Tuesday, 28 June 2011

(9.30 am)

PROFESSOR CHRISTOPHER LUDLAM (continued)

THE CHAIRMAN: Good morning. Ladies and gentlemen, before we start, I should tell you that we will be having an unscheduled break at 10.30. There will be a broadcast at that time from the Court of Session of a tribute to Lord Rodger of Earlsferry, who died on Sunday morning. And I think every member of the bar in particular, and no doubt the legal profession more generally, would want to listen to that. So I think the arrangements have been made to allow that to happen. It might substitute for coffee. But we will see.

Questions by MR GARDINER (continued)

MR GARDINER: Professor Ludlam, inevitably there are a couple of loose ends that I would like to ask you about before Mr Di Rollo asks you some questions.

I would like you, please, to tell us briefly if you could, what work you did to identify the batch of blood which was thought to have infected the patients in 1984, which has been called the "implicated batch", starting from the first results that you received from Dr Tedder. You have told us a little bit about this. Perhaps just to remind us what you have told us, we could have a quick look at the transcript: Day 36, page 19. Could

we go to line 11?

Could you just read that through, just to remind yourself what you have told us and then answer the question in your own time. (Pause)

A. My --

Q. I think there is a bit more actually. (Pause)

I think by the time you get to line 10 on page 20, it's finished with, but just a brief description, if you would, of the work that you did to identify this batch?

A. Yes. When we had the first three positive -- anti HTLV-III positive results on patients who had only received SNBTS Factor VIII, I noted that all of those three individuals had received at least one batch in common, possibly two or three others, but there was certainly one batch. We then, with the results of testing the larger number of people -- we had the figure of 16 or 18 individuals who were positive, we thought, from NHS material. We then drew up a spreadsheet -- is my recollection -- with all the patients' names down the left-hand side and the batches along the top. And we went very carefully, as carefully as we could, through the manual transfusion records that you have copies of, noting which batch each patient received. We might have put ticks in the box, then counted them up to see how many patients had received each of the batches.

Then -- I think it was probably after that, we then looked at the information we then had available on the last negative and first positive anti HTLV-III test and it became clear that some batches that patients had received -- that quite a number of patients received -- were given before the patients became -- sorry, after they became positive. So they were sort of excluded on the basis of probability.

That left us with, I think, about two or three batches, of which the 0090 batch seemed to fit best with the time of seroconversion and with the number of bottles given to those patients, but also I think the -- what emerged then was that if patients got more of this -- more bottles of this batch, that then they were more likely to be anti HTLV-III positive. So it appears there was a dose effect, and if it was not this batch, then you probably wouldn't have seen the dose effect.

Q. When you say "we", who was that?

A. Dr McClelland, myself, my other colleagues in blood transfusion and the people who were authors on the paper.

Q. Yes. At what point did you have the last negative and first positive results information? You are describing a period of time, are you not, in coming to your conclusion?

A. Yes. It would have depended upon going back in the -- in the archive, having identified batch 0090, statistically as the most likely one, as far as I recall, we then needed to look back and see whether we had archive samples before the batch was transfused. And we clearly had them afterwards but did we have them close to the transfusion, which would help pin down a sample taken shortly after the batch had been given? If that was positive, then that was slightly more suggestive evidence that it came from this batch. Although, of course, as I'm sure you are aware, there can be very long periods between exposure to HIV and seroconversion.

Q. Yes. So this exercise was an exercise in deductive reasoning?

A. I suppose you could call it that, yes.

Q. Yes. What was your view at that time -- I'm talking about 1984/1985 -- about the likelihood that the implicated batch was the batch that was responsible for the infection?

A. I was reasonably convinced. The other possibilities, of course, which we did wrestle with, is: had there been two implicated batches? And how do you piece that particular jigsaw together with the dates of seroconversion? But we went over it as carefully as we

could and Dr McClelland did a very thorough job and I helped him.

I think perhaps he led it more than I did but we did it together. It took us quite a little while to do and to try and do it as accurately as we could. And we know subsequently, from studies done much later on the virology, that at least 12 of the 18 individuals had probably the same virus. So it looked like it came from a single source.

So that was -- that evidence didn't become available until what was called "PCR testing" became available. It was a paper written in about 1995.

Q. Yes. So your conclusion at the time was that you were reasonably convinced that the implicated batch was the correct batch. Is that right?

A. Yes.

Q. And what is your view now about that?

A. I still -- I have no evidence to suggest that it, I think, wasn't the most likely batch, the implicated batch.

Q. Yes. So you are still reasonably convinced or are you more convinced? What's --

A. No, I still feel it's the implicated batch.

Q. Yes. Thank you.

Okay. That's the first loose end. The next loose

end is about heat-treated Factor VIII. If we could have a quick look at [SNF00013211], we see that this is a letter dated 10 April 1984 by you to Miss J Spooner. Who was Miss Spooner?

A. Miss Spooner was a lady who worked in the Oxford Haemophilia Centre. She had worked there for a very long time and was responsible for setting up and maintaining the UKHCDO database of patients.

Q. Yes.

A. And she got involved in correspondence about UKHCDO activities and haemophilia activities in general.

Q. Yes. Do you remember this letter?

A. I remember the context.

Q. Yes.

A. I think so, yes.

Q. So this is a letter from you to her. What are you responding to?

A. I think there was a request, a circular dated 29 March 1984, probably from Professor Bloom, who would be chairman of UKHCDO, encouraging haemophilia directors, if they were going to use heat-treated Factor VIII -- because there was a small amount of it around -- to not use it on a named-patient basis for treating patients, but rather to put it into clinical trials under the CTX arrangements, with the Committee on

the Safety of Medicines.

This had a number of advantages. One was that there would be a protocol for investigating patients, the data would be systematically collected and it was much more likely to lead to a useful set of results. Giving patients medicines on a named-patient basis used to be an option that a doctor had the right to do; in other words outwith the product licence. If a doctor did that, more of the responsibility for doing so fell on his shoulders and also, particularly, if I remember correctly, he takes responsibility for, I think the quality of the product. I may be not absolutely right about that but with a CTX, which I think is applied for by the manufacturer, the manufacturer takes responsibility for the product.

The reason that I was not keen to test commercial products was several-fold, I think. One is, as I have explained before, I was keen to avoid the use of commercial products from the point of view of Hepatitis C, possibly the different sorts of Hepatitis C, and this would be North American potentially Hepatitis C. The record to that date was that none of the viricidal techniques, the heat treatment techniques that had been used to try and inactivate Hepatitis C, had been effective.

The number of patients in which you can test in inverted commas, "hepatitis free" concentrates are few and far between. They are patients who have never been exposed to really a blood or a blood product previously, and so these are in a sense very few patients at any one haemophilia centre. And if I had used them with heat-treated commercial products, that almost certainly at this stage would have transmitted hepatitis, I couldn't then have tested SNBTS products.

So I didn't feel the patients were missing out on a hepatitis-free product and I thought that there would be nothing to be lost, possibly a lot to be gained, by politely declining for the reasons I hope I have explained clearly.

Q. Just to be clear, what's on offer here is American heat-treated Factor VIII. Is that right?

A. That is correct.

Q. The reason I referred this to you, Professor Ludlam, is really to ask you about communication with patients. So my first question is: did you discuss the possibility of using what's on offer in this letter with your patients on an individual basis?

A. No, because I didn't think it was in their best interests; because they were not only being exposed to an American concentrate that had -- was likely to have

hepatitis in it, but it's an American concentrate derived from donors who appear to have HIV, and at that stage there was no evidence that heat treatment inactivated HTLV-III. That information became available in October of 1984.

Q. Yes.

A. And even that it was -- HTLV-III was heat sensitive in -- or should I say retroviruses, because it was a mouse retrovirus that was tested in October or thereabouts, 1984, we had no idea exactly how much heat would be necessary for how long to inactivate the concentrate. And as history showed, continuing in 1985, 1986, at least, possibly 1987, there were heat-treated concentrates made from North American plasma that transmitted HIV.

So I did not discuss this with my patients because I didn't think it was in their best interests.

Q. Yes. Okay. Just remind us where the material came from in October 1984 that showed it was inactivated, that the concentrates were inactivated by heat treatment?

A. Where the studies were done?

Q. Yes.

A. One set of studies were done by Cutter Laboratories, who, I think, had their headquarters in Berkeley, California. And I think other studies were done at the

Centre for Disease Control in Atlanta.

Q. Yes, thank you. My final question on this topic is: did you discuss the possibility of obtaining American heat-treated Factor VIII on a named-patient basis with your patients?

A. No.

Q. No.

A. Because I didn't think it was in their interests.

Q. Yes.

Sir, those are my two loose ends, thank you.

THE CHAIRMAN: Professor Ludlam, you were slightly hesitant in answering Mr Gardiner's question about deductive logic and I think I myself might have thought that the process was closer to inductive logic. Is that a distinction you would recognise?

A. Erm ...

THE CHAIRMAN: If not, just say so. I'm not going to take you into an area of my interest.

A. That's why I hesitated. I thought it was more inductive. That was the reason for my pause.

Q. Is the critical distinction that an inductive logic, you would be tending towards a measure of probabilities?

A. Yes.

THE CHAIRMAN: Approaching it on that basis, what degree of probability do you think was established by the exercise

you and Dr McClelland carried out in seeking to identify the suspect batch? Low probability, medium probability, high probability?

A. High probability at that time.

THE CHAIRMAN: Thank you.

Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Thank you, sir.

Good morning Professor Ludlam.

A. Good morning.

Q. Can I make it clear to you before I start that what I want to ask you about are really four main topics: firstly, the information given to patients about risks, secondly, the studies carried out by you, thirdly, the testing of patients for the HTLV-III virus and the identification of the implicated batch and fourthly, the communication of the results to the patients concerned.

I think in your evidence you mentioned at one stage at least two reasons why it was unfortunate that the phrase "AIDS study" had been used in connection with the study of immune function. The second reason that you gave in relation to that, you said in your evidence that a story had come to you that HTLV-III had been put into bottles of clotting factor concentrate, heat-treated and then given to patients.

I do have some questions for you this morning. I'll try to choose the language of those questions as carefully as I can, but I want to make it crystal clear to you and to everyone else that absolutely nothing in anything I put to you should be taken as suggesting to you that there is any factual basis of any kind in that story.

A. Thank you. That's helpful.

Q. When you arrived in Edinburgh, you have indicated to us in your earlier evidence that there was a different approach taken to that of your predecessor, that Factor VIII products were given on a much more widespread basis after you became involved as consultant at Edinburgh. That's correct, isn't it?

A. That is, yes.

Q. Obviously, that change of approach, you would hope to be beneficial to your patients but it would become apparent to you, I think, in the spring of 1983 that there may well be a virus which was blood-borne and which potentially could be fatal to patients at that time -- an HIV virus, or what was to become known as the "HIV virus". Is that a reasonable working diagnosis at that time?

A. I think by the spring of 1983, it was becoming clear that there was an agent that could be spread by clotting

factor concentrates that seemed to cause AIDS.

Q. One of the things that you did at that time was to begin to carry out a study with a view to seeing whether the effect of taking these products would suppress the immune systems of your patients. Is that right? You began a study at that time for that purpose?

A. Well, I did the study because I was, as I mentioned a moment ago, beginning to assume that there was an agent that could be found in clotting factor concentrates that could result in AIDS.

The clotting factor concentrates were made, obviously, from donor plasma, and the donor plasma in North America, obviously, was different from the donor plasma in Scotland. And I was of the view that if there was this agent in the donors in North America, it wouldn't be in the donors in Scotland, and therefore I thought it very likely that the immune system of the patients I looked after would actually be normal because there had never been any suggestion that people with haemophilia were immune-depressed.

There is a little bit of evidence to suggest that wound healing in people with haemophilia was a little slower than those without haemophilia and that they may possibly have been at slightly greater risk of bacterial infection, but really that was all.

Q. There had been studies in the United States that had found immune abnormalities in haemophiliacs and you wanted to find out whether there were similar immune abnormalities in your patients. Is that reasonable?
A. That's correct, yes.
Q. I think it's fair to say that, as a result of the work that you did carry out, it was discovered that there were certain immune abnormalities in your patients?
A. That's correct, yes.
Q. Did you inform the patients that such immune abnormalities were present?
A. I didn't make a point of informing them because we were really a little taken aback by them, not quite sure how to interpret them and what their clinical significance was, and I was also a little hesitant because the technology we were using was not what we would use today. It doesn't have the high degree of sophistication for counting numbers of cells. I think I described how we counted cells manually. It's a very imprecise way, particularly when there are small numbers of lymphocytes.

So the results didn't seem to have the same degree of precision as I would have liked and I think these were not standard laboratory tests for which there were well defined normal ranges, and there was a high degree

of quality control, like there is, for example, when we measure haemoglobins or total white counts. These are very carefully quality controlled. This was not, and couldn't be at that stage, well quality controlled.

Q. Should I take it then that the answer to my question is a "no" then really? That you did not inform patients of the results of the studies?

A. I didn't make a point of doing.

Q. Not making a point of something and not doing it -- I think it's important that -- there may be good reason why you didn't and I think you have given an explanation for that, but the position is that they weren't informed of the results of the studies. Is that too simplistic or is that correct?

A. I was going to go on to say that they probably were not informed of the results of the lymphocyte tests but the skin tests we did, it was obvious to the patient how they had or had not responded to the multitest device that I described some time ago. And it would have been clear when counting up the number of positive reactions that there were fewer, and I'm sure I and others would have said, "That's fewer than we would expect for someone who doesn't have haemophilia".

Q. But from spring 1983 onwards, from a patient's point of view, there wasn't any alteration in the treatment that

they were receiving in the light of the concern about the blood-borne virus, the suppression of the immune systems and the research that's going on, or the study that's going on in relation to that, the work that's going on in relation to that? There is no alteration to the treatment of patients, your patients, severe haemophiliacs, at that time. Is that right?

A. I think that's correct, yes.

Q. One possible option would have been perhaps to have reduced the amount of factor concentrates that severe haemophiliacs were in receipt of; is that reasonable?

A. Well, we looked very carefully at the relationship between the immune abnormalities and the amount of Factor VIII that patients had received over the past two or three years, and there seemed to be no correlation at all for the CD4 counts. They were independent of the dose of Factor VIII concentrate. So it didn't look like the more Factor VIII we gave, the worse the immune tests were. There was some other factor that was important.

Q. That's looking at it later on. Obviously at the time of taking the decision, one might have reduced the amount of Factor VIII that patients were going to receive. That was a possible option?

A. It was a possible option but, if I can say, as soon as we had the results, one of the questions we asked was,

"Was this related to the amount of concentrate the patient received?" So it was very quick to go back over several years' worth of transfusion records and try and relate the CD4 counts to the amount of concentrate and we couldn't do so. So that didn't lead us to think "Well, if we used less concentrate, the immune abnormalities might become less".

Q. Leaving aside the immune abnormalities, it is a fact that the more factor concentrate you receive, the more likely you are to seroconvert, if you receive an infected batch. That's right, isn't it?

A. That's correct, yes.

Q. So if a decision had been taken at an earlier stage to reduce the amount of factor concentrate that patients received, then perhaps certain patients may not have seroconverted. Is that not reasonable?

A. That is certainly a possibility. The difficulty I envisaged was that if patients used less Factor VIII or wished not to treat bleeds as intensively as they might normally, that they would develop a bleed, they would take either no treatment or a little treatment, and I'm sure you are aware bleeds into joints, particularly elbows and particularly knees, can be exceedingly painful. Untreated, a knee bleed lasts about a week or ten days.

Q. I think we understand that but --
A. Sorry, can I just finish, if I may?
Q. Sorry, yes, of course, please do.
A. If you decide not to treat at the beginning, the pain becomes so great, they are requiring large amounts of morphine or pethidine. At that point the patient might then opt for treatment and would actually require much more treatment to settle the bleeds down than if he had had treatment right at the beginning, because all the evidence is that if you treat very early a bleed, then usually a single injection is enough, whereas if you let a bleed develop for several days, then you need an awful lot of treatment and therefore a lot of Factor VIII.
Q. Would that apply to prophylactic treatment as well? It wasn't just a case of using Factor VIII concentrates to treat bleeds but it was also being used as a preventative measure, was it not?
A. Not a great deal at that time because to give effective prophylaxis, you need to give injections every other day and you need to give large doses because the half-life of Factor VIII is about 12 hours, and you want to keep the level over about 1 or 2 per cent and so you need to give about 3,000 units, roughly, for an adult, on alternate days. And that will keep a child mostly bleed-free with severe haemophilia. But it uses up

a huge amount of Factor VIII. And that's one of the difficulties we are having at the moment. We have got so many children on prophylaxis, and that's one of the reasons why the Factor VIII usage is rising so rapidly in this country.

Q. Are you saying there wasn't prophylactic treatment at that time, 1983/1984?

A. There wasn't.

Q. There wasn't?

A. There wasn't. I wasn't using prophylaxis, what you might call "primary prophylaxis", which is started when babies are usually about a year old and they have perhaps their first bleed, and you then start them on perhaps weekly injections of Factor VIII and build up the frequency over the succeeding year or so. No, our treatment was on demand at that stage; in other words, you wait until a child bled.

Q. What about adults? Would adults be treated prophylactically?

A. No. Occasionally you would get someone who had had recurrent bleeds into a joint and each of the bleeds had been treated with a short course of treatment and then they had rebled and one of the options under those circumstances is to treat them for two or three months, often every day, to try and keep the factor level up to

stop them bleeding.

Q. All right.

A. Prophylaxis came in in most of the country rather later.

Q. When is that then?

A. That would be, I would think, the late 1980s, the 1990s, for most centres, I think. Because, you see, prophylaxis requires a lot of concentrate and there wasn't a lot of concentrate around. That's why we couldn't do it and we would have liked to have done but it wasn't feasible. We merely had enough concentrate to treat patients on demand at home and that's what they really wanted.

Q. I think in relation to reducing the amount of Factor VIII that patients received then, it does seem then that you would not have discussed an option of that kind with patients in the period that we are talking about, between 1983 and 1985. Your view was, apparently, that it wouldn't be in their interests and you wouldn't discuss that with them. Is that right?

A. I'm sorry, I can't remember if it had been -- if the topic had been raised by a patient because there was some discussion in 1983 in the Haemophilia Society bulletin, for example, articles about "What is AIDS," and Peter Kernoff, for example, gave a very interesting interview to lay out what was known at that stage. But

if any patient had asked me about treatment, I would have explained my view, and I think my view would have been accepted by the patients. If a patient had said to me, "I don't want any Factor VIII concentrate," then I would have said, "Well, would you like cryoprecipitate? I can't guarantee that cryoprecipitate is free of a putative AIDS-causing factor but if you do want cryoprecipitate, I am afraid you would need to come up to hospital to get the treatment."

Q. Do you recall specifically any conversation of that kind taking place?

A. I don't think I do, no.

Q. I mean, I think in your earlier evidence, my understanding of your explanation, I think, for the position about cryoprecipitate was that SNBTS wasn't geared up to make a general switch back to cryoprecipitate. So there would have been manufacturing problems relating to that. That's what you indicated earlier. Am I right about that?

A. That's correct. We would have had cryoprecipitate -- if one or two patients had wanted to change, we could have changed those patients but if there was to be a wholesale move back to cryoprecipitate, my understanding is it would have taken a little while for the blood transfusion to acquire the necessary

equipment, get the staff trained up again and get the packs --

Q. Again, that was a conversation that you didn't have in mind to discuss with patients generally: the option of making that switch? If a patient had come to you and asked about it, you would have discussed it but if they didn't, it would be left and the default position was that you would carry on with the factor concentrates as planned, as it was?

A. Yes. Could I just add to that that I'm not aware of many haemophilia centres or any haemophilia centres that -- in the UK -- went to their patients and put this proposition. I know there was one or two haemophilia centres at which patients did ask about the use of cryoprecipitate.

Q. Again, from a patient point of view, I think the general message that patients would receive, right up really until the meeting in December 1984, was one of reassurance and even at the December 1984 meeting, efforts were made -- and I'll come to that later -- to try and reassure patients, but the general message that patients would be getting would be one of reassurance in relation to factor concentrates. Is that not right?

A. There was clearly -- and I pointed this out in things that I have written at the time -- there was clearly

a risk of the agent that would cause AIDS coming into the Scottish population and therefore into, potentially, patients. But from the epidemiology and what knowledge there was of it, it seemed that the risk in Scotland was very small and therefore it didn't -- I was not alerting patients explicitly to this risk. To any that would have asked, I would have said, "I think it's small".

Q. If we look at [SNB0048744], this is a newspaper cutting of an article that appeared, I think, in the Evening News in November, 28 November 1984. This is obviously quite late on, in fact it's after a time that a batch had been recalled on the basis that it had been implicated. If we look at this newspaper article, which presumably is intended for public consumption. I'm not obviously indicating that you personally were responsible for what is contained in this article. Again, I'm trying to look at it from a patient point of view. If we look at the first paragraph, it says:

"Not one person has contracted AIDS in Scotland as a result of blood transfusions or treatment with preparations made from Scottish blood."

Leaving aside the distinction between AIDS and the HIV virus, which distinction might be lost on someone reading the article, if we go further down under "Caring", the president of the Royal College of

Physicians is quoted as saying:

"I think the public should be reassured. I do not think people in Scotland have anything to worry about, whether they are getting blood transfusion or other treatment with blood products."

I'm just quoting that to you as an example that certain patients may, from their point of view, see that and think that they do not have anything to worry about, and that seems to be the message coming across in general terms to the patients until, as I say, the meeting where you have different information to impart. Is that reasonable to say that?

A. I think so, yes.

Q. Obviously a change in the message is likely to heighten the sense of disappointment, from one to the other. There is going to be, at the very least, a considerable amount of disappointment?

A. Yes.

Q. Can I just come to the research or monitoring? I don't want to get too bogged down in labelling it as either "research" or "monitoring". I would quite like to ask you exactly what was happening in terms of the work that you were carrying out. Various studies took place. No doubt work had been done before, but we are interested from 1983 onwards. The first matter I want to ask you

about --

THE CHAIRMAN: Mr Di Rollo, I think if we are going to see the broadcast, we should get the system set up now. I think rather than get started on the topic, it would be better to keep it all --

MR DI ROLLO: Yes, of course.

THE CHAIRMAN: Ladies and gentlemen, what's proposed is that we should have a brief adjournment now and get the link set up. If the work starts now, they will be ready for half past. So we will adjourn and then make whatever physical arrangements seem necessary so that we can view it.

(10.25 am)

(Short adjournment)

(11.04 am)

THE CHAIRMAN: Ladies and gentlemen, thank you, those of you who are not lawyers, for indulging those of us who are. Lord Rodger was my pupil, which takes him and me back a very long way into the past and I'm very pleased that we were able to watch the proceedings.

Mr Di Rollo?

MR DI ROLLO: Professor Ludlam, I was about to move on to ask you questions about the work that was carried out from 1983 onwards. Just before I do, can I just take you back to one of your earlier answers this morning.

I think you told us that prophylactic treatment was not available or being carried out in Edinburgh among adults at the time that we are talking about. Am I right about that?

Can I ask you to have a look, please, at a document, page 3 of [WIT0011494]? Just scrolling up that, this is a medical record, as I understand it, of a patient in 1982, which does have labelled on it "prophylactic", and obviously it's deal from 1982 onwards. As I understand, it, the medical record has the word "prophylactic" in reference to treatment from 1982 onwards. Can you explain that in the context of the evidence that you have already given?

A. Certainly. I think I said that sometimes patients got short periods of prophylaxis if they had difficult bleeds, often into a single joint, that kept on recurring, and one of the options in that instance is to treat the individual prophylactically with an injection once or twice a day, for a period ranging from a week or two to potentially several months. But what was not practised was, if I can put it this way, "long-term prophylaxis", as is now practised for children and increasingly for adults.

Q. In the context that we see here, would it have been feasible to have reduced the amount of factor

concentrate that the person was receiving in the light of information in 1983 onwards? I'm not really dealing with this specific case, just to let you understand. I'm not asking you about any particular case individually. Obviously there are different senses of the word "prophylactic", and I'm trying to tease that out.

A. If I could return to what I think is the clinical scenario, of a patient having recurrent bleeds into a single joint, sometimes called a "target joint", and a number of things happen in these circumstances, one of which is the more bleeds you have into a joint over a short period of time, the greater the risk is actually that you have a further bleed because you get hypertrophy, increased growth of the synovium, the lining of the joint. That becomes more friable and therefore more likely to bleed. So with these sort of joint problems, they can get worse and worse and bleed more and more frequently. And the aim, obviously, in prophylaxis, is to try and stop the bleeding and let the joint heal up. And therefore less Factor VIII is used in future.

If you don't give prophylaxis, then you have to go on treating the bleeds as they arise and, as I say, they often arise with increasing frequency. And the other

thing that happens with recurrent bleeds is you get weakness of the muscle around the joint and that reduces the stability of the joint and makes it more likely to bleed. So in short-term prophylaxis, the aim is, as it were, to get the knee to heal up, for the muscles to strengthen and therefore to reduce the risk of needing further treatment.

Q. Can I move on then to the study and the initial study that was carried out. I want to ask you: how did you decide which patients you were going to look at for the purposes of the work. This is the work that began in response to the research that had been reported in the United States. So the work that was labelled "AIDS study". How did you decide which patients to look at from that point of view?

A. This is the spring of 1983.

Q. Yes.

A. These were patients who were coming up for routine review, or perhaps coming up with an acute bleed and needed to have blood taken for their routine monitoring, either measuring the haemoglobins and chemistry or their Factor VIII levels or looking for inhibitors that I have previously described. So these were people who were coming up to the haemophilia centre. They weren't people who were specifically invited up.

Q. So if a patient happened to come in for whatever reason, then a sample might be taken and looked at for the purposes of this work as well as for other things; is that right?
A. It would be opportunistic, yes.
Q. Did you look at all of the patients that came in or just some of them?
A. It wasn't a systematic study, if you like, or assessment of all patients; it was the ones who were readily around and available.
Q. So would there be patients that would come in and you would decide not to look at them then?
A. Might have been certainly. We might not have been wanting to take blood from them for other reasons and we wouldn't have taken blood, I think, just to do these tests. It probably depended a bit on the time of day, because you may recall that the samples had to be ferried across from the Royal Infirmary to The Western General Hospital, and probably processed the same day. So if someone came late in the afternoon, for example, it may well be that we wouldn't have put their sample through for the lymphocyte assessment.
Q. The lymphocyte assessment is what we see on the record? It's labelled "AIDS study"; that's what's going on?
A. That's correct, yes.

Q. In relation to those patients, how would the staff know which patients to label with "AIDS study"?
A. All the patients would be seen by either myself or one of my registrars and we had agreed that if blood was being taken, we would assess them for lymphocytes.
Q. You say "we agreed;" whose decision was that?
A. Well, it would have arisen out of discussion between us.
Q. You say "us", who is "us"?
A. Myself and the registrars. It's probably initiated from me because I was the one, if you like, who was in touch with what was happening internationally.
Q. Right. Would there be any reason to pick one patient over another, other than this sort of administrative considerations that you have indicated?
A. I think we probably would have been more interested assessing patients, as I think I mentioned earlier, with moderate and severe haemophilia because they were the ones who had received a lot of concentrate. If a patient with mild haemophilia came up, we might not have done the test because we might have thought they might not have had any blood product treatment at all in their life.
Q. Was it just severe haemophiliacs that you looked at or did you look at moderates as well?
A. I think severe and moderates.

Q. It is a fact that Dr Steel carried out his work in a different lab from other tests. In other words, samples were taken and tests were carried out but what Dr Steel was doing was being done somewhere else. That's correct?
A. That's correct, yes.
Q. Patients were not specifically, on an individual basis or on a, if you like, a coherent basis, specifically informed of the results of the test. Is that right?
A. That's correct, yes.
Q. And the results that you obtained as a result of this work were analysed; you looked at this work and you analysed it. That's right?
A. Yes.
Q. And you did publish the results of the work?
A. Yes.
Q. I think we see that the initial prompt -- or maybe not prompt but the letter in the Lancet by Gordon, which you picked up on and replied or responded to, also in the Lancet, refers to doing a study of T lymphocyte subpopulations in a geographical area where AIDS is not introduced. That's what it refers to.
A. It does.
Q. And in your reply you indicate that work has been done, a study of haemophiliacs in the Southeast of Scotland.

That's what you refer to.

A. Yes.

Q. Did you seek ethical approval for this work?

A. No.

Q. Can you explain why not?

A. Because I considered it part of the monitoring of potential adverse effects to therapy or to a problem with haemophilia, like I had been monitoring the red cell count, the haemoglobin, the platelets. We had already been monitoring, not just the total white cell count but the number of polymorphs, eosinophils, monocytes -- these are all different sorts of white cells and lymphocytes. There are different sorts of lymphocytes, some of which you can distinguish looking down the microscope, some you need to put markers on them. This is what Dr Steel was doing. But there are lymphocytes that you can see and if we could have distinguished visually between CD4 and CD8 cells in our routine lab, then we wouldn't have needed to send them across to Dr Steel. And it's just their morphology was very similar but their function was a little different.

So we are already assessing lots of different sorts of while cells and this was just one more subdivision of the white cells and seemed to be important because of the abnormalities that were being reported, principally

from North America, in patients with haemophilia who were well at that time.

Q. So the result of that is that one feature of seeking ethical approval is that certain indications have to be given about involvement of the patients and consent. You have to indicate when you are seeking ethical approval that you have actually obtained consent from the patient, and of course, if you are not seeking ethical approval, you do not need to get that consent specifically. That was the way that you were viewing matters. Is that right?

A. No, no. I wasn't not getting ethical approval because I didn't want to get consent --

Q. That's not what I meant.

A. I'm sorry.

Q. That wasn't the question. What I meant was, it's a practical consequence of if you don't seek ethical approval, then it's not necessary to obtain the patient's consent for the purposes of seeking ethical approval. It follows that when you seek ethical approval, you have to indicate that you have obtained consent from the patient, don't you?

A. Usually.

Q. The point is that we know -- and I think you have indicated to us -- that the patients were not consenting

or aware specifically that this work was being carried out. That's right, isn't it?

A. Well, we considered this at some length when I was here a little while ago. My view is that at least some of the patients would have been aware that we were doing the lymphocyte tests, for reasons that we rehearsed at some length. I'm happy to do so again.

Q. No, there is no need for that, I don't think. The short point is it would really depend on whether they had actually seen the form which had "AIDS study" on it. It wasn't specifically drawn to their attention; it just wasn't hidden from them, as it were? Is that right? Is that too simplistic a way of putting it?

A. I think it's a little simplistic because the form would be written out by the doctor seeing the patient, discussing with the patient what blood tests were going to be done, and the doctor having written "AIDS study" on it I think is very likely to have said, "We are also doing lymphocyte tests because there have been some abnormalities shown in the United States and we want to check out people here."

Q. Did you require to take extra blood for the purposes of this work?

A. No.

Q. Did you have to perform skin tests?

A. The skin tests were a slightly different enterprise.
Q. Can I just be clear: were they in connection with this work or were they for something else?
A. My interest became in 1983: why does it appear that people with haemophilia have abnormal immune systems? And the simplest thing to do, for reasons that have been well rehearsed here, was to count the CD4 and the CD8 cells. We then wondered, "Well, how else can we look at the immune system in people with haemophilia?" Because in Scotland, if I can put it this way, at that time patients weren't getting opportunistic infections. They weren't getting PCP, like in North America. So the patients didn't appear to be clinically immuno-suppressed, at least to the extent at which they would get opportunistic infections.

I have to say that there were one or two situations where HIV negative people did get what would be classified as "opportunistic infections", and if they had occurred in 1983 -- 1982 -- they would have been classified as "AIDS", but by the time they occurred, we had the anti HTLV-III tests. So we knew they were negative.

So patients were not suffering from a clinical immune suppression. But we wanted to look at them in a rather more holistic way and that is why we went for

the skin tests, because I think I explained when I was here before that that assesses a much greater -- many more aspects of the functioning of the immune system than just counting CD4 and CD8 cells.

Q. Could I just be clear: skin tests were carried out as part of this work then?

A. They were carried out after we did the CD4/CD8 counts.

Q. When was that? When were these skin tests taken?

A. Skin tests were done in 1984.

Q. Who received them? Who was skin tested? Whose skin did you test?

A. Well, we found, I forget, about 20 willing people without haemophilia to act as controls, and again we were rather opportunistic. Some of them I think we may have invited up. I think in 1984, I think we were opportunistic. People who were coming up anyway, for whatever reason, to collect home treatment or for review, we might have said, "We are doing these skin tests", explained what it was, "Would you mind volunteering for this?"

Q. Can I just be clear? What is it you are asking them to give a skin test for?

A. Do you mean the procedure or ...?

Q. I'm a patient and you are taking a skin test on me. What are you telling me about why am I giving you

a sample of my skin? Why are you testing my skin?

A. I would be testing your skin because the reactions that we could measure in the skin reflect the way in which your immune system is working.

Q. Would you have told me that this is part of a study into the lowering of the immune system for haemophiliacs in Edinburgh?

A. Certainly, yes.

Q. You would be saying that?

A. Oh, yes, yes.

Q. And did you record that in their notes?

A. I don't think we did record it in their notes. We got verbal consent, which is what we were asked to get, I think, in the consent that I got from the ethics committee.

Q. In order to do that part of the work, in relation to the skin tests, you did seek ethical approval?

A. In 1984, yes.

Q. In 1984. I think we have some material in relation to ethical approval. I'm not sure that it's 1984. I think it's a bit later, from 1985. There are two items. One is [LOT0014957]. That's the first one and there is one which is [LOT0014973]. That's the second one, I think. I have put them both up rather quickly. Is there another document which reflects the ethical approval in

relation to carrying out skin tests for work that was being carried out between 1983 and 1985.

A. Yes, there is a letter from Dr De Bono, dated about March or April 1984.

Q. So these two documents that we see here don't relate to the skin tests that you are talking about in your evidence at the moment?

A. That's correct.

Q. At the stage of seeking ethical approval for taking the skin tests, what exactly did you seek ethical approval for?

A. For asking patients with haemophilia and about 15 or 20 controls, if we could use this multitest device on their forearm and explain how it worked, to measure their immune system.

Q. And measuring the immune system for what purpose?

A. To try and better define the apparent immune deficiency that we had shown up with the CD4 and CD8 counts.

THE CHAIRMAN: Mr Di Rollo, I wonder if this letter is available because I have to say that it will be a considerable advantage to see the document, if it's readily available to us.

MR GARDINER: I don't think that's in court book, sir.

THE CHAIRMAN: That's not the question I asked, it is whether it's readily available.

Do you have it, Professor Ludlam?
A. I don't think I have it with me.
THE CHAIRMAN: But it exists and you have a copy in your possession.
A. I have a copy of it. I think the Inquiry has the original.
MR GARDINER: I think this whole exercise arose in Dr Ludlam's original statement, or the notes of the meeting that Professor Ludlam gave to the Inquiry, and I think Professor Ludlam was using it as a comparison to the 1983 immune studies. But I don't think that we have that material.
THE CHAIRMAN: I'm not anxious that one should speculate about the content of a document if it actually does exist and could be obtained. It might be an easy answer to your particular question.
MR DI ROLLO: It might be. I haven't seen the document myself, I have to say, and I wasn't entirely sure what the position of the witness was on this particular topic and that was why I was asking the questions.
THE CHAIRMAN: It is unusual for Professor Ludlam to refer to a specific document if he hasn't seen it recently, Mr Di Rollo.
MR DI ROLLO: Indeed.
THE CHAIRMAN: And that's why I asked whether he has. So

I think, Mr Anderson, if you could perhaps take the responsibility for finding the document, then we can introduce is at some stage to clarify matters.

I don't know how far you need to go in pursuit of this. As I understand it so far, the skin tests were a follow-on stage and had not been envisaged as part of the original testing that was being carried out. So we will see whether there is a history in the letter that refers back, which I would be quite interested to see.

MR DI ROLLO: Is the ethical approval that you sought for this skin test from the same place that you go for the ethical approval that I have put up on the screen in relation to the two other forms that we see you have applied for? Is it the same place that you are looking to for the ethical approval?

A. I think it's in the same file, because I have one or more files that have miscellaneous papers in from that period. I think the file is dated 1979 to about 1990.

Q. What I mean is that, in relation to the two other items, you write letters to a Mr Redmond at the Ethics and Medical Research Subcommittee at the Astlee Ainslie. Was that the same place that you sought ethical approval for this work --

A. I think the arrangements changed around about this period, because my letter was, as I mentioned a day or

two ago, to the Royal Infirmary ethics committee and I think what has just disappeared from the screen was an application either to the Lothian or the South Lothian Ethics Medical Research Subcommittee for Medicines and Clinical Oncology, and I think that was a committee that had probably just come into existence.

Q. I think subject to that, I'll move on. What I would like to ask you is about these two applications and to see if there is any distinction to be drawn between what happened before and what happened subsequently. The first document is [LOT0014960]. I think there is a form that accompanies that, which is [LOT0014957]. The letter is dated 24 May 1985 and it refers to a study of immune function and HTLV-III infection in haemophiliacs treated exclusively with NHS factor concentrates. This is enclosing a protocol. The form is [LOT0014957].

THE CHAIRMAN: The first of the two we saw earlier?

MR DI ROLLO: Yes, indeed. Thank you.

Am I right, is this your writing on the form?

A. I'm embarrassed to say it is.

Q. Right.

A. By degree of clarity rather than its content.

Q. Can you just explain what it was you were seeking here?

A. Would you like me to read it?

Q. No, just what is the purpose of this application?

A. The purpose of the application was to consolidate the ethical approval that I had obtained for doing the skin testing and to explain that we were going to follow up patients who we thought had HTLV-III infection and also those who were anti HTLV-III negative. So this was really setting out very briefly that we wished to continue the monitoring arrangements that we had started some time previously.

Much of this --

THE CHAIRMAN: Mr Di Rollo, professor, I think actually it would be of great assistance to have it read into the transcript since otherwise the text will be difficult to retrieve.

MR DI ROLLO: I'm content with that. I think the main body of the text is in response to question 5. I'll read the question and perhaps you could read the answer:

"What is the object of the project?"

A. "There are a group of haemophiliacs at Edinburgh who have been transfused with a batch of NHS Factor VIII, which we believe was contaminated by the AIDS virus. We wish to follow the immune function of these individuals over a period of several years. We also wish to follow up other patients who did not receive this batch of Factor VIII as a control group."

Q. Then the next question is:

"In what way will this benefit either the individual patient or advance medical knowledge?"

A. I have written:

"Provide further insight into the relationship between HTLV-III infection, immune function and the development of AIDS and AIDS-related complex."

Q. Then:

"Briefly describe the design of the project."

A. "Venous blood samples will be collected every six months to assess immune function. Tests of skin reactivity will be undertaken once per year."

Q. How many subjects or patients will be involved."

A. "Up to 100, including 20 healthy control subjects."

Q. Then the next part of the form says:

"Will subjects/patients be ..."

Then you have ticked "Hospital outpatients" and also ticked "Healthy volunteers", is that right?

A. That is correct.

Q. Then it says:

"State how the subjects/patients will be selected."

A. "Patients with haemophilia, healthy controls from hospital staff."

Q. Then you are asked:

"Has professional statistical advice been sought on the size and design of the project?"

Your answer to that is?

A. "No".

Q. "What procedure will be carried out on the subjects?"

Then you have indicated?

A. "1. Venesections up to 30 mls on each occasion.

"2. Skin tests by 'multitest' applicator."

Q. You are asked to list any drugs to be administered and your answer to that is "none", and then you are asked:

"What risks to the subjects/patients can you foresee?"

Your response to that is?

A. "Minor skin irritation at site of skin tests."

Q. Then you are asked:

"What discomfort to the subjects/patients do you foresee?"

You say:

"As above."

Then:

"Will informed consent be obtained from all subjects?"

What is your response to that?

A. "Yes".

Q. Were all of the patients who were looked at here aware that they were HIV positive?

A. A lot of these patients were HIV negative.

Q. Yes, I understand that. That was a bad question. I'm sorry. The question I meant to ask you is: all of those who were HIV positive that you were looking at, were they aware that they were HIV positive?

A. They might not have been.

Q. Those that aren't, how would they give informed consent for this work?

A. Because I was explaining to everyone at the beginning of 1985 that we were wanting to monitor as many people's as possible immune status for their own benefits. What I perhaps should say at an appropriate place but let me say it now.

Q. Do.

A. In the beginning of 1985/the end of 1984, it became clear that we were going to require large changes in hospital practice and in resources within the hospital, particularly in the haemophilia centre, to help manage the situation as we found it. One of my responsibilities was to go out and get resources to help provide the services and the facilities we needed. So I would write to the health board, I would write to the Scottish Office. I thought, "Well, I can possibly get funds from organisations offering research funds", and that's how this came to be written because I wanted money to make sure we could monitor our patients

properly. Because, if you like, the tests I had done in 1983 were a relatively small number in relatively few patients. The situation had now arisen where I needed to -- for the patients' welfare -- to be able to monitor a lot of patients and the only way I could do that was to get extra money into the system and if someone would give me money from a research fund, so much the better.

Q. I understand what you are saying, I think, but I really would quite like to press you on this question: how do you get informed consent from someone in the category of person that I have just suggested to you? How do you get informed consent if they don't know that they are HIV positive?

A. I would say to them that some people have developed or been exposed to HIV. There are some people who we don't think have been exposed to HIV and there appears to be something not quite right about the immune system, and we need to follow that up because if we think back to when I was talking about the non-viral causes of immune aberration, it wasn't at all clear at that time whether or not the immune abnormalities were getting progressively worse. We had a snapshot in time and it was very important to make sure that they weren't deteriorating. And that was important for the HIV antibody negative patients because all we could say was,

"Your blood test is negative". But by following up their CD4 counts, for example, we showed that those were stable and that was very potent evidence that these particular individuals didn't harbour the HIV virus, whereas regrettably, those who were anti HTLV-III positive, their CD4 counts tended to decline. And it in fact turned out that it was the rate of decline of the CD4 count that was important, not the absolute level because there were some patients who, prior to HIV infection, had quite low CD4 counts and for reasons that I didn't and don't understand actually, they stayed free of the symptoms of AIDS for quite a long time, despite having low levels, but constantly low levels, of --

Q. Professor Ludlam --

THE CHAIRMAN: Professor, I don't think you are actually answering the question. I think the point, as I understand it, is this: if you have a patient who has tested positive for HTLV-III antibodies, who is invited to take part in skin tests, say, how can that person be thought to give informed consent if not informed by the clinician of the prior results? Can you give informed consent to a test if you don't know the context in which you are being tested?

A. Erm --

THE CHAIRMAN: Is that --

A. I understand the question and the testing was, if you like, irrespective of the anti HTLV-III status of the subject.

MR DI ROLLO: I know that but I think we have to look into the mind of the person that you are testing. We have to try and look at what he or she -- he in this case -- is consenting to. If that person doesn't have the knowledge that he is positive, then how can he give consent to the test in an informed way, that is being carried out?

A. We considered that some time, last time I was here or the time before, about how patients acquired their knowledge of their anti HTLV-III status, and we, as a team, made the decision to -- at least initially, to do it as I laid out before. And it wasn't just my decision, it was the psychiatrist and social worker and other doctors. So it was up to the patients, knowing that the information was available, to come and ask for it, and we didn't want to use this as a way of applying, if you like, more pressure to patients because the tests, whether or not we did the tests, were independent of the anti HTLV-III status.

Q. Do you see the problem that I have with this, that a patient who doesn't know that he is HIV positive, might take a different view as to whether or not he

wants to participate in work of this nature. It may make no difference or it may mean that they want to participate even more. One doesn't know. But it's obviously their decision and without all the facts, then they can't make a decision in the light of all the facts. Do you follow the problem?

A. Yes, if they had thought it was an important fact that was going to influence them, then they might have asked.

Q. That's really putting the onus on them, though, in that situation.

A. Yes, but on the other hand, in a sense there are lots of other viral infections, for example EB virus, which is a common virus amongst young adults, that may well have affected the results of these tests and we didn't go round and test them for EB virus or ask if they had had glandular fever.

Q. Can I ask you another question arising out of this informed consent issue, which is: did the negative patients, those people who were negative for HTLV-III or HIV as it became, know that they had received the implicated batch? Would they have known that?

A. They would have known that if they had asked, certainly.

Q. Again, they might not have known whether to ask or not. Were they specifically told that?

A. When I had a discussion, if they came up and wanted to

know their result, I would have explained that there had been a batch and a bit about the history and I would have left it a bit open.

Q. So you wouldn't have said to patient X, "You are negative as far as we know. We have carried out tests but you did receive the implicated batch."

A. I don't think I would have done, no, because that would have added extra stress potentially to the patient and the patient might have wanted to believe he was anti HTLV-III negative and happy to leave it at that. It's another stage going on. If he was to ask for that additional information, I would have given it. If he hadn't asked, I wouldn't have offered it because it would have added to his degree of uncertainty.

Q. There is an element, though, of you then choosing what information to give to the patient and what information to retain. Definitely that is going on here, in the sense that obviously, if the patient wants to know, you will answer the questions but if the patient doesn't ask, you will not necessarily tell or share everything that you know about them with them.

A. That's correct, yes.

Q. The next question that's asked on the form is:

"How will consent be recorded?"

And it says:

"Written in the case notes."

Is that right?

A. Can we -- this was a draft form.

Q. Right.

A. Can we look through to the end. I hope I didn't send this in to Lothian Health in this form, but have I signed it? So it's not signed or dated. So this was clearly a draft. Can we go back to the --

Q. Yes, I think I have missed out a question, which is 17, where you are asked:

"What information will be given to subjects/patients?"

And the answer there is?

A. So:

"Patients and controls are very well-informed about our studies."

Q. Right. Then it says:

"How will consent be recorded?"

And it says:

"Written in the case notes."

That's right? That's what it says?

A. That's what it says.

Q. Are you saying that this isn't the form that went for ethical approval?

A. I can't tell you because I don't have it but I'm not

sure that the final version would have had that in it because I didn't want, either for me or for the patients, to write in their notes that they were having these tests that related to AIDS for the reasons of confidentiality about AIDS that I have mentioned from time to time. So I can't tell you whether this went in on the final version. Lothian Health should have a copy of this and that may well be available and we could see.

Q. Can we just take it stage by stage? This form says:

"How will consent be recorded?"

And the answer is:

"Written in case notes."

Are we to take it that it is not correct in fact, that consent was recorded by the consent being written in the case notes. That didn't happen?

A. The consent was not written in the case notes for the reasons that I have just described. What we did do -- and we were very obsessional or perhaps I should say the nurses were very obsessional -- we kept a record of every blood sample that was taken from the patients in the haemophilia centre, what blood samples were taken, what they were taken for and where they were sent for processing. That record was for every patient who came up any day of the week. So we had a record of exactly who had given blood and for what.

Q. It does appear that certain patients appear to have been unaware that this follow up work, as we see, was actually taking place and were unaware that it was going to be published in due course. Do you have any reason to think that's wrong?

A. I think by far and away the majority of patients, come beginning of 1985, will have been very well versed in the fact that we were keen to monitor their immune function and also to -- and we got permission for this, in the anti HTLV-III negative individuals, to repeatedly assess their anti HTLV-III status, and I think --

Q. There were some that were not aware. Is that not fair?

A. I obviously can't say that all were. I would say the vast majority, particularly those who came up for routine clinic reviews, when there was a bit more time to explain to patients what we were doing. If patients came, for example, in the afternoon with an acute bleed and hadn't come to their review appointments, I think we might not have taken some of the blood for some of these investigations because they had to be ferried across the city and processed the same day, and I don't think we could have done that late in the afternoon.

Q. Just dealing with the rest of the form, the question is:

"Will the subjects be informed of the right to withdraw."

The answer is "yes":

"Has the Committee on the Safety of Medicines' approval been given."

That's "not applicable". The next number of questions are negative down to question 23:

"What information will be given to the patient's general practitioner and by whom?"

What do you say there?

A. Sorry, which question?

Q. We are now on the following page. It's question 23.

A. "Probably not unless important clinical results emerge from studies."

Q. Then the next two questions I think we can ignore. You say that there is an application for financial support, is that right. Question 26?

A. Yes.

Q. Down at 28, it says:

"Has a submission been made to any other appropriate ethical committee (including university ethical committee ..."

Et cetera. What's your answer to that?

A. "... skin tests received approval of South Lothian Ethics Committee in 1984."

Q. That's what you referred to earlier. Is that right?

A. Yes.

Q. Then question number 29:

"Are there any other points you wish to make in justification of the proposed study?"

What's your answer to that?

A. "Part of this study was previously submitted and approved to the Ethics of Medical Research Subcommittee, follow-up of anti HTLV-III negative haemophiliacs. Your letter dated 14 March 1985."

Q. Right. So it does appear that some of the patients who were undertaking this, who were being looked at for the purposes of this study, would not have been aware that they were HIV positive at the time that this work was being carried out. That appears to be the case?

A. Yes.

Q. They would be aware, if they were told by you about the work, that there doesn't appear to be any record of their consent in the case notes. Is that right?

A. That's correct, yes.

Q. Is it right to say that there wouldn't then be any written record of their consent at all to this?

A. There would be verbal consent but no written consent, yes.

Q. What they were told, as I say, about this would depend on who it was that spoke to them about it and what exactly they were told about it at the time.

A. I think that's fair but I think I would emphasise that we were explaining to individuals very clearly at the beginning of 1985 because of the open meeting we had had and the circular we had sent round, and all the patients were coming up to ask, we were very clear about what we were doing.

Q. Would they have been specifically told individually that it was the intention to publish in relation to this matter?

A. I don't know that any of us were thinking about publication at that stage. We were keen to -- we had a job in hand to do: looking after the patients. Publications weren't anywhere on the horizon.

Q. That may or may not be so. So the answer to the question is that they wouldn't have been told that it was the intention to publish?

A. If anyone had said, "we are going to publish these results," I would have said, "Well, we need to see what they are and we might well do".

Q. I can understand that but usually patients don't ask those kinds of question, normally, I would think. So they wouldn't be told by you that there was an intention to publish?

A. Only if they had asked.

Q. Right. Can we just take the next item, which is the

28 February letter, which is another application for consent. It's [LOT0014970]. The accompanying form, which is [LOT0014973]. Again, can you just tell us what this relates to and what this is for?

A. Yes, this was a letter I wrote to, as you see, the secretary, I think it's actually Mr Redmond, the secretary of the Ethics of Medicine Research Subcommittee, which was to seek consent to serially assess the anti HTLV-III status of HIV/anti HTLV-III negative haemophiliacs. Because we wanted to demonstrate the safety of the heat treatment process.

I think it's interesting in retrospect that I put this in as a research study. If I had not done this in the patients, I think my colleagues would have thought I had been negligent; in other words, this was an absolutely obligatory assessment to offer patients and it was offered to the patients and it wasn't in any sense a research endeavour except in that it was to hopefully demonstrate -- and it did demonstrate -- that the heat treatment process for Factor VIII concentrate was effective.

Q. The form that we see there, the various questions and answers in relation to that, it's a similar form to the one we saw earlier. Again, I think it appears to be the same handwriting as we saw in [LOT0014973]. The title

of the project is:

"Follow-up of anti HTLV-III negative haemophiliacs."

The object of the project, this is question 5, just tell us what that is?

A. "To follow up haemophiliacs negative for anti HTLV-III (viral cause of AIDS) who are treated with heated SNBTS Factor VIII in which it is anticipated the virus will have been killed."

Q. Again, similar questions to the other form. I won't go through the form in as much detail but what you do say at question 16 over the page:

"Will informed consent be obtained from all subjects?"

And your answer is?

A. "Their cooperation will be sought."

Q. Is there something wrong with not just a simple "yes" there? What's the difference between "yes" and "their cooperation will be sought?"

A. I think what I have written is just a little bit more emphatic, that I'm keen for them to agree. For most "research studies" there should be no pressure on the individual to agree. These were rather unusual circumstances and I was very keen that as many people as possible who were anti HTLV-III negative would agree to us continuing to monitor their anti HTLV-III status

because the more individuals studied, the greater the strength that could be interpreted of the result.

Q. You then say:

"What information would be given to patients?"

It says:

"They will be told that it is part of our AIDS research programme ..."

Then you are asked:

"How will consent be recorded?"

You say:

"I was not planning to record this."

That's what you have recorded there. And is it correct to say that the plan wasn't to record it and it wasn't recorded?

A. That's correct but we were asking all patients at that time who came to give blood -- we were asking specifically for them to give consent to anti HTLV-III testing and if they didn't agree, then we wouldn't have sent the blood for that.

Q. So in relation to recording of consent in clinical notes in relation to the earlier form, the first form I showed you, in the form that was submitted ultimately, the answer to the question was not that it would be written in the case notes?

A. I don't know what the final form said. Lothian Health

might well be able to provide it for you but we didn't record it in the case notes because we didn't want to write about AIDS-related studies.

Q. In relation to the earlier question that I asked you about skin tests, if we have [LOT0014972], the Inquiry team have been carrying out a bit of research and is this a letter which relates to at least the consent to the carrying out of the skin tests?

A. Yes, this was the letter I referred to earlier this morning, written by Dr De Bono in May 1984.

THE CHAIRMAN: Professor Ludlam, in testing the negative patients, by this stage of the application that we have just been looking at, 4973, did these patients know that they were negative?

A. If they had asked -- they almost certainly would have known they were negative; they would have asked, yes.

THE CHAIRMAN: But it would be the same mixed position as with the positives?

A. Yes.

THE CHAIRMAN: Yes.

MR DI ROLLO: If you don't record consent to the work in the case notes, how do the staff know who is taking part and who is not taking part in this?

A. Because they were asked each time they came up and there were occasions when it would have been not at this time

because we weren't taking actually, beyond these anti HTLV-III, regular samples. Later on, if we move on to about 1988, we were doing virological studies and we needed an extra sample for doing those, about an extra tablespoon of blood, again taken at the same time as they were taken -- blood was being taken for the routine tests.

The nurse, if the patient either arrived in the afternoon or was perhaps preoccupied with something else, would not ask them to give the extra sample for the research studies because it was adding a little bit of extra stress to possibly a difficult situation.

So the patients were always asked if additional blood was being taken on each occasion and I had to pay credit to all the patients, virtually all the patients were very willing and very helpful through very difficult clinical situations, as I'm sure you will appreciate, but they were almost to a person very willing to give consent each time and we did ask each time. It's not like some studies, where you sign your consent form at the beginning and then the study sort of rolls out and it requires, if you like, extra effort to withdraw. Patients had the opportunity on each occasion to give consent that blood was taken.

Q. If we look at [LIT0010895], this is the publication of

work in the Lancet, 28 May 1988, by yourself and a number of others. It says:

"Of 32 patients exposed to a single batch of Factor VIII contaminated with ... (HIV), 18 became antibody positive."

Then you describe analyses over the following years. If we look further down in the introduction we see the sentence:

"31 have participated in follow-up studies that have included regular clinical examination, virological investigations, and analysis of circulating TC subsets."

Over the page we see a table which contains patient numbers of the 18, their dates of birth, et cetera. A patient looking at that might conceivably, knowing that they are a severe haemophiliac and knowing that they are one of your patients, one of the Edinburgh patients, and by that stage having been informed of what the position is for them, might well realise that they are one of the people that is being talked about in this article. Is that reasonable?

A. They might or might not. It depends how many patients were born in a particular year. 1963, I have no idea how many patients under my care were born in 1963.

Q. But we are dealing with the 18 that are positive, are we not, seropositive?

A. We are, yes. You are correct.
Q. So if I know I'm seropositive and I know my year of birth, I know this is about me, don't I?
A. Yes.
Q. I mean, if I hadn't given consent for publication, specifically, it might concern me that I'm being looked at and published about without my knowledge.
A. I think in retrospect -- I wasn't the primary author of this paper but I think in retrospect, I think it would have been better if we hadn't published the years for the reason that you have raised and I'm sorry about that. This was on the spectrum of how much you could publish and how identifiable patients could be and that, as we discussed a little while ago, was changing.

In retrospect I think it was unfortunate that the years of birth -- it is not dates of birth, it's years of birth -- went into this table.
Q. The phrase in the earlier introduction was:

"31 have participated ..."

And someone might feel that they hadn't actually participated or volunteered. It is the passive voice, I think, that we see there:

"31 have participate in follow-up studies."

And the extent to which they are fully aware of what is going on might in certain cases at least, depending

on what information they had, vary from patient to patient. Is that reasonable?

A. In a sense they had participated in follow-up studies. That was part of their monitoring for their medical condition.

Q. Can I come now to the testing of patients for HTLV-III antibody and identification of the implicated batch? The question that I want to ask you first and foremost is what the purpose of carrying out the tests was, initially?

A. The samples I sent to Dr Tedder?

Q. Yes.

A. That was to see whether any patients in Edinburgh were anti HTLV-III positive.

Q. Did you think that the answer to that question would be in the negative? Did you think that they would not be positive?

A. I thought they would not be positive. At least those that had received SNBTS material.

Q. Was the purpose for the test being carried out for the benefit of the patients in terms of finding out on an individual patient that he was positive or negative or was there a reason for looking at this from the point of view of looking at the blood supply in Scotland?

A. It was to look at individual patients, so that we knew

who appeared to have been exposed to the virus and those who had not.

Q. So how did you select the individual patient?

A. I think, as I think I mentioned earlier, they were individuals with severe or possibly moderate haemophilia.

Q. As I understand it, there were ten that were sent originally.

A. They would have been ten individuals with severe haemophilia, samples taken from the deep freeze.

Q. You say "would have been". This is obviously quite important. It's a critical point in the history of events, these tests, and what I would like to know is why a particular ten have been chosen. Is there any particular reason for the ten?

A. Only that they had severe haemophilia, were large users, or moderately large users of SNBTS concentrate.

Q. Was it your instruction that these ten samples be sent for testing?

A. Yes.

Q. And what instruction did you give in relation to the ten that were selected?

A. Well, I think that ten samples should be sent from ten people with severe or moderate haemophilia.

Q. So who did you give that instruction to to make the

selection?

A. That would have been given to probably someone in our laboratory, who could look out the samples.

Q. Do you remember what instruction you gave?

A. I can't remember whether I chose the names, if this is what you are getting at, or whether one of the laboratory staff went down the list, the catalogue, and said, "This patient, that patient and the next patient has severe haemophilia, so we will take those samples out".

Q. Why did you do it on a named-patient basis rather than doing it blind, as it were?

A. On an anonymised basis?

Q. Yes.

A. Well, we knew what the transfusion histories were of the samples that we sent. We were very keen to find out this information. It could have been done on anonymised samples. We could have picked out ten and not put any names on them. That process of anonymised testing really wasn't in the vocabulary at that time. It was a -- anonymised testing really came in in this sort of context in the 1990s, partly in response to the HIV situation, informed consent and named samples and all this sort of thing. So it wasn't part of our vocabulary. I had patients that, if they were positive,

I would want to know. So that's why it was done on a named basis and not an anonymised basis.

Q. I mean, you say if they were positive, you would want to know but that rather gives the impression that at least part of you is thinking, "I need to cater for the possibility that they may be positive, I need to consider the consequences of a positive outcome".

A. That is true.

Q. And in looking at that, considering the consequences of a positive outcome, do you not have to have in mind the problem which is there, which is that you are carrying out this test without the patient's consent?

A. I think, when we had got to the stage of AIDS having been around for about three years, 1981 to 1984, and there were so many theories about its possibility, how it was arisen and what markers might be available, and the CD4 cells that we have discussed at length, you know, we are, in a sense of a bit of a false start and confused the issue in some ways. When the anti HTLV-III tests became available there was -- we felt, "Gosh, at last we have got a handle," that therefore it's a handle that would be very useful to us and therefore we are going to need to know individually on patients whether they are negative or positive, and therefore the samples were sent as named individuals or named samples.

Q. But I mean do you see the problem? There is obviously going to be a problem that if you know that they are positive and you haven't obtained their consent for the test, then you face a difficulty of the type that you did face and it doesn't seem that that difficulty has been anticipated.

A. I think it fair to say that we hadn't, or we certainly hadn't anticipated all the consequences of testing and why informed consent became so important. This was at a time when AIDS was -- increasing numbers of people were developing AIDS and we were desperate to have a reliable marker and that's why it was useful to have them on a named basis. I entirely agree that, come 1985 and some of the things that we thought about here over the last little while, the whole picture of testing changed and it became desirable to talk to patients in advance of testing.

Q. You referred there to a reliable marker and therefore a named-patient basis. That tends to suggest that there must have been some anticipation there that a positive result was, if you like, on the cards, a possibility, at least for one or two of the patients, that was something that could as well happen. Is that not right?

A. You mean: did you anticipate the result would be reliable or that it would be positive?

Q. That it would be positive.
A. I thought it possible that one or two of the patients that had received the commercial concentrate over previous years might have been positive but I hadn't anticipated that those who had received SNBTS concentrate could be positive.
Q. But even those that are commercial, the same problem arises over the difficulty about what to tell them once you have the result of a test that you haven't told them you are carrying out.
A. Yes, in a sense that applies to any test, virological or otherwise, and I think that's where the whole ethos and practice of medicine has changed really as a result of what happened in the mid 1980s in relation to HIV.
Q. One option you might have had would have been to have paused. You got some results back, they were positive at that point. You did know that not just commercial but SNBTS product patients were positive, apparently, and you then sent further patients down, again without their knowledge or consent, for that test, and on a named-patient basis. Again, did you not think at that point, "Hang on a moment, I had better stop or at least consult colleagues or whatever to see what I should be doing now?"
A. I can see your proposition and I can see its attraction.

In the autumn of 1984 we were desperate to know the extent of anti HTLV-III positivity, potential infection. It really was a horrendous time. I think it would have been a counsel of perfection, potentially to have done it as you suggest, to have sent off some. The difficulty would have been if I had sent ten and they had come back negative, I might not know actually who the individuals were and I might perhaps say, "Those weren't the best people to have sent". I might have had to send many more anonymised samples to satisfy myself that there wasn't a problem.

Q. No doubt you have other things to think about apart from just individual patients. That's perfectly understandable. And so do other clinicians, but from an individual patient's point of view -- remember we are still in the reassurance phase here. We haven't got to the meeting yet. Once you get to the meeting we get the disappointment and then the realisation afterwards that testing has been taking place without consent potentially and this is going to add to a patient's disappointment and concern, is it not, what subsequently emerges? Is that not true?

A. I'm sorry, I have lost the thread.

Q. I'm just suggesting that perhaps the fact that patients have not been told about the fact that a test has been

performed and they subsequently discover a test has been performed without their consent, that's going to add to their disappointment, potentially?

A. I would agree with you. What I would say is I don't recall any patient saying to me, "I wish you hadn't tested me."

I think later on there were expressions of anger about testing and I think that was very understandable, the projection of the anger to me and to blood transfusion and to other areas, but I don't recall anyone saying to me, when we came to discuss their results, that they wished I hadn't tested them.

Q. When samples were taken from patients' blood samples, were any taken specifically with the intention of carrying out a test?

A. Yes. There were the monitoring tests that I have talked about and those --

Q. The test for HIV, I mean.

A. I'm sorry.

Q. Yes.

A. Could you repeat your question?

Q. Sorry, it's my fault.

The question was: when you were taking samples of blood from patients, were any specifically taken for the purposes of carrying out the HTLV-III test by Dr Tedder?

A. Subsequent to January 1985, yes, consent was obtained.
Q. No, I'm talking about before that.
THE CHAIRMAN: Mr Di Rollo, I think that there is legitimate scope for misunderstanding because you have not specified the period.
MR DI ROLLO: I understand that. The specific period I'm interested in, Dr Ludlam, is the tests that were carried out by Dr Tedder, the results of which you obtained on October 26th 1984 relating to the ten and then subsequent testing that was carried out up until the end of 1984. Were any blood samples taken from patients specifically for the purposes of a test?
A. I don't think so, no. I think they were all samples that were taken from the deep freeze.
Q. You talked about it being the counsel of perfection to pause and seek advice at that particular time but we have heard evidence that it is possible one other physician in Scotland did do that, that there was a situation, as I understand it, that has been spoken about in evidence, in Glasgow, where testing was anonymised and then there was a pause before anything further was done. You heard the evidence, I think, of Dr Wilkie about that. You say that's the counsel of perfection but it doesn't seem to be beyond the scope of something that could have been done.

A. I agree. It could have been done. Testing just two is a very small number but my understanding of what was done at very many other haemophilia centres throughout the UK was along the lines of what I did, although probably larger numbers of samples would have been sent initially.

Q. If we look at the memo from Dr McClelland, which is [SNB0065996] --

THE CHAIRMAN: Mr Di Rollo, I have an interest in what led up to the selection of ten. Are you going to deal with that or is this a point at which I could interrupt you?

MR DI ROLLO: I'm content for you to ask your questions about that at this stage.

THE CHAIRMAN: Professor Ludlam, I have an interest which you have just, I may say, reignited, in the procedures over the time prior to submitting your samples to Dr Tedder. In the first place, where did the number ten come from? Was there a quota agreed between you and Dr Tedder?

A. I knew Dr Tedder -- when I contacted him initially, he was inundated with requests and I think it was a bit of bartering: how many would he do, and he said, "I'll do ten".

THE CHAIRMAN: That's fine. I don't think I need to go beyond that but what I am interested in is the context

in which you had to barter, as it were, and you have mentioned the fact that other centres throughout the country were doing the same.

Was that something that had been discussed by the haemophilia directors? Was there a sort of general agreement to test before you began individually to make contact with Dr Tedder?

A. No, I think it grew on an individual basis, if I can put it that way, by the larger haemophilia centres, who were very actively concerned about the whole situation. Certainly one or two of the big ones in London had been in touch with Dr Tedder. But there wasn't, if I can put it this way, universal testing of people with haemophilia in late 1984. There was the letter sent out after the meeting of 10 December, a letter by Professor Bloom, dated about 14 or 18 December, in which he recommends that patients are treated and they are sent to not only Dr Tedder but -- I'm sorry, I have forgotten his name.

THE CHAIRMAN: Mortimer?

A. Yes, Philip at NIBSC.

THE CHAIRMAN: So really getting right down to the basics, as it were, did it depend on whether the particular haemophilia director knew that Dr Tedder had managed to get a test available?

A. Yes.
THE CHAIRMAN: So the bigger centres would have been in contact and they would be looking for a slot, as it were, in the limited programme that he could carry out?
A. That's correct, yes.
THE CHAIRMAN: So your number is set at ten and then one comes to the questions that Mr Di Rollo was asking you about how you filled your quota.
A. Yes.
THE CHAIRMAN: That was when you personally had to lay down some criteria for selection?
A. Yes.
THE CHAIRMAN: Mr Di Rollo, I think that's enough for me to understand the background but clearly you may wish to follow some aspects.
MR DI ROLLO: Thank you.
When you got the first ten back, how did you choose the next lot to test?
A. I think those would be the individuals who were the largest users, probably, of clotting factors. It, as I think I indicated earlier with just the three results, the batch 0090 was one of the possible batches that might have caused the infection and I might have chosen -- I can't remember -- more patients who received that batch to see what the situation was.

Q. If we look at [SNB0065996], which is Dr McClelland's memorandum, this is a memo to Dr Perry and copied to Dr Cash. He says:

"Dear Bob, events leading up to the recall of Factor VIII batch."

Then a number is given:

"I feel it might be helpful to record the events which preceded the decision to recall this batch."

He obviously feels it necessary to record something on paper about the events which clearly are of considerable importance at about this time. Is that right?

A. Yes.

Q. One thing, it's not clear to me, Professor Ludlam, is what records existed of the work that you were carrying out in relation to the testing; in other words, the test results and the identity of the patients that were tested, the results that came back, and your work in analysing those results.

Presumably records of that kind did exist at one time?

A. Indeed, yes.

Q. Do they still exist?

A. If they do, I don't know where they are. I think they probably don't exist.

Q. Are you able to help us as to what has become of them? Do you know anything about that? Can you help us with that?

A. When we moved from the Royal Infirmary in Lauriston Place to Little France, we were instructed to dispose of as much paper as we possibly could because there was only a little amount of storage space at Little France. I tried to preserve as much of my records as I could. It may be in that process they were disposed of. I have a feeling that the spreadsheet that I referred to earlier might have gone to Dr McClelland because we had sort of drawn it up together and I think he took it away to think about. But I'm sorry, I don't know where that is now.

Q. The paper trail, as it were, for the inductive reasoning process that we heard about earlier, no longer exists. You say there was a paper trail of some sort presumably but it doesn't exist any more. That's right?

A. I'm sorry, I don't think it does.

Q. In the memorandum on the first paragraph there is a reference to you telephoning Dr McClelland and it refers to you stressing a desire to have confirmatory tests carried out. At this stage, are we just dealing with the first ten or are we beyond the first ten?

A. No, this is the first ten.

Q. Right. The confirmatory tests are a reference to what?
A. Well, there were six of the ten who were anti HTLV-III positive. The test was under development at that time and I knew from talking to Professor Tedder that there was a degree of uncertainty about positivity, about the interpretation. The test was being refined and therefore I was not keen to put too much reliance on just single results. There is always possibility, as I mentioned earlier, of samples getting mislabelled somewhere along the line as well. So it's such an important test that I would want it doing at least in duplicate.
Q. So who is going to be carrying out the confirmatory tests?
A. I would suspect that -- I can't remember in detail but it's possible that some of the second batch that was sent may have been from the same individuals, but certainly when Dr Peutherer set up the tests in Edinburgh in the virology department in early 1985, samples would have been sent to him for confirmatory testing.
Q. The desire to self-confirm confirmatory tests carried out and to give the results of these as soon as possible, tends to suggest a bit more urgency than even early the following year. Is that not a reference to

something a bit sooner than that?

A. There was only one place in the UK where you could get tests and that was Dr Tedder's laboratory and he was developing his test, refining it, as he went along.

Q. So what is meant here by "confirmatory tests" here then?

A. If you like, repeat tests, probably with Dr Tedder because that was all there was.

Q. Were repeat tests done?

A. I think they must have been done, yes, on this small number.

Q. On the original ten or of the six?

A. It ought to have been on the ten. I might have asked Dr Tedder to put through the samples given. Maybe he did put them through again when his test was more robust.

Q. I think you were asked in your earlier evidence that if this information came to you on 26 October 1984, it was quite quick for you to attribute the seroconversions to PFC products at that stage. In other words, it rather looks as though it might have needed a bit more time than 26 October to actually consider the material that you had and carry out this inductive reasoning process?

A. No, I don't think it did. If there were six and three of them were patients who had received commercial Factor VIII, I knew exactly who those were and this was

one of the advantages of having the names of the patients.

Q. If you knew who they were, you would just simply say "none of those have had commercial product, therefore it must have been SNBTS"?

A. No, there were six that were positive and from consideration of this -- one of these earlier sessions, I agreed that three of those were probably from recipients who at some stage or other had received commercial Factor VIII. Because there were only a small number, I knew who those were in my memory.

THE CHAIRMAN: Professor, you have made it clear that you set the criteria for selection. I would have understood that you could move very quickly indeed if you had all the information from the point at which the samples were sent to Dr Tedder. Did you have that information in advance.

A. Sorry, which particular --

THE CHAIRMAN: The information about the patients whose samples were sent. Did you know what their treatment history was when you sent the material to Dr Tedder or was that worked out at a later stage?

A. I think it likely that I would have selected several patients who had received commercial concentrate and a number who had received only SNBTS.

THE CHAIRMAN: I would have thought that likely too, which is why I was asking.

A. I'm sure that's what I did.

MR DI ROLLO: I wonder whether what you had seen -- you had been watching these patients for some time -- their immune function -- and I'm just wondering whether that observation of the immune function informed your selection of the samples to take or influenced the decision to test the original ten.

A. I don't think so. At that stage in fact the CD4 counts and CD8 counts on those who were anti HTLV-III positive were actually the same as those who were anti HTLV-III negative; they hadn't started to decline. I'm pretty certain that the selection was made on the basis of a concentrate history and not on immune tests.

Q. And not on clinical signs either then?

A. There weren't any clinical signs.

Q. If we look at [WIT0011491], just scroll up a little bit. We have March 14. We have date collected there. I think that's from -- can you look at that and tell me what date that appears to relate to?

A. 14 March 1983.

Q. Yes. This has "AIDS study" on it, and if we look at the next page, that's June 1984, can you interpret for me what it says in the box there?

A. "AIDS study 200 cell diff. Please keep ..."

I'm sorry --

Q. What is the significance of the "please keep"?

A. It says something about:

"... of report to Dr Craig, please."

That's scribbled out.

THE CHAIRMAN: I think it's:

"Copy of report to Dr Craig, please."

That has been scored out.

A. Yes.

MR DI ROLLO: Then if we go to the final page, this is November 1984:

"Haemophilia AIDS study. 200 cell diff. Please ..."

Is that:

"Please + keep S plus card"?

Then it has:

"High risk sample."

A. Yes.

Q. Could you just explain what those words refer to there? Can you explain what's meant by what's in there?

A. I think -- oh, yes, I can help you. "Haemophilia AIDS study", self-explanatory. "200 cell diff, please. Keep S plus card." The request forms consist of two parts. The top part, which is a thin piece of paper, which is

what you have an image of here, the back card -- the back sheet is actually a thin piece of card and the card was the top sheet on it. It's fixed to it and the top sheet has non-carbon copying facility. So when you write on the top sheet, it comes through onto the card below.

The top sheet -- sorry, the whole card with the top sheet on it, goes into our Coulter counter, which is called a "Coulter S Plus". And so the S Plus card, I think, is the back card, the laboratory card, if I can put it that way, the record of this particular blood count, and that would be put aside, waiting for the CD4 and CD8 counts to come back from Dr Steel at the Western General Hospital. And then they would be multiplied by the lymphocyte counts a bit further down this form.

It then says:

"High risk sample."

And that was because we decided that all individuals with haemophilia who had been treated with blood products should be considered as "presenting a risk of infection" or high risk, when it came to processing them in the laboratory. This was a term that was used for samples that were, for example, Hepatitis B positive, and it meant that the sample was handled rather more carefully, under stringent conditions within the

laboratory.

We labelled -- or designated or decided that all individuals with haemophilia, irrespective of their anti HTLV-III status, should be so categorised.

Q. When was that decision taken?

A. That decision was taken probably some time in November 1984.

Q. Who took that decision?

A. That was in discussion with the staff in the centre.

Q. You say it was in discussion with the staff in the centre. Who was involved in relation to that? Obviously you are --

A. I am.

Q. You say we --

A. The other doctors, we may well have consulted Dr Peutherer, the virologist, but this was a very important way of making sure that patients weren't identified and stigmatised who were anti HTLV-III positive, or for that matter, Hepatitis B positive, although that was a very much smaller and lesser problem.

Q. You see, maybe someone looking at a high risk sample might interpret that as meaning that the person had a positive test?

A. Absolutely not.

Q. You say "absolutely not" because you know what you intend by it, but somebody else looking at it might not appreciate that?
A. These forms were prepared, written by members of the haemophilia centre staff, there had been a lot of discussion in our laboratories -- our laboratories are well used to handling samples that presented increased risk of infection, and it was well understood by our laboratory that all these samples would be handled the same, irrespective of their anti-HTLV-III status. This was a way of very specifically not wanting to stigmatise --
Q. All the nursing staff would understand that?
A. Yes.
Q. And this is obviously an early stage because we are dealing with -- this is 21 December 1984 and it's only a matter of three or so weeks since a positive result has been obtained. So is the discussion that you had just within your hospital or was it taken to a higher level in terms of other haemophilia doctors or throughout the country or beyond? Was it just something in-house as far as you were concerned, the discussion just referred to?
A. It was initially in-house.
Q. So in relation to this passage of evidence, your

position, I think, clearly, before and now, is that you were not testing on the basis of any clinical observations, and I think you have indicated also on the basis of any -- in advance in relation to any theories that you might have in relation to the earlier results that had been obtained in relation to patients; you didn't select patients because they looked as though they might be more likely to be infected than others?

A. I think I heard what you said. It's being a bit noisy with the traffic.

Q. I'm sorry.

A. But I think I can agree with you, yes.

THE CHAIRMAN: Mr Di Rollo, if you are changing tack at all, I think one minute to one it is perhaps a suitable time to rise.

(1.00 pm)

(The short adjournment)

(2.00 pm)

MR DI ROLLO: I'm moving on to the meeting in December 1984. Just before I do, the state of play at that stage, up until that point, was that as far as the patients were concerned, what they knew could be seen from the article that I pointed out earlier, and the meeting that took place in December 1984 was obviously to indicate the result of the tests that had been carried out by

Dr Tedder at the end of October. Is that right?

A. Yes.

Q. It does appear that if ten samples were sent at random to Dr Tedder for testing, if six out of ten proved positive and were positive, then obviously that's quite a high strike rate. Obviously other tests later on on other samples, the proportion of positive to negative goes down, but the initial batch appears to be 60 per cent positive. Is that right?

A. That is correct, yes.

Q. That must have been quite alarming then, presumably, to you.

A. I suspect, thinking about it, that probably they were -- well, we know they were selected from individuals who were large users of Factor VIII, either with severe or moderate haemophilia, and it may be that I included three who had received commercial and the remainder who had received NHS -- I'm sorry, I can't be more specific than that.

Q. If that's correct, then, Professor Ludlam, it wouldn't have been totally at random then, the ten, there would be some thinking going into this. I know it's a long time ago and there is no written material for you to look back on and remind yourself how all this was done, but if that last answer that you have just given me is

correct, then it does looks as though there might well have been some thought going into who to select for testing.

A. There was clearly a degree of selection for severe and moderate haemophilia and probably large users of concentrate, and it may well have been that I selected three people that I knew had received commercial concentrate and the remainder would probably -- would have been ones who had received SNBTS only, if I had selected three who got commercial concentrate.

Q. Again, the purpose of this exercise, is it for those individual patients to find out if they are positive or is it for some other, no doubt good, motive, to find out more about what's going on or both?

A. I think both.

Q. Obviously there is activity in November, and I won't go to the material because we have seen it already, we have seen various meetings and discussions take place and the Scottish Home and Health Department are aware of the position to some extent at least, that there is a positive test and then we become aware that there is a journalist from the Yorkshire Post who is aware of this also, the matter having been discussed at a meeting, and a meeting has to be arranged in order to advise patients of the position in advance of the story

coming out in the press. Is that right?

A. Yes. Could I say, I'm having a bit of difficulty hearing you and I can't see you because one of the computer screens is in the way.

Q. I'm sorry, Professor Ludlam, I'll bring the microphone closer to me. I have got quite a lot of equipment and papers here. Is that better?

A. Yes, I can see you better.

Q. Do you want me to repeat the question?

A. You were enquiring about leading up to the meeting, yes.

Q. As I understood your evidence earlier to the Inquiry, you have told us that the meeting in December with the patients was arranged because the press had the story about the positive tests and it was important to let the patients know first, before reading it in the papers.

A. Yes.

Q. And you indicated that this wasn't an ideal way of communicating this information and it's not the way you would have chosen to have done it if you had had a choice. That's right, isn't it?

A. Yes.

Q. We know that you first became aware of the information at the latest at the end of October 1984 and obviously there would be discussions taking place of the information. It wasn't until some weeks

later, December 1984, that the patients were advised in the way in which you have given us evidence about.

What I want to ask you first of all is, if you had had the choice, how would you have informed patients?

A. I would have discussed it particularly with our nurses and social worker and our psychiatrist to see what their views were as to the best way to approach this. I think it would have been probably to let people know about the topic in general, perhaps write to them and say that it was a developing area, that there were test results available on some patients and if people would like to know more, to contact -- this is where I would need to discuss with my colleagues whether it should be me or whether it should have been the social worker or another member of the team, and take it from there.

Q. And when would you have done this?

A. I think I would have done this after -- the plans would probably have been laid before Christmas 1984 to roll out in January the following year.

Q. Had any steps been taken up until 19 December to roll out the plans, as it were?

A. Well, I think there was -- the meeting on 10 December and then, as I say --

Q. Sorry, what meeting was that?

A. That was the meeting down in London of blood transfusion

haemophilia directors, to consider how to proceed in the UK now that there was testing available and what to say to patients and whether or not -- this was perhaps the most important aspect of the meeting. Whether or not to recommend heat treatment.

So I had only just got back from that meeting before the Yorkshire Post was in touch with me and so that became the focus of my activities and trying to consider the best way to deal with that situation and let as many patients know as possible without them reading it in the press.

Q. Nothing had happened in terms of sorting this out. Clearly there was a need to do something as soon as you got results of the kind of results you did get. It was obvious that something was going to have to happen about informing patients in some way.

A. Yes.

Q. And until 10 December, nothing had been done. Is that right?

A. I think that's correct locally. As you may recall, our previous social worker had just left, our new one actually hadn't taken up her appointment, although she came along to that meeting on 19 December and I had had some discussions with her. She was still doing her previous job. So she was in the stage of transitioning

between these two jobs.

Q. We don't have the letter inviting patients to the meeting. So we don't know exactly what that says and it's obvious that not everywhere came to the meeting of your patients. There may or may not have been patients from other parts of Scotland. I don't want to waste any time on that but it's obvious that not necessarily all of your patients were there and presumably you wouldn't be necessarily specifically conscious of whether all your infected patients had turned up or not. Were you taking a list of that or not?

A. No, I saw that there were some individuals in the audience who I knew to be positive.

Q. But you would be aware of all the positive patients. You knew all these patients individually and personally. Is that right?

A. The ones from Edinburgh, yes.

Q. You told us that the meeting had had to be arranged in a bit of a hurry. Is that fair?

A. Yes.

Q. There was no written material handed to patients at the meeting. It was just purely an oral presentation. Is that right?

A. That's correct.

Q. I don't get the impression from your evidence that

a great deal of preparation on your part went into deciding what you were going to say and how you were going to say it. I may be wrong about that but that's the impression that I have obtained from your evidence earlier.

A. I don't think much preparation was needed. I was explaining the recent history and that was well in my mind and I didn't need, in a sense, to prepare it. There weren't, if you like, slides, overhead projections or anything. It was purely without these visual aids.

Q. You didn't have any notes in any event of the meeting?

A. No.

Q. There is an article in the newspaper I want to look at, the Yorkshire Post article, because I think that's the only contemporaneous, or roughly contemporaneous written account of the meeting. It's [SGH0026491]. The journalist had been in touch with you before the meeting. You had had a discussion --

A. Yes.

Q. Did you have a discussion with the journalist after the meeting as well?

A. I don't recall doing so.

Q. The by-line, if we see on the article, does appear to be from the medical correspondent. So it does seem to be someone who has some sort of interest at least in

medical matters. If we look at the article itself, it's apparent that that person has spoken to not just yourself but to other haemophilia doctors. I think Dr Peter Jones is mentioned for example. We see that if we look at the article, it does say:

"Dr Christopher Ludlam, a consultant haematologist and director of the haemophilia centre at Edinburgh Royal Infirmary, admitted yesterday that antibodies to the suspect AIDS virus had been found recently in 16 of his patients who were receiving only the NHS material. He told the Yorkshire post: 'We picked up the HTLV-III antibodies as part of a research project. We had hoped that this would not be there. What this means is that these patients have been exposed to the virus'."

It's a long time ago but could you have said to the journalist that it was as part of the research project?

A. I think these quotation marks, I'm not sure are actual words from me. He came to me with all this information. He had learned it before he picked up the phone to me.

Q. Right. You are being quoted directly there, apparently. The phrase "research project" is used. Is that inaccurate?

A. I think it is, yes.

Q. What would you describe it as?

A. I would describe it as I have done before, as monitoring

the patients.

Q. I'm not sure if any of the patients did read that at the time but possibly not given it's the Yorkshire Post, but a patient reading that would see that as a "research project", obviously, and not as "monitoring". That's the way it is being presented, at least in the newspaper. Is that right?

A. That's what it says.

Q. The report carries on:

"We know it was not from an American blood product because all these patients have been treated only with Scottish Factor VIII. They may or may not still have the virus. It is something we cannot tell."

Is that part accurate?

A. You mean did I say that? Or is that an accurate statement?

Q. I think, "Is that an accurate statement?" was the question I intended to ask.

THE CHAIRMAN: Is that correct, Mr Di Rollo, that's what you want, the professor to express a view on whether the content of that statement is accurate, or do you want to know whether it is properly attributable to him or not?

MR DI ROLLO: I do want to know if it is properly attributable to him.

A. I'm sorry, at this stage I can't tell you.

Q. What I am interested in knowing is how much contained in the article you would say is inaccurate. You have obviously pointed out "as part of a research project", but is there anything else that's inaccurate in terms of what's said in the newspaper?

A. Well -- and I'm sorry, I can't see the whole article but it says in the paragraph that you have just read:

"We know it was not from an American blood product because all these patients have been treated only with Scottish Factor VIII."

I'm not sure what it says further up in the article but clearly there were patients who had received commercial Factor VIII who were positive. So in a sense, if it refers to "all patients", it is not quite correct.

Q. "Found recently in 16 of his patients."

I think the 16 that's referred to there are all those patients that had only been treated with Scottish Factor VIII. Isn't that right?

A. I'm sorry, you have lost me. In which part --

Q. Just go through the article to the part that's attributed to you. I think it starts with:

"Dr Christopher Ludlam ..."

Et cetera, and then carries on:

"'We picked up the HTLV-III antibodies as part of a

research project. We had hoped that they would not be there. What this means is that these patients have been exposed to the virus. We know it's not from an American blood product because all these patients have been treated only with Scottish Factor VIII. They may or may not still have the virus. It is something we cannot tell. This amounts to evidence that the material in Scotland has been contaminated with HTLV-III and this must have come from a donor or donors who have the virus. I can categorically say that to date there have been no cases of AIDS in Scotland attributable to Scottish Factor VIII and my patients are all clinically well at the moment. On present evidence it would appear that although AIDS may be caused by HTLV-III, only a small percentage of people who become infected actually develop the disease. We do not know why. Partly, as a result of this discovery, all Factor VIII in Scotland is being heat-treated to kill the virus. This does not mean that people who will unknowingly carry the AIDS virus will stop giving blood. Whole blood cannot be heat-treated to make it safe because it just congeals'."

If you can scroll down just a little for me:

"News of the positive testing was broken to haemophiliacs from Edinburgh and Glasgow at a meeting

last night. They were told collectively that ..."

If you go to:

"Some of them were carrying AIDS antibodies. Dr Ludlam said: 'If individual patients want to know where they stand, I shall tell them.' Patients were strongly advised that from now on they should wear contraceptive sheaths during intercourse to protect their partners from danger. They were also urged to take every precaution when making up their Factor VIII for home injections and disposing of needles, syringes and plastic gloves. Stringent safety precautions are already in force to protect medical and laboratory staff when are handling the blood at Edinburgh Infirmary."

I think that's the Edinburgh section of the article. Which parts of that article are inaccurate, as far as you are concerned?

A. I think the gist of it is accurate. I was merely querying the bit about SNBTS or commercial Factor VIII being amongst the positive individuals. It is not quite clear.

Q. If you are referring to 16 patients, the 16 patients are the ones that you know are not commercial. Those are the 16 that form part of what later became known as the "Edinburgh cohort". Is that not right?

A. I'm not trying to be evasive or difficult but one or two

of the patients who got infected in the cohort in the spring of 1984 actually also received commercial concentrate previously but didn't seroconvert to it. So they were commercial users but they were also infected from the cohort. That's why I'm just being a little bit cautious about interpreting this. It's a small point but I just -- they are slightly overlapping groups, if I can put it that way.

Q. What I'm suggesting to you is quite a lot of detail in that piece, and a lot of it obviously comes from you, and the information may not be complete as to the picture but it seems to have the gist of what the information is there, doesn't it?

A. I think the first part of the quotation is information that was given to the reporter from whatever source it was, from the meeting on 10 December.

Q. Did you read the article at the time?

A. I'm sure I did, yes.

Q. Did you take up any inaccuracies with the Yorkshire Post?

A. No.

Q. So the meeting took place and we know that some of those that attended the meeting appear, from information that we have, to have got the impression or hadn't understood if your intention was to communicate to them that in

order to find out the results of their tests, they would have to ask. It appears that they haven't fully understood that was what you were communicating to them. Do you accept that that may well have happened at the meeting?

A. I accept that they might not have wanted to know whether they were positive or not. They might not have understood that they needed to come and enquire, although it seems that quite a lot of people did get that message because a lot of people came along subsequently to enquire.

Q. So the answer to my question is that you do accept that some of them may not have understood that they did have to come forward?

A. I would accept that and -- but the vast majority did.

Q. Obviously, there might be some patients that aren't there and you weren't taking a specific register or note of that. Is that right?

A. That's correct, yes.

Q. So the message about finding out, if that was in fact given at the meeting, wouldn't come to those that aren't there, clearly?

A. Well, they were sent a circular, with an accompanying letter, that we discussed some time ago. They would have come up to the haemophilia centre in the course of

needing treatment or collecting supplies of home treatment and the nurses might have asked them if they wanted to see me.

There were other clues that things were changing. We were inviting them all to bring back their non-heat-treated Factor VIII and issuing them with heat-treated Factor VIII. There would certainly have been some discussion as to why that was happening. We were providing all patients with condoms, with their home treatment, and those that weren't on home treatment could pick them up anonymously from brown paper bags based in the haemophilia centre waiting room.

So there were a lot of things that were changing at that time and people were encouraged to come and ask and talk to us about the situation.

Q. Did you approach individual patients and say, "Do you want to find out the results of your tests?"

A. Not a great deal, but usually patients actually approached me because it was so generally known what the situation was.

Q. One option would have been to write to patients on an individual basis and have them in and discuss with them specifically the question of whether or not they wanted to approach the matter by having a confirmatory test done or have the matter discussed to find out whether or

not they would want to know the result of a test and do it that way?

A. I think we might -- if we hadn't had the Yorkshire Post -- if I can put it -- led meeting, I think that's probably what we would have done and we would have probably invited them to come and see Geraldine Brown, our social worker, for an initial think about the issues before coming to see me to get the result, if they wanted the result.

Q. Notwithstanding having the meeting, you could still have done that anyway?

A. We could have done that but actually the word went round extremely quickly actually what the situation was and it really wasn't necessary. There is all the things that I have described a moment ago about how patients would find out. Patients have a very tight network, particularly in those days when a lot of patients had been used to coming up to have treatment and got to know each other. I'm sure you will be aware that haemophilia runs in families and some families have several individuals with haemophilia, and I think it is rather likely that they discussed it amongst themselves as well. So the information went round very quickly.

Q. Well, we are aware, I think, of certain patients who appear not to have appreciated that they required to

ask, as it were, for the results. Some patients may well have considered that they were not positive, given that they might have assumed that the positive patients would have been told on an individual basis.

A. It would have been in a sense the easy option, to have written round to people. We thought this was a rather better way, actually, to do it, because there were people who didn't want to know for a whole variety of reasons and want to think about it for quite a while, and so I think one has to respect that point of view.

Q. Do you still think it was the better way?

A. I think actually it is very difficult to go back now because of all that has happened. It started off as a relatively straightforward viral infection and within the space of six months, between about December 1984 and the middle of 1985, all sorts of other implications and difficulties and the need for counselling and pre-test counselling became evident.

Q. So what's the answer to my question? I think the question was: do you still think it's a better way, the way you chose?

A. It would be much simpler -- and we could easily have done that if we thought it was the right way to do it -- to just send everyone a letter and ask them to come up. That was easy. We were trying to approach it in

a rather more oblique way and give people some responsibility and some freedom not to be pressurised to learn their results.

Q. The trouble is as time goes on, there is more pressure to tell them because obviously treatment becomes available, the possibility of suffering symptoms becomes apparent, the need to see them is obvious, and as time goes by, that kind of freedom that you are talking about evaporates, doesn't it?

A. Well, no, I don't think it does for the majority because the majority of people came along during 1985 in their own time and we talked to them and gave them the information as appropriate, and it was -- we were only left with a small number of people by 1986 who hadn't come along and as you say, the situation as we were agreeing a little while ago, was changing in the form of the options for prophylaxis and therapy and it was important that when it became appropriate, particularly, these were of potential help to individuals, that they should then know their status.

Q. If we look at [WIT0010438], please. This is a patient that you are writing after the death of, I think, and you indicate in a letter that:

"So far as I can ascertain [the patient] did not have any treatment in the years 1985, 1986, 1987, and

therefore there would not be any transfusion records available.

"I have looked back at his records and find that he was negative for the HIV antibody test on 31 January 1984 and was found to be positive on 29 May 1984. During this five month period he was treated exclusively with Scottish National Blood Transfusion Factor VIII ... It seems highly likely that he became infected from this concentrate."

I think we can tell from that that this particular individual patient was one of the 16. Is that reasonable?

A. One of the 18?

Q. One of the 18, yes.

A. Yes.

Q. And somebody who you would be familiar with? You would know that individual's position well because you had studied that individual, you have looked at the blood transfusion records, the date of seroconversion and you have carried out specific research in relation to that particular person. Is that right?

A. He had been studied like the others.

Q. Indeed. And apparently, from this letter, he didn't have any treatment in the years 1985, 1986, 1987?

A. Yes, I don't know if you are going to go on and show --

if it's appropriate for me to offer you further information about this individual.

Q. I'm slightly sensitive about this because I don't want to get too bogged down on individual cases and also don't want to do anything that's going to prejudice confidentiality or anything of that kind. I'm just trying to look at or scrutinise your position, which is that it's all right to leave the matter in the air, as it were, with the patient. How does the patient know that they are positive during this three-year period, or make an informed decision as to whether or not they need to know or not know about this during this period of time? Where is the interaction between doctor and patient?

A. Well, the situation is that in the third paragraph it says:

"As far as I can ascertain ..."

He didn't have treatment. He did in fact have treatment. My search of the manual records had been sub-optimal and I had overlooked that -- because he had had treatment, I think, in those three years.

Q. The impression one might get reading the letter is that this person is not terribly familiar to you and it's necessary to carry out an investigation to provide the information contained in paragraph 4. Would you not

have been aware from a very early stage that that information was in fact correct? Do you see the point I'm making? That looking at the letter one might think that it's some sort of exercise that's necessary for you to look back at his records in order to find out this information, but in fact this particular patient would be very familiar to you because he is one of the 18, as it were. Do you see the point?

A. I'm sorry, you have lost me.

Q. Right, all right.

THE CHAIRMAN: I think the letter is dated 3 June 2003.

A. Yes.

THE CHAIRMAN: And I think that Mr Di Rollo's suggestion is that you knew this patient so well that there shouldn't have been any doubt in writing that letter about his medical history.

A. Well, this was ten years after -- nine years after the episode of infection in the spring of 1984 and I think --

THE CHAIRMAN: I think the arithmetic is not quite right. 20.

A. 20. Sorry, 20 years.

THE CHAIRMAN: I don't want to know the identity but do you know the sort of person you are writing to here because it is completely blank as far as I'm concerned. It

could be a journalist from the Yorkshire Post.

A. I know who the letter is written to.

MR DI ROLLO: Was that question directed to me or to the witness?

THE CHAIRMAN: I think if you know it, you might be able to help me without embarrassing the witness.

MR DI ROLLO: I think it's to a firm of solicitors.

MS DUNLOP: No, it's to a widow.

UNKNOWN SPEAKER: I think that's correct.

THE CHAIRMAN: It might be quite important to know, Mr Di Rollo, because that may affect the way in which one answers a letter or writes a letter.

MR DI ROLLO: Looking at the file, I do beg your pardon, my learned friend is correct. It is in fact to the relative rather than to the solicitors. There is other correspondence close to this one, which is solicitors, but this particular letter is to the relative in fact.

I think the chairman has indicated the point I was trying to make was that: don't you think it might have been more to the fore front of your mind as to who this particular person was and what the history was, given the familiarity you had with these 18 cases?

A. I knew entirely who the individual was. I couldn't remember the dates in my head and I certainly couldn't remember, without trying to look through our records,

exactly what his transfusion history would be. So I would need to do that.

Q. So are we to take it that the assertion that there wasn't any treatment in the years 1985, 1986 and 1987 is not accurate, that in fact there was --

A. There was treatment. I can explain how I overlooked his records but I would rather not do so for confidentiality reasons.

Q. I'm content with that.

Another point that I wanted to ask you about was information that comes from your colleague, Geraldine Brown, and her statement, which is page 2 of [PEN0120401]. This is in her statement and it's paragraph 3 of that page. The paragraph begins:

"After consideration of their position, patients began to ask Dr Ludlam to tell them their antibody status. This happened gradually. My recollection is that I was present on three occasions when patients were told their status. One had been infected through IV drug use."

Then the second was a young African student about to return home:

"Both had present as haematology patients. There was no suggestion that they had been infected by blood products."

Then this is the sentence I am interested in:

"The third was a haemophiliac in his teens who had become very ill and died soon afterwards. My feeling was that although Dr Ludlam clearly explained what was causing these symptoms and described HTLV-III infection, he was at that point too ill to grasp fully the implications or to take up the opportunity to ask questions."

The question really is that the earlier this is discussed with the patient, the more able one is to discuss the implications, potential outcomes and all the rest of it, and by leaving it in the way that you had left it or it had been left, it presented a problem for the person once they had actually developed full symptoms and deteriorated. And again, leading back to what I had asked you earlier, about whether the route that you chose was better, I'm suggesting that it wasn't the better way of doing it. The better way would have been to inform people.

A. Perhaps I can clarify the situation. This was a very unfortunate young man who acquired HTLV-III. I am concerned that actually -- about patient confidentiality but I think this is very important and I think his parents would understand.

I was very keen to tell him about his anti HTLV-III

or his HTLV-III situation and they were very keen that I shouldn't, and we had a dialogue about this over quite a protracted period, when this was before he was ill, and I felt that it would be better if he knew. His parents were adamant that he shouldn't be told and he was ill, very ill, and I took it upon myself, because I felt I owed it to the young man, to try and explain to him why he was ill, what was wrong. And I did that as best I could with Mrs Brown with me. And it has left an indelible mark upon me because I'm not sure that it was the right thing to have done, but I did my very best in what I found were dreadful circumstances and his parents did understand the dilemma I was in.

Q. The position really that I would like to come to then is to put to you a number of points. You would agree that the relationship between the doctor and the patient has at its core trust by the patient in the doctor?

A. Yes.

Q. And obviously with a condition like haemophilia, which involves continuous and prolonged treatment, that is particularly the case?

A. Yes.

Q. And in deciding whether to receive factor concentrates, patients require to trust the medical advice that they were given. Do you accept that?

A. That patients should trust medical advice.
Q. They were required to trust the medical advice that they were given.
A. I hope patients respect the advice that they are given.
Q. And if they were using factor concentrates, they were following medical advice?
A. Yes.
Q. And in Scotland it was thought that NHS products were safer than the alternative commercial material. That's what patients were told?
A. That was my view.
Q. Well, it did turn out that factor concentrates were not safe, at least not entirely safe. That's right?
A. The NHS concentrates were safer from the point of view of HTLV-III than commercial concentrates.
Q. But they weren't entirely safe, as it turned out.
A. No, but they were safer, substantially safer.
Q. Those patients we are talking about were studied during a period; there were a number of studies that were carried out from 1983 to 1988?
A. I'm sorry, what was --
Q. The proposition I'm putting to you is that there were a number of studies carried out on patients at Edinburgh, haemophilia patients, between 1983 and 1988. A number of studies were carried out.

A. They were being monitored for their medical situation, yes.
Q. And plainly some patients were unaware of the precise extent of those studies. They didn't necessarily appreciate all those studies entailed?
A. I think that is fair. It would be difficult for the patients to understand perhaps everything. Not everything was done on all patients. And there were some investigations that were done on not all patients, like the skin testing.
Q. The patients were aware that they were being tested from time to time, they may or may not have been precisely aware of what the purpose of these numerous tests were at any particular time. They wouldn't necessarily know exactly what tests were being carried out for.
A. They would know -- and I had made it explicit that we were studying their immunity and HTLV-III status.
Q. And testing for the HTLV-III virus was carried out without patients' knowledge or their consent?
A. Not after 1985.
Q. Professor Ludlam, in 1984, in October, or whenever it was that the tests were carried out, it was carried out without their knowledge or their consent?
A. That's correct, yes.
Q. And not all of the positive patients were specifically

informed of their results until later on?
A. Until later, that's correct.
Q. And it appears that some of those patients didn't appreciate that in order to find out whether they had been tested or to find out the results of those tests, they needed to ask specifically for that?
A. Well, I think I have made my position very clear, that I consider that the information was readily available and there were some patients who, for a number of reasons, were keen not to know.
Q. I'm thinking about people that may have been keen not to know but didn't realise that they were positive and needed to ask in order to find out?
A. I think in these circumstances they may have been afraid to know. Maybe we should have helped them but -- and eventually, as you know, everyone was told.
Q. But it does seem that some patients did assume that they were negative on the basis of the information they had. Wrongly; they may not have understood what you were saying at the meeting, they may not have fully picked up properly on the leaflet that was sent, they may not have understood the message that you were trying to convey. That's the point I'm making.
A. I suppose the information was given out in very many different ways, in many different formats, and if at the

end of the day someone still says they didn't appreciate it, I find that difficult. I fully accept they may find great difficulty in accepting that they might be positive or that they feel very ambivalent about coming to ask but we did ensure that everyone knew and no one suffered medically with any delay there was.

Q. I have no basis for suggesting to you that they did suffer medically, Professor Ludlam; I'm just suggesting to you that what there is a basis for, I think, is that certain patients didn't appreciate that that information in relation to them was available and that the way it was put across at the meeting, it may not have been clear to them, or to some of them, and it wasn't made clear in subsequent correspondence or leafletting?

A. Well, it was made very clear to a lot of people, who clearly got the message and came along early in 1985 to ask.

Q. The point I'm making is that there are a number that didn't come along?

A. No, and we gave them -- we gave them the opportunity to consider the situation, to talk to us, to talk to people in their family. People don't live in isolated bubbles, they live to communities, and particularly people with haemophilia in those days lived very much in the haemophilia community, and it would have gone round the

haemophilia community very quickly, what had happened at the meeting, even if the person wasn't there. And so there was every opportunity for them to pick up that things were changing and that there was new information, that they might like to come and talk about even quite apart from whether they wanted to know their anti HTLV-III status. They might want to know why there are condoms being handed out with the concentrate.

Q. The message you were conveying at that point was that everyone who had received Factor VIII products could be at risk. So that wouldn't necessarily lead you to think that you had been tested and were positive?

A. No, what I mean is that if you suddenly come to collect home treatment and you suddenly find you have not only got bottles of home treatment in your bag but you have got a packet of condoms, you might look a bit askance and perhaps ask the nurse why this was extra with the concentrates.

And I'm sorry to come back to the whole exchange of concentrates, the non-heated for the heated. Everyone who was on home treatment, which was a lot of people by this stage, brought back their products and there would have been a short discussion with the nurse to explain what it was all about and that they could come and talk to me or Mrs Brown to learn more.

Q. But we do have a situation, do we not, that, as I say, people who are disappointed about their result, they are not told the result until years later, their position is that they didn't know, that they had to ask for the test. They get a positive result and they find out and it's obviously a devastating result for them. They didn't appreciate that in order to get that result, they had to ask for it. They don't know of the research or the monitoring that's going on. And so what we have is a situation that we have disappointment, a lack of communication, I'm suggesting to you, with the patients, or at least with some of them?

A. With a small number -- but of course, it depended upon patients coming to their routine clinics to have an opportunity to talk about these sort of things, and if patients don't come to their routine appointments, it does make it rather difficult.

Q. Then you add to that rather difficult mix of culture the publishing of follow-up studies, apparently without any consent or knowledge. I mean, it does happen that there is publishing of results of research on certain patients, where some of them didn't appreciate that that's what was going to happen, that work would be published about them. We are adding that to what's already going on before. Is it not surprising that in

certain quarters that culture of suspicion and mistrust, seroconverts into something much more sinister?

A. I can see that patients -- HIV was a little bit like a tsunami. You saw something on the horizon and it gradually got closer and it overwhelmed us in the late 1980s. The demands of all sorts of difficulties that these patients -- and very sadly many here who can't attest to how they found the service that we provided.

People with haemophilia have over the years been very generous in participating in research studies, monitoring studies. And as a result, treatment has been improved. And part of the responsibility of these sorts of activities, is to publish the results. It's quite important to publish the results and I think patients appreciate the results are published and made more widely available for more patients to benefit from what has been learned.

Q. Provided they will have been kept properly informed. My suggestion to you, Dr Ludlam, is that with better communication and greater transparency, there would have been a more wholesome outcome not just for the patients but for the professionals themselves. Is that not the case?

A. I think that I had a very good relationship with the majority, the vast majority of the patients, and I think

they were very supportive of what I was doing and appreciative. They would know that these studies would be written up to help other people with haemophilia.

Q. So you don't agree with that last proposition?

A. No -- well, clearly, one's relationship can always be improved, but I think I had a very good relationship -- I do have a very good relationship with the vast majority of people with haemophilia that I look after in Southeast Scotland.

Q. Well, nobody can get on with everybody all of the time, I don't imagine, but I'm just suggesting to you that different decisions, better communication, greater transparency in relation to the numbers of things -- I won't go through them again -- would have produced a better and more wholesome result, as I say, not just for the patients that may have been in the dark, but also for the professionals who were dealing with them.

A. I can see that communication can always be improved upon. I think we were very transparent to the patients what we were doing for them and with them.

Q. Just one matter I want to ask you about in relation to the implicated batch. You were asked questions about the probability of the implicated batch being responsible for -- is it the 16 or 18 we should refer to as far as the implicated batch is concerned?

A. We think it's 18.
Q. We know that there were 23 in Edinburgh, I think, that were HIV positive. Some of the other five, did they all get commercial product at some time or another or did some of them only get SNBTS products as well?
A. That information, I think, has been made available to the Inquiry, right at the beginning, when I first appeared. My recollection -- and I may be wrong. My recollection is that, of the 23 patients who got infected in Scotland, one was from commercial and the remainder appear to have been from NHS concentrates.
Q. Some of the patients that received the implicated batch, some of the 18 would also have received the same SNBTS products as the other five did; in other words, there would be a commonality in terms of the batches that they received, between some of the 18 and the five?
A. Some would have been, yes.
Q. And the more exposure to HIV that you have, the more likely you are to seroconvert?
A. Yes.
Q. And we know that the implicated batch is only weakly positive. That's the information that we have had, that the implicated batch is only weakly positive in its test.
A. That's my understanding. Weakly positive in one of the

tests.

THE CHAIRMAN: I'm not sure that's absolutely right. It is now tested by a much more sensitive test and found on a very narrow 200 base couples(?) to be positive. "Weakly positive" is an expression that applied to a different test, Mr Di Rollo.

MR DI ROLLO: Yes. I think Dr Perry's evidence was that you could certainly be exposed to the implicated batch and not seroconvert. I think the suggestion was that maybe the strength of the infection within it was not that great. That's what I'm trying to put across. That's my understanding of the evidence that we have heard.

A. Yes, I think the infected -- the amount of infection -- assuming it was equal in each bottle -- was almost at the threshold that it would not infect someone.

Q. Right. That was the meaning of the phrase I used, which was not very satisfactory, I understand that.

But I'm just putting to you this proposition that it may well be that the 16 or the 18 were infected not just by the implicated batch but also by other NHS product as well. Is that a possibility?

A. It is not for 12 of them because 12 of them have a very similar virus. This was work published by Professor Lee Brown(?) in about 1995. There were two patients out of the 18 who had a different virus or

characteristics of a different virus, and then there were the other -- I think those were the only ones they studied actually.

So it looked like at least 12 of the 18 got the infection from probably a point source, as I understand it. The other two, although they got the implicated batch, just possibly might have got the infection from some other concentrate. After we had this information, we went back and looked in great detail, as it were, did the same analysis or a similar one that we did in 1984, to see whether we could have found a second infected batch but we couldn't piece it together to make results consistent with a second significant batch.

Does that help?

Q. Are you saying that's not a possibility or it is still a possibility?

A. I think it is possible that, although we have attributed these 18 to have got their infection from 0090, it is possible that they got the infection from a batch that was given at round about the same time because we have got the dates of seroconversion and we know when they seroconverted. So it would need to be a batch that was given within six months or thereabouts of seroconversion. So it is possible that -- well, there clearly have been other infections. It appears to be

from SNBTS products. Yes.

Q. And some of them -- you said 12 -- that the virus is the same but in the others it is not possible to say that, so it's not possible to confine it in that way with the others apart from the 12?

A. I have forgotten the detail. 12 were examined and found to be very similar and another two were examined and found to be different. The remaining four I don't think were tested in the study.

Q. Sir, that's all the questions I have to ask.

THE CHAIRMAN: We will have a break.

(3.18 pm)

(Short break)

(3.40 pm)

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: I'm obliged, sir.

Questions by MR ANDERSON

MR ANDERSON: Professor Ludlam, good afternoon.

A. Good afternoon.

Q. Perhaps I should assure you that I don't intend to detain you any longer than is absolutely necessary.

THE CHAIRMAN: Do you wish to put a time limit on it?

MR ANDERSON: No, sir, I do not, since I have never got one of those right.

Can we start by looking at the document

[PEN0120774]. This is the notes of the meeting between yourself Gemma Lovell and Douglas Tullis. Can we look, please, at page 0078?

You see in the first full paragraph it says:

"In 1983 we started looking at lymphocytes. The haematology lab continued to assess patients' full blood counts in the usual way except that instead of counting 100 white cells, which was then done visually by microscope, they counted 200 white cells. Lymphocytes are a type of white cell. There are 4-5 different types of white cells. Lymphocytes form a small proportion of the total number of white cells (approximately 15 to 25 per cent)."

On the first day in which you gave evidence on this topic, if you can remember that far back, professor, you explained that the lymphocyte count was but a number of investigations carried out in the haematology department, and you referred to this as "routine haematology investigations". Could I just ask you: what comprised the routine haematology investigations?

A. Yes. It would be as set out in this paragraph, but there was analysis of the different types of white cells. Lymphocytes are one variety. There are what are called polymorphs that are another, eosinophils, that are another, basophils and monocytes.

Q. Sorry, it's probably my fault, professor, but really what I was looking for was what other investigations were done into the blood that was taken other than simply the lymphocyte counts? I think you mentioned on your first day red cells, platelets, haemoglobin, that sort of thing?

A. Yes, I'm sorry. There would be a measure of the haemoglobin, the degree of redness, oxygen-carrying capacity; a counting of the number of red cells. The red cells would have their size measured. That's important for diagnostic reasons. We would assess the number of new red cells, what are called reticulocytes in the blood count. It is a measure of how much blood is being produced by the bone marrow. There would be all the different types of white cells that I have described and there would be the platelets, which would be counted as well, electronically. So there are quite a range of tests done on this one sample of blood.

Q. We heard, I think, that the lymphocyte testing started in 1983. For how long would these other tests have been carried out?

A. These other tests have been carried out for decades.

Q. Sorry, had ethical approval ever been obtained for these test over the years?

A. No.

Q. Why not?
A. Because they would help in the clinical assessment of the patient; in other words, if you had an increased number of, shall we say, eosinophils, that might be because you have got some allergic reaction in your body.
Q. When you began this lymphocyte count in 1983, did it strike you that this was somehow in a different category from these other routine tests?
A. Not particularly, in that although many lymphocytes look the same, there are some that actually look a bit different and you can distinguish them down the microscope. There are some lymphocytes that look rather similar but have rather different functions. And so to distinguish between them you have to stain them and that's what we were doing, or Dr Steel was doing for us down at the Western.
Q. I mean, did it ever occur to you that it was necessary or mandatory to obtain express consent for this additional investigation?
A. Not really, in that it was -- we were looking at the white cells which we had done -- the different sorts of white cells for long enough as monitoring our patients. They might have had an infection and they got an increase in their polymorph count, for example, which is

another sort of white cell.

Q. Did it ever occur to you that you might not have implied consent to do this investigation?

A. I felt I had at least implied consent for it and I thought that a goodly number of patients would have understood that we were doing these tests as well, but I certainly felt we had implied consent.

Q. Was there any risk to the patient in carrying out these investigations?

A. None.

Q. Put in modern parlance, was there any downside, as far as the patient is concerned?

A. Only if we gave them the result and it was very low, but, as I indicated earlier, I'm not sure that anyone came back to ask.

Q. When you started this particular investigation in 1983, what did you think might be the outcome of your observations?

A. I thought they would be normal numbers of CD4 and CD8 cells.

Q. What, if any, were the benefits of this new investigation, the lymphocyte count?

A. I undertook it, added it on to, if you like, the screening list because of the observations in the States that lots of people, apparently well people with

haemophilia, had low counts, and -- in inverted commas -- it was being used in the United States as a potential surrogate marker for HIV or an AIDS-causing virus.

This is obviously before there was a virus known. And this was the only investigation that seemed to possibly indicate that there was something more widespread in people with haemophilia in the United States than was apparent clinically. In other words, there were a lot of patients who had these lymphocyte abnormalities, a bit like gay men. A lot of them have lymphocyte abnormalities and obviously a much larger number of the gay men had developed AIDS by 1983.

THE CHAIRMAN: Professor Ludlam, before the knowledge that in New York and other places they were measuring CD4 absolute numbers and CD4/CD8 ratios, had it ever been suggested or was there ever any published information that the treatment of haemophilia, from the days of Cohn Fraction I through cryoprecipitate and into concentrates, had had the effect of changing the proportions and numbers of these cells?

A. No. It was only a short while, I think, before this time that actually it was possible to distinguish between these two types of lymphocytes. It might only have been a year or two or three sooner.

THE CHAIRMAN: Right.
A. They all look the same down the microscope and these cell markers were only identified and the tests set up to distinguish between them, I think, only two or thee years sooner. So there wasn't a great amount of knowledge about them.
THE CHAIRMAN: Thank you.
Yes, Mr Anderson?
MR ANDERSON: We know, professor, that one result of this lymphocyte count was firstly a letter to the Lancet, and I don't think we need to look at these specifically but for the purposes of the transcript, there was a letter to the Lancet in May 1983. That's reference [LIT0010416]. We have looked at this on a number of occasions but it's really simply setting out the finding, isn't it?
A. Yes.
Q. It's just giving information?
A. Yes.
Q. Without any form of analysis. Is that correct?
A. Yes.
Q. And then we know that there was a later article in June 1984. Is that correct?
A. That's correct, yes.
Q. The reference for that is [LIT0010425], and would it be

fair to say that really, although there are some discussion and analysis there, that really it's inconclusive?

A. It was not clear what the cause of the lymphocyte abnormalities were.

Q. And because it was not clear what the cause of the abnormalities was, did that play a part in your decision to send samples to Dr Tedder?

A. I don't think so. The decision to send samples to Dr Tedder is that he had what looked like the best test for identifying individuals who might have been exposed to HTLV-III. That was, in a sense, quite different.

Q. All right. I think we have discussed at considerable length the lymphocyte count and what it may or may not have shown but before you sent samples from the deep freeze to Dr Tedder, did you ever pause to think that you were perhaps taking matters onto a different level, as it were?

A. No. I mean, it was -- here was a -- concern about the virus causing AIDS, seemed to be spreading from North America into Europe, into England -- and really the question is: had it moved up into Scotland? Were our patients unfortunately infected?

Q. Yes. You have told us here you were excepting an answer in the negative to that?

A. Yes, I thought it possible but very unlikely.
Q. All right. In the document with a reference [PEN0120351] -- that's the Edinburgh Haemophilia and Thrombosis Centre document -- at paragraph 15 you say that:

"Dr Tedder had a limited supply of reagents and he was receiving many requests from other clinicians."

I think in evidence today you actually suggested he was being inundated. These clinicians would be what, directors of other haemophilia centres?
A. That would be correct, yes.
Q. So presumably you weren't alone then in seeking Dr Tedder's assistance?
A. By no means. There are, in any one year, 2,000 or 3,000 patients with haemophilia treated in the UK and all the physicians looking after those patients I think would have been keen to get their patients tested.

So that was several thousand potential requests and then, of course, there were all the other physicians looking after other risk groups, who were keen to have their samples tested as well. This was just a small research laboratory, specialising up until then in Hepatitis B.
Q. On the first day of your evidence, professor, you described this lymphocyte count or immune study or AIDS

study -- call it what you will -- as part of the monitoring of the patients, which you said was "my responsibility". Do you think it would have been responsible not to carry out these investigations?

A. It certainly would have been irresponsible not to have carried out anti HTLV-III tests.

Q. I suspect we know the answer but can you just tell us why you think it would have been irresponsible not to have done that?

A. If I hadn't done that, then it would not have been clear, regrettably, that there was HTLV-III in the UK blood supply. If I hadn't discovered that in such an explicit way as emerged, then I think it's unlikely that the meeting that was held on 10 December would have been held on that date.

Certainly my observations were a potent stimulus to getting that meeting brought together. The importance of that was that was the meeting that made the decision to go for heat treatment. Not only was that effective but actually it set part of the example to the rest of the world that heat treatment was probably the way to go because the UK had gone that way.

Q. Can we move on, professor, to a slightly different matter? You will be aware that some patients have now apparently expressed concern that they may have been

tested without their express consent or they did not know that the tests were being carried out. I think in an answer to my learned friend, Mr Di Rollo, you said that. At the time you never received any complaints about that. Is that correct?

A. That's my memory and I don't recall receiving complaints subsequently. I heard Dr Richardson's evidence that some of the patients complained to her in the group or individually and I can understand that in a sense that -- I think it was a projection of their anger. Some of it was against me, some against the Blood Transfusion, some against the wretched test.

I suppose I do -- I'm very conscious of the fact that I run a monopoly service for Southeast Scotland. There is no choice about where you come to get your haemophilia treated. And over the years I have tried to provide a flexible service to fit in with patients' wishes and needs and times of day that they can come and so on.

It's something of satisfaction to me that I have been responsible for the service for the last 31 and a bit years and I don't think -- I don't recall the hospital ever receiving a complaint from a patient about the haemophilia service.

Q. Sorry, carry on.

A. But to be more specific, I don't recall any patient saying to me, "I wish you had never done that test," or, "I wish you would have asked me first before you did it."

Q. Even if it's not at that sort of level of complaint, do you remember anyone saying anything such as, "You might at least have asked me," or "had the courtesy to ask me."

Do you remember anything like that being said?

A. I don't, I am afraid.

Q. Can I take up with you, please, really the matter that my learned friend, Mr Di Rollo, was asking you about towards the end of his questioning? That was the way in which it was effectively left, I think as it was put, to the patients to make enquiries themselves as to their HTLV-III antibody status.

What I noted him saying in one question was, "Well some didn't appreciate the need to ask," that was the basis of one question. And in another question he said there was a number that didn't come along. I think earlier in your evidence and also today, you suggested that by the end of 1985 the vast majority of those had sought information as to their testing. Is that correct?

A. Yes.

Q. I don't think it was today but on an earlier occasion you said that was a shifting picture over the course of the year. Is that right?
A. Yes.
Q. So that by the end of 1985, as you put it, I think, the vast majority were aware of their status. Is that correct?
A. Yes.
Q. Can we just concentrate on this -- briefly, I hope? What sort of numbers are we talking about altogether?
A. There would be about 150 patients or thereabouts who will have been tested over 1985 because those are the numbers that we had on our books who had been --
Q. By the end of 1985 can you assist us with how many individuals, do you think, would not have known, for whatever reason, of their HTLV-III status?
A. I think probably only three or four or five, probably.
Q. All right. In his questioning to you, Mr Di Rollo said, "Let's take out those that simply didn't want to know and were quite adamant that they didn't want to know," the implication being that there was a third category, as it were. There were firstly, those that knew, secondly, those that were adamant they didn't want to know and there was a third category who just didn't appreciate the need to come and ask. Can I just be sure

about this? How many, if any, were in that third category?

A. I can only think -- who were positive, anti HTLV-III positive?

Q. Yes.

A. I can only think of two individuals.

Q. Lest there is any confusion, those are not two individuals who had expressly said, "I don't want to know"?

A. No, that would be another individual.

Q. All right.

A. While there is a pause, could I just add -- I was thinking over tea about information that was available for patients. What has not featured here is information from the Haemophilia Society that was available for patients. They issued bulletins about -- called Haemofact sheets about HIV and AIDS from 1983 onwards. The haemophilia bulletins had articles related to HIV. I made a catalogue of these available to the Inquiry.

Q. Yes. I think we know that after the meeting on 19 December 1984, of which we recognise only a proportion probably, a relatively small proportion of those affected, attended, there was the circular letter, which again we needn't look at I think, but has a reference [PEN0120495], and that's the letter that

talks of 10 per cent in Scotland have exposure or are positive. Do you remember that one?

A. Yes.

Q. And about half in England. But I think the point you make is that any haemophiliac who is a member of the Haemophilia Society would have further information, disseminated to them from the Society. Is that right?

A. Quite frequently.

Q. Did you have any input into information that was being disseminated by the Haemophilia Society at that stage?

A. I'm sure I was consulted from time to time. I was a member of the medical advisory committee. I was invited to be a member of the medical advisory committee about 1986 onwards, for about ten years. And I'm sure I would have been rung up about these sort of issues for my view as to what should go in the literature.

Q. Do you have any current relationship with the Haemophilia Society?

A. I have quite a close working relationship with the Haemophilia Society in Scotland and also with the UK Haemophilia Society. UK Haemophilia Society is going to hold its annual conference this year in Edinburgh and I was quite touched and felt honoured that the national director of haemophilia Scotland sent me an email two or three days ago asking if I would give a key note lecture

on future developments in haemophilia at that conference, this November.

So I worked closely with the Haemophilia Society and with the European haemophilia patients' organisation and with the World Federation of Haemophilia, whom I'm helping to rewrite their haemophilia guide book at the moment.

Q. All right, thank you. Those individuals who came to be known as the "Edinburgh cohort", Professor Ludlam?

A. Yes.

Q. Am I right in thinking that the unique feature of those individuals is simply that they were all infected from the one batch?

A. We think they were all infected from the one batch, yes.

Q. But on that supposition, that it is understood or accepted that they were all infected from the one batch, other than that, is there any distinguishing feature? By which I mean were they treated in any way differently from any other patient?

A. Oh, absolutely not. As I think became clear in looking at some of the statistics about HIV, at the beginning of these hearings, we had 29 patients in Edinburgh with haemophilia who were HIV positive. A number of those had unfortunately become infected outwith Scotland, either in England or elsewhere, and these patients were

monitored and treated in exactly the same way as the cohort. They were indistinguishable in what investigations were done for them, how they were looked after, and how they were managed.

Q. All right.

A. It was only really when they came to be, if I can put it this way, "written up" in the papers that they became the cohort. It's rather artificial and when you see the papers stacked up, like in the papers for these hearings, then they look more like a cohort. But that was gathering the data together. From the point of view of running the service, they were all the same.

Q. Yes, I'm obliged.

Do you remember just quite recently my learned friend, Mr Di Rollo, asked you about this young man who was very ill when you told him the news. There was a reference, I think, to Geraldine Brown's statement. Do you remember that?

A. Yes.

Q. And you told us about that. Can I just ask you a few questions about that? Can you remember what year it would have been that you told him his results?

A. It might have been -- it might have been 1986 or 1987.

Q. All right.

A. It would have been 1986 or 1987, I think.

Q. All right. You told us that he was very ill at the time?
A. Yes.
Q. Would I be right in thinking that he had an AIDS-related condition at that time?
A. Yes.
Q. And was he receiving treatment for his condition at that time?
A. Yes.
Q. All right.
THE CHAIRMAN: Mr Anderson, you will take care. We are beginning to build a picture --
MR ANDERSON: That's all. I have no further questions in relation to that, sir.

Do you remember, on the second day in which you gave evidence, Professor Ludlam, we looked at an excerpt of your case notes in relation to your patient, Mark. Do you remember that?
A. Yes.
Q. And the document which the chairman suggested we should designate as "X"?
A. Yes.
Q. Which I don't think is in court book. This entry in your writing, I think, and the question was whether it was 1988 or 1986. Do you remember that?

A. Yes.
Q. All right. Again, with the caution in relation to confidentiality, so we don't want to know dates of birth or anything like that, have you had the opportunity of making further investigation to assist us with whether that is 1986 or 1988?
A. I have been shown a letter about the patient that I wrote after seeing him in January 1986 that alludes to his circumstances, and although it's a redacted copy --
Q. Perhaps if you are looking at, we should all do so. I think it's page 18 of [WIT0040240]. Is that correct?
A. That's correct, yes.
Q. Perhaps we should just have that up on the screen. It's not terribly easy to make it out. This is in relation to Mark. Is that right?
A. That is correct.
Q. Is this a letter to his general practitioner?
A. Yes.
Q. And it's dated January 1986?
A. Yes.
Q. What do you take from this, please?
A. In the third paragraph:
"At present he is working for highers at school and hopes to get a job as an ..."
Which has been redacted:

"... when he leaves later this year."

So he was taking up an occupation. And I think -- I have not seen the unredacted copy of this but in my note that I think was dated 13 November 1986, I have said "working as ..." and it's been redacted:

"... started nine weeks ago."

And I think he left school in the summer and then started working at this occupation, probably in September-ish, and I saw him a couple of months later.

Q. We have already looked, I think, at an entry in 1989 from the registrar which suggests in I think fairly unequivocal terms that he does not want to know the result of his antibody result. Without labouring this, I take it that that was your understanding during those years that you were looking after Mark. Is that correct?

A. My understanding ...?

Q. Of his position in relation to knowing the results of the test?

A. Oh, yes.

Q. Have you any doubt about that?

A. No.

Q. When he gave evidence, he told us that you told him of his HIV status in 1991. Do you think that would be

correct?

A. I think that is correct from the principal case records, yes.

Q. What I think we haven't investigated yet, that being so: why did you tell him when you did tell him; in other words, why did you tell him in 1991, given his apparently expressed desire not to know his results?

A. Well, I was concerned that by that stage we clearly knew anyone who was anti HTLV-III positive was infected with the virus, so he was infected. There were various potential therapeutic options. My recollection is that he had allowed us, on the few occasions he came up to the centre, to take blood from him and to measure his CD4 count. That was important because when the CD4 count -- as you know, the CD4 count falls with HIV infection, and in those days, if it fell below 200, then it was recommended the patient got prophylaxis against PCP or they might be eligible for Zidovudine treatment.

My recollection is that in 1991 his CD4 count had fallen. I don't think it had reached 200 but it was on its way down, and clearly it was going to reach 200 and he would then -- it would be appropriate for me to offer him prophylaxis against pneumocystis or Zidovudine treatment.

But before that point, the wisdom -- medical wisdom

at that time was that it wasn't appropriate to do so.

Q. I think you told us earlier that those that might have been equivocal or might not have wanted to know the results, you would seek to encourage them to do so, and a stage may come where it was clearly in their best interests, from their health point of view, to know their results. Is this simply an example of that?

A. Yes, yes. It was definitely in his interests to know at that stage.

Q. Can you just clarify that for us, please?

A. It was not appropriate to offer either PCP prophylaxis or Zidovudine until the CD4 count had fallen below 200 per cubic millimetre.

THE CHAIRMAN: I'm not absolutely sure that that meets the point.

A. There was no other medical intervention --

THE CHAIRMAN: It's not the absolute, Professor Ludlam; it is the relationship between the clinician and the patient, I think, which, I thought, was changing once a view had been formed that medically it was appropriate to have therapeutic intervention at this stage but ...

MR ANDERSON: You may not be able to see this but essentially what you said, Professor Ludlam, was that before that point -- that is the reaching of 200 -- you say:

"The wisdom -- the medical wisdom at that time ..."

And I think what you meant to say was, "It was not appropriate to do so"; is that correct?

A. That's correct, yes.

Q. When you did tell Mark in 1991, or rather at any time later, did he make any comment to you about the fact that he had not been told earlier, either then or at any later stage?

A. He was apparently surprised when I told him -- this is in 1991. And I saw him again the following week. This is recorded in his principal record, the case notes which I reviewed a little while ago. And he seemed to have coped well with the information in the first week. I suppose I was a bit taken aback when I saw him many years later. I saw him in 2005 with his father for a special reason. I'm not sure whether I --

Q. I don't think we need to know that, professor.

A. No, okay. I saw him with his father because I wanted to review with him how he had felt about his HIV and its treatment and being let known about his situation. I was quite taken aback because he said that he was very pleased not to have known until 1991, that it allowed him to lead what he described as a normal life until then. After I had told him -- and this is what he told me in 2005 -- was that he got very depressed. I think

he said he bought himself a large motorbike and rode around on it despite -- we knew he had one at that time and we tried to dissuade him but he wouldn't be dissuaded. But I was very interested that he said that he was very pleased that he hadn't known for all that time.

Q. What about when you did tell him? He told us in evidence that you had said that he would have only a year to live, and secondly that you presented various forms to him that he had to sign apparently in order to get compensation. Do you recall any of that?

A. In 1991?

Q. Yes.

A. I certainly would never have said to him, "You have only got a year to live". I would never say that to any patient. And even without new quadruple therapy that's now available, his prognosis in 1991 was clearly more than a year because his CD4 count was still above 200. And so his outlook would have been better than many and he was young, and that was a good prognostic attribute.

Q. There was a suggestion that you said, "Here are these forms and you have got to sign them now or you won't get the compensation", or something to that effect?

A. No, I would not have had -- I think he was referring to Macfarlane forms for the Macfarlane Trust or forms to

get some financial help. I would not have had those forms. I certainly wouldn't have had them in the clinic and I certainly wouldn't have asked him to sign them when I was telling him what I perceived to be very difficult news under very difficult circumstances.

Q. All right. Mark was one individual you tell us, who was quite clear that he didn't want to know his results. Can I just be clear in case there is any doubt about this: how many individuals do you remember that were in that category that said, "I just don't want you to tell me"?

A. I think he was the only one. There might have been one or two others who said, "I want a bit longer to think about it". I'm sure there were one or two of those in 1985 but they came round to wanting to know. But I think Mark was the only individual who, when we offered -- wanted to try and encourage him to ask, was adamant that he didn't want to know. I think he was the only one.

Q. Let's try and put a time on this. By the end of 1985 he clearly was one who was persisting in not wanting to know. Were there any others, do you think, by the end of 1985 who had said quite categorically, "I don't want to know what my results are", that you can remember?

A. No, there was no one else who said to me by the end of

1985, "I didn't want to know".

Q. Again, lest there is any avoidance about this, were there any, at the end of 1985, that didn't appreciate the need to come and ask? Who simply had neither been told their results nor had said categorically, "I don't know to know", but fell into what I have termed this "third category"?

A. There were two or three who fell into that category of the 150 and we knew exactly who they were in our group.

Q. And how was that? How did you know who they were?

A. Because the staff in the haemophilia centre -- we had our weekly meeting between the medical, nursing staff, the social worker, the psychiatrist, and we discussed who had been up to ask, who had been told, who didn't know. And increasingly our thoughts centred on the people who didn't know because we were quite concerned about them.

So they weren't forgotten in any way whatsoever. They were discussed quite extensively at this weekly meeting, not every week, but we were left with this small number of people who we had the information on and we felt that, you know, they increasingly ought to, and we took guidance from the psychiatrist particularly as to the best way to approach this.

Q. Right. How did it resolve itself? Can you remember?

With those few individuals?

A. I think eventually I either wrote to them or an appointment was made for them to come and see me and I would tell them.

Q. Just finally, professor, we have heard of the dreadful consequences of HIV from those afflicted with the disease and we have also heard that this was a new and unique virus, the like of which hadn't been seen before. What effect did it have upon the clinicians charged with the care of such patients? Can you help us with that?

A. Stressful. Very stressful dealing with uncertainty, severe illness, and at that time there was very little we could do by way of specific therapy. So it was very distressing for everybody. There are a number of layers of difficulty, working in a small team, dealing with an incurable, at that time, illness, that had arisen out of the blue, that had implications for the whole family, led to tensions within the unit because we were very concerned about confidentiality. And so when we met at our weekly meetings, for example, I might know something about someone who had asked me not to tell it to anyone else and someone else sitting round the table wished to discuss the patient. They might know something they had been told by the patient that they could share with the group. I might know something that would actually be

very useful but the patient had asked me not to explain it. This led to quite a lot of difficulty, quite a bit of stress and we needed help on one or two occasions because of the stress of the whole difficult situation.

As I mentioned earlier, it was a bit like a tsunami. You could see it coming and all of a sudden in the late 1980s, it was all over us and wreaked havoc upon patients who were getting on so well ten years previously, with a prospect of almost cure for their haemophilia, and now here they were dying of this awful virus. It was just dreadful.

Q. Professor, thank you very much indeed.

I have no further questions.

THE CHAIRMAN: Mr Johnston?

MR JOHNSTON: No questions. Thank you, sir.

THE CHAIRMAN: Right.

MR GARDINER: I have nothing further, thank you, sir.

THE CHAIRMAN: Professor Ludlam, thank you very much.

MR GARDINER: Sir, the next witness we had planned to have is Professor Lowe who has sat here all day patiently.

THE CHAIRMAN: Patiently or otherwise, he has been all day. Is it proposed that we try to deal with him? How long can you go on?

MR GARDINER: It's truly in your hands, sir.

THE CHAIRMAN: It's not really. I have been keeping very

quiet. It is in the hands of those who ask questions and those who answer them. I think that in the circumstances we mustn't go beyond five, but you might find that you can make progress in that time.

MR GARDINER: Yes, sir.

Professor Lowe, please.

PROFESSOR LOWE (sworn)

Questions by MR GARDINER

THE CHAIRMAN: You have been so much, professor, that I couldn't remember whether we had actually had you as a witness or not.

Yes, Mr Gardiner.

MR GARDINER: Thank you, sir.

I think this is the first occasion that you have given evidence, Professor Lowe. Is that correct?

A. That's correct.

Q. To the Inquiry at any rate. We usually start off with the CVs of our witnesses. Could we have a look at [PEN0161246]?

THE CHAIRMAN: Would it be a terrible discourtesy to the professor just to pick out things that are really important?

MR GARDINER: Indeed.

THE CHAIRMAN: I hope not. I hope that you assume that we will read it all.

MR GARDINER: We see that your current position is emeritus professor at the University of Glasgow and that you started that in 2009. Above that we see your qualifications, MB with the gold medal, St Andrews, 1972. Membership, 1974, FRCP, 1986. We see that looking down to "Previous Positions", you were a honorary consultant physician at Glasgow Royal Infirmary between 1985 and 2009. Is that right?

A. That's right.

Q. Then if we go down to the bottom of that column, just five or six lines up, we see "Honorary Senior Registrar, university medical unit, Royal Infirmary, Glasgow", 1978 to 1985. Registrar in general medicine, university medical unit, 1974 to 1977, and senior house officer, general medicine, City Hospital, Nottingham, 1973 to 1974.

If we go over the page, we see that you have been the recipient of many impressive awards, which I won't go into. We see a list of your National Health Service clinical and administrative duties. We see your professional society and college activities as well. If we go over the page, we see your University of Glasgow administrative activities and teaching activities, and also at the bottom we see a list of examinations,

undergraduate and postgraduate, that you carried out.

Over the page we see reference to your research activities and your membership of various editorial boards.

I'm sorry that I went so quickly there, Professor Lowe, but you will appreciate that we are trying to make progress now.

This particular block is concerned with information to patients, that's the B5 topic. And you have provided the Inquiry with a statement on that topic. If we could have a look at [PEN0161250]. Sir, I think you have copies.

THE CHAIRMAN: Yes.

MR GARDINER: So if we just have a look at question number 1. The bit I want to focus on is four lines down:

"When did Professor Lowe first have responsibility for the care of haemophilia patients at Glasgow Royal Infirmary? From that point did he discuss the risks of using factor concentrates (for example, infection with NANB hepatitis) with his patients?"

Could you just briefly answer that for us, Professor Lowe, please?

A. Well, I was one of a number of junior doctors in various specialities, medicine, haematology, rheumatology. We all participated in rotas, covering the haemophilia

unit. You can see that I was a registrar in general medicine, 1974 to 1977, and during that time I developed an interest in thrombosis particularly and vascular disease, which became my main clinical and research interest, but also I participated in the haemophilia unit as one of the number of junior doctors.

My inspirations really were my two bosses, Dr Colin Prentice and Dr Charles Forbes, who both became professors and moved elsewhere. And, as I have said in my statement, it was probably about 1976 I first became involved in medical cover of the haemophilia centre. That was particularly participating in out-of-hours cover. You always have to have a doctor knowledgeable in haemophilia to come and see patients who attend in the middle of the night.

So during that first position I developed an interest and awareness in haemophilia. Then, when I became lecturer in medicine and an honorary senior registrar in 1978, I continued this interest. I never had the position of a senior house officer or registrar in haemophilia.

So what I'm saying is there was a specific post held by various people, usually changing every two years, all through the 1970s up until about 1990, and the prime duty of that junior doctor was to be there at the

haemophilia centre, do most of the actual assessment of patients and the annual reviews, but as part of our training about a dozen of us over that period of time participated in seeing patients at clinics and just learning about haemophilia and participating in the service.

So with regard to the question about when were the risks of --

Q. Could you clarify the period that you are talking about there, when you were providing services to patients with haemophilia?

A. Well, all of us who were junior doctors involved in the haemophilia centre would have a rota for out-of-hours cover and then during nine-to-five, if, for example, the registrar or senior house officer in haemophilia was away or on holiday or whatever, then we would be doing their work. So it was a team of junior doctors who were assisting Dr Forbes and Dr Prentice with haemophilia management.

Q. Yes. What period of years was that you were doing that?

A. Well, as I have said, from about 1976, I would think, and then I became a consultant at the end of October 1985. And that was when I joined Dr Forbes in sharing the responsibilities for the unit. So up until the end of October 1985 I was a doctor in

training.

Q. Yes. So throughout that period you were providing services to patients with haemophilia?

A. Yes, on and off.

Q. On and off?

A. I think for about -- I would be on the on-call rota probably most years from 1976 until I became a consultant in 1985. That's out-of-hours treatment. And then for --

Q. Sorry, just to clarify: are you saying that you weren't a senior registrar during that period or ...?

A. As it says in the statement, I became a honorary senior registrar in 1978.

Q. Right. Okay. Thank you.

I think you also say in your answer there that for a period you went to Dr Lawson's medical unit, between 1983 and 1985?

A. That's right, yes. You will see I was getting a bit long in the tooth. I had been a senior registrar for five years come 1983, and at that time most people had moved on to consultant jobs. My ambition was to be promoted within the university from lecturer to senior lecturer, because only as a senior lecturer can you then apply to become a honorary consultant, and that would be a permanent job split between the university and the

health service.

But by 1983, as you can imagine, the senior registrar committees were saying, "Well, what are you going to do? When are you going to get a proper job? And suppose the university, which is cash strapped," it was the 1980s, "doesn't promote you ..."

So partly for that reason, to move me on to diabetes -- that was my plan B: "Okay, if I'm not going to get a permanent academic job, I will do a bit of diabetes and end up as a general physician with an interest in diabetes in a peripheral hospital." That was plan B. In the event the university eventually promoted me.

So partly for that reason, to give me different experience, and partly because Professor Lawson's unit had just lost a consultant and were feeling a gap, I was seconded there. So I did my general medical duties and acute medicine in that unit. So I was really kind of off the university medical unit at the time.

So I wasn't as involved in haemophilia during that period of time, 1983 to the middle of 1985.

Q. Were you still seeing patients with haemophilia during that time?

A. Yes, but not as much because there were a plethora of other junior doctors who said, "You have done your

training in haemophilia, we want our share". So I did less, for example, of clinics and so on but I was still around the unit when I had the time.

Q. Just to give us an idea, how much less were you doing during that period of 1983 to 1985?

A. Up to 1983 I would always be on the ward, wards 2 and 3. It was a general medical ward. But ward 3, the male ward, was where those patients with haemophilia who required inpatient treatment would be admitted. So anyone with a major problem like a joint bleed or surgery, or whatever, would be on the ward. So I would be in day-to-day contact just in -- on the ward with patients with haemophilia and then the haemophilia outpatients unit was actually at the end of that ward. Just as you came into the ward there were a couple of rooms where the haemophilia sister and Dr Forbes, Dr Prentice and the other junior staff were giving the outpatient treatment. But if you move off the unit, then obviously you are just less on it to see outpatients.

Q. I understand.

A. But I kept an interest in haemophilia. My plan A was still that I would get promotion and then carry on and work with Dr Forbes and continue a haemophilia interest.

Q. Yes. So in terms of seeing patients during the period

1983 to 1985, what percentage of your time was spent with patients with haemophilia?

A. Oh, I suppose maybe a couple of hours a week.

Q. Yes. So in percentage terms, what would that be?

A. Well, I used to work a 60-hour week.

Q. Okay. I'll work it out.

Yes. Okay, so now, having got that background, during the period that you were working primarily with patients with haemophilia, were you able to examine, diagnose and treat patients with haemophilia?

A. Oh, yes. If a patient came up with an acute problem, sometimes it would be my turn to assess them, see if they needed treatment and decide how much treatment and if they needed to come back.

So there was always a doctor there who did the assessment of a patient and I participated in that. The treatment they had was allocated. That was a consultant decision. That was decided by the haemophilia directors. So every patient with haemophilia would be prescribed Factor VIII or Factor IX and there would be a calculation made as to the usual dose, depending on their size, severity, et cetera, that they would need and that was all set. So you didn't have to, you know, work on that.

Q. It's the phrase "trainee doctor" there. Do I take it

that that's really training to become a consultant; yes?
THE CHAIRMAN: It's building up to a permanent position?
A. Yes, well, that's the important thing, as you have gathered. You have a permanent job. More important than that, it's as a consultant you then start making important decisions about the type of treatment. For example, if there is a choice of treatment and things like home treatment and prophylaxis, these are all kind of consultant level decisions.
THE CHAIRMAN: It sounds as if Professor Kennedy wasn't over generous in promoting your interests for a period.
A. That's how I felt.
MR GARDINER: With that background, Professor Lowe, can you recall if during this period you did discuss the risks of hepatitis with patients who had haemophilia and who were prescribed factor concentrates?
A. Absolutely. Right from the start, because I came to the unit at the end of 1974 and, you know, the haemophilia unit was sitting there. It was obvious. And the first thing I saw going into it was big red signs saying "Hepatitis". So every room in the haemophilia unit had a big hepatitis warning.

Clearly by that time, by the end of 1974, hepatitis was a big issue, particularly Hepatitis B. It was a serious illness, some people may remember that in

Scotland, Edinburgh Royal Infirmary had a very serious outbreak of Hepatitis B in the early 1970s. Several junior doctors died and a well read book "The Houseman's Tale" by Dr Colin Currie was written about it.

So in the early 1970s, Hepatitis B was a big threat. It was a big threat to hospital staff and it was a big threat obviously to multitransfused patients, not only patients with haemophilia but people in kidney dialysis units, which were taking off, obviously liver units, et cetera. So hepatitis and Hepatitis B, the one that could be tested for at the time, the serious one, was a major threat.

So right from my very first day at entry to the haemophilia unit, I saw that the patients were being regularly tested for Hepatitis B. Liver function tests were being done. The staff were tested. At the start we all had our Hep B status assessed. That only lasted, I think, for a few years but there was a lot of excitement about Hepatitis B and emphasis right from the start in reminding patients to be careful with needles, blood, et cetera, disposing of all equipment. And it was clearly a big thing. There was absolutely no doubt in anybody's mind that hepatitis was the big issue at the time.

Q. Yes. Did you discuss the risk, the possibility of

getting the non-A non-B virus, with your patients?
A. Yes, that was standard practice on the unit. So right from the mid 1970s, there were routine blood tests, which you have heard about from Professor Ludlam and others. So at regular intervals, at least an annual review for all patients regardless of severity of haemophilia, but particularly for the more frequently attending patients, probably every three to six months. Blood would be taken for the full blood count, that you have heard all about. Biochemistry, particularly renal function, which could be a problem due to bleeding into the kidneys. And liver function. Liver function tests were routinely done, that's liver function tests and Hepatitis B.

Hepatitis A testing would be done if a patient had clinical jaundice, because that would be in the differential diagnosis. And I think the Inquiry has established in the literature that by the mid 1970s, reports from several units were that perhaps at least half of regularly treated patients with haemophilia had intermittently or occasional elevation of liver function test. Only a minority of those were Hepatitis B positive and that was when the term "non-A non-B hepatitis" was coming into use.
Q. You are describing tests there, professor. I'm

interested in the communication of information to patients. Is it your recollection that you would routinely communicate to the patients that by continuing with factor therapy, they were running the risk of getting hepatitis?

A. Oh, absolutely. In several ways. I mean, I think for the second part of this Inquiry, obviously my colleagues and I are presenting a pile of your recollections around Scotland as to what was said to patients at the time. But when I would sit in on haemophilia clinics, like any junior doctor learning the tricks of the trade, I would listen to the senior doctors or my senior colleagues saying, "Okay, we have taken a history. We have examined you. We are now going to take blood tests and we will do your blood count to check for oedema, et cetera. We will do your biochemistry, we will do your liver tests and we will check you for hepatitis, which is a risk." And the great majority of haemophiliacs who attended the unit had been treated since childhood. They knew all this, and it was, "Yeah yeah". None of this was any surprise to patients that I can recall.

In addition, as you have heard, the Haemophilia Society issued a lot of booklets and pamphlets over the years about hepatitis, and again we have a big list of

those that we can produce to the Inquiry later in the year.

Q. So it sounds to me as though the information is communicated to the patient as an explanation for why tests are being done on them. Is that right?

A. Yes, but every educational book or pamphlet produced for patients, for example by the Haemophilia Society, would in addition include information about the risks of hepatitis.

Q. Yes. Perhaps we could move on to page 2. We see at the bottom of the page, the second question:

"Did Professor Lowe discuss the relative risks of cryoprecipitate as opposed to factor concentrates with his patients?"

What was the answer to that, Professor Lowe?

A. Well, the unit policy, which was decided by the haemophilia directors, was that while concentrates had come in, in the 1970s and were increasingly used, there was still a small amount of cryoprecipitate prescribed, and as I have said here, that's for patients with moderate severity Haemophilia A or von Willebrand's disease.

So in the 1980s, although we are starting to use desmopressin, DDAVP, a synthetic drug for people with mild haemophilia, it would not be effective for patients

with moderate severity Haemophilia A. And the policy of the directors at the time, as with many other haemophilia centres, was to keep cryoprecipitate and use it preferentially to concentrate, particularly for these patients who had rarely required -- well, less frequently required treatment. Severe haemophiliac concentrates had come in and they had all had concentrates.

But given the lower risk of hepatitis, or when HIV appeared also -- HIV because of the smaller blood donor pool -- there was a policy that a small-ish number of patient's with moderate severity haemophilia or von Willebrand's disease were preferentially treated with cryoprecipitate.

So that was the policy by the time I became a consultant. And then, as I have said, the first UK haemophilia centre directors' guideline on choice of blood products came out in May 1988, and after a lot of debate it was decided that cryoprecipitate no longer be used for such patients, because by this time concentrates had been heat-treated, virally inactivated, and were generally thought to be safe. And the problem is that cryoprecipitate couldn't be treated in the same way.

Q. That's the policy. Did you discuss the relative risks

of cryoprecipitate as opposed to factor concentrate with your patients?

A. Yes. I have said at the bottom, we would all discuss these policies with patients where appropriate. So, for example, maybe once a year I would see a patient with moderate severity Haemophilia A or von Willebrand's disease and they had to come in because of a post-traumatic bleed or for tooth extraction, and we would say, "No, you are assigned cryoprecipitate instead of concentrate because it has a lower risk of hepatitis". So the patients would know about why some were getting concentrates and some were getting cryoprecipitate.

Q. So yes. You say "where it was appropriate"?

A. Yes.

Q. When was it appropriate to discuss it with patients and when was it not appropriate to discuss it with patients?

A. Well, I guess it would be part of the annual review that you would say to all patients, "This is the treatment you are currently getting. Have you any questions about it and, obviously, your hepatitis." By, I suppose, about 1983 AIDS would come into that discussion.

Q. We are going to have a look at that. Question 3, which is over the page -- I think you have already answered this. I think we can take this short:

"Could Professor Lowe describe his approach to the treatment of patients with mild haemophilia ... prior to 1986?"

You say there:

"The policy was to treat patients with mild Haemophilia A preferentially with DDAVP, where appropriate and tolerated, and mild Haemophilia B preferentially with fresh-frozen plasma."

Is that right?

A. That's right.

Q. Just moving on, I would like to ask you about some immune studies or immunological studies that you were involved in. Could we have a look at [PEN0121600]?

THE CHAIRMAN: Mr Gardiner, is there the remotest possibility of dealing with this in five minutes?

MR GARDINER: Actually, I think there is.

THE CHAIRMAN: Right.

MR GARDINER: This is a brief statement that you have given us in connection with immunological testing. The first study is [LIT0010215]. We see that that's "Immunological abnormality in haemophilia." We see that your name is on that paper.

A. Yes.

Q. Briefly if you could, Professor Lowe, what was your involvement in this paper?

A. Well, not that much because this study was performed at the time that I was really moving on to another unit. Within the department of medicine we had our haemophilia group. We had a group of rheumatologists, headed by Professor Sturrock, and they had been involved with particularly the management and some papers on the main problems of haemophilia, which was joint damage, joint disease, arthritis, surgery, et cetera.

With the emergence of papers discussed earlier today about immunological abnormalities in haemophilia in America, then clearly in Glasgow, as well as in Edinburgh, we are concerned about, okay, do you see these immune abnormalities in patients in Scotland, treated by this time usually with NHS Scottish Factor VIII.

So --

Q. What was your involvement, professor?

A. Not much. Because during this time I wasn't really doing much in the way of clinics. I think the relative roles of the people concerned was that Dr Froebel was in charge of immune studies, she was a research scientist in the rheumatology group, Dr Madhok was, I think, a registrar in rheumatology with a particular interest in haemophilia and I think he took most of the samples from the patients.

Q. Just focusing on your input, professor, am I right in thinking that it was really critical review?

A. Yes, indeed. You see, I was a lecturer in the department and I was doing a lot of research studies, which you will see in my publications list, particularly on thrombosis and vascular disease. I was starting to get into epidemiological work and had done courses in statistics. I think my role in this was not directly involved in the studies but more in the interpretation.

So I would advise on the statistical analysis. I'll say, "Did you have a study that had adequate statistical power to support your conclusions?" It was sort of peer review pre-publication. I would constructively criticise it and say, you know, "Can you defend your conclusions from the data presented?"

But I wasn't at the hot end in terms of saying to patients, "We would like to measure your immune function."

Q. Yes, thank you. So in a word you can't help us with whether the patients that were examined in this case gave their consent -- in a word.

A. No.

Q. Thank you very much.

THE CHAIRMAN: Did you do a viva on Karin Froebel to make sure that she had got it all right?

A. We were quite informal in the department of medicine. We would sit and have coffee. We would present the results to each other. We had a weekly seminar where everybody would present their research. But my role was, I think, critical adviser here.

THE CHAIRMAN: Mr Di Rollo, are you concerned with the role of a critical adviser or otherwise with Professor Lowe?

MR DI ROLLO: No.

THE CHAIRMAN: No? Mr Anderson.

MR ANDERSON: No.

MR GARDINER: Sir, I'm stopping because it's 5 o'clock, not because I'm finished with this witness.

THE CHAIRMAN: Oh, dear. I'm terribly disappointed, you are going to have to come back.

We will adjourn now until Thursday.

(5.01 pm)

(The Inquiry adjourned until 9.30 am on Thursday, 30 June 2011)

I N D E X