your husband's got pancreatic cancer, he's probably going to die within a couple of weeks". He would then say, "Do you think he would want to know?"

So the whole process -- this was standard. You did not tell the patient first; you went to the relatives and asked the relatives what they wanted. And some of the relatives said, "Oh, yes, we must tell", and some of the relatives said, "No, do you know, I think it would be kinder if we just let him go". So that's the background to everything.

Then we've got the situation, and I'm fully aware -- exactly as you say -- of people being told in corridors. There was one group of patients I know who got their results by letter from the centre, and it said, I've seen the letter: It turns out that you're testing positive for HTLV-III. If you have any concerns about this, you should go and discuss this with your general practitioner.

So I think I wanted to say -- I very much wanted to say -- that I think a lot of patients have a right to feel very badly let down by the way they were told by their centres, and this is nothing to do with medicine being different in those days. I can only say it was down to a lack of humanity, for want of a better expression.

Q. Your consultations, therefore, were private consultations with the patient, and it was the patient's choice as to whether they brought their

partners --

A. They were encouraged to because I felt it was better that they had somebody with them.

Q. It was arrangements, if any, were made for testing or offering testing to partners?

A. That came a bit later. I think I had learnt or -- my feelings were you shouldn't overload them with lots of things at the start. I said, "Let's get the important things sorted out". Obviously, I spoke to them about the importance of the dangers of viral transmission through sexual activity, and then at the next interview or the one after, I started to say to them, "You know, you have had a chance to think about this very difficult news I've given you, and how does your wife feel? Would you like to have a test? I think that would probably be a good idea."

A number of people said, "No, thanks. I don't want to". A number of people said, "Yes, please."

In one case, quite an elderly couple, they said no, and they came back to us about several months later and said, "We realise now we've just been in complete denial. We were so, so shocked at what you told us". And they said, "we think she ought to have a test" which she did, and she was positive.

Q. That was the process of telling adults --

A. Yes.

Q. -- which you said you started with. Then you had 15 or so children in respect of whom the results were positive. How did you go about the process of informing their parents or them of the diagnosis?

A. So, again, this had been discussed at national level. No formal recommendations. There was a conference which took place, and I remember vividly half the day was taken up on children -- should you tell and should you not tell? And the first presentation was by a Scottish group who thought it was better not to tell. By the way, we should record that at UKHCDO -- Dr Craske had said initially, advising haemophilia doctors, that in the first instance it was probably all right not to tell patients, which I didn't think was the right advice.

Anyway, at this conference, I was the sort of follow-up after the talk that said, we don't think you should tell. My talk was why you should tell. You know, we'd discussed it a lot with other people. The argument seemed quite clear really. If adults have rights to know, so do children. I felt it was a very dangerous situation not to tell. I felt that many of the children probably suspected anyway, or would suspect. I felt it was better to be honest and tell

them. If I did tell them, a few weeks later if I said to them, your blood tests are looking better, they would believe me. They would say, if a doctor tells me news like that, I can always believe what they are telling me.

So I decided to tell, and I had a counsellor by this stage who was extraordinarily helpful. And we just sat down one day and said, "How are we going to do it?" And we thought we would just -- again, no guidelines; nobody advising us. We just said, "Well, let's do basic principles. Let's just do it briefly. Let's do it when they're well. Let's do it in the school holidays. Let's follow it up with a quick appointment. We don't want too many people there" -- the parents, me and the child probably, unless the parents wanted anybody else.

Q. Just pausing there. The parents had already been told, or --

A. No. This was before. This was a principle of what we felt we ought to do. So once we got an agreed thing of what was our view, the next step was I approached all the parents, and -- just on their own, both of them, and told them the results of the test, which was obviously very distressing. And I said to them, "It's our view we need to tell the child". There were some

exceptions. There was a boy who was four, so we didn't tell him.

Q. The --

A. Can I -- I just want to go on.

Q. Yes, of course.

A. I'm just having a moment.

So we then sat down with the parents and said we'd really like to tell and I got varying responses really. One or two of the parents were very, very reluctant. It was too distressing to think about. But eventually they had all agreed. And so we then went on, and that's what we did. We told them in the way in which I just outlined to you, and then they all knew, apart from the very young child.

Q. I think -- I won't put it on the screen, but we've got the text of a talk you gave which was all about why you thought a child should be told and how to tell the child.

One of the observations you make in your statement about the information you were giving to your patients at this time is, you told them not to inform too many people, or you advised them not to inform too many people, not to share the news too widely. Is that correct?

A. Yes. That works for all patients. You know,

everybody. You know, this was a time of great stigmatisation. As if there was not enough for the patients to bear, this was a disease where -- I mean, we had people who had windows smashed. We had somebody went into a laundrette and they wouldn't clean their trousers because they knew they had HIV. We had kids on the school bus chanting, you've got AIDS. You know, there was widespread stigma.

So we said to the patients, you know, we really advise you to be careful who you tell.

Q. In terms of the stigma specifically in relation to children, your statement refers to schools reacting particularly badly. Can you just explain a little bit about what happened in relation to that.

A. Well, there was -- all of the schools said, we can't have this child anymore; it's not possible. For a variety of reasons that were given. One of the schools produced a long document saying, he couldn't go on the school bus because he might bump into somebody and bleed. He couldn't have lunch because he might stab himself with a fork and bleed. He couldn't do pottery classes because he might scratch himself and bleed, and so on, and so on.

There was an especially difficult encounter with a school where I was trying to get a child in who had

recently come under my care who extraordinarily had never been to a normal school because of his haemophilia, a practice that had been abandoned ten years previously when Lord Mayor Treloar was closing down really. This school was adamant they would not have this child, and there was a very, very spectacular series of meeting with the school and the Education Authority.

Eventually, the Education Authority agreed to employ a nurse who sat alongside the child, holding a burn bin and a bottle of disinfectant, wearing gloves, so that if the child had a nosebleed she could clean it up. And I obviously very vehemently protested against this because, you know, the whole thing was completely inappropriate, and the child was being stigmatised in a very dramatic way.

So things did settle down after a bit but, yes, it was a very difficult initial exercise trying to get the schools to accept the children.

Q. Do you recall over the months that followed -- so this is towards the end of 1984, perhaps beginning of 1985 --

A. Yes.

Q. Over the course of 1985, how often would you typically see the patients who had had a positive test result in

order to monitor them, talk to them, counsel them?

A. It would depend on how their tests were looking. If I had someone whose tests showed quite advanced immunosuppression who was particularly vulnerable for opportunistic infections, I would have wanted to see them every month. If they were very stable and healthy, it might have been, you know, every couple of months, something like that.

Q. I'm just going to ask you about two particular cases -- not identifying anybody by name -- that you refer to in your Archer and Penrose, and that will probably be it then, sir, for today.

In your Penrose evidence, you referred to two cases of patients in the area for which the centre was ultimately responsible who became infected with HIV.

I just wanted to ask you a little about both of them. The first is a child with mild haemophilia who was, in April of 1984, given Factor VIII -- not by you but at the William Harvey Hospital in Ashford -- and infected with HIV as a result, and the patient subsequently died.

Do you know how it came about that a child was being given Factor VIII as at April 1984, not under the care of a specialist centre or clinician, but in a local hospital?

A. Well, I'm actually reluctant to talk about individual cases, but in this particular case, the boy's haemophilia was not known. He had a routine tonsillectomy. This is the four-year-old boy. He had a perfectly routine tonsillectomy. He bled excessively. He was in a hospital ten miles from my hospital, the haemophilia centre. So he bled excessively after his tonsillectomy, and his mild haemophilia was diagnosed correct. At that point, as they were not a haemophilia centre, they should have been on the phone to me ten miles away, you know, 24-hour response service. Somebody should have rung me to say, we've got this situation with this boy. What do we do? How do we treat? But that didn't happen. They treated him with commercial Factor VIII which they'd got hold of, and he was infected with HIV on that first treatment and eventually died.

Q. And the second case you referred to is a patient who was one of your patients treated with heat-treated Factor VIII in May of 1984 in the way in which you have described but was then -- again, I think at the William Harvey Hospital in Ashford -- given non-heat treated Factor VIII -- not by you, obviously, but by a different hospital -- and infected with HIV as a result.

Do you know anything -- again, nothing to do with individuals. It's about looking at systemic issues. Do you know anything about how that came to occur?

A. Well, yes, I do because this was a man with mild haemophilia who was under my care. He'd never had Factor VIII in his lifetime because of his mild haemophilia, and he had to have some sort of surgery, and it was May 1984. So he timed that well I thought because the surgery was significant enough for me to want to cover him, but I had heat-treated. So I gave him heat-treated Factor VIII in May/June 1984, and then a couple of months later, he cut his arm on a greenhouse, had an accident and was taken into this other hospital bleeding, and they gave him commercial Factor VIII un-heat-treated, and he got HIV, and then eventually died.

Q. I know you want to talk about the December 1984 document issued by UKHCDO. That will take a little while, but it's the right moment in the chronology, but rather than do it today, given the time, sir, I am going to suggest it's an appropriate moment to stop, and then we can pick that up tomorrow morning.

SIR BRIAN LANGSTAFF: Yes, indeed. So we will do that now. We will break for the day. Thank you very much,

indeed, Dr Winter, so far.

Tomorrow we start at ten o'clock, as we did today, so we look forward to seeing you back then tomorrow. For those of you who are coming back tomorrow, I look forward to seeing you too. In the meantime, stay safe.

MS RICHARDS: Sir, before we end, can I just update on the timetable for next week in relation to the presentations?

So we'll continue and conclude Dr Winter's evidence tomorrow. We have the evidence of Dr Brian Colvin on Tuesday and Wednesday of next week, and then the proposal is that on Thursday I will complete the Cardiff presentation, there's probably about an hour or so left of that; then the presentation on St Thomas' Hospital and Professor Savidge on Thursday; then we are going to sit on Friday as an extra day for the Oxford presentation. So I wanted to make that clear now so that both those here and anyone watching remotely will know what the position is for next week. We will be updating the timetable on the Inquiry website to reflect that.

SIR BRIAN LANGSTAFF: Thank you very much. So a full four-day week next week. Thank you.

(4.28 pm)

(Adjourned until 10.00 am the following day)

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