Friday, 2 October 2020

(09.58 am)

DR MARK WINTER (continued)

MS RICHARDS: Dr Winter.

SIR BRIAN LANGSTAFF: Dr Winter, you are still under oath.

Further questioned by MS RICHARDS

MS RICHARDS: Dr Winter, you'd been telling us yesterday about the decision that you made in relation to heat-treated products in the middle of 1984 and in your statement you say of that decision:

"No patient since that time was infected by any virus at our centre."

I just wanted to ask the basis upon which you are able to say that. In relation to HIV -- and you may well be right, I'm not seeking to challenge your conclusion -- what's the basis for your ability to be confident that no-one treated at the centre with heat-treated concentrates from May 1984 was infected with HIV? Because you weren't able to do the historic exercise because there were no stored samples under your predecessor.

THE WITNESS: Yes. So I mean, I'm talking about the major viruses that we were dealing with, hepatitis B, hepatitis C, HIV. I mean, of course that remark is in the context of, as we discussed yesterday, it turned

out that all but one of my patients had HIV already and all of them presumptively had hepatitis C already if they'd been previously exposed to concentrates in the years prior to that, and of course they were screened regularly for hepatitis B and they were vaccinated against hepatitis B.

So there was no patient in our centre and as far as I'm aware -- we were obviously particularly close to St Thomas' and their information as we were part of the same regional network, I wasn't aware of anybody becoming HIV positive or hepatitis C positive, subsequently, who'd previously tested negative at the time of the change. Of course, in that statement it's important to stress there were very few patients left who could seroconvert because most of them had been infected anyway.

I obviously in my statement -- that would not include sort of minor viruses like parvovirus, which we couldn't or didn't test for. I didn't know or wouldn't know whether the heat-treated concentrates transmitted that but that was a pretty low profile virus.

Of course it did turn out -- and this is an important point -- you will understand the reason for the change was based on theoretical concerns and not

on any sort of very solid science, and there are papers we may look at later which later than this date did show that heat treatment did indeed inactivate HIV, as the experimental work had suggested. But it also turned out, very importantly, that this first generation of heat-treated products, which didn't heat for very long or to a very high temperature, in the end did not seem to inactivate hepatitis C.

So this was the first time an attempt was made to make treatment safer, and we now know it did make treatment safer -- really importantly, for HIV -- but it turns out that if you did switch to heat treatment and you at that stage did not have hepatitis C, you might still have been vulnerable to get hepatitis C.

Q. You I think wanted to make some observations about the UKHCDO's publication, the AIDS Advisory Document, in December 1984.

We can put that on screen. Henry, it's HCDO0000270_007.

It should come up before you.

A. So it seems to me this is a really sort of important document because it's coming at this very critical time -- this is December '84?

Q. December 1984?

A. So most centres will have had their HIV results a few

weeks prior to this. We spoke yesterday of the very unexpectedly high level of positivity which nobody had really expected. So there was this very strong sense amongst doctors like me suddenly it's apparent we're in a major health emergency in the haemophilia world, adjacent with what we already know about severe chronic liver disease, the evolving story; so now we have two major problems. This is isn't a minor thing, as some haemophilia doctors had predicted; this is going to be a major healthcare problem and how do we deal with it?

So this is not the whole of the haemophilia directors, this is the Reference Centre Directors. I don't know whether this is -- this could have been a scheduled meeting because they meet every three or four months, and they've got there -- where it says "in consultation", these are some blood transfusion experts and virologists and, in particular, they have got Richard Tedder and John Craske as virologists there.

So they start by reporting the current state of play, that there are three haemophiliacs, and then it stresses to haemophilia doctors the availability of the tests, which now also include the PHLS.

I mean, by now most of the centres should have

done the tests but we know, I think, that that wasn't always the case.

Q. We do know that, yes.

A. Can you go next page?

So then, as we've just been discussing, they then talk about this research evidence, laboratory evidence, that it seems like HIV might be susceptible to heat, some "spiked" concentrates. So what that means is that somebody's taken Factor VIII concentrate and spiked it in the laboratory with HIV and then heated it and then shown that the HIV is inactivated.

So that's something that proved to be true. And then, exactly as I've been saying:

"It is unlikely that this process completely inactivates Non A Non B hepatitis."

Absolutely correct.

Something we haven't discussed so far, another problem about heat treated was that you get less Factor VIII out of the manufacturing process. So not only was it 50 per cent more expensive but you lost a bit of Factor VIII in the manufacturing, which was another sort of slightly minor factor about switching to heat treated.

Then it talks about the dry heat-treated product and tells you the price of it. And by now, since the

Alpha, which is the one we used, had come in in the April and May, now you see that last paragraph, under Factor VIII, there are now several heat treated -- these are all commercial, all American plasma, but all heated in various ways. There were two ways of doing it. There was dry heat or wet heat. I'm not quite sure what the difference was between dry heating and wet heating.

SIR BRIAN LANGSTAFF: I think the difference, as I understand it, but you may not have understood it that way at the time, is that wet heat is pasteurised so you have the virus in solution. Dry heat is after the product has been freeze-dried and the heat is then applied to vials of freeze-dried concentrate. I think there is a third intermediate where the freeze-dried concentrate is diluted a bit in a solvent so it is somewhere in between the two. But those I think, as I understand it, are the three different production methods available at the time, if that's any help.

THE WITNESS: Well, it is. You know a good deal more about fractionation methods than I seem to, so --

SIR BRIAN LANGSTAFF: Well, I'm only taking it from what I pick up.

THE WITNESS: That is very helpful.

Now, the BPL, halfway down or towards the end

here, so BPL is being rebuilt, all this money's gone into it, but it can only dry heat, at that stage, 30 per cent of its output from January 30 -- these dates are really important. So this is about eight months after some of us have switched to commercial dry heat. BPL, eight months down the line, can still only dry heat 30 per cent but more coming, as promised.

Then we know about Scotland.

Then they talk about recommendations for doctors as to what they think they ought to do and, as you can see here, they're really -- where I'm talking about options in decreasing order of safety, they are still recommending concentrate. You know, the haemophilia directors never prioritised a switch back to cryoprecipitate at any stage, and in any case we know that there were not the supplies of cryoprecipitate to do that. But they do, under option 2, suggest that you could use some cryoprecipitate.

MS RICHARDS: Just pausing there, Dr Winter, we are told this is in probable decreasing order of safety. So it does seem as though their first priority was the heated UK concentrate. But, as you already observed, comparatively little of that available at this time.

A. Yes.

Q. Single donor cryo or FFP is then prioritised in order of safety, in this document, over imported heat treated.

A. Yes. But we discussed all the problems around cryo usage and the very significant problems with it, and we've also discussed the supply problems, certainly in -- you know, the Tooting -- as we discussed, the Tooting centre could not put out supplies of cryo to any significant level, although, as you said yesterday, in other parts of the country like Southampton, supplies of cryo appeared to be greater.

But this is an important document because they are clearly saying to doctors -- reinforcing that it is better to use heated than unheated.

Q. Yes.

A. Because this is at a time when an awful lot of centres have not gone across to using heated. They are saying, as you would expect, that UK concentrate heated, if you could get it -- a key phrase -- was a lot better -- was better than heated imported.

This is a snapshot in time. All this is going to change radically over the next few months.

Then, again, these key phrases at the bottom:

"Concentrate is still needed; bleeding is the commonest cause of disability and death."

So we've heard of these calls: why could Factor VIII therapy not have been suspended? Well, in the view of the clinicians, it could not have been. They used DDAVP, we've talked about already -- can we go on to -- and then they talk about what used to be called the "virgin" -- the PUPs, how to treat them. That's pretty uncontroversial. And then the using heat treated, and then for haemophilia B -- I'm just reading.

The evidence lower down:

"The evidence that heated US Factor VIII is safer than unheated NHS is debatable ..."

So this was at the core of the argument.

After all the things we said yesterday, I got home last night and I remember a meeting -- Professor Bloom said to Dr Savidge and I, "You are mad to switch. There will never be HIV in BPL Factor VIII."

Q. Can I just ask you -- it's very useful evidence to know. Do you have any recollection roughly when that meeting would have been?

A. It was at a scientific meeting. It was outside of the meeting.

Q. Yes.

A. He actually --

Q. In the course of 1984?

A. Yes, he actually -- when he learnt that we were going to switch, he actually came up to us and said, "You are mad to do this, it's completely unnecessary. You know, this is not going to be a problem in BPL Factor VIII", as we'll see from other correspondence of Professor Bloom.

So there was this major, major split of haemophilia directors, for all the reasons we talked about. One camp saying, "I'm terribly worried about this data. Haemophiliacs are so vulnerable. We now know it's a virus. Increasing number of patients in the US. Plus by now -- oh no, we don't have the testing data yet -- but we're going to switch".

I mean, but we do have the testing data by the time of this document.

Then this counter-argument, "This is only a problem for American Factor VIII, it's not going to happen in British Factor VIII. Look at the Germans, they use twice as much as we do, they've had no problems. I'm really worried about inhibitor formation. I'm just going to monitor the situation".

So there was this split. Probably, in Britain, 20 major treaters, there was about, you know, four to start off with and then a few more, and a hard core of

sort of 10 to 12 with a totally opposite view. So for the next few months there is this complete -- it's like Brexit, okay, leavers and stayers.

Q. Then I think if we go on in this document -- well, in fact if we just look there, it says:

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

And then the passage you referred to.

So it would appear from this document that although this is much more detailed advice than anything previously published by UKHCDO, the idea of clinical freedom which you referred to yesterday still appears to be represented in that passage; would you agree?

A. Well, I would. I mean, if you read all the haemophilia directors' minutes over the 10 or 15 years --

Q. I have.

A. -- the phrase "individual directors may wish to make up their own minds" occurs again and again and again and again. Now in medicine, of course, it's not like

that. You have standardised protocols which are issued to doctors and they're expected to follow them. But there was this sort of ambience, if you like, of working as a haemophilia director where the function of these bodies was a guidance, which -- steering you, as they are, they are saying what we think, or what the virologists think, but actually at the end, it's down to you.

Q. I think you have also observed yesterday that there was something in this document about testing, so I don't know if we just carry on further down -- is there anything before we go to the next page --

A. Yes, so --

Q. Is there anything before we turn to the last page which deals with testing that you wanted to comment on?

A. So I'm just looking at section 2 there. We spoke about this, this 50 per cent jump in price and all the problems that that caused. I think again that -- you know, a number of directors would have looked at that and said, "How am I going to get the money, you know, at the start of an NHS financial year? I'm never going to be able to do it". I think that was another deterrent:

"Funding will need to be negotiated at local

level ..."

Correct. That's what it was like. I think we can go to the next page.

So "Antibody testing":

"It is recommended that patients be ... tested."

It does not say anything at all about pre-test counselling. This was not a concept in clinical medicine at that time. Then it says, quite rightly -- well, firstly it says:

"... people should be informed ..."

Quite rightly.

Then the use of a very strange word: "reassured". On what basis did they feel able to say, "You are testing positive but there's nothing to worry about"? It seems an extraordinary word to use.

"... counselled regarding transmission to spouses ..."

Of course that's important.

"This seems to be the most practical method available."

So here we here, it's clearly saying for the first time to doctors: You must treat -- you know most people should have treated already, most of us had -- and this is the way to do it.

Could we -- is there anything else later on?

Q. The rest of it deals with arrangements for the care of -- if we go on to the heading "Clinical", so it's personal protective equipment -- a topical issue -- and arrangements for nursing.

Could we just go to the very top of that page, please, Henry.

We can see there at the top of the page there's also a point about assessing the need for elective surgery in the light of supplies of heated concentrate. This appears to be the first time that UKHCDO make any reference to that. I think you told us yesterday that, in your own practice, that was something you had already considered.

A. Yes. I mean, all these changes are happening against a context of doctors trying to not use concentrate unless they had to. So you probably talk about prophylaxis programmes being suspended, making sure that patients were using concentrates in the home setting only when it was very strictly needed, making sure they absolutely understood when they should and should not be giving concentrate, avoiding concentrate in mild patients and von Willebrand's, as we discussed yesterday, and haemophilia carriers, and then also looking at surgery.

You know, if you had a patient who had a hernia

that had been there for a year and needed doing but from which he was not getting major symptoms, you would be inclined to say to him and the surgeon, "I really don't think we should go ahead at the moment. Your symptoms are not major, and I really think we should put it on hold for a few months and see what the situation looks like in a few months' time."

So this was one of the devices, if you like, that would be used to minimise risk.

Q. Now, we know that this document, which is dated 14 December 1984, arose out of a meeting that took place on 10 December 1984. There is just one issue in relation to that meeting I wanted to ask you about, so I'm going to put that on screen. HCDO0000394_117. It's about the issue of telling patients the test results. I won't go through the thrust of most of the meeting. You can see there it was a special meeting that was arranged on 10 December 1984 to take place at Elstree.

Henry, could we go to the fourth page, please. If we go towards the bottom of the page, second half of the page, after the reference to Dr Jones, there's a paragraph which says this:

"A long discussion took place on whether persons

found to be positive were to be informed. Several differing views were expressed. It was agreed that each clinician would decide for each case depending on the facts of the case, but in general to provide information if asked for."

Then if we go to the next page, please, Henry, halfway down there's a passage saying:

"The Chairman [that we know was Professor Bloom] summarised by saying that testing should be instituted as soon as possible and that information on the test results should not be given automatically but if asked for."

Now, that doesn't appear to have made its way into the advisory document that we've just looked at, but just looking at this, I think it follows from everything you told us yesterday that you would, at the time, have profoundly disagreed with the view being expressed here, that it was for a clinician to decide in every case whether to communicate the results of the test to a patient. Your view, as I understand it, was that absolutely every patient needed to be told?

A. Well, I would have very strongly disagreed if I'd been at that meeting. I mean, I think if a patient has a blood test, they need the results of it told to them

as a matter of right. But, secondly, there's all the implications about possible sexual transmission. So it seems inconceivable, frankly, that a group of doctors could sit around a table and say, well, you don't really need to give the results unless the patient asks for it. I mean, you know, 30 years down the line, this seems an utterly bizarre meeting.

Q. You rightly mention the health implications, in terms of the risks of sexual transmission, if a patient is positive but does not know. Presumably, in the context of patients with bleeding disorders -- these were the cohort of patients being discussed here -- there were further possible health implications -- if you are having a bleed and a member of your family is helping dealing deal with that -- transmission of HIV through that route?

A. Of course. I'm not sure, by the way, looking at who was there, why they've got so many BPL people there. That's an unusual thing to do, to have people from a company at a meeting of the Reference Centres, unless there was a major agenda item about BPL expansion or something.

Q. I think not specifically, but that may be an issue that we will need to explore with those who were there in due course.

Now, before moving on to events from 1985 onwards, in terms of your own care of your patients, I want to ask you a few more questions about the issue of consent and provision of information to patients, and then a number of questions which the representatives of Core Participants have raised with me to explore with you arising out of your evidence yesterday. So we will be going back to a few of the topics from yesterday, and then moving on to events from 1985 onwards.

Just dealing broadly with issues of consent and the provision of information to patients, would you accept that, as a matter of principle, whether to take the risks involved in a treatment -- and in this context, the risks would be the risk of developing liver disease, or the risk of being exposed to a new and potentially fatal disease -- or whether to take the risks of not being treated (which, as you pointed out in this context, could involve risks in relation to haemorrhage), that is ultimately a judgment for the patient; would you accept that?

A. Yes, but I've said to you already that was the choices I gave them, and they were choices. You know, okay, I said to them, "I'm your doctor. This is a very difficult time. We've got important decisions. This

is what I think, I'm your doctor."

I mean, many of the patients I had this conversation with, when I said, "What do you think?" they said, "You're the doctor. I expect you to tell me what to do". Now we're in a different world where, quite rightly, this is a car being driven by patients. But there was passivity in the air, to a certain extent.

Remember, these people, it's congenital disease, inherited disease. From their earliest memories of coming to a hospital, somebody in a white coat gives them an injection that stops them bleeding, they were a very different -- by and large, a very different group of patients, from gay people with HIV who I looked after who tended to be much more -- I generalise, of course. But, you know, the gay patients with HIV changed the nature of practice in the sense that they, in many ways, were a new generation of patients who came along to doctors, quite rightly, and said, "Hang on a minute. This is my life, my illness. I want all the facts, and I want to do all the decisions," all of which is completely correct.

So I'm just trying to get across to you there were several patients -- when I had this conversation,

you can only say they were bemused. They said, "Well, why are you asking me? Because, you know, I've been a patient of yours a long time. I've been in the centre all my life. You know, I don't know what to do. I rely on you to tell me what to do." And I would say, "Well, I'm giving you the choice." And they would say, "Well, I'll do what you think I should do".

Q. That choice was so important to give in this context, and I understand indeed your evidence in particular in relation to the switch in the middle of 1983 is that you gave that choice to your patients. But the choice was so important, even judged against the standards of the 1980s, because it was their body, their health, their life, their death.

A. I agree.

Q. And, as you've just alluded to, in order to make that choice, they would need to be given information, potentially advice, potentially clear recommendations, but, at the very least, information by their clinician.

A. Isn't that what I said to you?

Q. Yes, absolutely. I'm just trying to establish, as a matter of principle, even in the '80s -- and we know that in many respects paternalism and so on --

A. Oh, yes. This is nothing to do with medicine being more paternalistic. These standards should have applied then.
Q. Now, in relation specifically to testing now, not for hepatitis C later on, which we'll come to, or HIV in 1984, but the array of blood tests that would be done on what I think you described as the regular full review that your patients would have. I'm not going to distinguish here between Guy's and Margate, unless you tell me that there were different practices when you were there.
What were the tests typically that would be undertaken at a regular review of that kind?
A. So these would be done about every three months as part of a comprehensive care review, as we walked about, and they would always include a check for this inhibitor. So about 10 per cent of patients with haemophilia develop this antibody which neutralises the Factor VIII. It's a very important and negative development. So that would be number one on the list, would be an inhibitor test. We just do a general blood count to make sure they hadn't become anaemic because of bleeding. We might check their iron levels if there was any suggestion that they had been bleeding significantly. But we would check at that

stage, you know, depending on which date we're talking about -- I think early 1980s hepatitis B vaccine became available. So we'd be monitoring their hepatitis B status, and if they were hepatitis B negative and hadn't been exposed, didn't have hepatitis B antibodies, we would be offering them vaccine if it was available by then, and then we would be screening them regularly to make sure that the vaccine was still producing antibodies. So that's the hepatitis B part.
Then these indirect markers for non-A, non-B -- we haven't got a hepatitis C virus to test, or level, so we -- for every visit, we'd be monitoring their liver function tests. But we now know, as we discussed, that the differing results we got actually didn't really help us because they weren't actually a direct sort of predictor of what the state of the patient's liver was like. We'd certainly be looking at their liver function tests. I guess a general sort of wellness check -- the body electrolytes and blood sugar. That would be it.
Q. In relation to the liver function tests that you would be looking at -- I mean, leaving aside the fact that you may have learnt later that they weren't the best predictor -- at the time, you were looking to see

whether there were abnormal liver function results. If there were, is that something you would expect to discuss with your patient and explain to them the significance or otherwise, as you then understood it to be, of those results?
A. Well, yes. But, I mean, it's clear -- it was clear then -- that nearly every patient who had had Factor VIII concentrate from a commercial origin was going to have this non-A, non-B. We had one patient with hepatitis B, but nearly all the other patients, if they were regularly treated, had abnormal liver function tests, and they were aware of that. I told them that, and they knew we were monitoring it, and they knew about the concept of non-A, non-B. But they knew there wasn't a specific blood test, and I would say to them, and the Haemophilia Society would publish that, you know, the presumption is you may have this third virus, and one day we hope that we'd be able to do the blood test.
Q. That would feed in then potentially to, as you said yesterday, the lifestyle advice that you might give?
A. Yes.
Q. Would there be -- this is now talking about testing more broadly; testing for whether it's HIV, or hepatitis B, or obviously later hepatitis C. Can you

think of any circumstances in which you would have thought it right to withhold that test result from a patient for any significant period of time, unless it was a patient who lacked mental capacity, but we're not dealing with patients within that category.
From your own perspective as a clinician publishing then, can you think of any circumstance in which you wouldn't be telling a patient that they have tested positive for HIV, hepatitis B or hepatitis C?
A. No, I cannot.
Q. Can I then just ask you -- these are just a handful of questions about various consent issues as they emerge. We know that -- and you referred to it yesterday -- centres sent data to Oxford at the time, later to Manchester, and although we haven't seen it from the documents we've looked at with you, Dr Winter, we've seen from other documents that that data was not just the material we looked at with the overall amount of concentrate but really quite detailed information about individual patients -- patient names, dates of birth, status and so on, in terms of their treatment.
That was, as I understand it, material routinely sent by centres to Oxford in the early days.
A. It was sent once a year.
Q. And that was at the beginning of each year?

A. At the beginning of each year.
Q. I'm not expecting you to be able to speak for other clinicians in relation to this, but in terms of your own practice, were your patients made aware by you or your colleagues that that data was being shared with Oxford and later with Manchester?
A. The Haemophilia Society had said to patients in their publications, this data, it's extremely important that it should be centralised at Oxford, so we have a national database, and, you know, it's going to give doctors invaluable information about how many people with haemophilia did we have in the country, how many are severe, what percentage have inhibitors, how many are on home therapy, how many are on prophylaxis, how much Factor VIII is being used every year.

They published -- you know, when you registered with the Society as a new patient, this was part of the information that was given as, you know, "welcome to the world of haemophilia"; this sort of activity does go on through the doctors. And they supported the doctors in that enterprise which was seen as being very important.
Q. Yes, and I'm not seeking to criticise the exercise, just to explore what patients would have known about it at the time.

A. It certainly was not the case, obviously. The patients were not individually approached and asked to sign anything then -- which in later years they were -- nor, of course, were they asked to sign any consent to having Factor VIII. You know, we never -- it was never considered necessary to ask a patient to give signed consent for that. All of that came later.
Q. In relation then to patients knowing that information about them was being sent to Oxford for these various purposes, is it the case that -- did you work on an assumption that they'd have known that because of Haemophilia Society publications, or did you have any conversations yourself with patients about that? Because I'm conscious most patients may have been members of The Haemophilia Society, but not necessarily all, and not necessarily all would have read material provided to them.
A. Yes. So each patient on diagnosis was registered with Oxford, given a designated code and was issued with a book -- a booklet, a small booklet like a diary that had their name, their UKHCDO registration number, and they were instructed to always carry this book with them wherever they went and, most importantly, always take it wherever they were because if they had a car crash one day whilst they were on a day trip to

Brighton, this book would be found, and the doctors in the hospital would be able to see it and know that they were a patient with haemophilia. So every single patient had this booklet, and it had their name and their registration number in it.
Q. And so are you able to be fairly confident that your patients were aware that information about them was being sent on a regular basis to Oxford?
A. I had that confidence for my centre.
Q. One of the observations you made in your evidence, I think to both Archer and to the Penrose Inquiry when you were exploring the issue of different medical culture, clinical cultures of the '70s and '80s, you made some observations about the way in which haematologists of an older generation would have been trained, as compared to haematologists of your generation and onwards.

Could you just explain to us, please, what the issue is that you were raising?
A. Yes. I mean, this is an observation that came out of my Macfarlane Trust, which we may talk about later in the day, because I had -- my feeling is that I had insights that other doctors didn't get because I was having to interact through the Macfarlane Trust with every centre in the country. So my major role at

Macfarlane Trust was: a patient who was a registrant of the Trust would apply for help -- I need a chair lift -- and my role was to contact the haemophilia director and ask for a report. You know, why -- how -- please give the relevant background information.

Plus, you know, going -- running regular haemophilia residential seminars was a very powerful experience. You'd sit in a room on a Sunday morning with ten patients from different centres. You'd be talking about one topic, and you'd be utterly bemused by the different way in which ten patients could be treated by ten different doctors. I mean, it was astonishing, and something that will surely come out of this Inquiry is the great variability of care that patients received.

We've already heard how variable was the way in which haemophilia doctors arranged for testing. We've already heard about the variability in which haemophilia doctors told the patients their test results. We've heard about the variability of switching to safer treatment and I developed a view -- you should ask this to the doctors that follow me. I know that some of them don't agree with this view which I've expressed previously, but I will say it as

follows: I did feel that you could split the haemophilia centres, obviously, into centres that were doing as well as could be expected in a very difficult time and centres that were doing things that just seemed inappropriate and not very appropriate. And, developing this theme, some centres, like St Thomas' and ours, their philosophy was: haemophilia's a very rare, complex, specialised disease. We want to know you, as a patient, every single thing that's happening to you. So if you've got earache you think it's nothing to do with haemophilia, but if you go to accident and emergency, somebody might operate on your ear without telling us and you'll bleed; or they'll give you aspirins which will bleed; or they'll give you an intramuscular injection which will make you bleed.

So we would say, we want to be the filter for every single thing. Don't go to any other doctor ever for anything without coming to us. We might say to you, okay, you've got earache. We'll fix for you to go and see somebody, and then we'll communicate. So that's philosophy number one.

Some centres, the attitude was: you'd ring up. I've got earache. Oh, it's nothing to do with your haemophilia. Go and see your GP. So, if you like --

I don't know if there's a word in the English language that's the opposite of holistic. Some centres were holistic. Some centres were not holistic. When you broke it down, my -- I stress -- controversial view is that I thought you could, by and large, relate it to the nature of the doctors. It was down to the doctors in that centre.

And to eventually get around to answering your question, there was a very important change that happened in about 1973/74 in the way in which haematologists were trained. So, before that time, if you wanted to be a haematologist, you did your medical training. You did your houseman's year, and then you went straight into laboratory medicine. So you had -- never had any time on the wards really working as a doctor.

You ran a haemophilia centre. You had patients who you spoke to about their haemophilia. If they had to be admitted to the hospital, they were admitted under a general physician whose name was at the end of the bed, and the laboratory doctor would go and see him. In 1974, quite rightly because haematology was becoming so much more clinical, the Royal Colleges said, we're completely changing training. If you want to be a haematologist, you have to do general medicine

first after qualifying. So I was the first -- I think it was the first year -- about ten of us, we wanted to be haematologists. We could not go straight into haematology after the six years of training. We had to do at least two years of general medicine, and we had to do this exam, the membership of the Royal College of Physicians.

So the importance of that was, in those two years, we were working as medical registrars. We were working with all the things that general medical wards bring: talking to sick people about very serious diagnoses; telling people they were going to die; being with people while they died. So, if you like, there was a group of us who, for the first time, were a group of doctors who dealt with the sort of problems that HIV suddenly brought. The older doctors were really good laboratory scientists. They were fine as haemophilia doctors dealing with the haemophilia. They'd got no experience of saying to somebody, "I have to tell you this test shows that you've got HIV, and this is a very serious thing, and your life might end," and then being with them while they got ill, and talking to the relatives and all the things that we've seen that didn't go well in some centres. So I make that observation.

But, you know, please do ask the same question to the other doctors next week who will probably think it's not true.

Q. I will.

There's then just one document I want to show you. This is a later document. It's from 1995. There's just an issue about consent that is discussed, and I just wanted to ask for clarification as to what you think the issue was. Henry, it's HCDO0000015_005. Go to the next page, please. It's a meeting in 1995, September 1995, of the centre directors. Dr Colvin is now the chair. We can see the bottom of that list there that you were present.

If we go then, please, Henry, to page 5, paragraph 8. You may have no recollection of this, Dr Winter, but you are the first person I can ask about it. It's under the heading "Consent for treatment". I'll just read it out:

"Dr Colvin said this matter had been raised at the Regional Directors' committee meeting. Agreement had been reached in principle to formal written consent for first treatments with concentrates and also that perhaps further consent should be obtained when there was a change in the product used for treatment. There was no uniform agreement about this.

Dr Hill said that consent needed to be informed consent. He thought there was a need for a standard form. Dr Colvin said that the Executive Committee could prepare a form if required to by the AGM, but he thought it might be difficult as NHS trusts have differing policies. Dr Ludlam suggested the matter should be reviewed again [et cetera, et cetera]. Dr Savidge said he felt that legal advice should be sought about this matter."

Then this:

"Some directors did not agree that written consent should be obtained as they felt that this could be held against them."

Then it says:

"It was agreed that the directors accepted that informing patients was important, but there was no agreement as to whether or not written consent should be obtained."

So we can see the context there is the issue of whether there should be written consent and standard consent forms in relation to treatment with concentrates, either for the first time or change in product.

But I wondered whether you were able to assist with the suggestion that some directors apparently

expressed at this meeting that written consent -- they didn't agree written consent should be obtained as they felt it could be held against them.

Do you know what concern underpinned that? Why did people think written consent could be held against them?

A. No, I don't. I mean, I do remember these meetings because it was around this time, you know, with the changes of medical practice, we began to say as an organisation we should surely be, you know, getting signed consent at the start of each process. You know, when we get a new patient, they should give signed consent to comprehensive care passages. We should get signed consent for the first treatment, and we should get signed consent for the data that was being sent to Oxford, or then Manchester, and we should get signed consent for any change of treatment.

My recollection was that there was a sort of consensus but, as usual, there were a few outliers who had reservations. But I don't recall -- it doesn't seem intelligible, does it? Why should asking a patient to sign a consent form be a problem for the doctor?

SIR BRIAN LANGSTAFF: There may be a school of thought that thinks that consent is more than a question of

process, legalistic formal process, but is a reality which depends upon the degree of information which is given and the relationship between the patient and doctor.

A. Yes.

SIR BRIAN LANGSTAFF: It might see the need for paperwork and signatures as being consent as simply concentrating on process rather than reality.

A. Yes.

SIR BRIAN LANGSTAFF: What would be your view on that?

A. Well, my only recollection is that, you know, if -- I've not been aware of this view, to my recollection, and it's not really a view that I can find any empathy with. It seems to me, if I ask a patient to sign consent, that's a good thing for me as a doctor. It's saying, you know, if you like, I have explained this situation to the patient, and she's put -- or he or she has put pen to paper saying, "I agree to what Dr Winter is asking me to do."

SIR BRIAN LANGSTAFF: The critical thing about that might be that you had explained it to the patient.

A. Yes. That's what I mean.

SIR BRIAN LANGSTAFF: Rather than simply obtained the patient's signature.

A. Exactly.

SIR BRIAN LANGSTAFF: Yes, I see.

MS RICHARDS: Dr Winter, as I said a few moments ago, I am going to ask you now a handful of questions arising out of your evidence yesterday which are requests for clarification or a few further matters to explore that have been put forward by the representatives of Core Participants.

A. Can I ask you who are the Core Participants?

Q. There's a whole range of them. We have the largest number of Core Participants of any public inquiry, many of those who were infected, or their relatives, but also health bodies, Government departments and the like.

SIR BRIAN LANGSTAFF: Can I help? Essentially, it's a question of what's in the rules that govern inquiries, but a Core Participant is someone with a very particular interest in the inquiry, either because they have an interest in the outcome, or because they played a real part in what took place. Something along those lines.

MS RICHARDS: So the first matter I wanted to ask you about is just the developing state of knowledge, or the state of knowledge about risks from American concentrates and the basis for that, and then the developing state of knowledge about possible risks

from British concentrates.

You alluded to this yesterday and, as I understand it, there was a general understanding that American concentrates posed a risk, in terms of transmission of hepatitis viruses, because of two factors: pool sizes -- large pool sizes -- and the paid donors from whom the plasma might be collected. Is that right? That was the basis of the concern about the American concentrates.

A. Yes.

Q. For that reason, your preference had been, as between the two, you'd rather use British concentrate than American, and you told us yesterday about the supply problems with Elstree and Tooting that meant there were shortfalls.

A. Yes.

Q. Then when you were talking yesterday about the decision-making that you were then taking -- when we get to 1983 and 1984, you talked about there being an awareness, certainly for you and Dr Savidge and the other group who made this decision in 1984, that you couldn't assume that British concentrates were safe.

Could you just explain how that fear, that concern, developed? What was it that led you to understand that both sources might pose dangers,

rather than simply the American?

A. So let's use hepatitis C as an example and the knowledge that we later developed about hepatitis C.

So here we are. Here's this highly vulnerable group of patients because of the nature of the concentrate process. 20,000 donors. If one of the donors is positive, patients may get infected. So we now know that in the 1970s the incidence of hepatitis C in US plasma was, what, 1 per cent? So let's do the maths. If you were a British haemophiliac attending a British haemophilia centre on regular treatment in the 1970s after the concentrate had become available '73/'74, a doctor gives you an injection of Factor VIII from paid donors in America, 1 per cent of whom have got hepatitis C, and it comes from 20,000 blood donors, you're probably getting maybe 200 different hepatitis infections.

We now know that the incidence of hepatitis C infection in British blood donors was much less than that but it was still about 1 in a thousand. So, instead of being exposed -- getting 200 doses of hepatitis C each injection, you might be getting 20, so -- which is no better than 200. So this was our major concern. We accepted that British Factor VIII was likely to be safer than American but still not

safe. And, of course, if I may say so, we were right, because it turned out that some British concentrates did transmit HIV.

Q. You have talked about how patients had a general preference for British over American if they could have that. What was the first time, roughly, you think that you would have explained to patients that British concentrates weren't necessarily safe? Would that have been when you were doing the heat treated --

A. Yes, that was -- you know, this was a conversation you always had at these seminars on the weekends. You talked about the nature of concentrates and where they came from and commercial and the need for self-sufficiency. These were a very, very regular sort of items that on a Sunday morning would be discussed in one of these workshops.

But the key moment for me was this switch to heat treatment because it was a reversal of the preferred system.

Q. Then, looking at the period in the late 70s/early 80s, where hepatitis is the main concern -- I think you were candid yesterday, you and your colleagues were not hepatologists, you were not virologists, you were haematologists. To what extent, in either Guy's or Margate, in this period up until sort of late

70s/early 80s was advice sought from hepatologists or virologists by centres such as yours?

A. Well, it was sought. I mean, the UKHCDO, as you said yesterday, they did have a liver working party at that time, so they were doing those interactions and taking advice, and they would have passed down anything to us in terms of specific recommendations.

I think there was a feeling that, you know, hepatitis B we could identify and we knew about that, we were monitoring the liver function. We believed, at that time, that we could see whether somebody was clinically well, fine, and we had a belief -- subsequently untrue -- that we could monitor somebody's liver function by looking at their poorly named "liver function tests", which don't, we now know, reflect liver function.

We had the theory, as we talked about, of non-A, non-B, and then the liver biopsy findings of Professor Preston. But there was no therapy. I think this is a key issue in answering your question. There was no great move at that time to have people automatically reviewed by a liver specialist -- that came later -- and that was driven by the advent of Hep C testing but most especially by the availability of treatment, because haemophilia doctors did not have

the expertise to make a decision, "Should this patient have interferon?" which was the first of the hepatitis treatments.

So no, I don't think there was. If I had somebody who was jaundiced and who wasn't well and their bilirubin was getting worse, I would, of course, refer him to a liver specialist.

Q. When you gave your evidence yesterday, after I played that first extract from the 1988 documentary, your comment was that you didn't have any regrets about having said that, and I have been asked by a number of people to ask what you meant by that, about not having any regrets about what you said. Was there some form of criticism of you for making those comments?

A. You will have to remind me what I said.

Q. I'm going to have to remind myself. I think the first extract was an extract in which you talked about the knowledge about American concentrates and the potential risks from an American concentrate and the general state of knowledge in relation to that.

A. Yes. That sounds all right, doesn't it?

Q. Yes -- no, absolutely. I've been asked to ask you what you meant by saying "no regrets"; do you mean that's still your view?

A. I've listened to myself, looking much younger,

30 years later, and I've listened to what I've said and I don't -- I haven't looked at it and said, "Oh, I wish I hadn't said that."

Q. Thank you.

A. I'm, you know, obviously reassured to find that what I said sounded reasonable.

Q. Then I just wanted to ask you about the phrase you used yesterday and again this morning about "presumptive non-A, non-B hepatitis". What did you mean by that?

A. Well, again we've talked this. We didn't know -- we invented that phrase but we didn't know what it meant. I mean, we -- theory number 1, which turned out to be true, was that it was just hepatitis C. But there was a lot of talk about could it be several viruses. You know, we subsequently got hepatitis E and whatever. So we didn't know whether we were dealing with -- whether it was all one disorder or could it be several, is what -- that's why I've used that word. Because in theory it could have been one virus, Hep C, or it could have been an array of viruses, all of which were non-A, non-B.

Q. Was it your assumption by the late 1970s that -- and I'm looking at what you knew at the time rather than what you now know, with the greater knowledge that you

have -- was it your assumption then, do you think, that many or most of your patients had non-A, non-B or was it just a concern that they might have?

A. I thought from the moment I -- you know, from about '78 onwards, that every single patient of mine who had had Factor VIII concentrate had Hep C, for all the reasons we've just discussed about the risk of being exposed to donors with -- you know, we had all this data by this stage of infectivity rates of American donors.

I mean, indeed, going back to Garrett Alan, the late 1960s, of all the risks of commercial donations compared with voluntary donations in the US. So I was completely signed up at a very early stage that -- you know, I was working on the assumption that any patient who had had Factor VIII had Hep C or had -- had non-A, non-B.

Q. I know when I asked you about this yesterday you couldn't recall what you told patients about the risks of that, although you agreed that they should have been told but you couldn't recall what you'd said to patients over 40 years ago. Do you recall whether you told patients that you thought they probably had non-A, non-B hepatitis? Did you use that term with your patients --

A. Very much so, because we've talked about the monitoring of liver function and part of that package was to say to the patient, "As you know, you know, your blood tests include these liver functions which are abnormal and this is because, as you know, you haven't got hepatitis B or A, you've got this third virus". And in the early years that would have been, you know, accompanied by a phrase, "You're very well, and you're doing very well and I know you're very pleased with the concentrate treatment and we're monitoring it". And then later on, after the Sheffield data, we'd have started to qualify that with, you know, "We are looking significantly at this because we're, you know, there's some evidence that some people might be getting or might get sick in the future with this hepatitis virus."

Q. I asked you yesterday about --

SIR BRIAN LANGSTAFF: Just before we move on, can I just be clear about your use of your word "presumptive", because it seems to me at the moment you may have used it in one of two different senses or both.

In your answers to counsel, what you have said is that it was presumptive non-A, non-B, presumptive Hep C, because there might be other viruses, and so one presumed it was an entity: non-A, non-B.

Presumptive in that sense.

The other "presumptive" was your reflection on what the patient might have, your assumption that whatever non-A, non-B was, one or more viruses, they had it?

A. Yes.

SIR BRIAN LANGSTAFF: Now which one was it or was it both?

A. There's something going on with the loop system. I think you're --

SIR BRIAN LANGSTAFF: My fault. Which one was --

A. You've cured it. Yes, I've heard you. There's just a lot of interference suddenly.

SIR BRIAN LANGSTAFF: My fault.

A. No, that's fine.

I think what I was trying to say to a patient was, "Your blood tests show a pattern suggestive of viral hepatitis. Number 1. 2, that hepatitis is not hepatitis A and it is not hepatitis B, so here's the presumption: you have a third type of hepatitis which we're calling non-A, non-B but we don't really know anything else about that virus or viruses at the moment."

That was the presumption.

SIR BRIAN LANGSTAFF: And the assumption was that most patients had it because they had had -- if they'd had

commercial concentrates?

A. Yes, on two bases. Firstly, for all the sort of statistical reasons we've discussed, if they had had Factor VIII it would be extraordinarily unlikely that they wouldn't have it. But then, secondly, if they had abnormal liver function tests for no other reason, they didn't have hep A or B and they weren't an alcoholic, that would make you even more certain.

SIR BRIAN LANGSTAFF: Thank you very much.

MS RICHARDS: I'd asked you yesterday about Chief Medical Officer guidance, and I'll come back at a later stage today to the absence of overarching guidance in more detail, but specifically in relation to Chief Medical Officer guidance, we know that, from time to time the Chief Medical Officer, for example, issued what were called "dear doctor letters".

A. "Dear doctors", yes.

Q. Was the expectation at the time that if the CMO issued a dear doctor letter that doctors would comply with whatever was being said?

A. No, I don't think we worked at that level. I think -- you see, we had -- the Department of Health had a doctor who was designated to attend UKHCDO meetings; so we had a link, a formal link. I think it would be fair to say we were always, I'm sorry to say, pretty

frustrated about the nature of that link, because we had wanted and expected that that medical link would go back to the DoH and put a bomb under them basically. We expected they would go back and say, "There's a very serious situation in haemophilia and there are some very important things we need to do. One of them is absolutely putting as much funds as quickly as possible towards self-sufficiency, the other thing is making sure we've got communication networks open with transfusion centres and also that we're issuing appropriate directives to haemophilia doctors on a much more formal basis."

So I think that all the time I was a haemophilia doctor by and large we were always very frustrated by the lack of DoH involvement. These doctors changed regularly. I'm sorry to say they didn't seem particularly interested or motivated. You know, we went to them with all sorts of issues: could we have more cryoprecipitate? We need more funding for concentrate. We want to switch to heat treatment. What's going on with self-sufficiency? Where's the recombinant Factor VIII? And each time the response was nothing like as dynamic or helpful as we would have wished.

Again, Dr Colvin, next week, who was Chairman of

the organisation, he would have had those links more closely than I, and I would wish to have his view.

Q. I absolutely understand that as a matter of fact there was potentially limited guidance coming out of the Department of Health, but in general terms dear doctor letters from the Chief Medical Officer, were they, as far as you can recall -- I know there weren't any on the issues that we're talking about --

A. Yes.

Q. -- but were they generally materials that doctors would expect to comply with?

A. Oh, very much so. If the Chief Medical Officer wrote a dear doctor letter and it was an area of medical activity that you were involved with, you would be expected to follow it.

Q. Thank you.

Then a very specific question about a particular form of test that we have seen some evidence that some patients underwent in 1983, possibly 1984. Some have recounted to the Inquiry in their evidence that they were given some form of skin prick test in the late 1980s in relation, in some respects, to monitoring for signs of AIDS.

Do you know what that would have been or is that a practice that you were familiar with?

A. I'm not familiar with it. This seems to be something very inappropriate but there's a -- you could test for somebody's -- it was perceived that you could test for somebody's immune function. There's a limb of immune activity called cell immunity and, as I recall, you could assess somebody's cell immunity by some sort of patch test on the skin where you provoked -- like allergy testing. The gay patients who had originally presented with AIDS, they had some of these features of suppressed immune function, hence the pneumocystis pneumonia as well.

I've never heard of that being done for people with haemophilia. It was not at all a good idea. It was certainly not going to give you any accurate information and it was certainly not going to tell you whether you had this virus or not.

Q. Thank you.

Then moving to you taking up your post in Margate, do you know why your predecessor, Dr Sterndale, was leaving? Was it just routine retirement or were there other --

A. Yes, he was retiring.

Q. Yesterday when you were talking about providing information and advice to your patients who had tested positive for HIV, you talked about the sexual health

advice that was given, the risk of transmission, and said that was the first time haemophilia clinicians had to give such advice to their patients.

What about sexual transmissibility of hepatitis B? Because that was known to be a risk. Is that something you were aware of and had had to counsel patients?

A. Well, I only had one patient who had hepatitis B and I had spoken to him.

Q. About that, the sexual transmission?

A. Yes.

Q. Are you aware of any practice, in any centre of which you have any direct knowledge, of taking blood samples from patients with bleeding disorders for the purposes of research into either the development of the hepatitis B vaccine or any other forms of research?

A. I am aware -- I was taught by my professor at the Middlesex always a good idea to take an extra vial of blood and store it. You never know what it might be useful. He did with that all of his patients. He had a vial of Winston Churchill's blood, I remember.

That was a practice that was followed in a small number of centres and, as in one particular instance at the Royal Free, came to provide extremely important information. But there were some centres that did --

this wasn't an extra blood test, it was while these routine bloods were being taken some centres -- I'm sure without saying anything to the patient -- took -- just filled up an extra ampoule and froze it and held it in deep freeze for long-term usage, for a research purpose.

Q. Do you know -- and if you don't, please feel free to say so -- but do you know whether any of those research purposes included any work on development of the hepatitis B vaccine?

A. I've never heard of that but I've certainly heard it used for other purposes which we'll talk about.

Q. Which were what?

A. Well, Dr Kernoff's work. Do you want me to talk about that?

Q. Yes, please.

A. So the Royal Free with 100 positive -- so let's go back to where we started this morning: the balloon's gone up; the world has changed; it's October 1984, late October; the results are in. So at the Royal Free -- you are going to get Professor Christine Lee who was part of that team, you can ask her. They have got at least 100 positive patients. At the Royal Free, they did what we talked about. They had stored blood.

So the director at the time or co-director, Professor Peter Kernoff, did the obvious thing in the terms of he then retrieved from the deep freeze the samples on all of the patients who were positive and tested them for HIV. So this was an -- you can argue about the morals and the ethics of he should have told the patients he was doing it or whatever, but this was a quite extraordinarily important exercise because there were two very major observations.

Firstly, when he started to do the retrospective testing, all his 100 patients positive in October 84 all of them had been positive for at least three years. This was not a new virus in the blood supply: this virus had been in the blood supply for three years; the patients had been infected for three years; if you extrapolate that to other patients round the country, the haemophiliac (unknowingly) had not been taking any precautions; the doctors and nurses in the hospital had not been taking any barrier precautions, they didn't know the patients had this unknown virus. So that's was first extraordinarily important observation.

The second extraordinarily important observation was when he got as far as back I think as 1980/1979 the tests were negative. So this was the second --

I can't stress the importance of this work. It told us HIV seems to have entered the blood supply around 1979 to 1980. Now, this has got immediate major references to Dr David Owen's initiative. I might as well go on to say this now.

Q. Yes.

A. I might as well go on to give my whole sort of overview of the virus changes over the years. If you look at -- we've just been talking ten minutes ago about the chances of getting hepatitis C in American donors compared to British donors in the 1970s, and I've said to you even if Dr Did Owen's initiative had been successful, let's say it's 1978 and we've gone from a high hep C incidence (1 in 100) to a low hep C incidence (1 in 1,000), for concentrate manufacture it's voluntary donation, it's still 1 in 1,000. So if you're a British haemophiliac in the 1970s on self-sufficiency, voluntary donated, you are still going to get hep C.

So my major conclusion number 1: the two epidemics I see as being different. I see the hepatitis C one if you were a regularly treated patient, it was inevitable that you got hepatitis C. You probably got many hepatitis C infections the first time you ever had Factor VIII and that lasted all the

way through, even if you then went on to British only and even on the first generation of heat treated. They all transmitted hepatitis C.

So until about 1985/1986 when the second generation of heat-treated concentrates came through, if you were a haemophiliac patient in Britain and you had had Factor VIII once, it was extraordinarily likely that you would have hepatitis C. So the major conclusion from that is I do not believe, from my experience, the hepatitis C epidemic was avoidable in regularly treated patients -- a key phrase. If you were a patient who had hardly had -- you know, it's 1985 and it's your first ever injection, that's different. But for regularly treated patients with severe haemophilia, this catastrophe could not have been avoided.

With HIV, my own view is the situation is different because Dr Kernoff's work tells us that HIV, reported as a disease in 1981, doesn't seem to have been in the blood supply until 1979/80.

We now know from the Scottish experience, self-sufficiency, when HIV broke they had very little HIV infection, less than 10 per cent. So if Dr David Owen's initiative had worked, as it was tantalisingly close to doing, if in 1979/80 we had

been self-sufficient at a time when HIV entered the blood supply, we wouldn't have been relying on a high HIV infection pool, we'd have been relying on a low HIV infection pool like the Scots.

So I think it is tempting -- this is all medicine's dangerous retrospectively -- but it is tempting to speculate that if Dr David Owen's initiative had worked, the experience in England would have been similar to Scotland and we would have had maybe 10 per cent, same as Scotland, instead of the catastrophic 90 per cent.

So that's my generalised overview obviously when I was thinking of the things that I would wish to say to you in giving my evidence. These are some of the most particular things I would wish to say to you. I think these two virus epidemics, which were both catastrophic, are different. You should look at them in different ways. I think the hepatitis C was generally, for most patients, unavoidable. I think that -- very poignantly, I think if Dr David Owen's initiative had worked, you have to think things could have been very different.

Q. Thank you, Dr Winter. Sir, I note the time and I have run over in my questions into the break, so is this a convenient moment to take the break?

SIR BRIAN LANGSTAFF: Yes, it is. We'll take a break now until 12 o'clock.

(11.15 am)

(A short break)

(12.00 pm)

MS RICHARDS: Dr Winter, just a couple of points on the issue of self-sufficiency. Lord Owen told us when he gave his evidence that the pledge he had in mind encompassed self-sufficiency on the basis of use of factor concentrates for home treatment but not prophylactic treatment.

Do you know whether that was the understanding of clinicians such as yourself that what was meant by Lord Owen in relation to self-sufficiency at least excluded prophylaxis?

A. I was only a trainee doctor at the time of Dr Owen's initiative but our understanding of self-sufficiency was always that it would encompass all aspects of haemophilia treatment.

Q. Thank you. Then the second point is not necessarily a question for you, Dr Winter, but it's just a point I have been asked by some Core Participants to raise.

In relation to the position in Scotland, I'm asked to point out that commercial concentrates were, as a matter of fact, being used in parts of Scotland

in the early 1980s. But, as I say, I don't think that's really a question for you, it just arose out of your evidence.

A. But they did end up in a situation where not only were they were self-sufficient, they had extra capacity, I believe, and there was even a suggestion that some of this -- that, you know, they might provide Factor VIII for some English patients.

Q. Yes. Then you told us yesterday, when we were talking about telling children about their HIV diagnosis, and we referred to the talk that you had given expressly on that subject, and you mentioned a Scottish group who delivered a talk on the possibility of not telling children their diagnosis.

Who was that Scottish group?

A. I honestly can't remember. I mean, they would have been from one of the major centres. They were counsellors and nurses, I think, from one of the major centres, which would be Glasgow or Edinburgh or Dundee I guess.

Q. What did you understand their main counter-argument to be? What was the reason being advanced by them for not telling children?

A. I think their main argument was that whilst the children were well this would only distress them and

that until we had more knowledge it was perhaps best not to tell them. All these years later, it's difficult, but I do remember it as being quite a powerful occasion because of the two divergent views in front of really quite a large audience who, again, were very split as to whether you should tell or whether you shouldn't tell, and, again, you know, no agency saying to us, "This is what you should do". We had Dr Craske saying, "You could tell but maybe you don't need to, and each director must do what they think is best". The familiar thing.

So, again, it was another moment of great uncertainty.

Q. Do you remember when -- the particular occasion that you're talking about where there was this discussion and your talk was delivered, do you remember when that was, very roughly?

A. Well, obviously it was -- so we're talking, I'm thinking it must be -- at the very end of 1984 the results would have been through and people are working out what to do with the results, and one of which was to say, "Should we tell children?" I'm tempted to say very early '85.

Q. Thank you.

Then can I clarify one aspect or ask you to

clarify one aspect of your evidence in relation to how -- or your approach to the treatment of severe haemophiliacs, severe regularly treated haemophiliacs, in the period from early 1983, when you're aware of the risk of HIV, through to May 1984, when you made the switch to the heat-treated product, was your approach and your advice to carry on as normal with heat-treated product -- sorry, with unheated product, or was it advice to treat only when necessary and to try to reduce the amount that you received?

A. Yes, it was the latter. It was to say: we're increasingly -- we have increasing concerns, firstly because of the hepatitis data, secondly because of this new disorder which seems to be in the blood supply, we're trying to reach a situation where Factor VIII might be treated to make it safer, but in the meantime you should only use concentrate when you need to. I guess was a core phrase and a core belief that we had round the centre, and that extended, as we've discussed, to restricting operations and restricting prophylaxis, et cetera.

Q. Then I've been asked to ask you to clarify your references to being a trainee doctor when you were at the Middlesex and Guy's because obviously the precise way in which different categories of doctor are

described may not be universally known and understood.

A. Yes.

Q. So what was your qualification and what did you mean by saying you were a "trainee doctor" at that time?

A. So I'm -- obviously I was a qualified doctor. That's five years of training. Then everybody has to do a year's houseman, house physician. So that's -- then you are registered. So I was a registered doctor. But then if you're going to work in a hospital you enter speciality training, so you are a trainee in that speciality even though you are a registered doctor. So that was what I meant by that phrase.

Q. So that period at the Middlesex and then Guy's, you were a senior registrar or a registrar?

A. A senior registrar for seven years in further training.

Q. As a haematologist?

A. Yes.

Q. Thank you.

A. And then you end up with this other exam, the MRCPath, and at that -- they now formally call it accreditation, and then you are enabled, you are qualified to become a specialist.

Q. Thank you. Then, in terms of the communications you had with patients, and I'm not going to go back over

the detail of what was being said to patients at different times, the question I'm asked to ask you is about the extent to which in the period we've been looking at, late '70s, first half of the '80s, to what extent would this kind of discussion be recorded by you in the patients' notes?

A. I stress yet again, you know, I was in training and not responsible for policy but my general recollection would be that -- hospital notes are a variable feast, firstly. Some doctors write, you know -- no doctor writes very voluminous notes because you are doing a busy clinic with lots of patients and you don't have time to write a great deal. Some patients, for a clinic visit, would write a very brief, "All well, no new symptoms to report, three months", and our little initials.

It would be, in those days, I think unusual for in the notes, where the doctors actually got to hand write it, to say, "I have counselled this patient against the situation concerning the latest evidence for hepatitis infection". What would be much more likely, and I've seen some of my own correspondence from the time, is that when we actually wrote a letter to the GP at the end of the clinic, into a Dictaphone, it was much easier to give more detail, and the

letters to the GP would be much more likely to say, "I've reviewed your patient, he's perfectly well, I've brought him up to date with the evolving situation concerning possible hepatitis infection in haemophilia patients", or something like that.

Q. Thank you. And then in the first half of the '80s but in particular 1982 to 1983, did you -- and I'm conscious at this time you are not a consultant -- did you put forward any of your patients, in particular mild haemophiliacs or those who were virgin haemophiliacs, PUPS, for any clinical trials?

A. No.

Q. We talked about the approach to children. Can I just ask you to clarify up until what age, for the purposes of the discussion that we've been having, would you regard someone as a child for the purpose of the treatment decisions?

A. Well, I think for the -- you know, there's semantic discussions as to what is a child. When I said to you to my best recollection of my 30-something there were 15/16, I would have included up to the age of 18.

Q. In terms of the guidance that came from UKHCDO, for example, in the middle of 1983 about how clinicians might want to treat children, would that be pretty much all children, up to the age of 18?

A. Yes. To complicate matters, obviously in some cities, like with Great Ormond Street or Birmingham Children's, there wasn't even a standard age of transition to the adult centre. So this was another area of not contention but there wasn't standardisation of practice.

Q. Now, I want to ask you to look a document that has been shown to you this morning. It's a Haemophilia Society publication.

Henry, could we have DHSC0001228, please. Thank you.

So this is The Haemophilia Society letter of 4 May 1983 which sets out advice from Professor Bloom that was then sent out by The Haemophilia Society to its members. The reason I am asking you about this, Dr Winter, is because you talked about information from The Haemophilia Society as one of the sources of information for patients.

Do you know whether you read this or would have been likely to have read this at the time?

A. No, I remember in particular covering this letter in detail at the two previous inquiries.

Q. In that case, can I invite you to set out what you can recall about this letter and what your view is of the advice that's contained within it.

A. Well, here's a doctor looking at an evolving situation and with the best of intentions, trying to be helpful. Professor Bloom was an awfully gentle, charming man who, you know, always tried to do his best. But he's given advice here to the Haemophilia Society which has gone on to patients which has turned out to be completely wrong.

Some of his phraseology, given that it's in a state of great uncertainty, with the evolving numbers of patients -- and indeed, we should say, was it not almost exactly the same date that the patient in his own centre was diagnosed with this disease, which he thinks isn't going to be a problem to people with haemophilia -- so when he says the cause of AIDS is "quite unknown", if "quite" means completely, which I assume it does, that was a strange use of phrase because any sentient doctor looking at the data would have to say there must be a very high chance it's due to a transmissible agent in blood and, if it's in blood, the haemophiliacs will be the most affected. So that's a very strange choice of phrase.

And:

"... it has not been proven to result from transmission ..."

Well, there are patients with haemophilia with

the disorder. So that's a strange choice of phrase.

Then it's interesting -- I haven't seen this before -- I was talking yesterday about the German experience. Here he is again putting out to some people with his views did, "This is -- you know, this is an American problem. If anything, it's not going to occur in British donated plasma, and look at the Germans, they use twice as much as us and they had no problems."

Can we look lower down the letter?

Q. Certainly.

A. Yes, so that's the phrase, isn't it, that stands out as being so very inappropriate. You know, one wonders why he didn't say, "We're monitoring the situation very closely and we're trying to get as much information as we can as to whether this might be an evolving issue for patients with haemophilia and as soon as we have more information we'll get it to you". You know it's the sort of certainty of saying the cause is quite unknown. Well, there were significant clues.

Q. Dr Winter, was this a communication that you saw at the time? I don't know whether you can answer that, but --

A. I would have been -- yes, I mean, I read the -- I had

been a member of The Haemophilia Society myself since the late 1970s, so I would have been sent this document.

Q. Do you have any memory of reading it and reacting to it?

A. Not at the time as a registrar. I mean, I must have read it and thought, that's a strange thing to say.

SIR BRIAN LANGSTAFF: Just before we leave that letter, the third from last sentence:

"In addition, the importation of licensed blood products has always been strictly monitored and controlled."

Is the -- would you understand the implication of that as being, well, the product must be safe because, otherwise, it wouldn't be let into the country?

A. Well, that's another big issue, isn't it? You know, what factors does -- are taken into account when a product is licensed? And did the people or the agencies in Britain granting that licence -- were they aware of the sort of events that had been portrayed in the World in Action documentary? Because, surely, if they had, would they not have had major reservations about granting a product licence?

I don't know if the Inquiry has as yet had

a chance to talk to the sort of people who would have granted such a licence to commercial concentrate.

SIR BRIAN LANGSTAFF: The next passage which I would invite your comment on -- I appreciate it is only a comment, and you may be considering this for the first time, though you have looked at this letter before -- is, the very last sentence:

"We should give those experts who are responsible a chance to continually assess the situation."

At that time, what experts did you see as being responsible for the quality of the factor product given from the States to individuals in this country?

A. Well, I think, obviously, in terms of the licence, it's the agency that will grant the licence. They surely must have had criteria to use behind the licensing of any blood product or drug. But I think what he actually means is -- he really means the other haemophilia doctors are going to continually to assess the situation. He is actually not referring to the agency. I think he means that doctors like him are keeping a very close eye for any sign of their patients getting this new disease.

SIR BRIAN LANGSTAFF: So it's "leave it to us"?

A. That's what I think he means.

MS RICHARDS: Thank you, sir.

Dr Winter, I'm going to move on now to ask you about various matters from 1985 onwards.

Can I have up on screen, please, Henry, ARMO0000409, please. This is a letter from Armour to you, June 1985:

"Heat Treated Factorate, Batch No. Y69402."

It thanks you for the information given in your letter of 10 June. I don't think we have that letter, I'm afraid, so we only have what is set out here. Then it says:

"In view of the fact that all three patients were HTLV 3 positive prior to receiving [that] batch ... any symptoms will be virtually impossible to relate to the Factorate batch in question ...

"Nevertheless, in the generation of an overall picture of all patients treated with the batch, the subsequent progress of these patients will be of interest."

Just two questions arising out of this, Dr Winter. The first is: do you recall why you were writing to Armour about that particular batch?

A. So this is quite a common occurrence in haemophilia treatment. As a standard practice, if a doctor gives a patient a product and there is a problem with that

administration of the treatment of any kind, the doctor informs the company, for obvious reasons, so that they can look at the batch and make sure that other hospitals who have received that same batch are not getting the same problems. That would range from, at the extreme end, the development of an inhibitor -- you would notify the company. Maybe in the manufacture of that batch something had happened, and the batch was more antigenic than other batches. That would be an extreme example.

Almost certainly what this related to was that the patients were getting some sort of side effect during administration of the sort of type that we were talking about with cryoprecipitate. So I expect these patients came to me -- they were probably all on home therapy -- and said, "Actually, I've got the shivers and the shakes with this one," which could happen with concentrates, and I felt obliged to report this.

The reply is rather curious. I don't know why -- I've obviously informed them. I would not have given the names of the patients, obviously. I would have said, "Three patients under my care," and then I would have given brief -- I would have said, "They've got severe haemophilia, and they are HTLV-III positive, and they've got these clinical signs, and

they have obviously then had some event under the treatment, and I'm just letting you know as a courtesy in case it's a problem that's being seen in other patients". But quite why he's talked about their positivity and lymphadenopathy, I don't know.

Q. Okay.

A. But this was a perfectly standard thing, and there will be lots of letters like this.

Q. It talks about -- in the next paragraph it says:

"The subsequent progress of these patients will be of interest."

Was that normal for a pharmaceutical company to ask for an update about the progress of particular patients?

A. I think he's just being courteous. No, it wouldn't. You wouldn't. You're just reporting the adverse event. You wouldn't expect to write further to the company.

Q. Okay, thank you.

Now, I don't think I need to put the document up on screen, but we've got a sample of your returns from 1986, 1988, 1989. What they show is you are predominantly using Alpha product, as you had been since the middle of May 1984 -- though, obviously, it may move on to further generations of that -- with

some NHS product.

Was there any particular thinking behind the continuing with the Alpha product as your predominant mode of treatment in the second half of the '80s?

A. Well, firstly, as a principle, you try not to change treatment in haemophilia. It's not considered to be a good idea. There are practicalities. The patient -- all the Factor VIIIs are drawn up in rather a different way according to the packs that the company provide. So the patients didn't like changing. The nurses didn't like changing. So it was -- you weren't going to change unless there were a reason.

Of course, from May 1984, I was greatly reassured because I knew my patients were -- well, I had hoped -- I didn't know -- at least I'd got my patients on to a heat-treated product, and I had reason to believe that was likely to be safe against HIV, which turned out to be true. I didn't know whether it was going to protect them from hepatitis, which turned out not to be true, but nearly all my patients had hepatitis anyway.

So, if you like, there was no clinical pressure. I could get the supplies. That was a major issue. Here's a time when Elstree in its new shape and form

after all the funding is taking off. It's still not firing on all cylinders. There's a lot of demand for Elstree product, as ever, for the new heat-treated product. So I'm -- you know, through the early part of the years from 1984, together with Dr Savidge, we're pretty comfortable with where we are.

What happens then is new generations of heat-treated products come in, where you heat them for longer and to a higher temperature. Then we move into a yet further generation of what's called monoclonally-treated, where there are antibodies in the preparation which pick out any viruses or proteins or whatever, and they were generally perceived as being -- remember our conversations yesterday -- not only safer but purer. So you move into a different generation of products which turn out, for the first time, to inactivate hepatitis, which the first generation heat-treated don't do, but are also much purer. And remember my comments of "purer" might also mean "safer".

So I'm thinking that around '87/'88, you're going to say that I moved across to -- away from Alpha to using other drugs like Monoclate and things like that. These are the third generation monoclonally-derived Factor VIIIs. In other words,

this first generation dry heat, like the Alpha and the other ones, major breakthrough, safe from HIV, but turned out not to inactivate hepatitis, and also not very pure. So they were soon replaced by more sophisticated concentrates.

Q. Then could we have up on screen, please, Henry, BAYP0000071_001. We'll see this is a Bayer internal document, 1 August 1991. It's headed "Koate HP study 0101". It encloses documents which we don't currently have. It says:

"I currently have all case record folders from Dr Winter in-house, and I'm hoping to collect the remainder from St Thomas' at the end of August. I feel that a meeting would be useful to discuss the reporting of this study involving both Drs Savidge and Winter."

Do you have any recollection of what this study was about?

A. Well, I don't. I've looked at this. It was almost certainly a PUP study, and I think in '91, I just wonder whether we'd -- the very, very early stages of being -- to get a recombinant product, although perhaps it's a little early for that. But this is -- we were not involved. It says "Phase 1 analysis", et cetera. We were never involved in multi-centre

evaluations of established products because we were a -- you know, we weren't an academic centre. I didn't have research registrars, but we did do a small number of PUP studies. So I'm tempted to think this must have been one of the new generation of monoclonal, or an early recombinant. I was working very closely with Dr Savidge who was in an academic centre with large numbers of research registrars. He would have said to me, you know, it may be a good idea if we consider putting some patients into this because this new product looks to be a very good one, and it will be good if we could, you know, evaluate it and get some patients on to it as soon as possible.

Of course, there was great interest and concern amongst the patients. Everybody knew about the advent of the Holy Grail recombinant Factor VIII that wasn't from blood donors, and there was a period of time where the only way you could get recombinant was to go into a research study. So it's possible that -- you know, the dates seem a little early for me because I'm thinking '93/'94 would have been the earliest for recombinant, but, anyway, I'm just making the point some patients were very happy to enter, or parents were, because they -- it was the only way of getting this perceived better product for their child.

Q. In terms of your own practice, if you had a patient, whether a previously untreated patient or otherwise, who you thought might be a suitable candidate for a study, what information would you provide to that patient? I ask that question, you will understand, because we've heard evidence of people being involved in studies of which they were unaware.

A. Yes. So any research study of this type has two major levels of control. Firstly, this would have been a study done with other centres, and there would be a lead investigator, perhaps Dr Savidge. And he would go to a centralised ethical committee in London called MREC, and this is the first phase of getting ethical committee approval for this study.

It's absolutely impossible for any sort of research activity like this to take place without these two committees having given their approval, and the first hoop is MREC. An absolutely central part of MREC is that they have lay representatives, and the lay representatives, quite properly, would be greatly exercised at the information produced for patients. Is it understandable, comprehensible, pitched at the right level? Is the patient fully aware of their responsibilities? Does the patient or the parent have the ability to come out of the study at any time?

These are very extensive procedures.

Once you've got through the MREC, the individual investigators, like me in Kent -- I would have to do a similar thing with my local ethical committee. So I would go to them in Canterbury and Margate and say, "I'd like to take part in this study." If I said, "I haven't yet got MREC approval," they would say, "We can't look at this until you have." If I said, "I've got MREC approval," I would go through exactly the same process with them. There'd be two or three -- I would have to go and physically present it, and the local lay representatives, who would be lawyers or whoever, local people of influence, would say, "We absolutely want a detailed look at all the patient information, and we've got some comments to make. We'd like you to make some changes, and we'd like you to come back at our meeting next month." They would be very particular about consent forms -- what was the patient actually consenting to -- and all these things are, of course, right and proper.

So these are very exhaustive processes. So for studies like this which are multi-centre with a new form of Factor VIII coming in, there isn't any way a patient could be entered into the study without being aware of it.

Q. You would be having that dialogue directly with your own patients?
A. I was obliged to, under the terms of the ethical committee.
Q. Can I ask you next about HCV testing for your patients?
Do you recall when you began hepatitis C testing?
A. I'm thinking -- my recollection would be HCV was isolated about 1989, maybe. And I'm thinking the test was -- about 1991, we got access to the test. I'm thinking that sort of date.
Q. Do you have any recollection of over what period of time you undertook the test? Was it something that went on for a prolonged period of time, or was it the test is available, and much as you describe with the HIV, you take the blood samples, and you send it off?
A. Yeah. So I was reflecting on this overnight. I think there was a difference in practice here. With HIV, as we discussed, there was great anxiety. We were really concerned to have the test. We didn't know what the results would show. We were astounded by the results.
With the hep C test, we had wanted to have it. We weren't expecting it to tell us anything we didn't really presumptively know. I've already said to you,

I'd already told my patients, "I think you've got this new virus". So I was expecting -- I wanted to have the patients tested but I was expecting that all the regularly treated patients would test positive. So I decided I would not send for them immediately, like I did with HIV, where I was so concerned to know. These are all patients that had upcoming appointments. I knew I was going to be seeing them within the next few weeks. So when they came in to their routine appointments, I said to them, "We now have this test available and obviously, you know, I hope you agree, we should get this test done". Then -- you know, then I said to them what I've just said to you. I said, "Probably, unless you're anxious, we could pick up the results of this test the next time you come. If you're really concerned you know we can make another arrangement to get the test result to you more quickly, but you know I really am expecting it is going to confirm kind of what we already know, is that you've got hep C."
Q. So your patients, you told them or you invited them to be tested, they weren't tested without their knowledge?
A. No.
Q. When you communicated the results to them, was that

invariably in person at an appointment?
A. Always -- yes, always.
Q. Can you recall what kind of information you provided at that early stage to those who tested positive about hepatitis C?
A. Well, it was really, you know, a confirmation of all the previous advice that had been given: that we now definitely know that this non-A, non-B we had been talking to you about for 15 years for severe regular patients aged 40-something under long-term treatment, we've always said to you we think it's hep C and we now know for sure it is hep C. That doesn't change the nature of our advice to you about healthy living, about avoidance of alcohol.
There was very little, if any, data at all (unlike HIV) about sexual transmission, which was an area of difficulty, and something that happened that came out of the availability of hep C testing around this time there was availability for treatment with this interferon.
Now, by then we were in an area where haemophilia doctors were outside of their expertise. So when I was looking after my patients I was looking after the haemophilia. As it happened, I was an HIV physician so I was looking after their HIV. Many

other centres would have sent their patients across to a different unit for HIV care but I was not a hepatitis specialist, of course, and I didn't have detailed knowledge about a whole range of things evolving around hepatitis C now that it had been identified. I didn't really know about advice about how common was sexual transmission and I didn't know whether a patient, now that hep C had been confirmed, I didn't know what criteria would be used to determine whether they ought to have interferon treatment, I didn't know whether the patient should be advised to have a liver biopsy.
So all of these patients in the fullness of time would have been referred to our liver specialist, to Dr Frank Muller -- we didn't do formal combined clinics but patients were referred to him for his assessment and he would see them and write back to me and say, you know, "This is what I think and, you know, we're going to" -- he would then monitor their -- he would then take over the formal management of their hepatitis, he would do all the measurement of the liver function tests, he would advise me about liver biopsy, he would advise me about evolving treatment. Sometimes the patients were sent up to King's College in London for evaluation for liver

transplantation. He, from that point in time, took over all that sort of hepatitis management and that would have been a very sort of commonplace thing across haemophilia centres.

Q. In terms of the prescription of interferon, and we have heard some horrific accounts of the side effects of interferon from patients, would that have been his responsibility then rather than yours?

A. Completely. I've never as a doctor prescribed interferon.

Q. There is some reference in documents -- I don't think particularly in light of your last answer I need to take you to them -- in the course of the '90s to there being difficulties in securing funding in your local area for interferon and ribavirin for patients. Did you have any involvement or recollection in that --

A. I had no involvement but I -- we had no -- nobody ever said to me that funding had not been obtained. So if Dr Muller, my colleague, he would write to me and say we're going to start this patient on interferon and ribavirin, they started. And the patient would turn up for their next appointment with me and would say, "Have you heard from Dr Muller, and I would say, "Yes, I hear you're on the treatment", and he would say, "Yes, I've started."

Q. Your statement says it was approximately 50 patients under your care who were confirmed to have hepatitis C when the testing came in. Are you able to recall what proportion of your patients at that time, 1991 or so, did not have hepatitis C?

A. So now we're entering a sort of wider group from the HIV group because you're picking up people with, say, mild haemophilia who have only had, say, one or two lifetime treatments. Mercifully, they've escaped HIV but inevitably, as we've been discussing, because they have had Factor VIII before 1985/6, they have got hep C. So that's why we've got this wider group of people with hep C.

So I would have -- I would have tested everybody under my care who had ever had a commercial concentrate: the Factor VIII patients, the Factor IX patients. Some people had a sort of pooled plasma given to them, patients in the hospital given pools of plasma to reverse anticoagulant therapy. So this has been a big issue, hasn't it, about hidden cases of hepatitis C in hospitals. There were cases of anti-D immunoglobulin, particularly in Ireland. So we were in a different territory then of also looking for patients who had been through the hospital, who had never had Factor VIII or Factor IX, who might have had

hep C. That wasn't my direct responsibility but other doctors would quite often talk to me and say, "You know, who should we be screening and looking at?"

Q. So in terms of your patients, your haemophilia or bleeding disorder patients, who had hepatitis C, was that all of the severe regularly treated haemophiliacs who'd -- there may, I suppose, have been a handful of new patients who had only received the later generation but --

A. I didn't have anybody -- as I've said to you, there was nobody -- I had two or three patients who only ever received heat treated. They were just either children born '84 or they were milds having their first, and none of those got hep C. Even though we now know that heat treatment wasn't terribly effective mercifully they didn't get hep C.

But I tested obviously -- there was quite a big group of people who had had Factor VIII once or twice, even some haemophilia carriers, very sensitive situation, and there was quite a big list of people who tested negative.

Q. In terms of the treatment of your patients who had HIV, and I'm talking here about the bleeding disorder patients, I know you had a wider cohort of HIV patients as well, did you have any difficulty in

obtaining funding for their treatment which was under your direct responsibility?

A. No, no, I didn't.

Q. Can I ask you then about counselling. You mentioned yesterday there came a point in time when you had a full-time counsellor at the centre. Roughly when do you think that was?

A. Well, I remember it was at a time just after we had been telling patients, and I remember going with her to other meetings where we discussed with other doctors telling patients, so I'm thinking she probably started about '85, sometime '85. And she was full-time based in our centre, which was a big thing to be able to have -- because there were very few -- it was at a time when hospitals were losing social workers, they were all going into the community, and it had been very difficult to obtain funding to get counsellors. Hospital counsellors were few and far between. And somehow, again, I managed to find the money to get her and she was an absolutely invaluable part of the service when the whole of the patient community was in such distress.

Q. What kind of counselling was she able to offer? Was she a trained psychologist?

A. She was a counsellor, a trained counsellor. She

wasn't a psychologist.
Q. And if patients wanted it, was there a facility for them to have counselling with her on an ongoing, long-term basis or was it a one-off?
A. No, it was very long-term. As I say, she was based in the centre. She had a suite in another part of the hospital. So she was employed by the centre, so she was responsible and accountable to me, she was one of my staff, she was based in another part of the hospital, and we would strongly recommend that everybody with HIV saw her. You know, even if you don't think it's necessary we said, "We just think it's a good idea if you have a talk to this person."
Most people found her extremely helpful, and then most people would go on on quite a long-term basis. I mean -- and some patients went on for several years. They would come in and say, "Is Juliet around today? I'd really like to see her". Then, of course, that service was extended to other patients who didn't have HIV who also had problems. So yes, she had a number of patients on a very long-term basis.
Q. Was that a facility that continued at your centre, whether it was her as an individual or a successor, up until the time of your retirement in 2011 or did there

come a point where the counsellor post ceased?
A. No, that's still gone on. So we opened the new centre in Canterbury in 1995 and she transferred and was still working there when I left the service.
Q. Then I wanted to ask you about a paragraph in your witness statement. I don't know if you have it to hand, Dr Winter?
A. Yes.
Q. It's paragraph 112 of your statement, page 16. It's very short so I will read it out for those who don't have it.
A. Okay.
Q. You say there:
"AIDS was not a notifiable disease.
"Because of the stigma surrounding this diagnosis it was not usual to use this term on a patient's death certificate as it had caused significant problems with the coroner, and with undertakers."
And then you say:
"No such stigma surrounded patients dying of hepatitis."
You were addressing there a particular question you had been asked to address.
Can I just ask you to provide us with a little

bit more context and background for that. We've seen different practices to some extent in different areas, so in relation to your area, what were the problems with the coroner and with the undertaker that led to not usually including the term on the death certificate?
A. So this was an issue that caused very great distress. AIDS was not a notifiable disorder. However, as a doctor, I was obliged to inform a coroner of any death that was not natural. And of course it was not natural for a person with haemophilia to die as a result of HIV.
So when I had a patient who died of AIDS who was not a haemophiliac, I did not need to inform the coroner. When I had a patient who died who was a haemophiliac with AIDS, I did need to inform the coroner. I had no choice. I did it very reluctantly. The coroner, in response, felt obliged to hold an inquest.
There was very intense correspondence along the lines -- from myself, and The Haemophilia Society got involved -- along the lines of, "This is going to cause the family, who are already greatly distressed, even more distress, and if the purpose of an inquest is to establish the medical cause of death, that is

already known. We know why this patient died. They had haemophilia, they were given contaminated blood and they died of AIDS. So why do you have to hold an inquest?"
The coroner would not be moved. To make a bad situation even worse, that meant that at the inquest I was commanded to attend, describe the cause of death, which would then be reported in the local press; on one occasion "Bad blood kills boy" on the front page, together with the name and address of the child.
So this was -- well, you'll gather, it was a very, very distressing episode, and it couldn't -- every time we had a death we had to go through this exercise.
Q. So your concern -- you talked your reluctance -- was because of the impact on families and what the families wanted?
A. It didn't serve me as a doctor any benefit because I had known why the patient died. All it had served to do was to cause very great distress to a family who were already greatly distressed.
Q. What was the particular problem with undertakers?
A. The problem with undertakers is you would inform them about the HIV infection, which I think you had to do,

but they would turn up wearing space suits. Which was inappropriate.

Q. You said no such stigma surrounded patients dying of hepatitis. It may be because of the evidence you have given about hepatitis care being under the control of one of your colleagues that you're not in a position to answer this but were there referrals to the coroner if a patient infected with hepatitis as a consequence of blood products or blood transfusion subsequently died as a result of the hepatitis, liver cancer or whatever the cause was, were those notified to the coroner?

A. That would have been handled by the hepatitis team, to my recollection. I don't remember any personal issues.

Q. If the term "HIV" or "AIDS" was not going to be used on the death certificate, what term was used instead?

A. Oh, you'd use a term like "pneumocystis pneumonia", and then, you know, under 2, "haemophilia".

Q. And then -- sorry, I put the statement away but I have a different question about a different paragraph in your statement.

Paragraph 94, please. Page 15 of your statement. This is a question about research.

You have touched on the process of seeking

ethical committee approval so I don't propose to ask you about that. Just a couple of questions again that I've been asked by others to raise in relation --

A. Which number?

Q. I'm so sorry. It's paragraph 94. It starts at the bottom of page 14 but it continues on to page 15.

So it's just some general questions about research. To some extent you have already answered them perhaps, when we looked at that Bayer letter. Any research involving your patients, there would have been, I think your evidence earlier, patient consent and knowledge. Were any of the research projects with which you were involved in relation to patients with bleeding disorders funded or initiated or prompted by pharmaceutical companies from whom you purchased products?

A. Nearly all of them would have been.

Q. How would it come about that you might be involved in that or that your centre might be involved in it? Would the approach come from the pharmaceutical company via Dr Savidge or directly to you?

A. They would approach usually one of the sort of leading clinicians who had experience at conducting clinical trials such as this, and he would then invite other directors to participate in the study. That would be

the process.

Q. Can I then ask you about the issue of recombinants. Your statement says that you switched to recombinant Factor VIII in about 1997, but I've seen from other documents, correspondence meetings, materials which I know you've seen, that the availability or non-availability of recombinant continued to be a significant issue over the following years. You had meetings. It was raised within UKHCDO. I think you'd at least one meeting if not more with Government ministers in relation to this issue.

We can look at the document in detail if we need to but I suspect you can probably give us an account. What was the issue with recombinant in terms of the inability to give it to all patients?

A. So here we go again with the very familiar story. A major change in therapy to the benefits of patients. Was it controlled by the DoH? No. Did the DoH have any influence over how we were going to switch to recombinant? No. Had the DoH secured funding for haemophilia directors to switch to recombinant? No.

The usual situation: a licence is given, haemophilia doctors all over the country and the patients want to use it, and you have to fight your own battles. Each doctor has to go, as I recall, to

their own finance and say, "I want to spend even more money on your favourite disease, haemophilia, that you already have a low opinion of because it's high cost, low volume and unpredictable, we need to push the boat out even more". Some finance departments were more sympathetic than others.

There was not enough supply to go round in the immediate changeover. Do I not recall that St Thomas', I think, started to switch '94 or something. I think we were a bit behind them. Anyway, there was -- the point I'm making is there was a gradual change across the country, depending on how active the doctor was and successful the doctor was in negotiating the change in getting the funding.

What then happened, I recall, is that quite soon after '97 there was a major problem I think with the Bayer plant. So there were only two or three recombinant manufacturers, in California, and one of them had a major lock-down because it had failed an inspection. So suddenly the bottom fell out of an already slightly insufficient supply. So I think you'll find that some patients maybe even had to switch back from recombinant to the best of the plasma products until the problem was righted. I'm sure that problem went on for several months at least.

Q. Then, in terms of variant CJD, what can you recall about how and when you learnt of the risk of patients -- of transmission for patients with bleeding disorders of variant CJD, and what can you recall about your involvement in the notification process, telling patients of this?

A. I've lost track of dates, but the variant CJD story is of interest because it gives the feel for the sort of continuing problems that doctors like me were having to deal with, and it was yet another Covid moment because we absolutely didn't know what the data meant. So whenever it was the year that some small number of people in Britain started to get variant CJD, there was evidence that it was due to an abnormal protein, that that protein was in the blood supply -- well, I remember a period of two or three months where, if you like, we were straight back to 1983.

I remember talking to Dr Savidge and saying, "This could be AIDS part 2. How do we -- you know, new disease in blood, one or two other non-haemophiliacs with it. How do we know in six months this is not going to be AIDS part 2, in addition to everything else?" So it was yet another worry. So that was a real difficulty.

Secondly, we had no way of testing. No way of

monitoring. Then you enter a series of, how can I describe this? What am I going to tell my patients? Should I tell my patients? You're going to tell me there was very varied stuff. I'm absolutely sure in some centres patients were never told, but let's walk through. I'm having a conversation in my centre with one of my patients. So I sit him down and I say, "I've got something else to tell you. You've heard of mad cow disease? And you may have heard that some patients, a very small number of patients, have got this variant of mad cow disease and died of it." And maybe I even said, "We now know that some of the Factor VIII you had in the past 15 years ago came from -- because we had -- nominated batches occasionally came from a patient who has now developed variant CJD and died. Fifteen years ago, you had Factor VIII from him, so I'm just telling you this. I haven't got a test which tells me whether you've got this or not. I haven't got any way of monitoring you as to how you're getting on. Don't worry. You'll probably be all right."

I mean, all the things that's been thrown at doctors in the past few years tell the patient everything, quite rightly, which I always believed in. Here's an example where the interchange between

a doctor and a patient, the patient must have felt, well, thank you very much. That's actually reassuring.

I remember vividly one patient said to me, "Mark, that's the fifth time in 20 years you've sat me down and told me I've got a virus. You told me I've got Hep B, Hep C, HIV, parvovirus, and now here's another thing." And he said, "I thought this was very good. You obviously don't know anything about it. It's just going to get parked with the other four, and we'll see how we get on."

The point I'm making was, if you believed in telling patients about everything, it was a very difficult and awkward and unsettling conversation. Any patient would have gone away from that and gone home to his family and said, "Dr Winter's told me this", and they would have said, "Well, we don't like the sound of that." I mean, mercifully, it didn't evolve into a major problem, but I didn't know that, and the patient didn't know that.

Q. We've seen examples of notification letters which -- to some extent, there seems to have been some form of standard form, but in the case of your patients, you had conversations with them directly?

A. I didn't send them a letter. I spoke to them.

Q. There's one other issue, a miscellaneous issue this one, but one of practical importance about prescription charges I wanted to ask you about. HCDO0000264_155, please, Henry.

This is a letter sent by you to all haemophilia centre doctors, May 2002, and I know you are familiar with this, Dr Winter:

"Prescriptions for haemophiliacs infected with HIV and/or hepatitis viruses. You'll be aware that a particularly iniquitous situation exists where in patients with haemophilia who have been infected with HIV and/or hepatitis viruses through the use of contaminated coagulation factor concentrates prescribed on the NHS currently have to pay for prescriptions for the treatment of these conditions. This has understandably caused great resentment amongst patients with haemophilia, particularly as patients attending GUM clinics who have acquired HIV through other means are traditionally ascribed a code which allowed them to have free prescriptions."

Then you go on to say:

"The Macfarlane Trust has been in dialogue with the Department of Health about this situation, but whilst a strong agreement that the situation is wholly unreasonable, there is no immediate prospect of being

able to create an exemption clause for haemophiliac patients as part of the national prescription form."

Then you said there was going to have to try and be some kind of local solution which, as I understand it, is the reason why you were writing to Haemophilia Centre Directors.

Can you just give us a little bit about the background to it and how at all it was resolved?

A. You will see that this is -- I am writing this as a Macfarlane Trust trustee as the doctor. This, again, is a very classical NHS story where, if you look at the back of a prescription sheet, some groups of patients are exempt from prescription charges. It's a very curious selection of patients. How anybody came up with those conditions, it's very strange.

Here was a situation that was clearly unfair. If you went to a sexual transmitted diseases clinic, you turned out to have HIV, you were given a code, somebody took your prescription to a pharmacy, and your drugs came back, and you didn't pay. My patients with haemophilia, I wrote a prescription with their name on. They went to the pharmacy. All these patients were on five, six, seven drugs. There would be a bill for £35. You then work your way up. You go

to the local pharmacy in the hospital, the district pharmacy, the regional pharmacy, the Department of Health, everybody says, "I completely agree with you. This is a completely unfair situation." "So what are we going to do it about it?" says I. And nobody -- I mean, essentially, they would have to rewrite the back of the standard prescription charges.

Q. It doesn't sound terribly difficult.

A. Well, it was very difficult for them -- far too difficult for them.

So, in the end, you can see the sort of note of exasperation. This has been going on -- I'd discovered -- when I went and chatted up my pharmacy, I said, "How would you feel if I gave you a list of my patients with haemophilia and HIV, their names, and we gave them a code? So if I sent you a prescription from my clinics with a code, you know it's one of these registered names, exactly like you are getting from STD clinics, and you could issue them with free prescriptions." And they said that's fine. So that's why I've -- it's the only thing I've come up with to bypass this incredibly frustrating and bureaucratic and very -- actually, very important problem.

These patients had to pay a lot of money to resolve to treat an infection that they'd got through

their NHS treatment, and they were being asked to pay for it. So, actually, quite rightly, the patients felt very resentful about this.

Q. Do you know whether it was resolved on a national level ever, and if so, when?

A. No.

Q. You don't know, or it wasn't resolved?

A. I don't know.

Q. I've got some questions to ask you about the Macfarlane Trust, but I see the time, and they'll take -- they won't take a huge amount of time, but they will take longer than a few minutes, sir, so is this a convenient moment to break for lunch?

SIR BRIAN LANGSTAFF: Yes, it is. We'll take a break until 2 o'clock.

(1.04 pm)

(Luncheon Adjournment)

(2.00 pm)

MS RICHARDS: Dr Winter, just before I come to the Macfarlane Trust just a couple of other matters, if I may.

The first is to ask you specifically in relation to haemophiliacs who were mild or moderate but not severe and regularly treated haemophiliacs. You talked earlier about the natural history of

haemophilia, dying of cerebral bleeding in the early 20s. Is that the same for mild or moderate haemophiliacs or is that data that relates to severe haemophiliacs?

A. That would only be for severe. So a moderate haemophiliac we would sort of classify as someone who had a Factor VIII level of between 1 and 5 per cent of normal. That doesn't sound very much but day-to-day that would probably not cause them any great problems but they would bleed significantly if they had accidents or had surgery without cover. They wouldn't get the very serious, sometimes spontaneous, episodes of bleeding into joints and muscles of severe patients.

Now, mild haemophiliacs, I mean, it's quite -- sometimes seen in centres, somebody will come in at the age of 45 who has been very healthy and have a routine surgery and bleed and been found to have mild haemophilia. So mild haemophilia you could live to be a good age, depending on your health experiences, before you were diagnosed.

Q. Then just a second point perhaps slightly related to that. You talked about the knowledge that haemophilia patients might acquire through family members having had haemophilia or because of the close-knit community

or attendance at Haemophilia Society meetings and so on, and no doubt that may be true for some people. Would you accept, though, that's not an assumption a clinician can make about everyone, that they will necessarily have that acquired knowledge?

A. Yes.

Q. In particular those who, for example, are mild haemophiliacs or moderate haemophiliacs, who haven't required regular treatment, may not have had that same interaction with others?

A. No, I mean, I recall that of the information that we did give to patients, if we had a new patient with significant haemophilia, Peter Jones from Newcastle (who you may or may not be going to interview), he had written a book called Living with Haemophilia --

Q. Yes.

A. -- and that had been made available by some sort of arrangement. So we had lots of copies of that book and that book was written by Dr Jones for patients with haemophilia and we would give that book to patients with significant haemophilia. We probably wouldn't have given it to a mild haemophiliac because if we saw somebody with mild haemophilia we would register them with our centre and with Oxford and we would instruct them to come to us if there were any

problems with bleeding or any surgical or dental planned, but we would then only see them once a year for follow-up, very briefly, just to make sure they were okay. We probably wouldn't have given them that book. But any haemophilia that was significant in addition to the things that you're talking about, the patients would have been given this really quite substantial book to read -- no internet in those days, obviously.

Q. Thank you.

Then I just wanted to ask you about relationships with pharmaceutical companies. You use the phrase in your witness statement that there was an element of symbiosis in the relationship between centres and pharmaceutical companies. I wonder if you could just elaborate what you mean by that.

A. So there were only, at any one time -- like all industrial companies, companies were forever changing and merging and changing their name, but at any one time there probably weren't more than four or five main providers of American, Japanese, Spanish, French origin that we would be buying concentrate from if we weren't using BPL.

They would come to us outside of the contractual arrangements. Firstly, they would come to us and say:

How can we help you in your community? You know, what could we do to make a difference to your centre? And the nurses would say, "Well, it would be great if you could run a weekend for our patients about prophylaxis" or the nurses would say, "It would be great if we could have some improved home treatment kits" or "it would be great if we could have a pamphlet on variant CJD".

The NHS was really good at sort of -- once you'd got it -- the core funding. What was very difficult on the NHS was what you might call providing the frilly, but actually they weren't so frilly, bits for patients. So we might talk later about the Haemophilia Alliance. Well, we wrote a National Service specification. I could never have got funding for that document through the NHS but I was able to get funding from a commercial company for this document, which was an important one for patients.

We wrote and published a home diary to collect Factor VIII usage. One of the really big issues in haemophilia care is home therapy is a great liberation for patients but it was essential for the centre to get good records of what the patients were doing. And if doctors are different, so are patients. Some patients weren't very good at keeping records of what

happened in the home. So we wrote this diary it was like -- it was called the Filofactor. So it was the age of the Filofax, and on each page was information about Factor VIII and space: Have you had Factor VIII today? That was funded by a commercial company.

I took 100 haemophiliac children to Disneyland in Paris as a sort of bonding exercise. That was funded by a commercial company.

They would sponsor the residential weekends for the patients that we've been discussing. The Haemophilia Society did not have their own funds sufficient for that. The Haemophilia Society would approach the companies and say, "How would you like to fund this residential weekend in Coventry, and you could come along and have a stand", so patients can come and say hello to you. The companies were only too happy to do that.

So it was those sorts of activities, really, that they did. BPL never did any of that, to my recollection. I mean, I had limited interaction with BPL but at the start we kept saying to BPL, "It would be good if actually you started to do the things that commercial companies did, because haemophilia centres have needs outside of Factor VIII and it's very difficult to satisfy those needs through NHS funding

and the companies are doing things which actually are very helpful."

Sometimes the companies might pump prime a post. If a centre said, "I really need a physiotherapist", the centre would say, "We will fund that post for a year", and the director could then go to the Trust and say, "You know, we've been talking about getting a physiotherapist, I've got funding for the first year". That was a sort of big help. And the Trust might then say, "Fine, let's go ahead with that post."

So there was a whole range of, from our point of view, beneficial things that they were doing for the haemophilia community at large and very much, you know, for the patient groups.

Q. I understand from the description that you give of those kind of facilities and services what the benefit might have been for patients and the centre. What was the benefit for pharmaceutical companies? What -- put crudely, what were they getting out of it?

A. Well, I think they got a sort of closer relationship and understanding of the way in which haemophilia centres worked and I think there was a feeling that -- I've no evidence for this and nobody ever said this but maybe they felt that by providing these icing on the cake services -- but they were regarded as very

welcome by the centres -- maybe that would make it more likely that they would get the contract from the hospital for the following year for Factor VIII.

Q. They're private companies, not altruistic foundations, so ultimately they wanted your business?

A. I think they wanted our business, of course, and they said to themselves this would be a way of making it more likely that they would get our business.

Q. Did that influence your decisions as to what --

A. Well, no. I mean, I've said to you we fell over backwards not to change product.

Q. The Macfarlane Trust then: you were a medical trustee of the Macfarlane Trust and the Eileen Trust '96 to 2009. I'll just look at the letter appointing you, just so that we can see how the appointment system worked. It's DHSC0003431_002. We can see from this it's a letter the end of 1995 addressed to you from the Department of Health:

"The Haemophilia Society have put forward your name for consideration for appointment by the Secretary of State as trustee of the Macfarlane Trust."

Then we can see -- then in the next paragraph, it said:

"There are ten trustees: six appointed by The

Haemophilia Society; four by the Secretary of State."

I think that changed over the years. Then:

"The trust deeds specify that one of the Secretary of State's appointments should be the director of a haemophilia centre."

Your name was put forward as a replacement for Dr Mayne, who had hitherto had that role. So you were appointed by the Department of Health, but were you in any respect answerable to the Department of Health?

A. Not in any way, no. Nobody from the DoH ever communicated with me and asked me how I was getting on as a Macfarlane trustee in the 12 years or so. Plus, we should explain the Eileen Trust was a parallel trust for patients who got HIV from blood transfusions. It was very, very small, 20 to 30 patients only, compared with 1,300 or so with Macfarlane Trust.

Q. Now, your role as a trustee -- you had, I think, the general role that a trustee had in taking decisions and attending board meetings, but you had a particular role as medical trustee. Could you just explain what that was.

A. Yes. Well, as you say, I attended the regular meetings which did have a medical element. You know, the Trust would be forming policy on what to do with

bereaved people or partners or establishing information. So there was a number of occasions at each meeting where they would need medical input which I provided. But my specific function was to deal with individual requests.

So the registrants they were called, rather than patients, they received a regular monthly payment from the Trust, but they also had the ability to lodge an application for an individual grant. If they had a problem and they -- something that was -- would be of great benefit to them, they could put in an individual application from the Trust.

The Trust needed, you know, medical background information as to how poorly the patient was, and why they needed to have this change to their life, and why should the Trust fund it. So I would read the patient's application, and then I would, with the patient's permission, get in touch with the centre that looked after the patient and say, "This patient has applied to the Macfarlane Trust for a chair lift or whatever. Please could you give me the background medical information as to, you know, how severe is the haemophilia, how is the state of the general health, what's happening with the HIV treatment." And I would send, obviously, the director a signed consent from

the patient giving consent for the director to give that information to me.

Then, in those days, the meeting was in two parts. So the first part of the Trust meetings were the sort of general agenda and then, later in the day, we would go on to hearing these individual requests and, for each request, I would then give, you know, "I've spoken to the centre, this is the medical background", and on that basis the Trust could form a decision.

Q. Were there occasions in which the centre was -- or the clinicians at the centre were less than forthcoming and you had to chase to try and get the information that was required to assess the application?

A. I think most people were pretty good, but some were a little harder than others to get communications from, but generally they were pretty good.

Q. Could we look at BHCT0000873, please, Henry. So this is a letter from the Macfarlane Trust to Dr Mayne, June 1996. We can see that it's a letter to her in her capacity as the haemophilia clinician for a particular patient who has made an application, and there's an explanation here of intended process:

"The trustees have decided that the anonymous case summaries which they receive in advance of their

meeting should contain up-to-date health information gathered in a consistent fashion. To meet this aim where the health information held on the particular patient is older than six months, a doctor's report will be requested."

Then it's said that -- information in the next paragraph about how often that's likely to be requested. Then the next paragraph:

"All information contained in the completed report will be treated as given in confidence to the Trust and will not be shared with the patient concerned. Information provided of a complex technical nature will be drawn to the attention of our medical trustee, currently Dr Winter from Canterbury, who will translate it for the other trustees."

I just wanted to ask you about the first part of that paragraph I've looked at, that the report that was being requested here would not be shared with the patient concerned. Do you know why the Trust adopted that policy?

A. No, and I can't think why they would have done because the process -- you know, this letter sort of supports, doesn't it, what I said to you about the way the whole sort of single grant process worked: it was health-related; there was a report from the doctor;

there's consent from the patient.

The doctor writing it back to me or the Trust would never have said, "This patient's actually, you know, very well and I don't recommend that you give this grant." You know, the doctors knew all their role was to give the Trust, through me as the trustee, medical information. Maybe the sensitivity was that a doctor might -- you know, if the original report to the doctor had said, "This patient would like a chair lift," if the doctor wrote back and said, "The patient's perfectly mobile. Why would they need a chair lift?" Maybe the Trust didn't want the patient to see that. But in my experience, the doctors never did write back like that. They wrote back to say, "As I have requested, this patient's got mild or moderate haemophilia. They've got HIV. This is their medication, and this is their state of the health".

Q. In your statement, you talk about or you raise a number of concerns about the Trust's actions and decisions. You say, first of all, that you initially had issues with the Macfarlane Trust because the board spent more time discussing finances rather than discussing the needs of registrants. Can I invite you to explain a bit more about that, please.

A. Yes. I'm not -- I presumably made those comments in a previous inquiry because I was asked to. When I first joined the Trust, the meetings did have the aura of a board meeting of Shell or something. You would spend a significant amount of time talking about the state of the investments of the Trust, and this I found rather bemusing. And there seemed to be nothing like as much time as I would have liked talking about the needs of patients.

I mean, eventually in each meeting, they would get around to talking about some matters, but I didn't really personally see the need why all these financial matters had to be discussed in a meeting that should really have been talking about: how can we provide the best possible service to the registrants? You know, the Trust deed said we're to relieve suffering in the haemophilia community. That's why I was a trustee; obviously to the help out with that general philosophy.

So I was disconcerted, would be a good word, at the sort of aura of the meetings at first. This was partly due to the personnel who were senior trustees at the time, and that did change as those personnel changed.

Q. You also talk in your statement about trust executives

seeming to follow a position of providing generalised welfare support where the culture was for registrants to be passive recipients, and your experience was that wasn't what patients wanted. Again, can I just invite you to elaborate upon that?

A. Yes. We went from one extreme to the other, really, where there did seem to me to be a culture -- which was very well intentioned, and these people were very caring and compassionate -- and it was a time when, you know, many people were dying, a lot of people were ill. The culture seemed to say to the registrants -- you know, it was like the Welfare State: we're here to look after you, you're not expected to do anything. You know, your role is to make applications to us for extra support, and that's fine and we will do what we can do give you all that extra money that we have at our disposal.

I learnt from talking to patients, particularly at residential weekends, as the treatment improved, particularly the advent of what we call protease inhibitors in about 1995, until then people with HIV would have been on two drugs, which were sort of quite effective but not very, and then the addition of this third drug was a major step forward, and for the first time it became possible to clear HIV from

suddenly the doctors are telling me they've cleared HIV from my bloodstream and I might survive. And that's great but I've got to rejoin the human race. I've got to think about the hole in my roof, I've got to get the fridge sorted out and I've got to get my life back on track."

So this was a very -- it wasn't -- if you thought that patients were in a state of, you know, emotional improvement, it was much more complex than that. It came on a background of -- everybody kept using the word "worn out". They'd lived with the virus, their partners had had to live with the virus, all the drama, people they knew had died, all the media exposure, having no money, everything -- you know, people had had such a difficult time and it was very hard for them. Yes, it was great they weren't going to die -- if you got as far as 1995, you were pretty unlikely to die of HIV. Nearly all of my patients died between '84 and '95. If you got to '95, most of those patients are still alive, but getting lots of problems with hepatitis now, but that's a different issue.

Anyway, this was all part of this retraining and a change of emphasis of the Trust to get people back on their feet again.

the bloodstream, people started feeling much better, and people said, quite rightly, "In any case, I don't want to be a passive recipient of largesse. You know, I want to rebuild my life. I want control and, now that I'm feeling so much better, I'd really like the trust to help me take my life forward. I'd like to go on a course. I'd like to retrain".

So there was, from people like me, an encouragement to sort of change the emphasis to what you would call a partnership. We even set up a partnership group where we met regularly with some registrants to see what they wanted. And the culture was, you know, "Let's not expect you to do nothing and we'll give you money when we can, let's work together to help you rebuild your lives".

This wasn't easy because for -- people had lived for a long time with HIV. I remember giving a talk at a World Federation meeting called "The Problems of Survival", and patients were saying, "You know, I'd expected to die, I'd been told I was going to die and I'd not planned to live, so I've got no money, my relationships are worn out, there's a hole in my roof, I never worried about that, the washing machine's bust, I haven't got a job, I didn't worry about any of that because I knew I was going to die, and now

Q. You I think identify in your statement a particular problem with the treatment of widows and the lack of financial support for them. How do you recall that arising and being considered by the Trust?

A. One of the chief executives brought this to my attention. The widows, under the terms of the Trust, were supported for six months only after the death of the patient with haemophilia. So there was obviously a very distressing situation where the wife had often given up work for 6/12 months to look after her dying husband, who had then passed on, and then after six months of support from the Trust, which wasn't very substantial anyway, she would be left with no support at all, and having not worked for 18 months or so. So we felt that widows were particularly hard done by.

You have provided me with papers reminding me of the regular meetings we had with various ministers. I remember meeting Hazel Blears and people like that each time, and we regularly I think flagged up that we would really like to do more for widows. Coming out of that, the Trust had set up a bereavement group and that, you know, put a lot of energy into trying to support bereaved women.

Q. I think this is right, that the position in terms of

financial support for widows didn't change during the time that you were there?

A. That's my understanding.

Q. Then you also set out your view that registered patients with the Trust, in your view were not receiving the level of financial support via lump sums to which they should have been entitled, considering the very serious viral infections they'd acquired through NHS treatment. You observe in your statement the financial support was significantly greater in other countries such as in Ireland. Again, can you just perhaps help us with how you formed that view and to what extent it was considered by the Trust?

A. Well, I don't know how society puts a value on somebody with a very unpleasant life-long blood disorder got infected with HIV and hepatitis from their NHS treatment which either killed them or made them very ill. How do you put a sum on that?

But what you could do is compare the funding, the grants that people in the UK had got compared with other countries. I made the Irish comparison. In Eire, I think if you had hepatitis alone -- they had a lot of cases through anti-D -- I think the patients who were infected were given something like the equivalent of about -- it was certainly well over

£200,000. That was way, way, way in excess of what patients with hepatitis in Britain were given and the general level of support was less than in other countries. I think that was the point I was trying to make.

Q. One feature of the documents, Trust minutes and so on, and we've given you a sample of them to look at, was the Trust not having enough money and asking the Department of Health for more financial assistance, for more money. Do you think, from your perspective as a trustee, attending the trustee meetings when this issue came up, sometimes attending meetings with the Department of Health as a trustee, do you think there's more that could have been done and should have been done by the Trust, first of all, and then, secondly, by the Department of Health?

A. I think the Trust, you know, had the -- were always of a view that they would like -- you know, given the task in front of them, they didn't have enough funds to provide the level of support for the registrants that they would have wanted. I think they did really try hard to increase that funding.

There were two or three politicians who we interacted with who were always very supportive. I can't remember who they were now -- Lord Morris

obviously, who wasn't an MP but he was always extremely supportive and helpful.

There was collaboration with The Haemophilia Society and we did have these regular -- it was, I think, a regular event that once a year maybe there was a little group that was taken off to the DoH to meet the minister. That was always top of the list when it came to the Trust's part of the meeting, would be to say, "Well, Minister, we've come to see you today, we really are very concerned that, you know, we're charged by the DoH with offering this level of support and we can't do it."

So I do think the Trust did try very hard to get extra funds and usually each time we went, the DoH did give some extra money but it was always sort of given with, you know, the caveats of, "We're under great pressure, and other competitive grants, and we've managed to find another 50,000 for you but that's all we can afford for this year and maybe we could review it next year".

That was the sort of response that we got. So it was like a sort of chronic drip-feed of minor improvements.

Q. Could we have up on screen, please, Henry, HSOC0029628_002.

This is the minutes of one meeting of the trustees. It's actually one you didn't attend, but I'm hoping I can still ask you about it.

So we can see it's 23 January 2006. We can see who is there: Mr Stevens and others. Apologies from some, including you.

Could we go to page 4, please, Henry.

I just wanted to ask you about this entry here under "Department of Health", and if you have any recollection of the issue that comes up here.

So we have the chair reporting on a meeting with department officials on 5 December. The main area of business discussed was the funding bid.

"The Chief Executive was asked to pursue the possibility of a ministerial meeting to discuss the business case."

Then there's reference to Lord Morris having tabled written questions.

Then it says:

"The board were of the view that as many contacts as possible should be exploited to further the case for the increase in funding such as the [All-Party] Parliamentary Group on Haemophilia ... and the All-Party Parliamentary Group on HIV ..."

Then the chair talks about having established

good relations with the local MP and the possibility of a meeting with the Shadow Secretary of State for Health.

Then we have Mr Spellman saying this:

"Mr Spellman urged that caution in respect of overt lobbying should be followed for the following reasons:

" (a) That the business case supported itself in terms of the requirement.

"(b) Overt lobbying might prove counter-productive.

"(c) If the business case is declined, the full board of trustees should be given the opportunity to debate a 'next steps' programme.

"(d) Further political activity might not help the situation."

Then we see it records the chair agreeing that:

"... no political activity should be undertaken which might impede a positive response from the Department."

Now, the impression that those minutes give is that some on the board were suggesting: maximise the opportunity, maybe undertake some form of campaigning, lobbying. Then there's a counter-voice on the board saying, "Well, no, let's not do overt lobbying".

What can you recall about any discussions about the kind of stance the Trust should take?

A. So, I mean, I wasn't at the meeting, and I actually can't remember who Mr Spellman was. He must have been a trustee, but he certainly wasn't a major figure in the trust.

So the first part of this document reinforces everything I've said to you. They've got contacts with the Society, they've got Lord Morris, and now that I read this, I mention the MPs. There used to be an All-Party Parliamentary Group. It had disbanded sort of spontaneously, and through encouragement from The Haemophilia Society and the Trust, it had got going again through Michael Connarty. I remember meeting him. So these were all the things I was saying to you, this sort of different pronged approach which was all very appropriate, and then these rather curious comments at the bottom, which I obviously don't agree with. But I -- you know, all of the meetings that I recall, the Trust, to my eyes, as someone who was -- you know, I'd done a lot of work with the Society and getting the publicity to get the Trust set up. I'd been to meet -- I'd been to the House of Commons with other patients and given talks, and I knew political influence was everything. This

is a rather curious thing which I think we can ignore.

Q. We'll, no doubt, be able to ask those working for the Trust and schemes full-time about that.

Just two further matters on the Macfarlane Trust, Dr Winter. The first is about the Trust's policy in relation to funding for aspects of assisted fertility -- sperm washing and the like. Now, there are a number of references to that in the minutes of meetings. I'm not proposing to go through them, unless that would assist you in terms of your memory. But it does appear that the question of the extent to which the Macfarlane Trust should fund such treatment was something the Trust considered over quite a number of years before it finally settled on a policy, and I wondered what you can recall about that.

A. So you get this familiar story from me now. If you work for the NHS and you have problems, here's yet another issue where everybody listens to you and says, "I fully agree. I completely understand." And then when you say, "Well, how are we going to fix it?" nobody has any idea.

There was another evolving area of concern. The Trust had a number of registrants it was supporting who were girls who had caught HIV from their

haemophiliac husbands, some of whom had died. The Trust also had a small number of orphans where both the mother and father had died of HIV. So this was -- you know, the importance of doing anything you possibly could to minimise any more haemophiliac men infecting their wives and partners was obvious.

It was -- you could make a little bit of difference by ovulation testing, by asking the girls to keep exact dates, but that was only a minor thing, and you had no reassurance that the girls would be safe. Ovulation testing was in increasing clinical usage across the country, and we were very keen for our patients to have it. The patients were -- well, a small number of patients were very keen to try. The particular issues about ovulation testing where -- the treatment took form of a cycle, and each cycle only had about a 10 per cent chance of leading to pregnancy, and each cycle cost about £1,000. Those were the issues.

So the issues were: how do I get any money at all? And if I get 3,000 and it hasn't worked, how do I get the next 3,000? So you know what I'm going to say: no centralised policy; no centralised funding; every centre director must do what they can. I am sure there's correspondence from me, is there not, to

haemophilia directors about this matter encouraging them to approach their own trusts. And, again, the variable response: some trusts were helpful; some trusts were not so helpful. My own trust in Kent were very supportive. I had one patient in particular who they funded and which led to a successful pregnancy and safe, and then repeated again two to three years later.

Now, I think the Trust -- the problems with the Trust was, it was brought to the Trust's attention by a trustee. He said, "We are obliged to follow the Trust deed which says you must alleviate suffering." And this trustee said, "Does that include providing funding for this sort of activity?" There was, you know, considerable discussion about that.

Then, of course, there was discussion -- well, if the Trust supported somebody for £3,000 and the registrants came back at said, "Well, thanks very much. It hasn't worked. Could I have another 3,000?" What would they do? These were the sort of conversations, as I recall.

What I do remember -- and I'm pretty sure about this -- is that the Trust did eventually, as you say after a long and protracted correspondence and discussion -- I'm pretty sure they agreed to consider

funding if the local trust had already provided some cycles of treatment which had not been effective. My recollection is the Trust did eventually, somewhat reluctantly I think, fund some treatment of this nature.

Q. The Inquiry's heard evidence from a number of individuals who, either as relatives or as people who were themselves infected, made applications to the Trust. We've heard expressions of unhappiness and dissatisfaction -- it's not the universal account, but it's certainly the account from a lot of people -- things like feeling they had to go with a begging bowl was the sense that some have described.

Does that surprise you, or do you understand that perspective, as someone who was a trustee for a number of years?

A. Well, that's exactly what I said to you. Patients would say, "I don't want to be the passive recipient of the Trust's largesse. I want to have a more active role, and I want to rebuild my life." So I do recognise that, and that's why I did welcome this eventual sort of change of policy of the Trust, to put more money into training and teaching programmes and getting people back to work.

I mean, I -- you know, the -- you see, the

individual grant scheme was always going to be a problem because you had large number of people. Some people would hardly apply for anything. I mean, I had patients who were very sick, very disabled. I'd say to them, you know, "Have you thought about applying to the Trust for ... ?" "No, I can't be bothered." So some sick people never applied. Some people applied for huge numbers of things, some of which were, frankly, well over the top. I won't give you examples, but there were some you just couldn't believe what they were applying for.

So that sort of scheme where people could apply for individual grants was always going to cause difficulties, I think, and, you know, I think we even discussed was it a good idea to have an individual scheme? But then we thought, well, some people can have unexpected financial needs, and we probably should have some mechanism for the registrants to come to the Trust on an individual basis. But it did cause exactly those sort of problems.

Q. I want to ask you about the Skipton Fund briefly.

Henry, could we have HCDO0000242_050, please.

This is a letter from you, December 2004, to Dr Hill, who was then the Chairman of UKHCDO. The subject matter, as I think you know -- we see it from

the next page -- is a letter you were drafting about the criteria for assistance under the Skipton Fund. But it was this phrase I wanted to ask you about:

"As the Skipton Fund is only the servant of the DoH -- and does not set policy -- on reflection, I think it would be better to direct the correspondence directly to the DoH with copies going to Peter Stevens and Martin Harvey at the Skipton Fund."

Can we look at the second page, Henry, briefly, so we can contextualise this. We can see the draft letter there is something that had been discussed by Haemophilia Centre Directors, and it was about the criteria for the scheme. I don't need to ask you about the detail of that, but if we just go back to the first page, what did you mean by the Skipton is the servant of the Department of Health?

A. So I think what I meant was -- this is all about who's going to qualify to be a registrant on the Skipton Fund and the issue, as set out in the second letter, is if you've got hepatitis C antibody, in theory, you could have been exposed to it and cleared it or something. You might not have live virus. So one school of thought said, well, maybe we shouldn't treat as registrants people who are just antibody positive. Maybe we should want them also to have

abnormal liver function tests because that would indicate they have got active virus. Whereas other people said, well, why don't we just do it with the antibody positives anyway?

So I think what I'm referring to here is -- I mean, the Skipton Fund obviously does set policy, once it's up and running. This was about who could the Skipton Fund accept as a registrant.

Q. And you didn't, I think, have any formal involvement with the Skipton fund?

A. No.

Q. Did you have much experience of its decision-making in your capacity as centre director between 2004 until your retirement in 2011?

A. No, beyond, you know, being asked -- I mean, I'm assuming there must have been a separate medical trustee for the Skipton Fund. Occasionally, I might have been asked for a medical report on one of my patients, but beyond that, I wasn't involved.

Q. Then leaving the Trust and schemes and just coming back to a handful of the more general issues that you've alluded to in your evidence so far, you've talked on a number of occasions during your evidence about the lack of national guidance, advice, decision-making.

Could I ask you to identify for the Inquiry some of the particular issues that you think could and should have been usefully addressed at a national level which weren't?

A. Well, I think that the DoH generally should have taken much more of an active interest in the evolving crisis, as a starting comment. As I've said to you, it was -- from a practical point of view, even though they had a doctor at our meetings, it seemed very hard to get them to take this as the very, very serious healthcare crisis that it became. I think that at times of all this variability that we've seen (about how to test patients, how to tell patients), that could have been much better handled if there'd been a DoH doctor at senior level working with the haemophilia directors, writing to haemophilia directors on behalf of the DoH about this very serious issue and this is the way in which it is recommended that you should handle the following issues, and we can go from how to test your patients; how to tell your patients; what treatments you should be giving at a time when we don't yet have sterilised treatment; how to switch to safe treatment; how to switch to recombinant treatment.

It seems to me these were such serious medical

issues. I mean, we all agree this was the greatest medical disaster ever to befall the NHS. Where was the DoH in all of this? Surely they should have been much higher profile working with the haemophilia directors to make sure that doctors like me and my colleagues were giving the best possible care. That's the core of my comment.

Q. Are there actions that you think the UKHCDO could or should have taken in that period that you've identified, 1978 to 1985, during these very sea changes that we've discussed, to promote safer care?

A. Well, if it was happening now, there's no way those type of documents could be written. All this stuff was, "Well, on balance it would be good to do this but every doctor must make up their own mind", that would never happen now, and, you know, in many ways it wasn't helpful, was it, because it opened the door to variability. That should not have been -- you know, it should have been done by a document saying: We're in a very difficult situation, we, the following, you know, directors of the major centres in Britain, this is what we think is best practice at this time and we strongly recommend that you do this.

Any doctor receiving a document like that would have been very wary of not following it. He would

have said, or she, "If I don't follow that and then something goes wrong, I'm dog meat for a legal case."

Once you get a letter saying, "Well, you could do this or you could do that but every doctor must make up their mind", a comment that seems to be in almost every communication, then the doctor might say, "Well, I've read that but this is what I think and it's not quite the same thing and I seem to be given carte blanche to deviate". And I obviously don't think that was a good thing.

Q. In your witness statement, your statement to the Inquiry, you say this:

"It has always been my view that the level of care offered to some patients in some centres was not what those patients had a right to expect, even by the standards of the day."

Now we've obviously alluded or you have alluded to some of those in the course of your evidence but can I invite you to set out to the Inquiry what particular aspects of care that you think was provided to patients in some centres that was not what they had a right to expect by the standards of the day?

A. Well, I think most particularly about testing and most particularly about the telling, and I've heard so many examples of the way in which that happened to patients

that I think was terribly wrong. I think some centres just didn't do well in supporting the patients generally.

You know, I've heard patients from centres say it almost felt like they had been rejected by the centre. They would ring up and say, "I'm not feeling well, I'm short of breath", to be told, "Nothing to do with the haemophilia, ring this other hospital."

The patient would say, "You know, I've been infected by you, through treatment in your centre, and now you are rejecting me, you're saying go and see somebody else."

So I think it sort of reflects back to the sort of way in which some centres were holistic and some weren't, and the way in which some centres worked was in such a manner that patients I think did feel rejected. You know, if there was any problems to do -- that wasn't to do with the haemophilia, they'd say, "Nothing to do with us, go to somebody else", and I think that went down badly with patients.

MS RICHARDS: Sir, I know you have a couple of questions you would like to ask Dr Winter. One of them relates to a Lancet article which Dr Winter hasn't yet had the opportunity to fully read.

A. Well, I've probably read enough.

A. The Lancet is a must-read, yes.

SIR BRIAN LANGSTAFF: So on 1 September 1984 -- now the importance of that might be the date -- your memory is that your tests conducted by the Middlesex came back to Thanet sometime the end of October/beginning November. Is that about right?

A. Yes, for certain -- see, on this list of authors is Dr Tedder from the Middlesex, he was the virologist, and it was his test that was made available to the haemophilia directors. And it's my recollection -- which fits with this -- this is the very early evaluation of actually two tests.

SIR BRIAN LANGSTAFF: Yes.

A. I can't remember which one we were offered or which Dr Tedder did. But anyway, it was very, very short, very early October that we got the news that the test was available and then, as we've discussed, it's a few weeks later that the process is finished.

SIR BRIAN LANGSTAFF: The authorship, if we just look at the top of it, there's Rachanee Chengsong-Popov is put as the first author but then -- was it Professor Weiss? I don't know if you have come across his name before but he -- as I understand it, on behalf of the Chester Beatty Laboratory, was developing the test which was proposed by him and by

MS RICHARDS: But, in any event, I should also find out from recognised legal representatives if there's anything further they --

SIR BRIAN LANGSTAFF: You are asking me for a break.

MS RICHARDS: I am suggesting it might be suitable to just have a short break -- we wouldn't necessarily need a long one, or as long as you want, sir -- just so that I can undertake that and Dr Winter can --

SIR BRIAN LANGSTAFF: We will make it long enough, shall we, for people to think a cup of tea if they want and I hope it might be available. So shall we say -- shall we come back at 3.30 if that's long enough.

MS RICHARDS: Thank you, sir.

(2.53 pm)

(A short break)

(3.29 pm)

MS RICHARDS: Sir, I have no further questions for Dr Winter but I think you have a couple of matters that you want to ask him about.

Questioned by SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: Just a handful of questions, if I may.

Can I begin with the article from The Lancet. You read The Lancet -- you read The Lancet at the time?

Tedder as a test to be rolled out across the country. And I think the Inquiry may hear later from various documents that the proposal was made perhaps in July, certainly by August there was a test, and it was this test which, from what you say, was used for your patients in due course.

Now it's a very -- fairly impressive list of authors, isn't it? It includes Pinching from St Mary's, Craske from Public Health Laboratory and Dr Barbara from the North London Transfusion Service?

A. Yes. There aren't any haemophilia doctors but they are just one of the subgroup of patients. But this is a distinguished list of HIV specialists. Ian Weller was head of the group eventually at the Westminster, I think, and the Middlesex, and Tony Pinching was obviously a leading light, with Weber, of the very large St Mary's HIV treatment centre.

SIR BRIAN LANGSTAFF: So if I can just draw one or two aspects of it to your attention and then ask some questions about it, if one looks at the summary -- left-hand column, very bottom, Henry -- the results were that testing those who were haemophiliacs -- doesn't tell you here how many there were -- 34 per cent --

A. There were 184 on one of the tables.

SIR BRIAN LANGSTAFF: Yes, I was going to take you to that, but you've answered that question.

So 34 per cent. That's 68 out of 184 haemophiliacs receiving pooled clotting factors tested positive. So roughly a third, very nearly a third, which, as far as this cohort was concerned, was rather less than you recollect in due course it was reported to you that Professor Kernoff's research had found in the Royal Free.

A. Well, the interest at this paper is this is just immediately before the haemophilia directors are about to test and find that 80 to 90 per cent of regularly treated patients are HIV positive.

So, against the context of Professor Bloom's remarks, "This isn't going to be a big problem", this might perhaps be an indication that the percentage of people affected is much greater than we had anticipated.

I mean, it's surprising the figure's only 34 per cent. But I just make the comment, looking at the patients they've got, patients were drawn from the Middlesex, Mary's and St Stephens. St Stephens actually isn't a haemophilia centre at all. The other two are small centres. And we're just told they'd had Factor VIII, including commercial. So that really --

to me, I'd like to know a lot more about those patients. They may not have been very heavily treated, very regularly treated.

SIR BRIAN LANGSTAFF: I think it says they were regular recipients. I think that's in the --

A. It does say "regular clotting factor replacement therapy".

SIR BRIAN LANGSTAFF: So that would suggest that they were not necessarily mild or moderate.

A. But my main comment is one is surprised that the percentage of positive people was not greater than 34 per cent, given the results that are about to emerge the next month using the same test.

SIR BRIAN LANGSTAFF: Might it be that the picture varied across the country?

A. Well, that wasn't a feature. I think wherever you were looking in England you found that all the major centres had very similar levels of incidence of HIV positivity.

SIR BRIAN LANGSTAFF: I think we'll have a look at that in the Inquiry and just see what they were reporting but thank you for that.

The next part I wanted to ask you about was, given that this said a third of all haemophiliacs receiving regular clotting factors, of commercial

clotting factors, appeared to have seropositivity -- and this in The Lancet, which is required reading for most if not all doctors -- what was the reaction to it in the haemophilia doctors' community?

A. You see, I think if we were testing beginning of October, I think we had already been told about this test and that it was going to come to us, because we would have had to line up the patients and write to them. If I was testing October, I must have written to them earlier than that. So I'm thinking that we already knew about what this survey had shown and that we had already been informed that the test was coming our way. So our attitude was: Dr Tedder, who we knew, has got this test. We're about to be able to do it, here's a preliminary report indicating the antibody positivity. And, you know, all the more reason for us to do our tests.

But it's rather slipped under the radar, this paper, because we've jumped from Professor Bloom and the theories of "this isn't going to be a problem" to our 80 to 90 per cent, this is a bit of a middle ground one, which I think has rather got -- rather got hidden.

SIR BRIAN LANGSTAFF: The introduction, on the right-hand column -- just the very beginning of that if you

please, Henry, if you can highlight that:

"The likelihood of the acquired immunodeficiency syndrome (AIDS) being caused by an infectious agent has been apparent for some years."

That's what the virologists appear to be saying.

"The exponential rise in the number of cases of this disease has been restricted to certain well-defined risk groups in a pattern that strongly suggests an agent transmissible by sexual or blood contact."

I think you would, from what you have said, agree that that's a fair summary?

A. Well, it was. I wouldn't have used a phrase like "for some years", but you'd certainly, as I've previously given evidence -- by the time you've got the haemophiliacs, in the summer of '82 in the US, the San Francisco baby at the end of '82, you would have to, in my view, strongly suspect. So I think I might have written, you know, the likelihood of it being caused by an infectious agent has been apparent since at least December 1982, which was less than two years after the paper was actually published. But it's a fair point.

SIR BRIAN LANGSTAFF: Then it says:

"Case-clustering supports this hypothesis."

So that would be an epidemiological construct, would it?

A. That would be in relationship to the sexual contact.

SIR BRIAN LANGSTAFF: I see.

So, if you like, further support for that hypothesis. If one needed one now, because by now, in September '84, it would be generally accepted, I think, that the cause was a virus and generally accepted it was to be known as HTLV-III or, for that matter, NAV.

A. Yes, HTLV-III was the initial terminology at that stage.

Q. I think the only other thing I need to ask you about, at page 480 -- it's the fourth page in, Henry, if you please, that's the page -- and the second paragraph beginning "high prevalence of":

"It says this:

"The high prevalence of HTLV-III antibodies in haemophiliacs found in this and other studies ..."

And it sets those out below. I think it cites just one, at footnote 12, it's probably a Danish study, Melby and others:

"... has to be set against the relative low incidence of disease in this risk group so far ..."

So the prevalence of HTLV-III antibodies set

against the relatively low incidence.

And:

"This high antibody prevalence also shows the retrovirus or its antigen, is present in pooled blood products, especially factor VIII concentrates."

Then this:

"The likelihood that infection resulted from commercial rather than National Health Service factor VIII concentrates is increased by our failure to detect HTLV-III antibody in over 1,000 blood donors from the North London Blood Transfusion Centre. This finding is also reassuring as to the low risk at present of acquiring HTLV-III infection or AIDS by blood transfusion in Britain."

A. So this is very important re-affirmation of my point about, if Dr Owen's initiative had been successful, these are the sort of donors who would be have been giving blood turned into Factor VIII in Britain. And in the 1,000 donors there's no HIV in it. So, you know, we would have moved from a high-risk population of donors with HIV to a low incidence of HIV and that might have made -- might -- a difference.

SIR BRIAN LANGSTAFF: Yes, I see that entirely. And I thought it would support what you had been saying to us throughout.

If I may say, taking a general view, asking something rather more general than specific to this article now, if I may, what you've described as a healthcare crisis and a treatment disaster in the course of your evidence, you've given me the impression that it is something which has caused, at the time and since, deep concern to you that it should have happened at all?

A. Well, of course. I mean, here's a disease, haemophilia, which is pretty unpleasant, and life-long, and my take on the whole thing, over a long period of years, is that decisions were made in the mid-1970s that were clearly, at the time, wrong, and that other countries looked at the same situation and made the correct decision, which was: it is not sensible, in terms of safety of patients, to be using clotting factors that have come from paid blood donors in the US. You know, no doctor would have signed up to that idea in the mid-1970s.

So those decisions are unfathomable, really, to a clinician. How could the body have looked at the evidence and said that's a perfectly sensible thing to continue to do?

So as a result of that decision, 1,500 people died.

SIR BRIAN LANGSTAFF: So if I were to ask: what do you see as -- amongst the various different contributory causes for different parts of what we have been discussing, what you would see as the single most important cause, either by taking action or failing to take action --

A. Yes.

SIR BRIAN LANGSTAFF: -- would that be it?

A. If you were only allowed to have one witness for this Inquiry, it would have been David Owen, because everything revolves around that moment in time.

I have already given evidence that I don't think the hepatitis epidemic could have been affected by becoming self-sufficient, but Dr Owen was so close, even had a press conference to announce self-sufficiency. We were so close in getting to be where Scotland was in being, effectively, more or less self-sufficient. If that had happened, given all that we've then learnt about the incidence of HIV in American plasma compared to British plasma -- this is retrospective speculation -- always dangerous in medicine -- but I've always thought -- hepatitis could not have been changed, by and large, but it always had been a matter of great concern, given all the people who lost their lives, would it have made a difference

if David Owen had not become Foreign Secretary and stayed for another year and got it through, as I'm sure he would have done.

SIR BRIAN LANGSTAFF: For some of the -- amongst the perhaps then lesser causes, you have identified a structural problem, if I can call it that, in the way in which advice was given, rather than direction, that you wanted to know what to do and no-one would tell you, except it was your decision -- words to that effect.

How would you have wanted the system to work? It goes back to your discussion of clinical freedom which you described -- well, you first mentioned it yesterday as dangerous.

A. Well, I've already expressed a view that, in retrospect, I think the UKHCDO, faced with a mix of opinions, issued guidelines to doctors that were too flexible. They should have been firmer, should have said: we think you should do the following. This is a very complex moment in time, but this is our best advice. We think you should do the following.

There should never have been phrases like "but every clinician must make up their own mind", because that was an invitation to flexibility and an invitation for doctors to carry on doing what they

wanted, which was a whole variety of different things. So I think that was -- I think it was well-intentioned but unfortunate.

As you will gather, I would very much like to have seen the Department of Health having a much stronger, more overt role in the whole crisis, which was apparent, and working together with UKHCDO to take matters forward. And I would have also liked to have seen Elstree and the transfusion services be much more politically active and doing much more, frankly, to, you know, improve the provision of clotting factor concentrates for people with haemophilia in this country. I think, you know, their activities were also a relevant part of what happened.

SIR BRIAN LANGSTAFF: So you would have wanted the department to have been more proactive?

A. Yes.

SIR BRIAN LANGSTAFF: In what ways in particular?

A. Well, I think they could -- as I've said, they had a nominated doctor who attended our meetings. It would have been all too easy for this doctor to say to UKHCDO, "This is a serious healthcare problem. We should work together. I would like a senior figure in the DHSS to be issuing this guidance to doctors, to make it more formal", rather than a -- UKHCDO, as

Dr Savidge always said, was an informal gathering of haemophilia doctors with no constitution. We just all got together and did what we thought was best. We didn't have a constitution.

If the DHSS had issued advice, that would have made it of more stature, and I think that could have been very helpful. To be honest, they could have had a wider group, looking at all aspects of the crisis. Are we doing everything that we possibly can to improve the production of clotting factor concentrates in this country? Is it happening fast enough? Is the funding sufficient? Is the staffing sufficient? What is getting in the way of this country producing more concentrate and stopping us having to import concentrates from America made from the sort of human beings we saw in the World in Action documentary.

SIR BRIAN LANGSTAFF: I think it is probably allied to that, but let me introduce the question in this way, that those who listened to counsel's presentation about Dr Bloom and the Cardiff Centre may have been struck by the number of different committees relating to the healthcare crisis, as you have described it, upon which Professor Bloom found himself sitting, all of which seemed to be discussing similar aspects of the same problem, perhaps -- that may be a comment

which may be wrong, but I can be addressed for that in due course -- and perhaps not always speaking with entirely the same voice.

Did that represent your view of what was happening at the time?

A. Not particularly. I think a lot of these other committees were sort of virological, and we were rather remote from that. You gather, what I would have liked, if you like, is a sort of SAGE. You know we have SAGE now. We would have liked a haemophilia SAGE. Let's get all the interested parties in, bang everything together and sort it out, instead of which, as you're implying, there was sort of an individual -- you know, one agency was doing something, another agency was doing something else. This was a serious enough healthcare problem for us to want a much more co-ordinated approach. It should have been the DHSS leading that, I think.

SIR BRIAN LANGSTAFF: So some authoritative body speaking directly to Government, through Government?

A. Yes, exactly.

SIR BRIAN LANGSTAFF: I see.

The next one -- the last thing I think I want to ask you about is in respect of your particular -- you're in a particularly good position to deal with

this because you are, in your thinking, the only or one of the only doctors who combined haemophilia treatment with HIV treatment.

Do you think that's been an advantage to your treatment of those with haemophilia who had HIV?

A. Well, I'd like to think so. I mean, I think it was -- it worked out well that I was able to look after their haemophilia and their HIV. Quite a lot of patients, they -- I've described already -- they would ring up the centre and be told -- many patients were going to different hospitals; some of them not even in the same town. So they were at haemophilia centre X, they went for their HIV care to another centre or hospital Y, and they went to a third place, Z, for their hepatitis care. So they were all over the place.

I think it was -- or I hope, you know, my patients felt it was good that at least they had the haemophilia and the HIV under one centre, and the only thing they had to move sideways to in the same hospital was for the hepatitis consultant, you know, in the out-patient clinic just around the corner. So it was all centralised. You know, I hope they found that helpful.

SIR BRIAN LANGSTAFF: Was there a reason you didn't do combined clinics?

A. I think they now happen. Now, eventually I was replaced as an HIV physician, when the work got too much, and I did then start to do combined clinics with this new HIV physician on HIV. I think the number of people being referred to Dr Muller, my hepatology colleague, was not enough and not regular and frequent enough to warrant regular clinics. But he was terribly helpful, and he saw the patients very quickly and dealt with them very promptly and communicated. So that was fine.

SIR BRIAN LANGSTAFF: Going back to the problem for the individual who is suffering from the condition of haemophilia, first of all, but the troubles that come with HIV infection, and possibly with AIDS, and the problems which come with infection with hepatitis, they might also have needs for physiotherapy, or needs for counselling. It might be thought that it would be an advantage to them, ill as they are, to have that all in one place. Would you agree with that or think that would have been difficult to organise?

A. Well, that would have been ideal, and that's what we -- we had a physiotherapist in our centre and we had a counsellor in our centre. So we ticked all those boxes, apart from the hepatitis one.

All I've been trying to do is just to make the

point that this sense of rejection that was spoken about was sort of reinforced by: not only can I not go to the centre that gave me the treatment that gave me the infection, I've actually got to travel to a different hospital for my HIV, and another hospital for hepatitis, and a GP. I've got four sets of doctors in four different places. For someone who's not very well, that's far from ideal.

SIR BRIAN LANGSTAFF: Yes. Well, that's all that I wanted to ask you myself.

Ms Richards?

MS RICHARDS: No further questions from me, but Dr Winter, is there anything else that you would like to add that we haven't covered?

A. I had a long list when I came in yesterday morning, but I'm extremely happy to say we've covered everything.

MS RICHARDS: Good.

Then that's it for today, sir.

SIR BRIAN LANGSTAFF: Well, not quite it, because I would like to say something to you personally, if I may.

It's never easy, I think, to give evidence, and particularly when we might have had every right to think that you would have given it in a rather jaded manner, having done it twice before to two other

inquiries, but you've shown absolutely no sign of that. I may say that I am very glad that we heard you first of the clinicians and that you had such a fluent recollection and an astonishingly good memory for dates and events and recollections.

But, in particular, I'd like to thank you for your frankness. You tell it like it is, I think, from your perspective, and that is really valuable for me -- that's as I see it, anyway -- and given us a valuable insight, a number of valuable insights, into what it felt like to be a haemophilia doctor in this most difficult of times, particularly coming into it, as you did, in the end or the start of December 1983 as a consultant and then having your responsibilities.

I suppose you would have left some of us wondering if they could bottle your secret for getting money out of your local finance director because that might be very useful to other people.

A. Yes. I'm still not sure how it worked.

SIR BRIAN LANGSTAFF: But it didn't seem to work on the DoH.

A. No. That was a different matter.

SIR BRIAN LANGSTAFF: Thank you much.

A. Pleasure.

MS RICHARDS: Sir, we reconvene on Tuesday to hear the evidence of Dr Brian Colvin.

SIR BRIAN LANGSTAFF: Ladies and gentlemen, that's it for this week. Thank you very much for your attendance. I have already thanked Dr Winter myself. If you are travelling home and going any distance, travel safely. But, in any event, stay safe, and those of you who are coming back next week, I look forward to seeing you then. If not, I may see you -- I am sure I will see you -- later. Thank you.

(3.58 pm)

(Adjourned until Tuesday, 6 October at 10.00 am)

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