Tuesday, 21 June 2011

(9.30 am)

PROFESSOR CHRISTOPHER LUDLAM (continued)

Questions by MR GARDINER (continued)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Good morning, Professor Ludlam.

A. Good morning, Mr Gardiner.

Q. I would just like to start off by clarifying a couple of points from Friday. Could we have a look at the transcript at the bottom of page 50. The context here, Professor Ludlam, is that we are talking about the AIDS study forms and whether the patients could have seen them. The question is about the exact procedure and your answer is:

"The patient would require a full blood count. As part of their monitoring procedure, they would have a full blood count. The chemistry and so on. The request would be sent on the usual request form for the haematology.

"Question: Who would send this request?

"Answer: The person who took the blood.

"Question: Yes?

"Answer: Yes.

"Question: Do please carry on."

And it is this bit I want to ask you about. You say:

"The person who took the blood would wrap ..."

And then you pause:

"... and then put the tube in a polythene bag along with the request form and put it out for the portering system to collect and take it down to the laboratory."

I take it that you are referring there to the practice of a doctor wrapping or rolling a request form around the outside of a sample. Is that right?

A. I think, technically, not being quite correct there. The system, I think, did change over the years and I think probably at this time there were polythene bags with two compartments to them. In one small compartment the blood sample was put and in the other, the larger sample, the request form was sort of slotted in and then sealed up.

Q. Yes. But it could be wrapped round the sample. Is that right?

A. Well, specifically it wasn't wrapped round the sample in case the sample leaked and the tube got covered in blood.

Q. Okay. I suppose the point I'm trying to make is that if it was wrapped round the sample and if it was wrapped round with the text on the other side, if you like, then

the patient wouldn't be able to see the text. He wouldn't be able to see the words "AIDS study"?

A. I think the point I was trying to make, if I perhaps say, is that the patient would have been -- might well have seen -- and there would be an opportunity to discuss -- what investigations were being done as the doctor was talking to the patient.

Q. Yes.

A. Talking to the patient and you fill out the form with the patient's name and particulars, and they would write on those that were applicable, "AIDS study", sitting next to the patient. And might well have explained, or would have explained, why we were doing this, would then have handed the form, possibly with one or two other forms as well for the monitoring, the chemistry form, to the patient, who would have then gone to sit in a queue of patients waiting to actually physically have the blood taken. It's after that point that the blood tube is filled and the form and the tube are put into the polythene bag.

Q. Or perhaps a blank form could be wrapped round an empty tube before the patient goes to the nurse to have his blood taken?

A. I'm sorry, a blank ...?

Q. Well, a form that has been prepared beforehand.

A. Oh. One that might have been filled out the previous day?
Q. Yes.
A. It would still be probably given to the patient. The forms made out the previous day would usually be for inpatients because the ward doctor had a lot of patients to go round and take blood from, and it was quicker if the forms were all made out in advance. If it's of any help, there is a letter that Dr Tucker wrote in about 2005 or possibly 2006 to describe his memory of how blood was taken from patients and how -- what they were told. That has been made available to the Inquiry.
Q. Yes. I think, Professor Ludlam, on Friday you described a situation where the form might be completed in front of the patient and then perhaps wrapped around the empty bottle and then the patient would take the bottle and have blood taken from the nurse. That's right, isn't it?
A. If I did, I have been misunderstood or I had spelt it out wrong.
Q. Okay. But if that was right -- let's proceed on that hypothesis -- you say it's not right but if that is what happened on occasion, if the doctor did not want the patient to see what was written on the form, he could simply reverse the request form and wrap it round the

sample. Is that not right?

A. Usually, the patients are given the filled-out forms to go to the nurse and it is the nurse who has the little bottles of blood and she asks the patient their name and date of birth and writes that on the tube. So the patient -- the doctor doesn't usually give the patient the tubes as well as the form. The doctor usually gives the form to the patient.

Q. Yes.

THE CHAIRMAN: Professor Ludlam, I'm sure that those of us who keep the medical science service going by providing ample supplies of blood today have our own knowledge of what happens, but looking back to this time, was there any fixed protocol that was applied generally within the hospital service for having blood samples taken? Was it all written down somewhere or was it more casual than that?

A. I don't recall a written protocol. I think it was custom and practice.

THE CHAIRMAN: And if one thinks of the practical operation of taking blood in this way, would there be a working position, where the nurse taking the blood would have a full supply of vials and needles and all the rest of it, or would they be spread all over the hospital?

A. Each ward and each clinic would have usually a tray with

the tubes -- or possibly a trolley with the different sorts of tubes on for the different investigations, with the needles and syringes or butterflies, if those were going to be used, and the antiseptic swabs, the cuff to go round the upper arm as I was describing yesterday -- they would all be on a small trolley in each ward or in each clinic.

THE CHAIRMAN: So sometimes the doctor would have immediate access to a supply of tubes when he was filling out a form and sometimes he might not.

A. Tubes and forms were readily available. I think it would be fair to say that samples would have been taken by doctors as well as nurses, and in fact haemophilia was one of the first, if you like, clinics in which nurses were able to take blood. It was always deemed to be a doctor's responsibility to take blood in those days.

THE CHAIRMAN: Yes, perhaps to the advantage of all of us that nurses now do it more readily.

A. I entirely agree.

THE CHAIRMAN: But my concern over this, Professor Ludlam, is that at some stage I'm going to have to decide what inferences I can draw and your suggestion is that because the forms are in use, and are at some stages in the possession of the patient, the patient would be

likely, as it were, to see for himself the words "AIDS study".

If there is no system, I'm not sure that I'm going to be able to arrive at a view that that is an acceptable proposition. So I think I really do need quite a lot of help to understand how there could be an inference that the patient would know for himself, if his attention wasn't drawn to the matter by the clinician.

A. I think -- maybe further light is shed on this by Dr Tucker's letter but one would be sitting at a desk -- at an outpatient clinic with the patient next to one or across the table and talking to them as one was filling out the form, the request form. And on those that we wrote "AIDS study", we would have said to many of the patients, "Look, we are keen to do some immune tests because of the association of a few patients getting AIDS in North America and we want to assess immune function in people in this haemophilia centre, who we don't think will have been affected by whatever the AIDS agent is."

THE CHAIRMAN: You see, Professor Ludlam, that depends upon the clinician communicating with the patient, not upon the patient reading the form for himself, which perhaps is a different approach -- or perhaps I should leave

Mr Gardiner to get on with it.

MR GARDINER: Yes, thank you.

Can I move on now to something that we talked about on Friday, which was your view of the number of initial samples that tested positive by Dr Tedder. I would like to ask you to have a look at [SNB0065996].

You remember that I suggested to you that Dr McClelland's recollection was that it was six patients who had tested positive initially and you thought that that wasn't correct but you weren't absolutely sure. Could you have a look at this memorandum here, which is dated 20 November 1984 from Dr McClelland to Dr Perrie and Dr Cash. Have you seen this before?

A. I don't think so, no.

Q. No. So 20 November 1984:

"Dear Bob, events leading up to the recall of Factor VIII batch 023110090."

Which is the implicated batch?

A. That is correct.

Q. Thank you. We see paragraph 1:

"On the evening of Friday 26 October 1984 Dr Christopher Ludlam telephoned me at home to let me know that six haemophiliac patients of his had developed antibody to HTLV-III. He thought that threat of these

seroconversions could be attributable to the use of PFC products. He stressed his desire to have confirmatory tests carried out and undertook to give me the results of these as soon as possible."

So this is a document which appears to have been prepared at that time and is recording six patients. If we just read on, paragraph 2:

"On Saturday 27 ... I called Dr Cash and discussed this information with him. We were both agreed that the information was insufficient to require any recall of PFC products.

"On 29 and 30 October I was off sick. Dr Ludlam contacted Dr Boulton to let him know that three of the haemophiliacs who had developed antibody had all received the above batch of Factor VIII. However, a number of other batches were involved. Dr Boulton telephoned this information to Dr Cash ..."

Then paragraph 4:

"On Friday November 2, Dr Ludlam telephoned me at home. He had, that afternoon, received further data from Dr Richard Tedder relating to a total of 16 of his haemophilia patients. An initial look at these data indicated that either 15 or 16 of these patients had received the above batch."

Now, first of all, would that accord with your

memory of the time between the two batches of results from Dr Tedder, 26 October and then 2 November?

A. I would have thought it would have taken me longer to get further results from Dr Tedder but this clearly says that it happened fairly quickly.

Q. Yes. I'm just wondering if that memorandum causes you to reconsider your recollection of the initial results. I think you told us on Friday that you had deliberately chosen patients who had only had SNBTS factor concentrates and that was why you were confident that it was only three and there weren't any patients who had had commercial concentrate. Could you perhaps just talk us through that, Professor Ludlam?

A. I'll try. It may be. The figure of three sticks in my mind because these were people who had all received SNBTS-only material and there may have been another three who had had commercial material and who were positive. And I would have made the quick assumption that maybe they got it from the commercial material. This would be before we had looked at the transfusion records. So that is a possible explanation. It was a long time ago -- I just remember the -- there were three that got one batch. That's what impressed me.

Q. Yes.

A. And it may be that there were three others who had got

commercial and because -- as I say, I assumed that they, in the first instance, without inspecting the transfusion records -- assumed that they might have got it from the commercial.

Q. Yes. But having looked at the transfusion records, you later discounted that. So that would mean that you had six positives initially. Is that right?

A. That's right, yes.

Q. Would that not be consistent with Dr Tedder's recollection of a litany, as he describes it, of positives on the phone, when he is describing "positive, positive, positive"? A litany. Does that suggest more than three?

A. I can't -- I have no evidence, written evidence, that there were three -- only three. I think that this document -- and it is written at the time -- suggests there were six and I think probably the explanation is, as I have just described, that the other three, if I can put it that way, had had commercial concentrate, and so in the first examination of these I had assumed that that might have -- those other three might have been infected from commercial concentrate.

Q. Yes. Can we have a quick look at [SNF0010255]? This is the note of the meeting of haemophilia doctors on 29 November 1984. If we go to paragraph 3, you see:

"Dr Ludlam explained the circumstances in which it had been discovered that 16 haemophilia patients treated exclusively with SNBTS Factor VIII had developed antibodies to HTLV-III ..."

So certainly by that stage you had decided that all of the positives were attributable to SNBTS concentrate?

A. Yes. I can explain -- I think I now can see the situation. There were -- and I made this information available to the Inquiry some time ago and I think we may have gone through it in the previous session, discussing B2, or the statistics.

There were two patients who received commercial concentrate in the early 1980s -- 1981/1982 -- but, because we stored serum samples on them, I was able to go back and test these, and in fact these two individuals did not get HIV from the commercial concentrates. We need to go forward a bit in time and I was able to show in fact that they got HTLV-III from the SNBTS batch.

Q. Yes. So perhaps your initial assessment was that some patients had had commercial concentrate. You later discover that that's not the case but that still leaves us with an initial report of six patients testing positive for the antibody. Is that right?

A. It would appear so, yes.

Q. Yes. So have you changed your assessment then of how many you were initially told by Dr Tedder had tested positive?

A. Sorry, I thought I had made that clear a moment ago. This is a document written within a few weeks of -- within a month, and it is likely to be more accurate than my memory.

Q. Yes. I think just to finish off the picture, I should also show you an email that we have had from Dr Tedder, which is [PEN0120856]. We will see that this is dated 11 May this year and it's a response to a question from one of the Inquiry team members, Gemma Lovell, and (i):

"We understand that Dr Ludlam sent you 10 samples initially and that three of these samples were found to be HTLV-III positive. When did you receive the initial samples? When did you inform Dr Ludlam of the results."

Dr Tedder:

"I simply am unable to give you the actual dates. I remember quite certainly that the results would have been generated in the early days of us using any radioimmunoassay rather than the more conventional and later EIA. I graphically recall my first discussion with Dr Ludlam as we went through a list of something like 10 to 15 samples where I gave him our results as positive or negative. This would have been around some

time in August 1984, when life was extremely taxing. I would have been likely to return results within a week or so of having received the samples."

He says August 1984 but you think that is not right for the reasons you gave us on Friday. You are nodding?

A. Yes.

Q. What about the 10 to 15 samples that were given initially?

A. Well, my recollection is we sent ten but if -- we might have sent 15 but -- yes.

Q. Of which six were initially reported as positive?

A. Yes.

Q. Thank you.

I would like to move on to the December 1984 meeting, which we started talking about on Friday, and I don't think that you gave us your assessment of how many people you thought were at the meeting?

A. I thought there were probably 30/40/50 people at the meeting. They were a little bit spread out in the lecture theatre. There were pairs -- or little groups of people who knew each other sitting together, and there were other groups of people and some people sitting by themselves. That sort of number is my recollection.

Q. Yes. How many people could the lecture hall hold?

A. It holds about 200 people.
Q. Okay. You told us that you remembered that Professor Forbes spoke first. Do you remember the audience reaction to what he had to say?
A. I don't. I think -- my recollection is people listened carefully to what was being said. I think there was surprise that patients had been found to be anti HTLV-III positive, particularly, it appeared, from Scottish blood transfusion Factor VIII concentrate.
Q. Yes. Were patients invited to ask questions after each speaker or was it questions at the end of the doctors speaking?
A. My recollection is that we each spoke in turn and then we had an open session for questions about anything that had been said or anything else that anyone wished to ask about.
Q. Yes. You told us that your recollection is that you spoke after Professor Forbes. Do you remember if you spoke from a prepared script or notes?
A. I don't think so, no. I spoke without either.
Q. Do you remember how long you spoke for approximately?
A. I would think about ten minutes.
Q. Ten minutes. Okay. I would like to return to what you told us just at the end of Friday. So could we look at page 133 of the transcript, please? You see at line 5.

"Question: Who spoke next ...

"Answer: I suspect probably me."

I think you are now starting to give us a description of what you remember you said at the meeting. That's right, isn't it?

A. Yes.

Q. You say:

"To explain what had been happening in Edinburgh, what I had been doing, what the results of the tests were."

And you explain that what you had been doing was sending samples to Dr Tedder and you also explain that:

"... it appeared that there had been this single batch of Factor VIII but also that there were other people who were or might be infected or might be antibody positive."

Then you talk about it being a time of great uncertainty. You talk about:

"Everyone with haemophilia might be infectious."

And:

"The safety advice applied not only to the possibility of sexual transmission but if there was spillage of blood."

What I wasn't sure of was were you telling us there that that was something you told the meeting as well?

A. Yes.
Q. Yes, thank you. Then if we just read on to page 134, at line 8:

"The very clear message given out was that we hoped that patients would come and see us and ask about their situation."

Then you say:

"We would have encouraged them to come and ask about the results."

I think you mean there. Then over the page to 135, the question is:

"What did you say about testing, if anything?

"Answer: If they came to see me, if I had the test result from Dr Tedder, and if they wished to know it, I would let them have it. But I would also want to suggest that they give another blood sample to, if you like, confirm the preliminary result from Dr Tedder, both because of the possibility of samples being misidentified or false positives and false negatives in Dr Tedder's test."

Are you suggesting that you remember saying that at the meeting as well?
A. Yes.
Q. Thank you. Then you say:

"And I would have talked round the importance of the

possibility they might be infected even if they were antibody negative."

Then:

"I would give them the result, if they wanted to know it."

Again, were you telling us there that that is something else that you said at the meeting, that patients, if they wanted the result, they could get it from you?

A. Yes, I was keen for people to make appointments to come and see me to discuss whether or not we had a result on them and if they would like to know it. And we could discuss that and I could give them the result. But it's a very important result and I think, to depend upon a single sample, particularly of a newly developed test that one had some hesitation about its sensitivity and specificity, I think was only prudent and perhaps essential.

Q. You say you were "keen". I know it's a long time ago but I'm asking you to specifically try to remember what you said about that.

A. Well, I would ask, "Please could we have another blood sample".

Q. I'm talking about at the meeting?

A. I'm sorry.

Q. Do the best you can to give us the words that you used to express what we are talking about here, getting results?

A. I think I would have said, "We are keen to see you. We can let you know the preliminary result if we have it, but we would also want to take blood from you to check it, if you are agreeable."

Q. Yes. I mean, if we have it, just to clarify, what percentage of your patients had been tested at this point?

A. I would have thought we had probably tested 40 or 50. Somewhere between -- as we have agreed earlier -- 10 or 15 in the fist batch. Professor Tedder was very helpful in wanting to help test more but not too many. So we had to be a bit discriminating. And so I think we chose samples from individuals we thought were perhaps more likely to be positive and those would be the big users or the people who had received this implicated batch, because we had a -- we thought this might have been the implicated batch from the initial few samples and we might well have looked out the samples from other people who got that batch.

Q. Yes.

A. But we must have -- we tested quite a range of patients because we then had the task of trying to pin down, as

best we could, which the implicated batch was, and that was quite a lot of work for Dr McClelland and myself: drawing up a large spreadsheet and counting up numbers of patients.

Q. We are going to come on to that, Professor Ludlam, but just to bring you back to the question: is that 40 per cent of your patients or 40 of your patients?

A. I would have thought 40 or 50, perhaps in the second tranche.

Q. 40 to 50 of about 200?

A. Well, I think there were 170.

Q. Yes.

A. Roughly.

Q. Yes. So was that explained to the meeting, that there was a category of patients who hadn't been tested? There was a category that had been tested and there are results available and some of them are positive but there is another category of patients. Was that explained?

A. Yes, surely, because we hadn't tested everybody and we would have explained that not everyone has been tested and we might have -- I'm sure we would have said, "We are sending -- we will be sending more samples to Dr Tedder or to the local virology lab when they have set up the test".

Q. Just to remind you that I'm asking about what you remember you said at this point. Right, well we have had a review of what you have told us about your recollection of the meeting about what you said, and we have clarified that a bit. Is there anything else that you remember that you told the audience at the meeting, when you spoke?

A. I think we have been over it most -- I think we have been over all this morning and on Friday -- the other obvious message I was very keen to get across was that everyone, irrespective of whether or not they had been tested or whether or not their test was positive or negative, should for the time being consider themselves potentially infected and use the safety precautions for the spilled blood and for sexual activity.

Q. Yes.

A. That was very important.

Q. Thank you. Do you remember what the reaction was to what you said?

THE CHAIRMAN: At the meeting at this stage?

MR GARDINER: Thank you, sir, sorry. At the meeting, yes.

A. There was surprise and I think some dismay that individuals who had been treated exclusively with SNBTS product had -- or appeared to have been exposed to the virus.

Q. Yes. You say that because of how you remember the audience reacting? I'm specifically asking about after you had spoken.
A. That's my recollection. There were people who were -- I think the best word is "dismayed". Surprised and disappointed and taken aback.
Q. Yes. What I'm not quite clear about, professor, is whether you remember whether you told the meeting how many of your patients had tested positive for the antibody.
A. I think it likely -- I'm sure I would have done because we were there to give out any information we had and it was a number and we would have said -- I would have said, you know, "So far it looks like there were 15 or 16 people," to put it in context.
Q. Yes, and that they had been treated exclusively with --
A. Yes.
Q. Scottish product?
A. Yes.
Q. Yes, thank you.
A. Well, that it had arisen -- the apparent infection had resulted from the SNBTS product.
Q. Yes.
A. Rather than they were treated exclusively with SNBTS product for the reasons we discussed earlier.

Q. We heard from Geraldine Brown, who was also there -- that's correct, isn't it?
A. That's correct, yes.
Q. -- that the lecture theatre was very cold due to some malfunctioning air conditioning or something. Does that ring a bell with you?
A. I had forgotten it until I heard Geraldine Brown -- because I was in the gallery at the time. I had forgotten that but I do remember that, and I do remember asking her to stand on the door, about the press, but I remember specifically at the beginning of the meeting asking if there was anyone from the press there. I have a very clear memory of doing that.
Q. Did anybody else speak at the meeting?
A. Dr McClelland.
Q. Yes.
A. Yes.
Q. And what did he say?
A. I think he discussed the -- what appeared to be the batch of contaminated material and how and I had looked at the records and tried to see if we could pin it down to a single batch. And then he went on to talk about what blood transfusion was doing to reduce the chances of another person -- or a donor giving a donation because they were in a high risk group and were

infected.

Q. Yes.

A. And he would have gone on -- I'm sorry, perhaps I should have -- because this was clearly an important item that Dr McClelland, and I suspect I and Dr Forbes would have mentioned it -- about the heat treatment. We would have explained that there was some evidence that HTLV-III was heat sensitive and that from then on, the middle of December, not only was the blood transfusion going to only issue heat-treated Factor VIII but we asked the patients to bring back their non-heated Factor VIII that they might have at home and exchange it for heat-treated material.

So we were asking people to bring back their bottles and we would give them out some heat-treated material instead. That was a strong message and I think we probably also -- the haemophilia sister afterwards would have been in touch with individual patients and said, "Please bring your material back", because not everyone was at the meeting.

Q. So you mentioned the strong message about exchanging non-heat-treated products. Is that right?

A. Yes.

Q. In addition to what you told us?

A. Yes.

Q. And your recollection is that Dr McClelland mentioned that as well?
A. I'm sure he would have done, I'm sure he did, yes, because that was very much a blood transfusion issue.
Q. Yes. How long did Dr McClelland speak for?
A. I would have thought 10 or 15 minutes at the most.
Q. Is it your recollection that he mentioned the specific numbers of patients that had tested positive as well?
A. Well, there was an agreed -- there was a number, 15 or 16, that was the figure we both used and worked on because that's the number that we had.
Q. Yes, and do you remember if he mentioned that to the audience?
A. I think he would have -- would well have mentioned it because he explained that we had been through the records and we had looked at the number of people who had received -- who were positive, who had received different batches, and that this particular batch, the 0090, was the one that most patients had received.
Q. Yes, thank you. Can you remember anything else that Dr McClelland told the meeting?
A. He may well have imparted discussion about asking donors to defer if they were in a high risk group. I think he would have discussed that he had had discussions with the gay groups in Edinburgh, because I know he had

worked quite closely with -- I think it was Derek Ogg and others to address this issue, which was a difficult issue.

Q. Yes. To defer from donating blood?

A. Yes.

Q. Yes, thank you. Perhaps we could have a look at [PEN0161294]. This is an article from the evening news from two days after the meeting. Have you seen this before?

A. I have.

Q. Yes. There are quotes from Dr McClelland there. If we look at the second column under the heading "Vulnerable":

"Dr McClelland said: 'The 15 people were discovered as the result of routine testing of those most vulnerable because of their reliance on frequent transfusions'.

The situation was explained to haemophiliacs at a meeting with medical experts in Edinburgh this week. All of them will be carefully monitored and hopefully none of the 15 exposed cases will develop the disease."

Is that broadly consistent what you remember Dr McClelland telling the meeting?

A. Yes, I could add that he would have made it -- he would have asked, which -- this being customary for a long

time -- for patients with haemophilia and now their families, not to be blood donors, to refrain for the time being from being blood donors.

Q. Yes, thank you.

A. That was a slightly sensitive issue.

Q. I understand. We can put that away now, thanks. So what happened next in the meeting?

A. There were question and answers. The floor was opened up to questions and I think -- my recollection is Charles Forbes, as chairman, invited questions and he, I or Dr McClelland answered them, depending on what the questions were.

Q. Yes. How long did that go on for, do you remember?

A. I can't exactly. It might have been half an hour/three quarters of a hour. We went on until the questions were exhausted.

Q. Yes. Do you remember what the questions were about?

A. I don't have a strong memory or really very much memory at all about the questions. I think there was -- as I say -- some anger and perplexity about the Scottish product having infected people, when we had hoped, for many reasons that have been rehearsed here already, we were going to not see this misfortune.

Q. Yes. Do you remember any discussion of the relative safety of commercial concentrates as opposed to Scottish

blood products?

A. There might well have been. I'm sorry, I can't remember but Dr Forbes will have told the meeting about the results that he had at that stage, and some of those were individuals who had become apparently infected from commercial products, and I can't remember at that stage -- as you see, some of my patients had received commercial concentrates and were anti HTLV-III positive, and almost certainly at that stage I wouldn't have known where -- whether it was the commercial or the NHS that had caused the infection.

So I might well have said there were some patients in Edinburgh who may have become infected from commercial. So I'm sure there must have been some discussion about NHS versus commercial.

Q. What about questions about the implications of these results? Do you remember any questions on that topic?

A. Well, there were implications -- we had spelt out some of the implications. I can't remember, but I suspect it very likely, someone would have asked me, "If someone is anti HTLV-III positive, what's their chance of getting AIDS?"

Q. Yes.

A. I think it highly likely someone would have asked that. I mean, they are a well-informed, bright group of

patients and it's the obvious question to ask.

Q. And what was the answer given?

A. I think the answer -- certainly the answer I was giving patients early in 1985 -- I would talk about the limitations of a positive test when I was seeing people but your specific question, I would have said, "At the moment the chances it appears of someone like you, who is anti-HTLV-III positive -- the chances of you getting AIDS appears to be very small." And I would give them the statistics, which was about one in 500. I well remember doing that.

Q. Yes. Thank you.

I think you told us that when the question and answer session finished, the meeting just broke up. Is that right? There wasn't any individual discussion with doctors. Is that right?

A. About individual patient results?

Q. Well, perhaps I can just ask you: what happened after the question and answer session?

A. Dr Forbes drew the meeting to a close and people chatted for a little while. They got up and went off home.

Q. Yes. Was there any individual discussions between patients and doctors, private discussions, if you like?

A. I don't recall any.

Q. No. Thank you. So just looking back at the meeting,

what do you consider was the message that you had given to patients about what they should do next about testing?

A. Oh, that they should come -- I was very keen they should come and see us.

Q. Yes.

A. If they wanted to.

Q. For a patient who had haemophilia and was one of your patients and had been receiving a Scottish factor concentrate, what was the message to them about whether they might have tested positive?

A. Well, the majority, we thought -- and now is the case with full examination -- the majority unfortunately of people who became anti HTLV-III positive in Edinburgh did so from this single infected batch.

Q. Yes. I'm really trying to focus on what a patient would think at the end of the meeting about their own personal situation, if they were one of your patients that had been receiving Scottish factor concentrate?

A. I think -- because the message I wanted to convey, which is, "You might be positive," the other side, of course, of this is that the majority of patients were actually negative. And I think from Dr Forbes' study, I think -- if I remember rightly -- something like 10 or 15 per cent of patients that he had studied had been

positive, if they have had Scottish material, and a higher percentage if they had received commercial.

So there were a lot of people who were negative and more people actually who were negative than positive. So a patient might have gone away with the message, "Oh, well, I'm likely -- because there were more people negative than positive, I'm likely to be one of the lucky ones". It's how one accepts bad news. We always like to think, to begin with, that we are on the winning side, if I can put it that way.

Q. Yes. But you are clear that the message that had been given was: "You might be positive"?

A. Yes.

Q. Okay. Can we just have a quick look at the transcript for 8 June. This is the evidence of Dr Alison Richardson, who I think you worked with?

A. Yes.

Q. Is that right?

A. She came to work with us in -- 1987 I was first approached. I think she actually started in about early 1988.

Q. Yes. At line 11, Dr Richardson told us that she saw some of your patients who had tested positive subsequently. You are nodding?

A. Yes.

Q. That's right, isn't it?
A. Yes.
Q. So if we just read from line 10:
"Question: In respect of their diagnosis with HIV, and you were made aware from that, from seeing these patients, there had been an urgent meeting with Dr Ludlam in about 1985, you say."
I think that should be "1984".
"Answer: I can't be sure of the date but certainly two or three of the haemophiliacs discussed it possibly, I think, within the group.
"Question: Right, but you obviously weren't in post at that time?
"Answer: No.
"Question: Were you at the meeting?
"Answer: No.
"Question: No. You say, further down that paragraph:
"'From what I have heard from the patients I spoke to subsequently, Dr Ludlam told them that some people with haemophilia in Scotland were Infected with HIV.'"
Just reading at page 8:
"That's right.
"Question: Yes. And you mention specifically what two of your patients had taken away from that meeting.

"Answer: Yes.

"Question: This was that they were told at the meeting to use condoms when having sexual intercourse with their wives."

It's the next bit I would like your comment on, professor:

"The general feeling, you say, of those two patients leaving that meeting was', Well, thank goodness I don't have it because if I had, he would see have told me'.

"Answer: That's correct."

These are two patients who did test positive.

Would you accept, Professor Ludlam, from that account that it seems that your message, "You might be positive," doesn't seem to have been picked up by at least some of the patients at the meeting?

A. Well, that substantiates what I was saying about two minutes ago, that we all like to think we are in the better prognosis group. This does not surprise me.

Q. I suppose there are two parts to the assessment. The first assessment, where the patient will be, "I am at risk", then the next assessment will be, "Am I in the group of people who have tested positive or have tested negative?" But the first part, "I am at risk", doesn't seem to have been communicated to these patients:

"Well, thank goodness I don't have it because if

I had, he would have told me."

A. I would see is differently. They went away appreciating the need to use condoms. So they must have picked up that there was a possibility that they had got HIV or HTLV-III. That was why we were saying, "you have to use condoms".

Q. Yes.

A. I appreciate that they may not have seen it that way.

Q. I think that you were at that point advising patients who had tested negative to practise safe sex as well. Is that not right?

A. Yes, because we weren't certain that they weren't infected. We were saying to everybody, "For the time being, you have to assume that everyone with haemophilia who has been treated over the last few years may well be infected with HTLV-III."

Q. Yes. Perhaps you would accept, professor, that these two patients that Dr Richardson refers to do not have appeared to have received your message, "You might be positive."

Would you accept that?

A. They have not synthesised the information that was available to them, in that they had taken away half the message and they would like to believe that they were in the larger group, who were anti HTLV-III negative.

Q. Just bear with me. (Pause)

All right. I would like to move to after the meeting now. Could you tell us what steps were taken after the meeting to communicate further with patients on this topic?

A. I think the next thing was to prepare the circular that we sent out to patients. This I prepared in conjunction with Dr Forbes in Glasgow, and the intention was to send it out to everyone with haemophilia in Scotland because not everyone had been at the -- at this meeting on 19 December.

Q. Yes. So do I take it that the intention was to communicate similar messages in the advice sheet to the messages that had been communicated at the meeting?

A. Yes.

Q. Thank you. Was that done?

A. Well, we sent out the information sheet. A copy has been shown here.

Q. Yes.

A. So, yes, that was done to everybody.

Q. How many patients was it sent to by your centre?

A. We would have sent it to everyone on our register.

Q. Yes. So about 175?

A. 170, something like that.

Q. 170. I think I'm right in saying that you have not

managed to recover a copy of the letter that sent the advice sheet out. Is that right?

A. That's correct, yes.

Q. Are you able to say when it was sent?

A. Probably 31 January.

Q. Why do you say that?

A. That's the day we wrote to the general practitioners and I suspect -- I have a sort of recollection of it all being done together.

Q. Right.

A. But -- I don't think we would have sent out the circular to the patients before we wrote to the general practitioners because the patients might have gone the following day, after receiving our circular, to the general practitioners. It was only fair to let the general practitioner know.

Q. Yes. Could we have a quick look at the letter, the letter to the GPs. [LOT0022489]. Is that an example of one of those letters?

A. It is.

Q. We see that's dated 31 January 1985?

A. Yes.

Q. I think you provided this copy letter to the Inquiry, professor. Where did it come from? I don't want you to say the name of the patient but did it come from

a patient's file?

A. I'm not absolutely certain. We did file these in the patients' notes. If I could see the -- if this was from a patient's notes, we would have whited out, so on the original you will see whiting out. We had copies of this -- this may have been one of the copies that wasn't sent. There were a small pile of copies that aren't sent. So, I'm sorry, I can't -- it looks such a clean copy, I suspect this hasn't come from a patient's notes.

Q. But are you clear that this is the text that was sent out at the end of January 1985?

A. I am.

Q. Thank you. Well, I want to come back to that but can we have a look at the advice sheet, please, [PEN0120495]? Is that the advice sheet that was sent out with the letter?

A. No, this advice sheet was not sent to the general practitioners. This advice sheet was sent to the patients.

Q. Yes. Thank you.

A. The general practitioners received the letter that was on the screen a moment ago.

Q. Yes. But not the advice sheet?

A. Not the advice sheet.

Q. Thank you.
A. We perhaps should have done so but we didn't.
Q. But this was the one that you told us was sent at the end of January 1985?
A. To the patients.
Q. To the patients. Thank you.
A. Yes.
Q. Thank you. Who drafted this advice sheet?
A. It was a combined effort between myself and Dr Forbes.
Q. Thank you. So do you know what he did with this advice sheet?
A. I think he actually did the first draft of it because he set it out with these questions. That's my feeling and he sent it across to me for -- for me to put in my suggestions.
Q. Yes.
A. I'm not absolutely certain about that. It's possible I started it but my recollection was it was probably him.
Q. But it was a combined effort?
A. That was a combined effort, certainly.
Q. Do you know if he sent it to his patients?
A. I don't because I have seen a further letter, dated 8 January 1985, which appears to be one that he sent to his patients.

Q. Yes. Thank you.

The thing that I have noticed, Professor Ludlam, is that this advice sheet does not appear to contain the important information, that some Scottish patients with haemophilia have tested positive for HTLV-III. That's right, isn't it?

A. I'm sorry, I can only see a small segment on the screen.

Q. Sorry.

A. If I have got a copy --

Q. Just take your time. If it's easier to work from a hard copy. (Pause)

A. Yes. Your question was again?

Q. The question was that this advice sheet does not appear to contain the important information that some Scottish patients with haemophilia have tested positive for HTLV-III.

A. No, but it mentions that individuals --

THE CHAIRMAN: Paragraph 6, professor.

A. Yes.

MR GARDINER: I think the closest it comes is perhaps paragraph 6.

A. And somewhere else I saw listing the risk groups. I thought I saw. (Pause)

In paragraph 3, I'm sorry, it says:

"Intravenous drug abusers, haemophiliacs and some

blood transfusion patients are probably infected by blood-borne transmission."

Q. So it's paragraph 3 you are referring to?

A. Yes, the penultimate -- it doesn't say the Scottish patients but it says that people with haemophilia --

Q. Yes.

A. -- are at risk.

Q. Yes.

A. Yes.

Q. Well, at risk?

A. Well, are probably infected.

Q. Just looking at paragraph 6, the third line:

"Exposure to the virus results in the body making an antibody (HTLV-III Ab) to the virus protein and this is now used as a marker of exposure to the virus. These tests are now available and will be carried out on your routine visits to your centre. About half the patients in England and about 10 per cent in Scotland have had exposure and are HTLV-III Ab positive."

I wonder if you think, Professor Ludlam, that that conveys the message to patients that, "You might be positive"?

A. As I was saying earlier, people would like to believe they are in the 90 per cent, rather than the 10 per cent. This would have been sent out with

a covering letter, encouraging -- saying that there were people who were positive and asking them to make appointments if they wished to know.

Q. But if we just stick on that paragraph there, can we really say that a patient reading that would clearly get the message there have been tests done, the results are that some people with haemophilia are positive and that they themselves might be positive?

A. They might have thought that they were going to be tested when they came up next to the clinic or they might have asked about it when they were coming up to the clinic. Are they going to be tested.

Q. I'm just wondering whether you think that that communicates the message that you were trying to get across at the meeting to a patient that, "You might be positive. Because of this new information that we have, you might be positive." Do you think it does?

A. I think if you get a leaflet of three pages closely typed saying "Acquired Immune Deficiency Syndrome", and this is known to be something of great concern in haemophilia circles -- you get this through the post with a covering letter, particularly in a situation where, you know, we had hoped this virus wouldn't come at that particular time. I would have thought it would make the majority of people sit up and -- and indeed it

did make people sit up and come and see us. That's what happened.

Q. Yes. Is it by putting together what's in paragraph 6 with what's in the covering letter that allows the patient to come to that conclusion?

A. Well, and also all the other things that were going on at the time, the reports in the press, the exchange of material for heat-treated, giving out condoms in the haemophilia centre, Geraldine Brown talking to the patients about their situation, the network of patients, which in those days was a much closer network because they knew each other better because they often attended for their treatments before home treatment became available. So the whole range of things that were happening, rather acutely, end of December/early into 1985, that would have alerted everyone, I would have thought.

Q. Yes. I am trying to focus just on this advice sheet at the moment. Is it what's in paragraph 6, taken with what's in the covering letter, that allows a patient to come to the conclusion that they might be positive? Is that what you are saying?

A. And all the other things that were going on that I have mentioned, at the time.

Q. Right. So the advice sheet and the covering letter on

their own are not enough to get the message across to the patient?

A. I would have thought they were enough to get the message across.

Q. Yes. Can we be clear about your recollection of exactly what was in the covering letter?

A. I would have said that, "Probably there has been a meeting that you may not have been able to come to" and that this was -- there was some important information to convey, "Some patients had tested positive in Scotland". I might well have said, "from Scottish Factor VIII". I might well not have done, I'm not sure. But, "Here is a leaflet explaining the current knowledge, as we understand it, and if you would like to know your results of the test, it may or may not be available but we could certainly -- if you would like to be tested, make an appointment to come and see us or come and discuss your situation with Geraldine Brown".

Q. Because the letter is sent to some patients that haven't been tested?

A. Yes.

Q. So how did you draw the distinction between patients who had been tested and whose results were available and patients who hadn't been tested but who could have a test?

A. They would all have got the same letter.
Q. But in the letter was there a distinction drawn between patients who had already had a test and patients who could ask for a test?
A. I would have said, "Some patients have been tested and found to be positive but we haven't tested everybody".
Q. Professor Ludlam, you would have realised at the time what you are saying now, that people won't want to believe that bad news applies to them, so did that not make it necessary to be explicit?
A. Well, I would have an obligation to inform patients of their antibody result if it was going to make a difference to either the way they lived or treatment that might be available for them. And at that time there was unfortunately no treatment available and there were some patients who clearly didn't want to know, and so, as there was no, in a sense, material gain from knowing, then it was a patient's prerogative not to know.
Q. Surely at this stage, at the end of January 1985, you didn't know whether patients wanted to know or didn't want to know?
A. I didn't know. That's why I was writing to them.
Q. What I was suggesting to you, Professor Ludlam, was that because everybody wants to believe that bad news doesn't

apply to them, did that not make it necessary to be explicit in this communication about what the situation was?

A. Well, it depends how much you want to encourage people, substantially encourage people, to be tested and to know the result.

Q. Yes.

A. And at this stage there was -- and I don't know if we are going to go on to discuss the ins and outs of the test later on, but at one level there was not a lot to be gained by knowing the result, and there was a school of thought amongst a few physicians that actually you should just assume that everyone is anti HTLV-III positive and they shouldn't be told the results. And there is not a great deal to be gained by testing.

Q. Yes. Were you part of that school of thought?

A. No. But I had to take cognisance of it. I was of the school of thought that it was not essential for medical reasons or for social reasons for a patient to know and, as I think is -- as it rolled out. There were some patients who have said they were very pleased that they didn't know at the time. That is -- all these patients are very different and have very different reactions and very different memories, I suppose, but very different reactions to where they find themselves in life and

whether they want to know this sort of information.
Q. Yes. At this stage, Professor Ludlam, the stage that you are sending out the advice sheet, were you encouraging your patients to find out the results of their tests?
A. I think I was encouraging them because it sort of -- it was, if you like, one -- removed one aspect of uncertainty. Uncertainty is -- can be very difficult to live with, very stressful, and when pre-AIDS -- pre-HTLV-III counselling came along, that added, in a sense, another tier to the uncertainty and difficulties, but it was -- it was a situation at that time in which there was a great deal of uncertainty and, as I say, I don't know whether we are going to go on to talk about how you might interpret an antibody positive or negative result, but that was added to the uncertainty and so by not knowing the results, you were taking away one uncertainty and substituting another.
Q. Yes. Are you telling us that part of the reason that this advice sheet wasn't explicit is because you were allowing for the school of thought which said that patients shouldn't be told about their results?
A. No, I was more of the view that patients -- perhaps just I would feel happier if the patients knew but I was not going to insist that they should know unless I could see

some positive gain for them.

Q. Yes.

THE CHAIRMAN: Mr Gardiner?

MR GARDINER: Yes.

THE CHAIRMAN: Is that an appropriate moment?

MR GARDINER: I think that is good time for a break, sir.

THE CHAIRMAN: We will have a break at that stage.

(11.11 am)

(Short break)

(11.37 am)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Professor Ludlam, just going back to the letter that sent out the advice sheet, could you tell us again, what did it say about appointments, if anything?

A. I think I would have invited -- I would have said, "If you would like to know more, phone up and make an appointment to come and see me."

Q. That's consistent with what you were telling us before the break, which was your intention not to insist that your patients found out the results of their tests. Is that right?

A. That's correct, yes.

Q. Thank you. Before we moving on, is it right that there was another advice sheet sent out, which was to do with

children?

A. I think there might have been, yes.

Q. Do you remember how that differed from the advice sheet that we looked at?

A. I think it didn't make mention of sexual activity.

Q. Yes. Thank you. Could we have a look at [LOT0034244]. This is a letter dated 8 January 1985. Have you seen this before, Professor Ludlam?

A. I saw it on Friday. It was given to me. I think I have seen it before. I saw it probably in about February or March 1985 because I think this was brought with a bundle of documents by Dr Forbes to a meeting of the UKHCDO AIDS group. I think it had its first meeting in February or March in London in 1985. This appears to have come from my files because I'll claim the writing at the top, "AIDS haemophilia directors working party."

Q. Yes. If we go to page 3 of [LOT0034244], the last page of the letter, we see there that that's signed by Dr Lowe and Professor Forbes?

A. Yes, that's right.

Q. Thank you. If we just go back to the first page, we see that the letter starts off by referring to:

"... recent publicity in the newspapers and television concerning an increasing risk of the disease known as 'Acquired Immune Deficiency Syndrome' in

haemophiliacs who have received treatment with clotting factor concentrates."

And goes on to talk about what has been recognised in recent months. Then the third paragraph:

"The risk of the disease, AIDS, in haemophiliacs appears to be very small and less than the risks of bleeding. We therefore recommend that you should continue treatment with clotting factor concentrates. Several steps have been taken to reduce the risk of viruses in the clotting factor concentrates. All blood donors discovered to be at risk of AIDS are being excluded from blood donation. All Scottish Factor VIII concentrate is now heat-treated to destroy the virus."

In the next paragraph there is a discussion:

"... we do not yet have a blood test for the virus particle but hope to have this within the next few months."

Then it goes on to discuss studies in England. In the middle of that paragraph:

"Recent studies in England have found that about half of regularly treated haemophiliacs have positive antibody tests. We have recently tested stored blood samples from many of our patients, of whom about 10 per cent have positive antibody tests."

So would you agree, Professor Ludlam, that that's

different from what is in your advice sheet in as much as it refers to "our patients". It's very much drawing attention to Glasgow patients? Maybe we could go back to page 2 of [PEN0120495].

A. Yes, this -- one must presume this refers to patients under the care of Dr Lowe and Dr Forbes, yes.

Q. Yes. I'll just wait to get it on the screen. So in your advice sheet --

THE CHAIRMAN: Could we have them side by side, possibly, Mr Gardiner, because there are several interrelationships between the documents that might be of interest.

We try to put things in context a little. If you look at the second page of the Glasgow letter, if I can call it that, we see that the series of recommendations under "Secondly" has, in effect, been adapted from paragraph 7 of the letter you described as the "agreed letter".

A. That's correct.

THE CHAIRMAN: One or two of the paragraphs have run into one another or have been combined rather than presented separately but the information is just the same.

A. Yes.

THE CHAIRMAN: In fact if you compare the font, at least in the copy I have, the hard copy I have, Mr Gardiner, you

will see that the second page of the Glasgow letter is in a distinctly different font from the first and the third.

MR GARDINER: Indeed, yes.

THE CHAIRMAN: It looks as if there has been a cut and paste job done to incorporate the advice. In each case, if we go back a little, the information in what was paragraph 6 in your agreed letter, or the letter you discussed with Professor Forbes, has been brought forward on to the first page, but each talks about 10 per cent.

One says 10 per cent in Scotland, and if Mr Gardiner's interpretation is right, the other one is saying that precisely the same percentage of infection applies in Glasgow. Would that ever have been accurate?

A. I think it fair to say that patients, as far as I recall, at this stage hadn't been tested in Dundee, Aberdeen and Inverness and therefore this estimate is based on patients looked after, I think, in the central belt of Scotland.

THE CHAIRMAN: I appreciate that that's so from other information. So it can't have been all of Scotland, if it were accurate.

A. That's correct, yes.

THE CHAIRMAN: And if it's the central belt, was it ever the

case that the prevalence east and west was precisely the same?

A. Almost certainly not.

THE CHAIRMAN: Yes.

I'm just not all that happy about spending a huge amount of time on a sort of analysis of language where what we may have here is just a very general estimate, Mr Gardiner, of a level of prevalence to communicate to patients that it is not everybody but is a significant percentage.

MR GARDINER: Yes, thank you.

If we read on in the Glasgow letter, at the bottom of the page, we see:

"We are writing to you now for three reasons:

"Firstly, we enclose an appointment to see you. It is important that we take a blood sample from you for the virus tests, so that we can monitor virus exposure in all our patients who have received factor concentrates. We would also like to perform some skin tests which measure the body's defences against infections. At the same time we will be very happy to give further information and to answer any questions you may have about the virus and the tests."

If we go to the final page, it says:

"We will be very happy to talk with them about such

concerns. Please bring them along with you if you would like us to do this."

Then:

"If the enclosed appointment is unsuitable, please ring Sister Campbell ... for another one."

So there is a difference there, Professor Ludlam, because this letter from Glasgow is making an appointment for the patient and if the appointment is not convenient, the patient is asked to phone up and make another one, whereas I think from what you told me earlier, your letter was less prescriptive about coming for an appointment and it was left more up to the patient whether they wanted to come or not. Would that be fair?

A. I didn't send out appointments. I invited patients, if they wished to be tested or to know more, to make an appointment to come and see me. And I think the difference in approach reflects the difficulties around at the time. I'm sure -- I think Professor Lowe is going to come and give evidence and I'm sure he will be able to tell you more about what happened in Glasgow. But it would appear from this letter that there was more of an emphasis in Glasgow on testing individuals and telling them the result.

Q. Yes.

A. Than on this side of the country, where I, in a sense, gave more responsibility to the patients, to think about it, to discuss it with their spouse, with Geraldine Brown. They could easily go to one of the counselling facilities that were set up independent of haemophilia centres, so that they could get an outside view, and I was making myself available to see them if they would like to come.

Q. Yes. That's consistent with your approach, which is not to insist that results are communicated to patients?

A. That's right, yes.

Q. Yes, thank you. I propose to move away from the advice sheet.

THE CHAIRMAN: Yes, thank you.

MR GARDINER: Professor Ludlam, I am afraid I would like to go back to the Dr Tedder communication and that is because the Inquiry is still a little bit uncertain about dates and I would just like to press you a little bit on the date that you found out from Dr Tedder about the initial tests.

Could we have a look at [SNB0065996] again, please?

I think you told us that as soon as you finished speaking to Dr Tedder, you got in touch with Dr McClelland by telephone. Is that right?

A. Yes, that's my recollection. That's what I would have

done.

Q. So how long would the interval be?

A. Five or ten minutes.

Q. Thank you. If we look at paragraph 1 there:

"On the evening of Friday 26 October Dr Christopher Ludlam telephoned me at home to let me know that six haemophiliac patients of his had developed antibody to HTLV-III. He thought that three of these seroconversions could be attributable to the use of PFC products. He stressed his desire to have confirmatory tests ..."

What is confusing us is how you were able to come to that conclusion that the conversions were attributable to the use of PFC products within the space of five to ten minutes? How did you work that out?

A. I'm sorry, I'm sure I telephoned Dr McClelland to say that patients had been found to be positive straight away.

Q. Yes.

A. But the fact that three were attributable to -- possibly to SNBTS material clearly would have required me to go and look at the transfusion records. Yes, that would take a little while to do.

Q. Yes. He seems to be recording the fact that he gets the information all in one phone call. I suppose what I'm

getting at --

A. I'm sorry --

Q. What I'm getting at, Professor Ludlam, is: is it possible that there was more of a gap than this time that you have given us between phoning up Dr McClelland and passing on this information? Is it possible that you got the information from Dr Tedder, then went and checked your transfusion records, then phoned Dr McClelland?

A. No. I can help you. I think I would know -- these were all named patients. There were, let us say, six that were positive. I would know from my memory which ones had had commercial Factor VIII and the other three, I would be pretty certain, hadn't had commercial Factor VIII because, us you know, only a small number of people had received commercial Factor VIII in Edinburgh and I knew their names. And therefore, as soon as I knew the names who were positive, I would know which had had commercial and which were probably SNBTS only.

Q. So at the time you would have remembered that three of the patients had had commercial concentrate and three had had SNBTS product?

A. Yes.

Q. Yes.

A. I would know the names -- there are only a small number

of people who had received commercial concentrate. Well, you have the information. And I could give you the names now -- you won't want me to do that -- but I knew exactly who they were.

Q. I seem to remember that on Friday you told us that you had deliberately selected ten patients who had only received SNBTS concentrates?

A. I was probably wrong. I probably included some commercial ones, you know, to see what the answer would be.

Q. So now that you have thought about it, you think you were wrong when you told us that on Friday?

A. I think I probably was, yes.

Q. Yes. Okay. Could we move on to the topic of arrangements for testing of your patients after the meeting or perhaps more accurately, passing over the results? Could you tell us what happened next with your patients in terms of receiving results and so on?

A. I was contacted through the haemophilia centre by patients who wanted to know the results and I saw them usually at -- outwith clinic times. It's a time when we were very short of clinic space. I have provided the Inquiry with a summary of the development of the haemophilia service but at that time we had a single room with a small partitioned area off in one of the

wards, which we called our "haemophilia centre", which was for the treatment of acute bleeds, basically.

The patients were seen for their routine reviews in the general medical outpatient department. So I did not have anywhere else to see people with some degree of privacy, and I remember having to borrow rooms in one or two of the other wards, to find out where there was a free room to see someone.

So it was unsatisfactory but I wanted to give the patients a bit of space and time and have a bit of privacy. The facility we had in ward 23, the partition wall between the waiting area and the tiny clinic room, was thin and I don't think there was even room to sit down actually in this little room. We had a couch and a filing cabinet. So I had to find other space. So it was not satisfactory but I had to make do.

Q. Yes. So when would this process have started?

A. Oh, I don't remember being contacted by patients before the beginning of January but thereafter they would ask to come up and see me. Sometimes they would come up to collect home treatment, for example, and the nurse would say, "So and so is here, they would like to see you if you are available."

Or the nurse might say, "Would you like to see Dr Ludlam?" And if I was available I would come along

and see them. So it was a very sort of ad hoc, unstructured arrangement.

Q. Yes. The Inquiry has heard evidence that one patient received his results by the end of December 1984. Is that --

A. That's possible. There may well have been people, because this meeting was on -- we are agreed -- the 19th. So there were a few days before Christmas and there is the time between Christmas and New Year. I may well have seen a small number of patients then.

Q. Yes. Our information is that it was by 21 December that this patient was told of his results.

A. It might have been, yes.

Q. Would you be able to estimate what percentage of your patients came and asked and received their results, let's say, in 1985?

A. I think the majority of patients came in -- some time in 1985.

Q. When you say "the majority", is that the majority of patients which had been tested at that stage?

A. A lot of the patients who had been tested at that stage. There would be some patients who hadn't been tested, who would have come along as well.

Q. I think you told us before that 40 to 50 patients had been tested by this stage?

A. Well, that's my recollection with Professor Tedder.
Q. Yes.
A. The samples I sent to Dr Tedder.
Q. Of that 40 to 50, how many of those patients had come and received their results from you by the end of 1985?
A. I think the majority.
Q. Yes. So more than 75 per cent?
A. I would think so, yes.
THE CHAIRMAN: That's an unusual definition of a majority.
A. I didn't want to quibble.
THE CHAIRMAN: But I'm more concerned with "tested by this stage", when one is covering a whole year.
MR GARDINER: Yes.
THE CHAIRMAN: There is a difference, Professor Ludlam, if we have 40 to 50 people tested by the end of 1984, then it makes sense to ask, I think, what proportion of those people were tested in 1985. But it doesn't answer the question whether a different percentage of your total population was being tested in 1985. I would like to get as much help as I can in understanding the pattern of testing.
A. I appreciate the distinction.
MR GARDINER: So I think the distinction is between the patients who had been tested by the end of 1984, which I think you told us was 40 to 50.

A. 40 to 50, something like that.
Q. Yes, 40 to 50, and then subsequently more patients -- I think are you telling us that more patients were tested?
A. Yes. We were keen to encourage patients to be tested because there was a public health side to all of this. We wanted to know whether the heat treatment process was effective. The studies published in October from Cutter Laboratories and MMWR, I think, were on a mouse retrovirus, heat sensitive tests, and there was some evidence from spiking, I think probably at both these places, that the virus was heat sensitive and that 60 degrees or 68 degrees for a short spell would be enough to kill the virus or to make it non-infectious.

As you know, from December 1984 only heat-treated SNBTS Factor VIII was provided in Scotland and we wanted to know whether the heat treatment process, which at that stage was for two hours at 60 degrees in the dry, was adequate. And the way to do that, potentially, was to follow up patients, who were negative, regularly, to see whether any of them seroconverted.
Q. Yes. Just looking at the 40 or 50 patients that had been tested by the end of December 1984, by what stage in 1985 had the majority of those patients received their results?

A. I would have thought at least 75 per cent of them by the end of 1985.
Q. Of course, that would include patients who had tested positive and patients who had tested negative?
A. Yes.
Q. Yes. As far as the patients who had tested positive, how many of that group had received their results by the end of 1985?
A. I think a larger percentage. My recollection is there were a small handful -- I'm sorry, I'm a bit guessing but let's say half a dozen at the most patients by the end of 1985, who we knew to be anti HTLV-III positive, who didn't know. It may have been fewer than half a dozen but it was a small number.
Q. Would it be fair to say, Professor Ludlam, that your approach in 1985 to patients receiving their results was to leave it to the patient to make an approach to you to ask for the results?
A. Yes.
Q. You told us that the nurse would sometimes say to the patients, "Would you like to see Dr Ludlam?" Was she under instruction from you to ask patients that particular question during 1985, with a view to encouraging patients to ask for their results?
A. Yes, yes. In general we felt more comfortable if

patients knew the results, but we weren't going to pressurise the patients to have the result.

Q. Yes. If you saw a patient who had been tested but who hadn't received their results in the clinic, what was your approach to them in terms of encouraging them to ask for their results?

A. It would very much depend upon the circumstances, as to why I was seeing them in the clinic. I might or might not have raised the subject. It would depend on many factors. Of course, that is assuming the patients come to the clinic. There are some patients who are not keen to come to clinics and we have difficulty sometimes persuading them to come regularly for a follow-up. And I can appreciate that such people, you know, won't see me as often.

Q. Yes. For patients who had come to the clinic and who had seen you, what were the factors that determined whether you would raise the topic of testing with the patient?

A. I think, if they had come up with a bleeding problem or a medical problem that required attention, I would have dealt with that issue, offered them some treatment -- or whatever else was wrong with them, maybe some investigations. And I think I would have concentrated on that because that's why they had come. If they had

come for a routine review appointment and we were reviewing their situation -- how they were, was the clotting factor working properly -- I ask that because if you develop an anti-Factor VIII inhibitor, then, when you inject the Factor VIII, you don't feel you are getting the same clinical response. So it's an easy way of determining whether the patient might have developed an inhibitor. And I might have asked generally how they were feeling, make sure that they didn't have symptoms of anaemia, for example, and would be particularly interested in knowing what bleeds they had had recently and if they had an active bleed that they were treating, because quite often patients get recurrent bleeds into one joint, called a "target joint", and it becomes a very difficult joint to manage. They require a lot of treatment, it's uncomfortable, it's a big nuisance to them.

So at a routine visit, and reviewing their general situation, I might well say, "Have you thought about HTLV-III? What do you know about HTLV and AIDS in haemophilia," and, you know, "We have been testing some people."

So it would have been raised. Not for everyone. If people had come up with a specific medical difficulty, I would deal with that and probably not think about AIDS

because it would be a bit confusing.

Q. Yes. So you raised it as a topic?

A. I raised the topic with patients when they came for review, not all patients, not all the time but some of them some of the time.

Q. Yes.

A. I may know that they have already been -- there was quite a lot of people that came fairly early, the first three months of 1985, who may not have been in the initial 50 and, you know, who hadn't been tested, and we would have offered them testing and that would have been given the results and moved on from there.

Q. You said you would have raised the topic with some of the patients but not with others?

A. Well, they might already have been told their results.

Q. Right.

A. Okay?

Q. I'm talking about patients who haven't had their results?

A. And I knew the result?

Q. Did you not know all of the results?

A. In my head?

Q. Yes.

A. I had quite a good memory initially of who was positive and who was negative, but, as the weeks and months

rolled on, it became harder to retain.

Q. So at these routine review meetings which patients would you raise the topic with and which patients would you not raise the topic with?

A. I said, if patients came and there was some medical issue that needed addressing, I would concentrate on that. If we had a more general discussion about their haemophilia, their general health, how they were, how was their work; were they being off work because of bleeds and their haemophilia or off, you know, prevented from doing things. And I might in that time, in the general discussion, say, "And have you thought about -- what do you know about AIDS?" and take it from there.

Q. You see, you are using the word "might". I'm trying to focus on when you would do it and when you would not do it. Did you have a rule of thumb?

A. No. As I say, I wouldn't do it if the patient had some other preoccupation.

Q. We are just talking about routine reviews at the moment?

A. A routine review, without another preoccupation, I would think about raising it with the patient.

Q. But would you do it?

A. Yes. Well, I would if I thought it appropriate. There are one or two instances I can think of -- I would rather not say what they are here but if you insist,

I will do so -- where you thought it was perhaps imprudent to raise the topic.

Q. Yes. I think you told us that by the end of 1985 there was a small handful of patients who had not received their results. Is that right?

A. Yes.

Q. Of those patients who had not received their results who were positive, did you have their identities clear in your head at the end of 1985?

A. Oh, yes.

Q. Right. What was your approach to those patients in terms of communicating results?

A. We were -- by the end of 1985 it was becoming clearer that if you were anti HTLV-III positive, then you probably harboured the virus. That's the first thing.

Secondly, it was becoming rather clearer that, if you were anti HTLV-III positive, the risk of progression to AIDS was greater than our original estimate of one in 500.

So if you like, there was a greater confidence about what an anti HTLV-III positive result meant, and conversely there was a bit more confidence that if you weren't anti HTLV-III negative, maybe you didn't have the virus. So there was a bit more of a dividing of the ways, if I can put it that way. Late 1985/early 1986 is

the sort of time I would put it. It was gradually evolving.

Q. Yes. Are you saying that by the end of 1985 the prognosis for patients who had tested positive was clearer?

A. I think by that stage the chances -- if you were positive, the chances of you getting AIDS was rising. So I can't put a figure on it.

Q. Yes. Sorry, I interrupted you. So because it was clearer at the end of 1985, what did that mean in terms of your approach to the patients who had been tested but who hadn't received their results?

A. Well, we were quite concerned and we discussed it at quite some length, I think you have gathered from what I have sent in as written evidence and maybe other people. We used to meet once a week as a team and think about individual patients, perhaps whom we had seen, particularly during the previous week, who we had given results to, what difficulties were emerging. This was a time when -- it was a fairly quiescent period at one level because patients were all feeling well. It was a sort of phoney war time, if I can put it that way. All the patients were well and we discussed each week who we had seen, exchanged information that seemed relevant and increasingly worried about the small number

of people who were -- had tested positive and who didn't know.

Q. Yes. Why were you worried?

A. Well, the significance in terms of their prognosis was beginning to look a bit worse. There was still no treatment or no prophylaxis at this stage, nothing that could be done, in a sense, medically to improve their prospects, and so we decided as a group -- and this was a group of Dr Masterton, the psychiatrist, Geraldine Brown, Michelle Jones, our haemophilia sister, our staff nurse -- before the time that Alison Richardson came to work with us -- myself, my registrar. Those were the principal people sitting round the table, thinking about these issues.

Q. What did you do about it?

A. Well, the advice -- there was the feeling that, well, maybe patients don't want to know. Maybe once they know they are antibody positive, there is no going back, and if you don't know, then you can believe that you are negative. And certainly I can think of instances when people have said they have been very pleased they didn't know and they were very angry when I eventually told them.

So it was a difficult area. We were taking -- Geraldine Brown had experience in counselling,

Dr Masterton was very helpful. It was a very new situation for us and we wanted to be sensitive to the patients because once you have told someone, you can't untell them.

Q. What you are describing there, Professor Ludlam, is discussions amongst medical staff. I'm interested to know if at that time -- and we are talking about the end of 1985 -- your approach to insisting, if you like, that patients know the results, changed at all?

A. No, I think it changed a little later. It changed a year or so later, because at that point there was beginning to be -- the possibility of treatment with Zidovudine was being talked about. There was the possibility of prophylaxis against pneumocystis, the awful pentamidine inhalations. At that time, in other words end of 1986/87, one or two patients were starting to become clinically unwell, I assume because of the virus.

So a time came when I felt it really was in the medical interests of the patients to tell them.

Q. Yes, and what time was that?

A. This would be the end of 1986/the beginning of 1987.

Q. So you moved to a position of insisting, if you like, that your patients were told their results?

A. Well, it was a balance and I thought it was becoming

more in their interests, medical interests, to know.

Q. Yes. So did you then move to a position where you were insisting that they found out their results?

A. I think at that point I was asking them to come and see me, and I can't quite remember how strongly I would have put it but I would have made it very clear that I thought there were good reasons to know and I would like to tell them.

Q. Yes. So that doesn't sound like you are insisting. You are perhaps -- how would we put it? -- encouraging your patients to ask for their results?

A. I think -- I'm sorry, I can't remember the -- exactly how insistent I was but I might have told people, saying "I think it's in your interests to know."

I'm not quite sure how much leeway, how much option. I don't think I was actually going to give them very much option at that stage, because potentially they might start to develop symptoms of AIDS and I felt it was actually important that people knew.

Q. Yes. You said that you wanted your patients to come and see you. So how did you make that happen?

A. I either wrote to them or someone would ring them up and ask them to come. I forget the --

Q. We are talking here about the small handful of patients whose results you had but they hadn't been communicated

to them?
A. Yes.
Q. And we are still talking about the group of patients that were in the 40 to 50 that were initially tested by Dr Tedder?
A. Not absolutely certain about that. They were people who I knew were anti HTLV-III positive towards the end of 1986.
Q. Yes.
A. You know, they would have been tested at some stage before that.
Q. Well, I think I had better clarify that with you. We have the first group, the 40 to 50, who were tested, and we know that in November 1984, 16 of these patients had tested positive and they had all received SNBTS product. I think that you had concluded that these patients had all received the same batch. Is that correct?
THE CHAIRMAN: Professor, I'm not sure it is necessarily absolutely correct because there were a range of values but perhaps the significant issue is whether it was understood by you and your colleagues at that stage that batch 0090 was highly likely to be the cause of transmission. I think if we proceed on that basis, that might be enough.
A. Yes, certainly.

MR GARDINER: Yes.

A. Yes.

Q. So that is the group of patients that have come to be called the "Edinburgh cohort"?

A. Yes.

Q. Yes.

A. But I'm not sure -- sorry, I'm tiring a little in the numbers. I'm not sure whether the 15 or 16 that were positive at that time were all from the cohort?

Q. I see.

A. If we are talking about November.

Q. Yes.

A. Because -- well, at least one of them was probably from commercial.

Q. Perhaps you could -- you have told us about the initial testing by Dr Tedder. Could you tell us about other testing that was done in 1985?

A. Yes, certainly. Very early in 1985 it became clear that anti HTLV-III testing would have to be set up in many centres in the country. My virological colleague, Dr Peutherer, who I had worked closely with over the Hepatitis B work we had done, made enquiries about setting up the anti HTLV-III test in Edinburgh. So I would think by about February/March/April there were a number of different commercial kits that were under

evaluation. I can't quite remember. I don't think he started with live virus because you required special containment facilities, which he had but I'm not sure that were used. But local testing was available in the spring -- by the spring of 1985.

That opened up the opportunity for many more individuals to be tested, not only people with haemophilia but a whole lot of other people, and as I think I alluded to and maybe was discussed earlier, we established, at my suggestion, what we called the "AIDS Advisory Committee" in Edinburgh, to cover Lothian. In fact its first meeting was on 19 December 1984. So that was quite a busy day.

We established this committee to try and address the myriad of problems that were coming out at us, because it became known that people with haemophilia were anti HTLV-III positive. And one of the consequences of local testing becoming available was that, particularly after it became known, I think in about February 1985 but I could be wrong, that anti HTLV-III positivity amongst intravenous drug users was quite high and so some of the medical staff, particularly in A&E departments in Edinburgh, and particularly surgeons and particularly orthopaedic surgeons, became very anxious about the possibility of getting infection from anti HTLV-III

positive people who were not known to be positive.

Q. Professor Ludlam, I wonder if I could interrupt you there. I'm really interested in the testing that was done at this stage -- and we are talking about February/March/April 1985. Do you think you could tell us how many of your patients were tested and what the results were?

A. At that stage I think we would have sent our samples to Dr Peutherer, and we would probably send samples from people that Dr Tedder had tested as well to make sure we got the same answer.

And we would have offered testing to people who crossed the threshold, if I can put it that way, for reasons I have already explained.

Q. Yes. So as a result of that testing, patients who crossed the threshold as you put it, how many of your patients were tested in that way?

A. Over the succeeding few months I would have thought 50 or 70 per cent of all our patients who were at risk, or more.

Q. What were the results of that group?

A. Most of those were anti HTLV-III negative.

Q. Yes. How many were positive, if you can remember?

A. Probably five or seven, maybe ten.

Q. And are you able to say whether some of that group, by

the end of 1985, had not received their results?
A. I'm sorry, I can't.
Q. Okay. Just to clarify the question about confirmatory testing, did you do confirmatory testing on all of the Tedder patients, the Tedder samples, if you like?
A. I think so, yes.
Q. It sounds as though if you didn't have testing until February/March 1985, some results would have been passed on before you had done confirmatory testing?
A. If I had a result from Dr Tedder on a single sample and a patient came to see me, I would give them the result and I would say, "That's as I understand it, but I think I would very much like a further sample from you to send to Dr Tedder or to Dr Peutherer to get a second result to see if it confirms the first."
Q. Yes. What would happen when you got the confirmatory test back?
A. I would inform the patient.
Q. Yes. In a meeting?
A. Probably at a clinic or the nurse perhaps would inform them. It was not new information. I would be happy for the nurse to give them confirm -- confirmatory tests, I think, for the negatives. Confirmatory tests for the positives I would probably have seen myself.
Q. Yes. I think you did tell us a little bit about how you

passed on the positive results. Could you tell us a little about what you advised the patients at the beginning of 1985, when you saw them, who had tested positive, about prognosis?

A. Well, I said that at that stage -- I'm sorry, I have forgotten -- I could look it up for you if you wanted -- the exact numbers in North America, who had -- haemophiliacs who had developed AIDS, but it was between one in a 1,000 and one in 500. So I would have said, as I described earlier this morning, I very clearly remember telling one particular patient that it was about this sort of level from the information we had available at the time.

Q. Yes. Thank you. I would like to ask you a few questions about your decision not to insist on advising patients and can I ask you to have a look at [SNF0013850]? I think we have seen this before. This is the notes of the haemophilia reference centre directors' meeting on 10 December 1985. I think you did tell us a little bit about discussions that were had at that meeting. Do you remember what the consensus of opinion was about telling a patient that they had tested positive at this time?

A. My recollection is that if a patient wanted to know, that they should be told. There was a view that -- as

I think I mentioned earlier -- that patients shouldn't be told. I go on the philosophy that if you are looking after patients on a long-term basis and have quite close relationships with them, seeing them quite frequently, it is actually quite difficult to withhold information from them. There is a degree of deception and I don't think that's terribly healthy.

Q. Yes.

A. So my philosophy in general is to make the information available if it seems appropriate. I mean, there may be bits of information occasionally that it's not appropriate to make available but that's my philosophy.

Q. If we look at page 5 of these notes, we see a reference to Dr Kernoff and then the paragraph underneath that, the chairman, who is Professor Bloom:

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

So that's consistent with your recollection of what was decided at this meeting?

A. I think so, yes, there was a long discussion about it and a spectrum of views but I think the chairman has summed it up succinctly and appropriately there.

Q. Yes. If we could have a look at [SNF0014020], we see

that this is a letter from Dr Craske dated 23 October 1984, and we see on the front there "copy D Ludlam". Do you remember seeing this letter at the time?

A. Yes, I think I got my own copy of it. This is one sent to the Blood Transfusion Service but I had a copy as a haemophilia director.

Q. Yes. If we look at 4024, the appendix which is headed "Ethical problems associated with HTLV-III infection in haemophiliacs":

"The accompanying letter details a protocol with two alternative strategies for the follow-up of patients who have received a batch of Factor VIII contaminated with plasma collected from a donor who subsequently is shown to have AIDS or to have acquired HTLV-III infection."

The two options that are given are:

"Informing the patient and his family of the risks."

Then:

"Restricted follow-up."

At the bottom Dr Craske says:

"In my opinion, option 1 is the only one tenable on moral and ethical grounds."

Do you read that as Dr Craske coming to a different view from the view that you came to?

A. No, I don't think so, because -- can you just bring the

page down a little bit, so I can see the top?

Thank you.

These were people who had been exposed to a batch of Factor VIII that was contaminated. And the option two, the restricted follow-up, makes no mention of advising the patient that he might be at risk of HTLV-III. It rather implies waiting to see whether he becomes infected. Clearly, that potentially could have exposed his wife or sexual partner to infection.

So -- I mean, the advice we were offering along with the physical condoms, were: everyone should consider they are infected, because even if they were negative -- let's just think of the worst case scenario or a worse case scenario -- patients were anti HTLV-III negative in January 1985 and the heat treatment process had not been effective, that was instituted in December, and some had got infected in the spring of 1985 from SNBTS concentrates, we now know, partly from some of the research that we did, that shortly after infection there is a big outpouring of virus into the blood and I think I would be right in saying that early in the infection you are probably more infectious than later on. I base that on the HTLV-III antigen results, which were a measure of virus in the blood. And you get a peak shortly after infection. I suspect you are more

infectious at that stage.

So it's not a case of whether or not you inform people, it is a case of whether they are positive or they have had an implicated batch, but that everybody must use -- assume that they either are or could be infected because we didn't know until about 1987 -- I mean, there were seroconversions of heat-treated -- following -- there were episodes of patients who got treated with heat-treated concentrate who seroconverted because the heat treatment was inadequate for a whole variety of reasons.

So it wasn't really until, let's say, 1988 that there was good evidence that the viricidal techniques were very effective.

Q. Would you accept, Professor Ludlam, that, as a patient, if you know that you are positive, you are more likely to take precautions with safe sex and spillages and so on, than if you simply know that you are potentially infected?

A. I think that's probably right, yes. That's why we gave out condoms to everybody as a way of emphasising it.

Q. Yes. My point really is that as a patient, if you know that you have tested positive, then you are more likely to take precautions?

A. To use them?

Q. To use them?
A. Indeed.
Q. You are agreeing with that?
A. I think so, yes.
Q. Can we have a look at [PEN0150250]? That's a letter dated 30 November 1984, addressed to you. That's also from Dr Craske, is it not?
A. It is.
Q. Do you remember getting that letter?
A. Yes.
Q. Am I right in thinking that there was an appendix -- I mean, we don't have it here but was there an appendix which was the same as the one that we have just looked at appended to the other Craske letter?
A. I'm sorry, I'm not sure but I suspect it probably was.
Q. Yes. Thank you. I would like you to have a look at the transcript of some evidence that we heard from Professor Hann. Could we have a look at the transcript for 10 June? This is page 30, please.

The context here is a discussion of the letter that we have just looked at, the Dr Craske letter, and at the top of page 30:

"Do you remember if this letter that you saw at that time informed the way that you approached this question?"

That's the question of communicating results.

"Answer: I think it was one of many actually. We had lots of discussions about this at the time and this was one of many. I think it helped to crystallise the situation, if you like, in, I think, quite a nice way and I tended to agree with him, whereas quite a few others didn't.

"You know, in the end, I think, as a clinician, there is one test above all others and that's a need to know. There are moral, ethical -- you know, you can go round in millions of circles with those discussions -- and legal ones too. But in the end, if you have a disorder which can be transmitted and where people can develop treatable sequelae, then it's not such a major issue in my view. The prion problem that came later was much more difficult -- much, much more difficult, and -- I think, you know, we still go round in ever decreasing circles with that but the fact is that in these circumstances I that you the argument against information was very weak."

Professor Ludlam, do you disagree with that analysis?

A. Yes.

Q. Well, could you explain to us why that is?

A. Well, I don't think -- he raises the issue of prions and

variant CJD, and in fact the issues around variant CJD and the prion were awfully reminiscent of where we were in -- at the end of 1984. The suggestion that it could be transmitted -- might be transmitted by blood, and there was nothing one could do for the patient. The big difference between prion and HTLV-III is that as far as I know, prion cannot be sexually transmitted.

But from the point of view of what could be done for the patient, then the two were remarkably similar and so I -- my point of view is different from Professor Hann. Professor Hann makes it clear that there was a spectrum of opinions.

Q. Yes. Even at the beginning of 1985, were there not treatment implications in not telling the patients?

A. Could you elaborate a little bit on that, please?

Q. Well, some of these patients you weren't seeing regularly.

A. Yes.

Q. Sometimes patients on home therapy, you might not see them for three or four months perhaps?

A. Yes.

Q. Yes. So if in the meantime a patient started to develop a cough or something like that, then would they not need to know that they should go and see a doctor about some kind of treatment? Was there not some kind of treatment

at that point if the patient had come to see you?
A. If the patient had -- we tended to provide not just haemophilia services for our patients, we provided general practitioner services as well. And so if patients were feeling unwell -- and they tended to come and see us even though it wasn't a bleed. Sometimes you -- a patient has symptoms. It might be due to a bleed, it might not be. They might have a sore tummy. It could be due to bleeding, it could be due to gastroenteritis or something. But in early 1985 it is unlikely that the patients who were anti HTLV-III positive would have developed symptoms of AIDS -- AIDS-related symptoms and, as I was trying to hint earlier, it was when that became more of a possibility -- in other words, the patients had been infected for potentially year or two, or a couple of years -- that the probability of them becoming symptomatic increased, and I was keen that they knew their anti HTLV-III status, their infection status, before they started to develop symptoms because I think it's not good for them to -- as happened in the early days, obviously, of AIDS, where people presented, as you say, with a dry cough from pneumocystis and that's the first they knew they had AIDS.
Q. So an important factor for you in the approach that you

were taking to this at that point was the fact that in your view there was no treatment available if a patient presented with symptoms?

A. When you say "symptoms".

Q. Symptoms of AIDS?

A. The majority of individuals with haemophilia presented with breathlessness and a dry cough, and I remember very well the first few patients who presented that way and the treatment for that was intravenous pentamidine, a fairly toxic drug but one that did actually work.

Q. Yes. Was that drug not available at the beginning of 1985?

A. Oh, yes, it would be available.

Q. Yes. Well, I think it's maybe time to --

THE CHAIRMAN: Yes, can I have some indication of progress, Mr Gardiner?

MR GARDINER: I hope to finish maybe within about 45 minutes after lunch. I am afraid my estimates haven't been very accurate so far.

THE CHAIRMAN: I think that I would accept that confession, if it is such, which is tending to suggest that we are going to fall very far behind in progress. Anyway, that cannot be helped. We will adjourn now.

I think, professor, you ought to make sure that you do get some relaxation over lunchtime. I don't want you

to suffer from being too tired.

A. Thank you.

(1.04 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Where are you going next, Mr Gardiner?

MR GARDINER: I wanted to just clarify one point very quickly with the witness, if I may.

THE CHAIRMAN: And then going onto what? There are one or two questions I would like to ask about testing. It depends whether it fits in with that or not. If there is something you want to clear up, first, let's do that.

MR GARDINER: My question is about testing -- shall I go on?

THE CHAIRMAN: Yes.

MR GARDINER: I just wanted to clarify something with you, Professor Ludlam. Before lunch you talked about "local testing". This is testing that was done in Edinburgh.

A. Yes.

Q. Yes. Did you obtain consent from your patients before that testing was done?

A. Well, I think what I was starting to say was that early in 1985, when testing became more generally available and there were calls from many different -- particularly surgeons, for screening for all patients, the whole complexion of testing changed and that's when we began

to think about pre-test counselling and who should get tested, because the surgeons were keen that everyone should be tested, or if you couldn't test everyone, were you going to ask everyone who came for an orthopaedic operation whether they had had sex with men or whether they had used intravenous drugs.

It was this difficulty -- and also, for example, the insurance companies wanting to know about whether someone had been tested -- that very rapidly, over 1985, led to us thinking about what's now called pre-test counselling, and that's why -- or how I came with my colleagues to draw up the guidelines for testing. These were fairly primitive guidelines that -- I think they must have been written in 1985, probably the end of 1985, because if I remember correctly, they give -- they don't give a definitive view about the significance of being anti HTLV-III positive.

Q. Maybe we should have them up, professor.

A. Please.

Q. That might be helpful. Just bear with me.

[PEN0161284].

A. Could I, while there is a pause, go back to something I said before lunch, about Professor Hann and whether I agreed with his testing or giving the results of testing.

Q. Yes.
A. I said that I did disagree with him. I was thinking about it over lunch and he looks after a different group of patients from me. His were children and I think HTLV-III infection will influence, will impede, development of children and I suspect, therefore, it would be a reason for children not to thrive, not to gain weight as they ought to, and therefore it would be important to know that they were positive.
THE CHAIRMAN: I think, had we gone on for another page or so, Professor Hann himself does draw the distinction between the treatment of children and adults and suggests that there was a different balance of opinion in the two groups.
A. Thank you, I apologise.
MR GARDINER: Yes. You were telling us about the guidelines. I think we have them here on the screen.
A. Yes, thank you.
Q. You say you think they were produced at the end of 1985?
A. I think so, yes.
Q. Who drafted them, Professor Ludlam?
A. I suspect I did but I would probably have -- I'm sure I would have discussed them with my colleagues.
Q. Yes. How did you use them in the centre?
A. I think they were primarily for the staff. It was a way

of focusing the staff's mind -- we had quite a bevy of staff at that point -- as to what the important things were to think about.

Q. Yes. I think you were using them to answer the question about whether you obtained consent for local testing?

A. So we would -- this evolved, if you like, out of our need to -- our realisation that it was appropriate to get consent and to think about some of the issues that we were thinking about before lunch, about whether people want to know about positive results or whether they want to be tested.

Q. Yes. So does that mean that for all local testing that was done by you before the testing took place, you obtained your patients' consent?

A. If they were taking a fresh sample, yes.

Q. Yes.

A. So the degree of pre-test counselling, if I can put it that way, evolved during 1985, the amount of counselling.

Q. Yes. But just to draw a distinction between the Tedder testing, which was on stored samples, where no consent was obtained, with local testing, your evidence is that you did get your patients' permission?

A. Not only that. We asked their permission, particularly for the negative patients, to test them repeatedly, and

we recorded this on our computer system and dated it, I think, on the second page of this -- no, sorry, it's at the top here. Second paragraph:

"Discussion of HIV testing must be recorded in the case notes stating clearly what has been agreed. The haemostatic screen on the computer must be appropriately updated."

That's so that we could quickly see that someone had agreed and a date to it.

THE CHAIRMAN: My questions were in the same area, Professor Ludlam. When did this document come into effect?

A. I think it has the feel as if it was written towards the end of 1985.

THE CHAIRMAN: The period I was particularly interested in was the transition until you reached here. I think we know by now that 40 to 50 people had been tested under the original Tedder regime, as it were, and I imagine that some of them would have responded to the invitation to come and speak to you as one approached Dr Peutherer's period, if I can call it that, but some would not.

So far as those of the original group who had been tested without their consent were concerned, was there repeat testing by reference to archived material in

their case, in 1985?

A. There might have been, to determine their date of seroconversion.

THE CHAIRMAN: Right. Would that have been done without their consent or with their consent?

A. Probably -- it was done fairly quickly, I think probably without their consent.

THE CHAIRMAN: So that there was some testing in 1985 of that original group that continued into 1985 under the original regime?

A. Yes.

THE CHAIRMAN: During 1985 and before the transition to this documented protocol had matured, was there other testing of patients without consent?

A. I don't think so. I think we would have then tested people as they came up, they came to the clinic, they came to collect home treatment, if it seemed appropriate. We might have been opportunistic to talk to them at that point. No, there wasn't -- there wasn't, if I can put it this way, retrospective testing done, I think, late in -- middle of 1985.

THE CHAIRMAN: Was there prospective testing done of any of these patients during 1985 without their consent, using new samples obtained in the ordinary course?

A. Not intentionally. I think our intention --

THE CHAIRMAN: I find that difficult. It must be intentionally by somebody.

A. Done intentionally and I would hope the patient would have been asked. That was the clear arrangement. Because at one stage the request forms, I think, may almost have asked if the patient's consent had been attended. Certainly, when we were taking blood in 1985, to send it for anti HTLV-III testing, we would asked about it and if the patient agreed, we would have taken it and sent it.

THE CHAIRMAN: So does it come to this: that there would be no "new" patient -- very much in inverted commas -- tested in 1985 by reference to blood taken at that time without the patient's consent?

A. I don't think so, no.

MR GARDINER: Thank you, sir.

I would like to go back to something that we were discussing before lunch again, and this was in the context of Professor Hann's evidence and the need to know reason for treatment being a reason that a patient would need to know.

I think you said, professor, that in early 1985 HTLV-III positive patients would be unlikely to develop symptoms of AIDS; yes?

A. Yes.

Q. So I would just like to get your position on that. Is your position that in 1985 there wasn't a need to monitor, for example, a cough because those patients simply wouldn't get PCP that quickly?
A. The evidence was at that time that it took usually several years between infection and the development of PCP. As we knew, our patients, or most of them, had only been infected less than a year. The chances of them developing PCP was small.
Q. Yes. Just to be clear, is your position that that would continue until the end of 1986 then?
A. Erm ...
Q. The absence of a need to monitor, because PCP just couldn't develop that quickly?
A. It was unlikely that it would develop within two years.
Q. Yes. And that was a factor in your decision about the need to give the patients the information about their condition. Is that right?
A. That was part of it, yes.
Q. Right. So the Inquiry has heard from one patient who didn't get his results until 1986, and the Inquiry knows of two other patients who didn't get their results until the end of 1986. Is it your position that from a treatment point of view, these patients didn't need to know until late 1986 because they simply couldn't get

PCP that quickly?

A. I think that's correct, yes. There was no, as far as I could see, medical benefit from knowing.

Q. Yes. So it's not the fact that there is no treatment, it's the fact that the patients would be, in your view, unlikely to develop a condition that would need treatment. Is that right?

A. Yes, there are two sorts of treatment. There is the treatment of PCP, for which there was a treatment, the pentamidine, and then there is treatment of their HIV disease, which wasn't available at that time and became available in 1987/1988. Those are the distinctions I would make.

Q. Yes. Okay. Right. Could we have a look at what Professor Forbes said on this subject, and that's the transcript of 15 June, page 162. The question starts actually at the end of page 161. I think this is Mr Di Rollo. The context again here is passing on the results of tests:

"So as soon as you discovered the outcome of these tests, you took steps immediately to inform them all of the results.

"Answer: Yes, all of them.

"Question: Why did you do that.

"Answer: On a personal basis -- well, I think it

was important. We were going to tell them very bad news. There were implications not just for them but for their families and their lifestyle, and it was to my mind very important that we tell them what had happened. Nothing was being hidden away."

Well, Professor Ludlam, do you disagree with that approach that Professor Forbes is outlining there?

A. It's a different approach. And it shows how two centres were coping with a new situation in which there was no national guidance, that we had to think it up from first principles. And there was a great deal of discussion, as you have already alluded to, at a number of meetings. Those are the minuted ones. There were many more discussions between colleagues -- around informal discussions. It was a very difficult time.

Q. Another reason for making sure that a patient knew his results would be what you might call "infection control", to make sure that third parties weren't subjected to any risk. I wonder if I could show you [LOT0010094].

This is a letter dated 16 November 1984 from you to Dr Sutherland. Who was Dr Sutherland?

A. As you see, he's a community medicine specialist. He might have been what you might call the "medical superintendent" of the Royal Infirmary.

Q. Yes. So if we look at the second paragraph, we see what you say there is:

"In consultation with Professor Collee, Dr Peutherer and Dr Edmond, Dr Parker and I have decided that haemophiliacs who have received concentrates of either Factor VIII or IX should be classified 'high infectious risk' patients. The epidemiology of HTLV-III is very similar to Hepatitis B and we therefore feel it appropriate that these patients should be managed clinically in the same way as patients who are positive for HBsAg."

Could you explain to us what the thinking there was?

A. Certainly. At this time we were faced with having some results, some anti HTLV-III results, on a small number of people with haemophilia. Some were positive, some were negative. It wasn't at all clear how to interpret an anti HTLV-III positive result. It ranged from the patient might have been exposed to dead virus and that, like a vaccine, this was purely an antibody response; the patient was not infected.

It could have been that -- in fact, this was thought at one stage that if you had an antibody positive result, you were actually better off because you had been infected, you had got the antibody and you had got rid of the virus. And then of course there was what

came to be known, as, if you like, the true situation: that if you are antibody positive, you also had the virus. But the other possibility is that they were false positive results; in other words, a laboratory artefact, if I can put it that way, the patient had never been exposed to the virus alive or dead.

Then the converse of that, if a patient was anti HTLV-III negative, was that either because they were incubating the infection, they had just been infected very recently? Was it that the test was insensitive, that they were infected? Was it a false negative? Or was it a true negative? The patient had never been exposed?

Q. Professor, we are very keen to finish your evidence this afternoon. I wonder if I could just ask you to answer the specific point. Is this infection control here, effectively?

A. This is infection control but it's also, I think, to make the point that we did not distinguish in handling people with haemophilia, between those who were antibody positive and those who were antibody negative. They were all considered to be a risk of infection irrespective of their anti HTLV-III status.

Q. Yes. This wouldn't cover the risk that a patient might obtain medical treatment elsewhere; if they went on

holiday somewhere and had a bleed or a cut or something like that. Is that not right?

A. And if they said they had haemophilia. If they are likely to have cut themselves, they are likely to have said they have got haemophilia, then the next thing that people would do is be very careful, as became what were known as universal precautions -- you assume that everybody actually has an infectious virus.

Q. Can you think back to an occasion when any of your patients, whom you knew were positive but who didn't know that they were positive were going to have procedures, can you remember a situation where you informed a medical practitioner of their status to minimise this infectious risk?

A. Yes. I well remember one patient who needed an orthopaedic operation, and I went to discuss it with the surgeon, who was a senior surgeon, an orthopaedic surgeon, who had done a lot of work with our patients, and I said, "This patient is anti HTLV-III positive. We must assume that he has the virus. He does need this orthopaedic operation." And the surgeon said to me, "It's better that I do it than my young colleague" -- who was also treating some of our patients -- "because if there is an accident, it is better that I am infected than my younger colleague is."

Q. And the patient didn't know of their status?
A. I can't remember. But what I'm getting at is I would tell the surgeon.
Q. Yes. Can you remember any occasions when you would have done that or when you did do that, when the patient himself or herself did not know about their status?
A. I can't remember but it is quite possible.
Q. Just to finish dealing with this particular topic, communication of the results, Professor Ludlam, would you accept that leaving aside all of the other reasons that we have been discussing for passing on the information to the patient, even in 1984/1985, there is the point that the information about the patient's condition is something that actually belongs to the patient and the patient should have that information?
A. I entirely agree if the patient would like the information.
Q. Thank you.

Professor Ludlam, the Inquiry heard evidence from a witness whose anonymised name has been given as "Mark". I would like to ask you a few questions about his evidence. Did you treat the witness Mark?
A. If it's the individual I think it is, yes.
THE CHAIRMAN: That doesn't actually help. I think that in the circumstances it might be better to communicate the

name privately to the professor just on a bit of paper so that we don't have any doubt at all that we are talking about the right person. Just write it on a bit of paper. I'll do it.

MR GARDINER: I think I may be able to clear this up, sir.

Professor Ludlam, would you like to think again about my question. You have been in contact with the Inquiry about this witness.

A. Yes, I think I know -- I know who it is.

Q. So are you able to say that you did treat the witness whose anonymised name is "Mark"?

A. Yes.

Q. Would that be sufficient, sir?

THE CHAIRMAN: That's sufficient, yes.

MR GARDINER: Mark gave evidence to the Inquiry and I would like to give you a two-part summary of his evidence on one particular topic and then ask for your reaction. You may have heard this before but I'll repeat it. Firstly, Mark told the Inquiry that when any form of testing was mentioned to him, he made it clear that if there was anything wrong, he wanted to know.

Secondly, Mark told the Inquiry that in relation to the perception of those who saw him at the Royal Infirmary, he didn't want to know the result of any HIV result on him, that any such perception was wrong and

that all he had ever said was that he didn't want to know the detail of laboratory measurements of his results, for example iron levels or something like that.

Have you got the sense of that?

A. I have, yes.

Q. You don't want me to repeat it for you?

A. No, thank you.

Q. What's your response to that evidence from your personal experience, Professor Ludlam?

A. I was hesitant to begin with to let him know of his result because of a number of social reasons, but I felt that a time came when it was important for him to know for the reasons that we have -- I have already rehearsed and we have discussed earlier today. And so I arranged to see him -- I forget the date, some time in 1986 -- and actually I was quite taken aback because he was quite categorical that he didn't want to know and I had not actually experienced that reaction in someone who was so determined that no way was I to tell him. I was a bit thrown.

So I said, "Well, okay, but look, we are telling everyone that they must be very careful with sex and blood and spillages."

And I was particularly concerned because he had an occupation that exposed him to being potentially

injured.

Q. Sorry, can I caution you, Professor Ludlam, we must try to be careful not to give out any personal details because this is an open session, of course.

A. That was all I was going to say. And that concerned me and that was all the more reason for my being anxious. We tried on at least two further occasions to convey this information to him. One was to potentially visit him at home and the other was when he came up to the clinic and he saw one of our very able young doctors and she tried to persuade him, very strongly -- this would be about 1988 or 1989. Because at that stage there was -- and I can't remember his counts at the moment -- there was the potential for him having PCP prophylaxis.

I further -- I have just remembered actually that he wouldn't have qualified for PCP prophylaxis because his counts hadn't fallen to the level at which it was considered appropriate to start PCP prophylaxis.

Q. Yes.

A. So there were several occasions when we tried very explicitly to explain to him and he adamantly didn't want to know. And this wasn't talking about iron levels; this was talking about HTLV-III and AIDS.

Q. Are you quite clear that 1986 was the first date that these discussions started?

A. Yes.
Q. Yes. Well, could we have a look at page 3 of [WIT0040706]?
You can put that away.
Professor Ludlam, it's our understanding that the earliest entry was 1988. Would you disagree with that?
A. There is the sheet that was in my private notes, if I can put it that way, that was from 1986.
Q. Yes. Thank you. What private notes were these?
A. This was a record of my seeing Mark in 1986, wanting to tell him about his result and he not being keen to know -- or didn't want to know the answer. I made a note of that and the advice that I gave to him and I felt it inappropriate to put it in his case notes for some of the reasons we talked about earlier, and I had a confidential file in my room, locked up, in which I kept that information. That information has now been returned to his principal case notes.
Q. Yes. Thank you --
THE CHAIRMAN: Have you seen it of late, Professor Ludlam?
A. Yes.
MR GARDINER: I would like to move on to the GMC guidance of 1988. So could we have [PEN0161165]? Could we go to the next page, 1166? Just down at the bottom of the page we see that that's a letter from Robert Kilpatrick, president, and Donald Irvin, chairman of the standards

committee. This is dated April 1991 and it says:

"In August 1988 the attached statement was sent to all doctors on the Principal List of the Register and to those holding limited registration. It contains important material offering guidance to doctors in approaching a number of ethical questions which arise in relation to the management and control of HIV infection and the diseases associated with it."

Then it says:

"... the statement stands as an expression of the Council's views in four main areas where ethical difficulties can arise:

"the doctor's duty towards patients;

"duties of doctors infected with the virus;

"consent to investigation or treatment;

"confidentiality."

Professor Ludlam, do you remember seeing this at the time?

A. Yes.

Q. Thank you. Could we go to page 3, paragraph 15, headed "Confidentiality". It says:

"Doctors are familiar with the need to make judgments about whether to disclose confidential information in particular circumstances, and the need to justify their action where such a disclosure is made.

The Council believes that, where HIV infection or AIDS has been diagnosed, any difficulties concerning confidentiality which arise will usually be overcome if doctors are prepared to discuss openly and honestly with patients the implications of their condition, the need to secure the safety of others and the importance of continuing medical care, of ensuring that those who will be involved in their care know the nature of their condition and the particular needs which they will have."

It's the last sentence I would like to refer to you Professor Ludlam:

"The Council takes the view that any doctor who discovers that a patient is HIV positive or suffering from AIDS has a duty to discuss these matters fully with the patient."

What I want to ask you simply is: do you consider that you complied with this guidance in your treatment of your patients during this period, 1985 to 1990?

A. This was issued in 1988. I had a duty, yes, to assess my patients' situation in relation to AIDS and in particular how he might suffer, but also his sexual contacts, and my recollection is Mark was well aware that he should be using condoms.

Q. Right. I would like to move on, please. Could we have

a look, please, at [PEN0120330]? This is a report from Dr Vivian Nathanson, who is the director of professional activities at the British Medical Association. Have you read this report, Professor Ludlam?

A. I have, yes.

Q. Thank you. The Inquiry asked Dr Nathanson several questions and the one that we are concerned with is number 6 at the bottom of page 9. The question was:

"What was the correct approach to communicating the results of a diagnosis of HIV between 1984 and 1990? What was the GMC guidance on this point? How did that guidance evolve?"

And the answer that Dr Nathanson gives is:

"In its 1988 guidance the GMC states that:

"'The Council takes the view that any doctor who discovers that a patient is HIV positive or suffering from AIDS has a duty to discuss these matters fully with the patient.'"

Her commentary on that is:

"At that time the GMC did not go into the level of detail that is in current guidance, but the use of the phrase 'a duty to discuss these matters fully ...' makes it clear that the intent is the same.

"It is important to remember that at that time the majority of doctors in clinical practice in the UK had

never seen a patient who was HIV positive or who had AIDS. The spread of the virus was limited, not least because of an effective public health campaign and significant behaviour change within certain high risk communities. Doctors in London and certain other cities might have case clusters, but HIV remained a relatively rare condition. Doctors in Genito-Urinary Medicine and some infectious diseases specialists gained the highest levels of knowledge and experience in managing the condition and in communicating test results with patients. Doctors treating patients with haemophilia gained comparable experience.

"In the late 1970s many doctors did not tell the patients the whole truth, especially where that truth was a diagnosis of an incurable illness. This was the well-intentioned legacy of Thomas Percival's influential text on medical ethics. The intent was to shield patients from disturbing information. The duty of beneficence was interpreted as an obligation to be reassuring rather than honest. But many doctors had begun to move away from this benign paternalism to a more equal relationship with patients."

Professor, my question is: in 1985 and 1986, were you still pursuing the kind of "benign paternalism" that Dr Nathanson was referring to here?

A. No. Because we were not -- in "benign paternalism", you are making the assumption that the patient doesn't want to know they have got an incurable disorder. I was giving the patient the control of asking whether they had this infection as best we could diagnose it.

Q. Yes. Thank you.

Sir, I propose to move away from this topic onto something else.

Just on a completely separate topic, Professor Ludlam, and this is just a quick question. We know that from about December 1984, Factor VIII concentrate was heat-treated in Scotland but I think it was about another year before SNBTS produced heat-treated Factor IX concentrate, and I think when you were here before during the B2 section, you said that the Edinburgh centre's practice after December 1984 was to prescribe unheat-treated Factor IX concentrate.

A. I think that's correct, yes.

Q. Yes. It's a very quick question, which is: to the best of your recollection, did you have any patients who required Factor IX concentrate between the end of 1984 and the end of 1985?

A. Yes, we had very few Haemophilia B patients. Rather fewer, I think, than we would expect for this population. And the guidance that was issued was either

to continue with NHS unheated Factor IX or to use heated commercial Factor IX. The infectivity, if I can put it that way, of Factor IX, even in those early days, was known to be much less than Factor VIII. The chances of someone with Haemophilia B being anti HTLV-III positive was very much lower and therefore I felt it was probably on balance safer to go on using NHS from our relatively AIDS-free population, if I can put it that way, than to use Factor IX that came from donors who may well have a very high prevalence -- a relatively high prevalence of HTLV-III and the heat treatment might have been ineffective, in a word.

Q. I think you told us that before. My question is: did you meet with your patients and explain the risk of using unheat-treated Factor IX during that period?

A. I think we must have done. We had very few patients. I think we must have done because it would have been -- everyone else was getting heat treatment and so they would have been a different group and we would have explained to them.

Q. Your recollection is that that risk was explained to them?

A. I think so, yes.

Q. Yes. Okay. Thank you. I want to move on to a separate topic. Can we have [LIT0010895]? What is this article,

professor?

A. This is an article primarily, or initially, written by my colleague, Dr Steel, as a result of his suggestion that we should HLA-type individuals with haemophilia.

Q. Yes. This is about the Edinburgh cohort, is it not?

A. It is, yes.

Q. Could we go to 0897? Just at the point that says:

"Discussion", if we could just expand that. This is a quotation which we used in the preliminary report. What's said here is:

"While there have been several longitudinal studies of HIV infection extending over three years or more and including much larger numbers of subjects, the Edinburgh cohort study is unique in at least three aspects. The patients had all been assessed before exposure to the virus; the period of exposure to infection has been defined with some precision; and since no other risk factor has been identified in any of the members of the cohort, all are presumed to have been infected from the same source (probably representing a single virus strain). Information on the subsequent clinical course of these patients is thus of special value."

Professor, this was truly a unique cohort of patients, was it not?

A. Yes.

Q. Would you agree that it had international attention?
A. Yes.
Q. And the cohort generated many research papers and medical articles?
A. Yes.
Q. Yes. I have a question for you about this, Professor Ludlam. We can see that the Edinburgh cohort was unique and very interesting from a research point of view. My question, Professor Ludlam, is: are you aware that some patients and relatives think that emphasising the research benefit that has accrued implies that the human dimension is insufficiently appreciated?
A. I have come to realise that but the patients who became infected in this cohort were treated and investigated no different from, I think, the other patients under my care who were HTLV-III positive. I regret that, as I think Alison Richardson said, some of them felt like guinea-pigs. That distresses me and distressed me and I'm sorry about that. On the benefit side, the patients were well investigated and monitored and it allowed us to get, I think, because of my research interests, earlier treatment for some of them.
Q. Yes.
A. But I'm -- I am sad that they felt like guinea-pigs, and as I mentioned a little while ago, this idea that

somehow I had possibly intentionally put HIV into bottles of concentrate to see whether the heat treatment process was effective -- I'm not quite sure where that arose but that's a very distressing and I don't know whether patients actually believed that. It's an awful thing if they did.

Q. Well, I wonder if I could ask you a few more reflective questions. Looking back now, are there any aspects of the AIDS study that you would do differently?

A. Do you mean of the cohort investigations?

Q. Yes, the early investigations, when you were using the forms being sent to Dr Steel?

A. Oh, in 1983?

Q. In 1983.

A. Well, I think we should have done one or two things. One would be to have called it an "assessment of CD lymphocytes" and made that explicit to patients, or the other actually was to say nothing to patients and just get on and do it. It was part of the monitoring process.

Q. Yes. Looking back now on the meeting in December 1984, would you organise it differently?

A. I don't know if I would have organised the meeting differency. I might have said things differently. I think perhaps it might have been -- would not have

denied patients their individuality or their right not to know, but perhaps if I had arranged for them to come and see Geraldine Brown for what you might call pre-test -- "post-test pre-telling you the answer counselling", if we had perhaps set that up and made sure that everyone came through that, I think that would have been another way to have approached it, and maybe I would do that if we were running this again.

Q. Yes. The third reflective question. Looking back now, would you handle the written communication with patients after the meeting differently?

A. I thought most of what was in the information sheet we sent out was as near as I could get to the situation. Perhaps I should have made it clearer that you, the reader, might be positive but as I say -- as I tried to indicate earlier, I think there was clearly a covering letter with the circular that I think would have made it clear that we were hoping to see the patient. Perhaps it could have been made a little clearer that, "You," as an individual reader, "might be positive".

Q. Yes. I have two further questions for you. For the first question I would like you to look at something that Professor Lever told us when he came here to give evidence. Could we have the transcript up at page 44. Could we go to the bottom of the page? There is

a question there about two different aspects of the risk/benefit analysis. Have you read this, Professor Ludlam?

A. I don't think I have read it all. I looked at parts of it. So assume I haven't.

Q. Could you just have a look at it at the moment and then read over the page to the beginning of 46?

THE CHAIRMAN: Can we all follow it through, please?

(Pause)

MR GARDINER: Have you read that, professor?

A. Yes, I have tried to take it in.

Q. Yes. Professor Lever is talking about an illness which had a very high mortality. What I would like to suggest to you that in 1983, when people with haemophilia were dying of AIDS, starting to die of AIDS, the risk/benefit changed so that it was necessary at that time for haemophilia clinicians to address that risk with each individual patient.

A. I don't know that the risk did change in 1983. The risk changed in 1984 or 1985 because the chance of bleeding in haemophilia, fatal bleeding, intracranial bleeding, in this country, each year about ten people died of intracranial bleeds, 1984, 1985 and 1986, and the number of individuals dying with AIDS in the UK were far below that number per year.

Q. I'm suggesting that that calculation is something that should have been addressed with patients on an individual basis, not the doctor making the calculation but discussing it with the patient.

A. I understand the question and I can say that it wasn't practice to do so, not just not in Edinburgh but I don't think virtually anywhere else, because -- again the risks were very small, perceived to be very small, of AIDS, the risks of bleeding were large, and if one was to try and reduce the risk of HTLV-III infection, then you might do that by offering cryoprecipitate and reducing the number of treatments and all the evidence is that that would have been very unacceptable to patients.

Q. Final reflective question for you, Professor Ludlam: a view has been expressed to the Inquiry that you were deflected from the need to have the risk/benefit discussion with patients because you were focused on the AIDS study. I would be grateful to have your comments on that view.

A. I would put it the other way round: I was acutely aware of AIDS being a risk from July 1982 onwards. And particularly by the end of 1982 when were several more patients had been reported with AIDS, haemophiliacs with AIDS, it was clear there was something unusual

happening. I was acutely aware of it. That's why I started to do the immune tests. That did not deflect me; it made me think very carefully about the risks as I perceived them.

Q. Just bear with me. (Pause)

Sir, I have no further questions.

THE CHAIRMAN: We will have a break at that point.

MR GARDINER: Yes.

(3.15 pm)

(Short break)

(3.42 pm)

THE CHAIRMAN: Professor Ludlam, I think it's obvious that you are quite tired. I am concerned that no one should be kept in the witness box beyond the point at which they feel comfortable. From our point of view, and I think from your point of view to some extent, to finish it is highly attractive as an option but if you feel that you are getting to the point at which the mind it no longer under the level of control that you would like, you really must tell me so that we can change course.

A. Thank you.

THE CHAIRMAN: Mr Gardiner?

MR ANDERSON: I wonder, sir, if I could interject at this stage.

THE CHAIRMAN: You are not going to tell me that you are tired.

MR ANDERSON: Sir, I'm always tired.

There is clearly an attraction for finishing, I think for everybody and indeed Professor Ludlam, but I understand that we are not sitting tomorrow, we are sitting on Tuesday and Wednesday and on Wednesday I think it's thought that we are going to have Dr McClelland in the afternoon. So there would be a whole morning slot next Wednesday, if that were considered attractive. I have discussed this with Mr Di Rollo and quite understandably he doesn't know how long he is going to be. He may be a very long time. He may be quite a short time. So I simply throw that into the equation as an alternative.

THE CHAIRMAN: In some context there is a law of diminishing returns, I rather suspect that in this there is a risk of a law of inflationary returns. The more time that's available, the more time will be taken. But what shall we do? I'm quite happy to take advice on this.

MR GARDINER: I'm not sure if we know the final position for Dr McClelland yet. I think it might be premature to start planning about that.

MR ANDERSON: I understand he is definitely available Wednesday afternoon.

THE CHAIRMAN: I understand it probably wouldn't be next Wednesday to continue with Professor Ludlam.

MR GARDINER: I don't think it's quite as clear as all that, sir.

THE CHAIRMAN: It's ten to four now, quarter to four now. I think my view would be that Mr Di Rollo certainly must not be compressed. You must not feel under any pressure. It wouldn't be fair. And I rather think that the two of you would simply get out of sync and matters wouldn't go well. I would rather that there was enough time for everyone.

So we will simply have to find another time, Professor Ludlam, for you.

Is there anything else that you want to finish off on?

MR GARDINER: I just have this one sheet of paper, sir.

Professor Ludlam, I promised that that was my last question. I apologise. I have one further one.

I think you should have a sheet of paper in front of you and it's a sheet of paper that at the top says:

"The Royal Infirmary of Edinburgh OP clinical notes."

Is that right?

A. Yes.

Q. This isn't in our database and I believe that this sheet

of paper has been produced by you. Is that right?

A. It's part of his -- the patient's principal medical records now.

Q. Yes. Thank you. Earlier --

THE CHAIRMAN: Let's just call it "document X".

MR GARDINER: "Document X". Thank you, sir.

This document X, is that the sheet that you were referring to from your private notes of the patient Mark. You referred to earlier?

A. It is.

Q. It is. I think you told us that you thought that this sheet dated from 1986?

A. That's correct.

Q. Yes. What are you basing that on?

A. Principally the date as written.

Q. That's to the left-hand column which says, "13/11 ..."

Then we see two figure?

A. Yes.

Q. You are reading that as an 8 and a 6.

A. I am.

Q. Yes, thank you. Just looking at what's written there, we see at line 4, that says:

"Working as ..."

Then redacted is the occupation:

"... started nine weeks ago."

Professor Ludlam, we heard from Mark that he had started employment when he was 19 and that would have been in 1988. So on that basis, is this entry not consistent with his evidence and does that not on reflection make it more likely that that is an 1988, as opposed to a 1986, entry?

A. My memory -- and I don't want to say what happened nine weeks before, but I -- my recollection is that he had started the work I have referred to here and I'm really -- I think, very sure that this was 1986.

THE CHAIRMAN: Professor Ludlam, is the original sheet in the records now?

A. Yes.

THE CHAIRMAN: Then I think that I will take steps with your help to see the original and perhaps we can come back to this some time in the future, because photocopies can do terrible things to documents.

And I suggest that we leave it there, Mr Gardiner, for the moment and then we will see if we can clear it up in due course.

MR GARDINER: Okay.

THE CHAIRMAN: Very well, ladies and gentlemen, I think we should adjourn at that stage, until Thursday.

(3.50 pm)

(The Inquiry adjourned until Thursday 23 June 2011 at 9.30

am)

I N D E X