

Tuesday, 28 June 2011

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(9.30 am)

PROFESSOR CHRISTOPHER LUDLAM (continued)

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

Questions by MR GARDINER (continued)

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

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

1 we go to line 11?

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

5 A. My --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16       A.   Yes.

17       Q.   And what is your view now about that?

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

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

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

24       Q.   Yes. Thank you.

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

1 end is about heat-treated Factor VIII. If we could have  
2 a quick look at [\[SNF0013211\]](#), we see that this is  
3 a letter dated 10 April 1984 by you to Miss J Spooner.  
4 Who was Miss Spooner?

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

9 Q. Yes.

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

12 Q. Yes. Do you remember this letter?

13 A. I remember the context.

14 Q. Yes.

15 A. I think so, yes.

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

18 A. I think there was a request, a circular dated  
19 29 March 1984, probably from Professor Bloom, who would  
20 be chairman of UKHCDO, encouraging haemophilia  
21 directors, if they were going to use heat-treated  
22 Factor VIII -- because there was a small amount of it  
23 around -- to not use it on a named-patient basis for  
24 treating patients, but rather to put it into clinical  
25 trials under the CTX arrangements, with the Committee on

1 the Safety of Medicines.

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

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

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

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

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

17       A.   That is correct.

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

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



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

6 Q. Yes.

7 A. And even that it was -- HTLV-III was heat sensitive  
8 in -- or should I say retroviruses, because it was  
9 a mouse retrovirus that was tested in October or  
10 thereabouts, 1984, we had no idea exactly how much heat  
11 would be necessary for how long to inactivate the  
12 concentrate. And as history showed, continuing in 1985,  
13 1986, at least, possibly 1987, there were heat-treated  
14 concentrates made from North American plasma that  
15 transmitted HIV.

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

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

21 A. Where the studies were done?

22 Q. Yes.

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

1 Centre for Disease Control in Atlanta.

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

6 A. No.

7 Q. No.

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

9 Q. Yes.

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

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

16 A. Erm ...

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

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

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

23 A. Yes.

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

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

4   A. High probability at that time.

5   THE CHAIRMAN: Thank you.

6           Mr Di Rollo?

7                               Questions by MR DI ROLLO

8   MR DI ROLLO: Thank you, sir.

9           Good morning Professor Ludlam.

10   A. Good morning.

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

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

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

8 A. Thank you. That's helpful.

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

15 A. That is, yes.

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

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

1 factor concentrates that seemed to cause AIDS.

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

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

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

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

1 Q. There had been studies in the United States that had  
2 found immune abnormalities in haemophiliacs and you  
3 wanted to find out whether there were similar immune  
4 abnormalities in your patients. Is that reasonable?

5 A. That's correct, yes.

6 Q. I think it's fair to say that, as a result of the work  
7 that you did carry out, it was discovered that there  
8 were certain immune abnormalities in your patients?

9 A. That's correct, yes.

10 Q. Did you inform the patients that such immune  
11 abnormalities were present?

12 A. I didn't make a point of informing them because we were  
13 really a little taken aback by them, not quite sure how  
14 to interpret them and what their clinical significance  
15 was, and I was also a little hesitant because the  
16 technology we were using was not what we would use  
17 today. It doesn't have the high degree of  
18 sophistication for counting numbers of cells. I think  
19 I described how we counted cells manually. It's a very  
20 imprecise way, particularly when there are small numbers  
21 of lymphocytes.

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

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

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

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

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

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

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

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

8 A. I think that's correct, yes.

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

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

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

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



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

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

12 A. That's correct, yes.

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

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

1 Q. I think we understand that but --

2 A. Sorry, can I just finish, if I may?

3 Q. Sorry, yes, of course, please do.

4 A. If you decide not to treat at the beginning, the pain  
5 becomes so great, they are requiring large amounts of  
6 morphine or pethidine. At that point the patient might  
7 then opt for treatment and would actually require much  
8 more treatment to settle the bleeds down than if he had  
9 had treatment right at the beginning, because all the  
10 evidence is that if you treat very early a bleed, then  
11 usually a single injection is enough, whereas if you let  
12 a bleed develop for several days, then you need an awful  
13 lot of treatment and therefore a lot of Factor VIII.

14 Q. Would that apply to prophylactic treatment as well? It  
15 wasn't just a case of using Factor VIII concentrates to  
16 treat bleeds but it was also being used as  
17 a preventative measure, was it not?

18 A. Not a great deal at that time because to give effective  
19 prophylaxis, you need to give injections every other day  
20 and you need to give large doses because the half-life  
21 of Factor VIII is about 12 hours, and you want to keep  
22 the level over about 1 or 2 per cent and so you need to  
23 give about 3,000 units, roughly, for an adult, on  
24 alternate days. And that will keep a child mostly  
25 bleed-free with severe haemophilia. But it uses up

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

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

8 A. There wasn't.

9 Q. There wasn't?

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

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

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

1           stop them bleeding.

2    Q.   All right.

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

4    Q.   When is that then?

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

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

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

1           if any patient had asked me about treatment, I would  
2           have explained my view, and I think my view would have  
3           been accepted by the patients.  If a patient had said to  
4           me, "I don't want any Factor VIII concentrate," then  
5           I would have said, "Well, would you like  
6           cryoprecipitate?  I can't guarantee that cryoprecipitate  
7           is free of a putative AIDS-causing factor but if you do  
8           want cryoprecipitate, I am afraid you would need to come  
9           up to hospital to get the treatment."  
10        Q.  Do you recall specifically any conversation of that kind  
11        taking place?  
12        A.  I don't think I do, no.  
13        Q.  I mean, I think in your earlier evidence, my  
14        understanding of your explanation, I think, for the  
15        position about cryoprecipitate was that SNBTS wasn't  
16        geared up to make a general switch back to  
17        cryoprecipitate.  So there would have been manufacturing  
18        problems relating to that.  That's what you indicated  
19        earlier.  Am I right about that?  
20        A.  That's correct.  We would have had cryoprecipitate -- if  
21        one or two patients had wanted to change, we could have  
22        changed those patients but if there was to be  
23        a wholesale move back to cryoprecipitate, my  
24        understanding is it would have taken a little while for  
25        the blood transfusion to acquire the necessary

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

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

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

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

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

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

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

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

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

1 Physicians is quoted as saying:

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

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

13 A. I think so, yes.

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

18 A. Yes.

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



1 about --

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

6 MR DI ROLLO: Yes, of course.

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

13 (10.25 am)

14 (Short adjournment)

15 (11.04 am)

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

21 Mr Di Rollo?

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

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

5 Can I ask you to have a look, please, at a document,  
6 page 3 of [\[WIT0011494\]](#)? Just scrolling up that, this is  
7 a medical record, as I understand it, of a patient in  
8 1982, which does have labelled on it "prophylactic", and  
9 obviously it's deal from 1982 onwards. As I understand,  
10 it, the medical record has the word "prophylactic" in  
11 reference to treatment from 1982 onwards. Can you  
12 explain that in the context of the evidence that you  
13 have already given?

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

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

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

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

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

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

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

16   A. This is the spring of 1983.

17   Q. Yes.

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

1 Q. So if a patient happened to come in for whatever reason,  
2 then a sample might be taken and looked at for the  
3 purposes of this work as well as for other things; is  
4 that right?

5 A. It would be opportunistic, yes.

6 Q. Did you look at all of the patients that came in or just  
7 some of them?

8 A. It wasn't a systematic study, if you like, or assessment  
9 of all patients; it was the ones who were readily around  
10 and available.

11 Q. So would there be patients that would come in and you  
12 would decide not to look at them then?

13 A. Might have been certainly. We might not have been  
14 wanting to take blood from them for other reasons and we  
15 wouldn't have taken blood, I think, just to do these  
16 tests. It probably depended a bit on the time of day,  
17 because you may recall that the samples had to be  
18 ferried across from the Royal Infirmary to The Western  
19 General Hospital, and probably processed the same day.  
20 So if someone came late in the afternoon, for example,  
21 it may well be that we wouldn't have put their sample  
22 through for the lymphocyte assessment.

23 Q. The lymphocyte assessment is what we see on the record?  
24 It's labelled "AIDS study"; that's what's going on?

25 A. That's correct, yes.

1 Q. In relation to those patients, how would the staff know  
2 which patients to label with "AIDS study"?

3 A. All the patients would be seen by either myself or one  
4 of my registrars and we had agreed that if blood was  
5 being taken, we would assess them for lymphocytes.

6 Q. You say "we agreed;" whose decision was that?

7 A. Well, it would have arisen out of discussion between us.

8 Q. You say "us", who is "us"?

9 A. Myself and the registrars. It's probably initiated from  
10 me because I was the one, if you like, who was in touch  
11 with what was happening internationally.

12 Q. Right. Would there be any reason to pick one patient  
13 over another, other than this sort of administrative  
14 considerations that you have indicated?

15 A. I think we probably would have been more interested  
16 assessing patients, as I think I mentioned earlier, with  
17 moderate and severe haemophilia because they were the  
18 ones who had received a lot of concentrate. If  
19 a patient with mild haemophilia came up, we might not  
20 have done the test because we might have thought they  
21 might not have had any blood product treatment at all in  
22 their life.

23 Q. Was it just severe haemophiliacs that you looked at or  
24 did you look at moderates as well?

25 A. I think severe and moderates.

1 Q. It is a fact that Dr Steel carried out his work in  
2 a different lab from other tests. In other words,  
3 samples were taken and tests were carried out but what  
4 Dr Steel was doing was being done somewhere else.  
5 That's correct?

6 A. That's correct, yes.

7 Q. Patients were not specifically, on an individual basis  
8 or on a, if you like, a coherent basis, specifically  
9 informed of the results of the test. Is that right?

10 A. That's correct, yes.

11 Q. And the results that you obtained as a result of this  
12 work were analysed; you looked at this work and you  
13 analysed it. That's right?

14 A. Yes.

15 Q. And you did publish the results of the work?

16 A. Yes.

17 Q. I think we see that the initial prompt -- or maybe not  
18 prompt but the letter in the Lancet by Gordon, which you  
19 picked up on and replied or responded to, also in the  
20 Lancet, refers to doing a study of T lymphocyte  
21 subpopulations in a geographical area where AIDS is not  
22 introduced. That's what it refers to.

23 A. It does.

24 Q. And in your reply you indicate that work has been done,  
25 a study of haemophiliacs in the Southeast of Scotland.

1           That's what you refer to.

2    A.   Yes.

3    Q.   Did you seek ethical approval for this work?

4    A.   No.

5    Q.   Can you explain why not?

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

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



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

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

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

14 Q. That's not what I meant.

15 A. I'm sorry.

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

23 A. Usually.

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

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

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

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

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

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

24 A. No.

25 Q. Did you have to perform skin tests?

1 A. The skin tests were a slightly different enterprise.

2 Q. Can I just be clear: were they in connection with this  
3 work or were they for something else?

4 A. My interest became in 1983: why does it appear that  
5 people with haemophilia have abnormal immune systems?  
6 And the simplest thing to do, for reasons that have been  
7 well rehearsed here, was to count the CD4 and the CD8  
8 cells. We then wondered, "Well, how else can we look at  
9 the immune system in people with haemophilia?" Because  
10 in Scotland, if I can put it this way, at that time  
11 patients weren't getting opportunistic infections. They  
12 weren't getting PCP, like in North America. So the  
13 patients didn't appear to be clinically  
14 immuno-suppressed, at least to the extent at which they  
15 would get opportunistic infections.

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

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

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

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

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

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

9 A. Skin tests were done in 1984.

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

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

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

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

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

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

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

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

8 A. Certainly, yes.

9 Q. You would be saying that?

10 A. Oh, yes, yes.

11 Q. And did you record that in their notes?

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

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

18 A. In 1984, yes.

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

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

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

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

8 A. That's correct.

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

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

16 Q. And measuring the immune system for what purpose?

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

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

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

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

1           Do you have it, Professor Ludlam?

2   A.   I don't think I have it with me.

3   THE CHAIRMAN:  But it exists and you have a copy in your  
4           possession.

5   A.   I have a copy of it.  I think the Inquiry has the  
6           original.

7   MR GARDINER:  I think this whole exercise arose in  
8           Dr Ludlam's original statement, or the notes of the  
9           meeting that Professor Ludlam gave to the Inquiry, and  
10          I think Professor Ludlam was using it as a comparison to  
11          the 1983 immune studies.  But I don't think that we have  
12          that material.

13   THE CHAIRMAN:  I'm not anxious that one should speculate  
14          about the content of a document if it actually does  
15          exist and could be obtained.  It might be an easy answer  
16          to your particular question.

17   MR DI ROLLO:  It might be.  I haven't seen the document  
18          myself, I have to say, and I wasn't entirely sure what  
19          the position of the witness was on this particular topic  
20          and that was why I was asking the questions.

21   THE CHAIRMAN:  It is unusual for Professor Ludlam to refer  
22          to a specific document if he hasn't seen it recently,  
23          Mr Di Rollo.

24   MR DI ROLLO:  Indeed.

25   THE CHAIRMAN:  And that's why I asked whether he has.  So

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

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

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

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

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

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



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

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

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

18 MR DI ROLLO: Yes, indeed. Thank you.

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

20 A. I'm embarrassed to say it is.

21 Q. Right.

22 A. By degree of clarity rather than its content.

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

24 A. Would you like me to read it?

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

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

9 Much of this --

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

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

17 "What is the object of the project?"

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

25 Q. Then the next question is:

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

3    A.    I have written:

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

7    Q.    Then:

8            "Briefly describe the design of the project."

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

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

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

14   Q.    Then the next part of the form says:

15            "Will subjects/patients be ..."

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

18   A.    That is correct.

19   Q.    Then it says:

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

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

23   Q.    Then you are asked:

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

1           Your answer to that is?

2    A.    "No".

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

4           Then you have indicated?

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

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

7    Q.    You are asked to list any drugs to be administered and

8           your answer to that is "none", and then you are asked:

9            "What risks to the subjects/patients can you

10          foresee?"

11          Your response to that is?

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

13   Q.    Then you are asked:

14          "What discomfort to the subjects/patients do you

15          foresee?"

16          You say:

17          "As above."

18          Then:

19          "Will informed consent be obtained from all

20          subjects?"

21          What is your response to that?

22   A.    "Yes".

23   Q.    Were all of the patients who were looked at here aware

24          that they were HIV positive?

25   A.    A lot of these patients were HIV negative.

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

5 A. They might not have been.

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

8 A. Because I was explaining to everyone at the beginning of  
9 1985 that we were wanting to monitor as many people's as  
10 possible immune status for their own benefits. What  
11 I perhaps should say at an appropriate place but let me  
12 say it now.

13 Q. Do.

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

1 properly. Because, if you like, the tests I had done in  
2 1983 were a relatively small number in relatively few  
3 patients. The situation had now arisen where I needed  
4 to -- for the patients' welfare -- to be able to monitor  
5 a lot of patients and the only way I could do that was  
6 to get extra money into the system and if someone would  
7 give me money from a research fund, so much the better.

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

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

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

14 Q. Professor Ludlam --

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

24 A. Erm --

25 THE CHAIRMAN: Is that --

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

22 A. That's correct, yes.

23 Q. The next question that's asked on the form is:  
24 "How will consent be recorded?"  
25 And it says:

1           "Written in the case notes."  
2           Is that right?  
3    A.   Can we -- this was a draft form.  
4    Q.   Right.  
5    A.   Can we look through to the end. I hope I didn't send  
6           this in to Lothian Health in this form, but have  
7           I signed it? So it's not signed or dated. So this was  
8           clearly a draft. Can we go back to the --  
9    Q.   Yes, I think I have missed out a question, which is 17,  
10           where you are asked:  
11           "What information will be given to  
12           subjects/patients?"  
13           And the answer there is?  
14   A.   So:  
15           "Patients and controls are very well-informed about  
16           our studies."  
17   Q.   Right. Then it says:  
18           "How will consent be recorded?"  
19           And it says:  
20           "Written in the case notes."  
21           That's right? That's what it says?  
22   A.   That's what it says.  
23   Q.   Are you saying that this isn't the form that went for  
24           ethical approval?  
25   A.   I can't tell you because I don't have it but I'm not

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

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

10                 "How will consent be recorded?"

11                 And the answer is:

12                 "Written in case notes."

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

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

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

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

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

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

23 Q. Just dealing with the rest of the form, the question is:  
24 "Will the subjects be informed of the right to  
25 withdraw."

1           The answer is "yes":

2           "Has the Committee on the Safety of Medicines'

3 approval been given."

4           That's "not applicable". The next number of

5 questions are negative down to question 23:

6           "What information will be given to the patient's

7 general practitioner and by whom?"

8           What do you say there?

9   A.   Sorry, which question?

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

11   A.   "Probably not unless important clinical results emerge

12        from studies."

13   Q.   Then the next two questions I think we can ignore. You

14        say that there is an application for financial support,

15        is that right. Question 26?

16   A.   Yes.

17   Q.   Down at 28, it says:

18        "Has a submission been made to any other appropriate

19        ethical committee (including university ethical

20        committee ..."

21        Et cetera. What's your answer to that?

22   A.   "... skin tests received approval of South Lothian

23        Ethics Committee in 1984."

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

25   A.   Yes.

1 Q. Then question number 29:  
2 "Are there any other points you wish to make in  
3 justification of the proposed study?"  
4 What's your answer to that?  
5 A. "Part of this study was previously submitted and  
6 approved to the Ethics of Medical Research Subcommittee,  
7 follow-up of anti HTLV-III negative haemophiliacs. Your  
8 letter dated 14 March 1985."  
9 Q. Right. So it does appear that some of the patients who  
10 were undertaking this, who were being looked at for the  
11 purposes of this study, would not have been aware that  
12 they were HIV positive at the time that this work was  
13 being carried out. That appears to be the case?  
14 A. Yes.  
15 Q. They would be aware, if they were told by you about the  
16 work, that there doesn't appear to be any record of  
17 their consent in the case notes. Is that right?  
18 A. That's correct, yes.  
19 Q. Is it right to say that there wouldn't then be any  
20 written record of their consent at all to this?  
21 A. There would be verbal consent but no written consent,  
22 yes.  
23 Q. What they were told, as I say, about this would depend  
24 on who it was that spoke to them about it and what  
25 exactly they were told about it at the time.

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

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

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

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

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

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

24 A. Only if they had asked.

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



1 28 February letter, which is another application for  
2 consent. It's [\[LOT0014970\]](#). The accompanying form,  
3 which is [\[LOT0014973\]](#). Again, can you just tell us what  
4 this relates to and what this is for?

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

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

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

1 of the project is:

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

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

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

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

12 "Will informed consent be obtained from all  
13 subjects?"

14 And your answer is?

15 A. "Their cooperation will be sought."

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

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

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

3    Q.   You then say:

4            "What information would be given to patients?"

5            It says:

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

8            Then you are asked:

9            "How will consent be recorded?"

10          You say:

11          "I was not planning to record this."

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

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

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

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

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

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

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

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

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

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

19 A.   Yes.

20 THE CHAIRMAN: Yes.

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

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

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

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

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

25 Q. If we look at [\[LIT0010895\]](#), this is the publication of

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

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

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

9 "31 have participated in follow-up studies that have  
10 included regular clinical examination, virological  
11 investigations, and analysis of circulating TC subsets."

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

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

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

1 A. We are, yes. You are correct.

2 Q. So if I know I'm seropositive and I know my year of  
3 birth, I know this is about me, don't I?

4 A. Yes.

5 Q. I mean, if I hadn't given consent for publication,  
6 specifically, it might concern me that I'm being looked  
7 at and published about without my knowledge.

8 A. I think in retrospect -- I wasn't the primary author of  
9 this paper but I think in retrospect, I think it would  
10 have been better if we hadn't published the years for  
11 the reason that you have raised and I'm sorry about  
12 that. This was on the spectrum of how much you could  
13 publish and how identifiable patients could be and that,  
14 as we discussed a little while ago, was changing.

15 In retrospect I think it was unfortunate that the  
16 years of birth -- it is not dates of birth, it's years  
17 of birth -- went into this table.

18 Q. The phrase in the earlier introduction was:  
19 "31 have participated ..."  
20 And someone might feel that they hadn't actually  
21 participated or volunteered. It is the passive voice,  
22 I think, that we see there:  
23 "31 have participate in follow-up studies."  
24 And the extent to which they are fully aware of what  
25 is going on might in certain cases at least, depending

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

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

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

11   A. The samples I sent to Dr Tedder?

12   Q. Yes.

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

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

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

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

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



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

3    Q.    So how did you select the individual patient?

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

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

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

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

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

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

20   A.    Yes.

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

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

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

1 selection?

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

4 Q. Do you remember what instruction you gave?

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

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

13 A. On an anonymised basis?

14 Q. Yes.

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

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

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

8 A. That is true.

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

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

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

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

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

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

1 Q. That it would be positive.

2 A. I thought it possible that one or two of the patients  
3 that had received the commercial concentrate over  
4 previous years might have been positive but I hadn't  
5 anticipated that those who had received SNBTS  
6 concentrate could be positive.

7 Q. But even those that are commercial, the same problem  
8 arises over the difficulty about what to tell them once  
9 you have the result of a test that you haven't told them  
10 you are carrying out.

11 A. Yes, in a sense that applies to any test, virological or  
12 otherwise, and I think that's where the whole ethos and  
13 practice of medicine has changed really as a result of  
14 what happened in the mid 1980s in relation to HIV.

15 Q. One option you might have had would have been to have  
16 paused. You got some results back, they were positive  
17 at that point. You did know that not just commercial  
18 but SNBTS product patients were positive, apparently,  
19 and you then sent further patients down, again without  
20 their knowledge or consent, for that test, and on  
21 a named-patient basis. Again, did you not think at that  
22 point, "Hang on a moment, I had better stop or at least  
23 consult colleagues or whatever to see what I should be  
24 doing now?"

25 A. I can see your proposition and I can see its attraction.

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

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

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

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

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

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

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

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

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

18 Q. The test for HIV, I mean.

19 A. I'm sorry.

20 Q. Yes.

21 A. Could you repeat your question?

22 Q. Sorry, it's my fault.

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

1 A. Subsequent to January 1985, yes, consent was obtained.

2 Q. No, I'm talking about before that.

3 THE CHAIRMAN: Mr Di Rollo, I think that there is legitimate  
4 scope for misunderstanding because you have not  
5 specified the period.

6 MR DI ROLLO: I understand that. The specific period I'm  
7 interested in, Dr Ludlam, is the tests that were carried  
8 out by Dr Tedder, the results of which you obtained  
9 on October 26th 1984 relating to the ten and then  
10 subsequent testing that was carried out up until the end  
11 of 1984. Were any blood samples taken from patients  
12 specifically for the purposes of a test?

13 A. I don't think so, no. I think they were all samples  
14 that were taken from the deep freeze.

15 Q. You talked about it being the counsel of perfection to  
16 pause and seek advice at that particular time but we  
17 have heard evidence that it is possible one other  
18 physician in Scotland did do that, that there was  
19 a situation, as I understand it, that has been spoken  
20 about in evidence, in Glasgow, where testing was  
21 anonymised and then there was a pause before anything  
22 further was done. You heard the evidence, I think, of  
23 Dr Wilkie about that. You say that's the counsel of  
24 perfection but it doesn't seem to be beyond the scope of  
25 something that could have been done.



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

7 Q. If we look at the memo from Dr McClelland, which is  
8 [\[SNB0065996\]](#) --

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

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

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

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

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

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

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

8 A. No, I think it grew on an individual basis, if I can put  
9 it that way, by the larger haemophilia centres, who were  
10 very actively concerned about the whole situation.

11 Certainly one or two of the big ones in London had been  
12 in touch with Dr Tedder. But there wasn't, if I can put  
13 it this way, universal testing of people with  
14 haemophilia in late 1984. There was the letter sent out  
15 after the meeting of 10 December, a letter by  
16 Professor Bloom, dated about 14 or 18 December, in which  
17 he recommends that patients are treated and they are  
18 sent to not only Dr Tedder but -- I'm sorry, I have  
19 forgotten his name.

20 THE CHAIRMAN: Mortimer?

21 A. Yes, Philip at NIBSC.

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

1 A. Yes.

2 THE CHAIRMAN: So the bigger centres would have been in  
3 contact and they would be looking for a slot, as it  
4 were, in the limited programme that he could carry out?

5 A. That's correct, yes.

6 THE CHAIRMAN: So your number is set at ten and then one  
7 comes to the questions that Mr Di Rollo was asking you  
8 about how you filled your quota.

9 A. Yes.

10 THE CHAIRMAN: That was when you personally had to lay down  
11 some criteria for selection?

12 A. Yes.

13 THE CHAIRMAN: Mr Di Rollo, I think that's enough for me to  
14 understand the background but clearly you may wish to  
15 follow some aspects.

16 MR DI ROLLO: Thank you.

17 When you got the first ten back, how did you choose  
18 the next lot to test?

19 A. I think those would be the individuals who were the  
20 largest users, probably, of clotting factors. It, as  
21 I think I indicated earlier with just the three results,  
22 the batch 0090 was one of the possible batches that  
23 might have caused the infection and I might have  
24 chosen -- I can't remember -- more patients who received  
25 that batch to see what the situation was.

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

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

6 Then a number is given:

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

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

13 A. Yes.

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

20 Presumably records of that kind did exist at one  
21 time?

22 A. Indeed, yes.

23 Q. Do they still exist?

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

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

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

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

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

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

25 A. No, this is the first ten.

1 Q. Right. The confirmatory tests are a reference to what?

2 A. Well, there were six of the ten who were anti HTLV-III  
3 positive. The test was under development at that time  
4 and I knew from talking to Professor Tedder that there  
5 was a degree of uncertainty about positivity, about the  
6 interpretation. The test was being refined and  
7 therefore I was not keen to put too much reliance on  
8 just single results. There is always possibility, as  
9 I mentioned earlier, of samples getting mislabelled  
10 somewhere along the line as well. So it's such an  
11 important test that I would want it doing at least in  
12 duplicate.

13 Q. So who is going to be carrying out the confirmatory  
14 tests?

15 A. I would suspect that -- I can't remember in detail but  
16 it's possible that some of the second batch that was  
17 sent may have been from the same individuals, but  
18 certainly when Dr Peutherer set up the tests in  
19 Edinburgh in the virology department in early 1985,  
20 samples would have been sent to him for confirmatory  
21 testing.

22 Q. The desire to self-confirm confirmatory tests carried  
23 out and to give the results of these as soon as  
24 possible, tends to suggest a bit more urgency than even  
25 early the following year. Is that not a reference to

1 something a bit sooner than that?

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

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

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

8 Q. Were repeat tests done?

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

11 Q. On the original ten or of the six?

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

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

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

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

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

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

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

18   A.   Sorry, which particular --

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

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



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

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

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

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

16 Q. And not on clinical signs either then?

17 A. There weren't any clinical signs.

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

22 A. 14 March 1983.

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

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

2 I'm sorry --

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

4 A. It says something about:

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

6 That's scribbled out.

7 THE CHAIRMAN: I think it's:

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

9 That has been scored out.

10 A. Yes.

11 MR DI ROLLO: Then if we go to the final page, this

12 is November 1984:

13 "Haemophilia AIDS study. 200 cell diff. Please

14 ..."

15 Is that:

16 "Please + keep S plus card"?

17 Then it has:

18 "High risk sample."

19 A. Yes.

20 Q. Could you just explain what those words refer to there?

21 Can you explain what's meant by what's in there?

22 A. I think -- oh, yes, I can help you. "Haemophilia AIDS

23 study", self-explanatory. "200 cell diff, please. Keep

24 S plus card." The request forms consist of two parts.

25 The top part, which is a thin piece of paper, which is

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

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

16          It then says:

17          "High risk sample."

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

1 laboratory.

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

5 Q. When was that decision taken?

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

8 Q. Who took that decision?

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

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

13 A. I am.

14 Q. You say we --

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

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

25 A. Absolutely not.

1 Q. You say "absolutely not" because you know what you  
2 intend by it, but somebody else looking at it might not  
3 appreciate that?

4 A. These forms were prepared, written by members of the  
5 haemophilia centre staff, there had been a lot of  
6 discussion in our laboratories -- our laboratories are  
7 well used to handling samples that presented increased  
8 risk of infection, and it was well understood by our  
9 laboratory that all these samples would be handled the  
10 same, irrespective of their anti-HTLV-III status. This  
11 was a way of very specifically not wanting to  
12 stigmatise --

13 Q. All the nursing staff would understand that?

14 A. Yes.

15 Q. And this is obviously an early stage because we are  
16 dealing with -- this is 21 December 1984 and it's only  
17 a matter of three or so weeks since a positive result  
18 has been obtained. So is the discussion that you had  
19 just within your hospital or was it taken to a higher  
20 level in terms of other haemophilia doctors or  
21 throughout the country or beyond? Was it just something  
22 in-house as far as you were concerned, the discussion  
23 just referred to?

24 A. It was initially in-house.

25 Q. So in relation to this passage of evidence, your

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

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

11 Q. I'm sorry.

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

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

16 (1.00 pm)

17 (The short adjournment)

18 (2.00 pm)

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

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

2 A. Yes.

3 Q. It does appear that if ten samples were sent at random  
4 to Dr Tedder for testing, if six out of ten proved  
5 positive and were positive, then obviously that's quite  
6 a high strike rate. Obviously other tests later on on  
7 other samples, the proportion of positive to negative  
8 goes down, but the initial batch appears to be  
9 60 per cent positive. Is that right?

10 A. That is correct, yes.

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

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

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

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

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

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

15 A. I think both.

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



1 coming out in the press. Is that right?

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

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

8 A. Yes, I can see you better.

9 Q. Do you want me to repeat the question?

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

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

16 A. Yes.

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

21 A. Yes.

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

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

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

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

16 Q. And when would you have done this?

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

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

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

24 Q. Sorry, what meeting was that?

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

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

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

12 Q. Nothing had happened in terms of sorting this out.

13 Clearly there was a need to do something as soon as you  
14 got results of the kind of results you did get. It was  
15 obvious that something was going to have to happen about  
16 informing patients in some way.

17 A. Yes.

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

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

1           between these two jobs.

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

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

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

17  A.   The ones from Edinburgh, yes.

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

20  A.   Yes.

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

24  A.   That's correct.

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

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

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

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

12 A. No.

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

19 A. Yes.

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

22 A. I don't recall doing so.

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

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

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

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

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

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

23 A. I think it is, yes.

24 Q. What would you describe it as?

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

1 the patients.

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

8 A. That's what it says.

9 Q. The report carries on:

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

14 Is that part accurate?

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

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

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

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

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

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

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

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

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

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

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

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

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

23 "Dr Christopher Ludlam ..."

24 Et cetera, and then carries on:

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



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

23 If you can scroll down just a little for me:

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

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

2 If you go to:

3 "Some of them were carrying AIDS antibodies.

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

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

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

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

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

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

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

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

17 Q. Did you read the article at the time?

18 A. I'm sure I did, yes.

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

21 A. No.

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

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

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

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

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

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

19 A. That's correct, yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 "So far as I can ascertain [\[the patient\]](#) did not  
25 have any treatment in the years 1985, 1986, 1987, and



1           therefore there would not be any transfusion records  
2           available.

3           "I have looked back at his records and find that he  
4           was negative for the HIV antibody test on  
5           31 January 1984 and was found to be positive on  
6           29 May 1984. During this five month period he was  
7           treated exclusively with Scottish National Blood  
8           Transfusion Factor VIII ... It seems highly likely that  
9           he became infected from this concentrate."

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

13       A. One of the 18?

14       Q. One of the 18, yes.

15       A. Yes.

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

22       A. He had been studied like the others.

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

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

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

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

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

17 "As far as I can ascertain ..."

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

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

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

9    A. I'm sorry, you have lost me.

10   Q. Right, all right.

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

12   A. Yes.

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

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

20   THE CHAIRMAN: I think the arithmetic is not quite right.  
21           20.

22   A. 20. Sorry, 20 years.

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

1           could be a journalist from the Yorkshire Post.

2    A.   I know who the letter is written to.

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

4           witness?

5    THE CHAIRMAN:   I think if you know it, you might be able to

6           help me without embarrassing the witness.

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

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

9    UNKNOWN SPEAKER:   I think that's correct.

10   THE CHAIRMAN:   It might be quite important to know,

11           Mr Di Rollo, because that may affect the way in which

12           one answers a letter or writes a letter.

13   MR DI ROLLO:   Looking at the file, I do beg your pardon, my

14           learned friend is correct.  It is in fact to the

15           relative rather than to the solicitors.  There is other

16           correspondence close to this one, which is solicitors,

17           but this particular letter is to the relative in fact.

18           I think the chairman has indicated the point I was

19           trying to make was that: don't you think it might have

20           been more to the fore front of your mind as to who this

21           particular person was and what the history was, given

22           the familiarity you had with these 18 cases?

23   A.   I knew entirely who the individual was.  I couldn't

24           remember the dates in my head and I certainly couldn't

25           remember, without trying to look through our records,

1 exactly what his transfusion history would be. So

2 I would need to do that.

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

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

9 Q. I'm content with that.

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

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

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

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

1           Then this is the sentence I am interested in:

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

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

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

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

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

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

18 A. Yes.

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

22 A. Yes.

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

1 A. That patients should trust medical advice.

2 Q. They were required to trust the medical advice that they  
3 were given.

4 A. I hope patients respect the advice that they are given.

5 Q. And if they were using factor concentrates, they were  
6 following medical advice?

7 A. Yes.

8 Q. And in Scotland it was thought that NHS products were  
9 safer than the alternative commercial material. That's  
10 what patients were told?

11 A. That was my view.

12 Q. Well, it did turn out that factor concentrates were not  
13 safe, at least not entirely safe. That's right?

14 A. The NHS concentrates were safer from the point of view  
15 of HTLV-III than commercial concentrates.

16 Q. But they weren't entirely safe, as it turned out.

17 A. No, but they were safer, substantially safer.

18 Q. Those patients we are talking about were studied during  
19 a period; there were a number of studies that were  
20 carried out from 1983 to 1988?

21 A. I'm sorry, what was --

22 Q. The proposition I'm putting to you is that there were  
23 a number of studies carried out on patients at  
24 Edinburgh, haemophilia patients, between 1983 and 1988.  
25 A number of studies were carried out.



1 A. They were being monitored for their medical situation,  
2 yes.

3 Q. And plainly some patients were unaware of the precise  
4 extent of those studies. They didn't necessarily  
5 appreciate all those studies entailed?

6 A. I think that is fair. It would be difficult for the  
7 patients to understand perhaps everything. Not  
8 everything was done on all patients. And there were  
9 some investigations that were done on not all patients,  
10 like the skin testing.

11 Q. The patients were aware that they were being tested from  
12 time to time, they may or may not have been precisely  
13 aware of what the purpose of these numerous tests were  
14 at any particular time. They wouldn't necessarily know  
15 exactly what tests were being carried out for.

16 A. They would know -- and I had made it explicit that we  
17 were studying their immunity and HTLV-III status.

18 Q. And testing for the HTLV-III virus was carried out  
19 without patients' knowledge or their consent?

20 A. Not after 1985.

21 Q. Professor Ludlam, in 1984, in October, or whenever it  
22 was that the tests were carried out, it was carried out  
23 without their knowledge or their consent?

24 A. That's correct, yes.

25 Q. And not all of the positive patients were specifically

1 informed of their results until later on?

2 A. Until later, that's correct.

3 Q. And it appears that some of those patients didn't  
4 appreciate that in order to find out whether they had  
5 been tested or to find out the results of those tests,  
6 they needed to ask specifically for that?

7 A. Well, I think I have made my position very clear, that  
8 I consider that the information was readily available  
9 and there were some patients who, for a number of  
10 reasons, were keen not to know.

11 Q. I'm thinking about people that may have been keen not to  
12 know but didn't realise that they were positive and  
13 needed to ask in order to find out?

14 A. I think in these circumstances they may have been afraid  
15 to know. Maybe we should have helped them but -- and  
16 eventually, as you know, everyone was told.

17 Q. But it does seem that some patients did assume that they  
18 were negative on the basis of the information they had.  
19 Wrongly; they may not have understood what you were  
20 saying at the meeting, they may not have fully picked up  
21 properly on the leaflet that was sent, they may not have  
22 understood the message that you were trying to convey.  
23 That's the point I'm making.

24 A. I suppose the information was given out in very many  
25 different ways, in many different formats, and if at the

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

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

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

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

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

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

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

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

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

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

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

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

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

3 A. I can see that patients -- HIV was a little bit like  
4 a tsunami. You saw something on the horizon and it  
5 gradually got closer and it overwhelmed us in the late  
6 1980s. The demands of all sorts of difficulties that  
7 these patients -- and very sadly many here who can't  
8 attest to how they found the service that we provided.

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

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

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

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

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

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

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

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

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

1 A. We think it's 18.

2 Q. We know that there were 23 in Edinburgh, I think, that  
3 were HIV positive. Some of the other five, did they all  
4 get commercial product at some time or another or did  
5 some of them only get SNBTS products as well?

6 A. That information, I think, has been made available to  
7 the Inquiry, right at the beginning, when I first  
8 appeared. My recollection -- and I may be wrong. My  
9 recollection is that, of the 23 patients who got  
10 infected in Scotland, one was from commercial and the  
11 remainder appear to have been from NHS concentrates.

12 Q. Some of the patients that received the implicated batch,  
13 some of the 18 would also have received the same SNBTS  
14 products as the other five did; in other words, there  
15 would be a commonality in terms of the batches that they  
16 received, between some of the 18 and the five?

17 A. Some would have been, yes.

18 Q. And the more exposure to HIV that you have, the more  
19 likely you are to seroconvert?

20 A. Yes.

21 Q. And we know that the implicated batch is only weakly  
22 positive. That's the information that we have had, that  
23 the implicated batch is only weakly positive in its  
24 test.

25 A. That's my understanding. Weakly positive in one of the



1 tests.

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

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

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

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

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

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

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

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

14 Does that help?

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

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

1 from SNBTS products. Yes.

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

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

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

11 THE CHAIRMAN: We will have a break.

12 (3.18 pm)

13 (Short break)

14 (3.40 pm)

15 THE CHAIRMAN: Mr Anderson?

16 MR ANDERSON: I'm obliged, sir.

17 Questions by MR ANDERSON

18 MR ANDERSON: Professor Ludlam, good afternoon.

19 A. Good afternoon.

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

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

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

25 Can we start by looking at the document

1 [\[PEN0120774\]](#). This is the notes of the meeting between  
2 yourself Gemma Lovell and Douglas Tullis. Can we look,  
3 please, at page 0078?

4 You see in the first full paragraph it says:

5 "In 1983 we started looking at lymphocytes. The  
6 haematology lab continued to assess patients' full blood  
7 counts in the usual way except that instead of counting  
8 100 white cells, which was then done visually by  
9 microscope, they counted 200 white cells. Lymphocytes  
10 are a type of white cell. There are 4-5 different types  
11 of white cells. Lymphocytes form a small proportion of  
12 the total number of white cells (approximately 15 to 25  
13 per cent)."

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

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

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

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

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

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

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

25 A. No.

1 Q. Why not?

2 A. Because they would help in the clinical assessment of  
3 the patient; in other words, if you had an increased  
4 number of, shall we say, eosinophils, that might be  
5 because you have got some allergic reaction in your  
6 body.

7 Q. When you began this lymphocyte count in 1983, did it  
8 strike you that this was somehow in a different category  
9 from these other routine tests?

10 A. Not particularly, in that although many lymphocytes look  
11 the same, there are some that actually look a bit  
12 different and you can distinguish them down the  
13 microscope. There are some lymphocytes that look rather  
14 similar but have rather different functions. And so to  
15 distinguish between them you have to stain them and  
16 that's what we were doing, or Dr Steel was doing for us  
17 down at the Western.

18 Q. I mean, did it ever occur to you that it was necessary  
19 or mandatory to obtain express consent for this  
20 additional investigation?

21 A. Not really, in that it was -- we were looking at the  
22 white cells which we had done -- the different sorts of  
23 white cells for long enough as monitoring our patients.  
24 They might have had an infection and they got an  
25 increase in their polymorph count, for example, which is

1 another sort of white cell.

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

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

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

10 A. None.

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

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

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

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

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

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

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

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

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

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



1 THE CHAIRMAN: Right.

2 A. They all look the same down the microscope and these  
3 cell markers were only identified and the tests set up  
4 to distinguish between them, I think, only two or three  
5 years sooner. So there wasn't a great amount of  
6 knowledge about them.

7 THE CHAIRMAN: Thank you.

8 Yes, Mr Anderson?

9 MR ANDERSON: We know, professor, that one result of this  
10 lymphocyte count was firstly a letter to the Lancet, and  
11 I don't think we need to look at these specifically but  
12 for the purposes of the transcript, there was a letter  
13 to the Lancet in May 1983. That's reference  
14 [\[LIT0010416\]](#). We have looked at this on a number of  
15 occasions but it's really simply setting out the  
16 finding, isn't it?

17 A. Yes.

18 Q. It's just giving information?

19 A. Yes.

20 Q. Without any form of analysis. Is that correct?

21 A. Yes.

22 Q. And then we know that there was a later article  
23 in June 1984. Is that correct?

24 A. That's correct, yes.

25 Q. The reference for that is [\[LIT0010425\]](#), and would it be

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

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

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

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

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

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

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

1 A. Yes, I thought it possible but very unlikely.

2 Q. All right. In the document with a reference

3 [\[PEN0120351\]](#) -- that's the Edinburgh Haemophilia and

4 Thrombosis Centre document -- at paragraph 15 you say

5 that:

6 "Dr Tedder had a limited supply of reagents and he

7 was receiving many requests from other clinicians."

8 I think in evidence today you actually suggested he

9 was being inundated. These clinicians would be what,

10 directors of other haemophilia centres?

11 A. That would be correct, yes.

12 Q. So presumably you weren't alone then in seeking

13 Dr Tedder's assistance?

14 A. By no means. There are, in any one year, 2,000 or 3,000

15 patients with haemophilia treated in the UK and all the

16 physicians looking after those patients I think would

17 have been keen to get their patients tested.

18 So that was several thousand potential requests and

19 then, of course, there were all the other physicians

20 looking after other risk groups, who were keen to have

21 their samples tested as well. This was just a small

22 research laboratory, specialising up until then in

23 Hepatitis B.

24 Q. On the first day of your evidence, professor, you

25 described this lymphocyte count or immune study or AIDS

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

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

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

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

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

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

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

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

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

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

25 Q. Sorry, carry on.

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

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

9 Do you remember anything like that being said?

10 A. I don't, I am afraid.

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

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

25 A. Yes.

1 Q. I don't think it was today but on an earlier occasion  
2 you said that was a shifting picture over the course of  
3 the year. Is that right?

4 A. Yes.

5 Q. So that by the end of 1985, as you put it, I think, the  
6 vast majority were aware of their status. Is that  
7 correct?

8 A. Yes.

9 Q. Can we just concentrate on this -- briefly, I hope?  
10 What sort of numbers are we talking about altogether?

11 A. There would be about 150 patients or thereabouts who  
12 will have been tested over 1985 because those are the  
13 numbers that we had on our books who had been --

14 Q. By the end of 1985 can you assist us with how many  
15 individuals, do you think, would not have known, for  
16 whatever reason, of their HTLV-III status?

17 A. I think probably only three or four or five, probably.

18 Q. All right. In his questioning to you, Mr Di Rollo said,  
19 "Let's take out those that simply didn't want to know  
20 and were quite adamant that they didn't want to know,"  
21 the implication being that there was a third category,  
22 as it were. There were firstly, those that knew,  
23 secondly, those that were adamant they didn't want to  
24 know and there was a third category who just didn't  
25 appreciate the need to come and ask. Can I just be sure

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

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

5    Q. Yes.

6    A. I can only think of two individuals.

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

10   A. No, that would be another individual.

11   Q. All right.

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

20   Q. Yes. I think we know that after the meeting on  
21           19 December 1984, of which we recognise only  
22           a proportion probably, a relatively small proportion of  
23           those affected, attended, there was the circular letter,  
24           which again we needn't look at I think, but has  
25           a reference [\[PEN0120495\]](#), and that's the letter that



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

3   A. Yes.

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

8   A. Quite frequently.

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

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

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

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

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

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

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

10 A. Yes.

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

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

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

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

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

5 Q. All right.

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

13 Q. Yes, I'm obliged.

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

19 A. Yes.

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

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

24 Q. All right.

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

1 Q. All right. You told us that he was very ill at the  
2 time?

3 A. Yes.

4 Q. Would I be right in thinking that he had an AIDS-related  
5 condition at that time?

6 A. Yes.

7 Q. And was he receiving treatment for his condition at that  
8 time?

9 A. Yes.

10 Q. All right.

11 THE CHAIRMAN: Mr Anderson, you will take care. We are  
12 beginning to build a picture --

13 MR ANDERSON: That's all. I have no further questions in  
14 relation to that, sir.

15 Do you remember, on the second day in which you gave  
16 evidence, Professor Ludlam, we looked at an excerpt of  
17 your case notes in relation to your patient, Mark. Do  
18 you remember that?

19 A. Yes.

20 Q. And the document which the chairman suggested we should  
21 designate as "X"?

22 A. Yes.

23 Q. Which I don't think is in court book. This entry in  
24 your writing, I think, and the question was whether it  
25 was 1988 or 1986. Do you remember that?

1 A. Yes.

2 Q. All right. Again, with the caution in relation to  
3 confidentiality, so we don't want to know dates of birth  
4 or anything like that, have you had the opportunity of  
5 making further investigation to assist us with whether  
6 that is 1986 or 1988?

7 A. I have been shown a letter about the patient that  
8 I wrote after seeing him in January 1986 that alludes to  
9 his circumstances, and although it's a redacted copy --

10 Q. Perhaps if you are looking at, we should all do so.  
11 I think it's page 18 of [\[WIT0040240\]](#). Is that correct?

12 A. That's correct, yes.

13 Q. Perhaps we should just have that up on the screen. It's  
14 not terribly easy to make it out. This is in relation  
15 to Mark. Is that right?

16 A. That is correct.

17 Q. Is this a letter to his general practitioner?

18 A. Yes.

19 Q. And it's dated January 1986?

20 A. Yes.

21 Q. What do you take from this, please?

22 A. In the third paragraph:  
23 "At present he is working for highers at school and  
24 hopes to get a job as an ..."  
25 Which has been redacted:

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

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

6            "... started nine weeks ago."

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

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

18        A. My understanding ...?

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

21        A. Oh, yes.

22        Q. Have you any doubt about that?

23        A. No.

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

1 correct?

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

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

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

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

25 But before that point, the wisdom -- medical wisdom

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

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

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

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

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

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

16 A. There was no other medical intervention --

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

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



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

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

4   A.   That's correct, yes.

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

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

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

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

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

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

12 A. In 1991?

13 Q. Yes.

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

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

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

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

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

12 A. I think he was the only one. There might have been one  
13 or two others who said, "I want a bit longer to think  
14 about it". I'm sure there were one or two of those in  
15 1985 but they came round to wanting to know. But  
16 I think Mark was the only individual who, when we  
17 offered -- wanted to try and encourage him to ask, was  
18 adamant that he didn't want to know. I think he was the  
19 only one.

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

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

1 1985, "I didn't want to know".

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

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

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

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

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

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

1 With those few individuals?

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

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

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

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

5           As I mentioned earlier, it was a bit like a tsunami.  
6           You could see it coming and all of a sudden in the late  
7           1980s, it was all over us and wreaked havoc upon  
8           patients who were getting on so well ten years  
9           previously, with a prospect of almost cure for their  
10          haemophilia, and now here they were dying of this awful  
11          virus. It was just dreadful.

12        Q. Professor, thank you very much indeed.

13                 I have no further questions.

14        THE CHAIRMAN: Mr Johnston?

15        MR JOHNSTON: No questions. Thank you, sir.

16        THE CHAIRMAN: Right.

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

18        THE CHAIRMAN: Professor Ludlam, thank you very much.

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

21        THE CHAIRMAN: Patiently or otherwise, he has been all day.

22          Is it proposed that we try to deal with him? How long  
23          can you go on?

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

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

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

5 MR GARDINER: Yes, sir.

6           Professor Lowe, please.

7                           PROFESSOR LOWE (sworn)

8                           Questions by MR GARDINER

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

12           Yes, Mr Gardiner.

13 MR GARDINER: Thank you, sir.

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

16 A. That's correct.

17 Q. To the Inquiry at any rate. We usually start off with  
18           the CVs of our witnesses. Could we have a look at  
19           [\[PEN0161246\]](#)?

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

23 MR GARDINER: Indeed.

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

1 MR GARDINER: We see that your current position is emeritus  
2 professor at the University of Glasgow and that you  
3 started that in 2009. Above that we see your  
4 qualifications, MB with the gold medal, St Andrews,  
5 1972. Membership, 1974, FRCP, 1986. We see that  
6 looking down to "Previous Positions", you were  
7 a honorary consultant physician at  
8 Glasgow Royal Infirmary between 1985 and 2009. Is that  
9 right?

10 A. That's right.

11 Q. Then if we go down to the bottom of that column, just  
12 five or six lines up, we see "Honorary Senior Registrar,  
13 university medical unit, Royal Infirmary, Glasgow", 1978  
14 to 1985. Registrar in general medicine, university  
15 medical unit, 1974 to 1977, and senior house officer,  
16 general medicine, City Hospital, Nottingham, 1973 to  
17 1974.

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



1           undergraduate and postgraduate, that you carried out.

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

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

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

13   THE CHAIRMAN: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 training.

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

4 A. Yes, on and off.

5 Q. On and off?

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

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

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

14 Q. Right. Okay. Thank you.

15 I think you also say in your answer there that for  
16 a period you went to Dr Lawson's medical unit, between  
17 1983 and 1985?

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

1 health service.

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

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

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

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

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

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

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

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

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

21 Q. I understand.

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

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

1           1983 to 1985, what percentage of your time was spent  
2           with patients with haemophilia?

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

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

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

6   Q.   Okay.  I'll work it out.

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

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

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

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

1           that that's really training to become a consultant; yes?

2   THE CHAIRMAN:  It's building up to a permanent position?

3   A.  Yes, well, that's the important thing, as you have  
4       gathered.  You have a permanent job.  More important  
5       than that, it's as a consultant you then start making  
6       important decisions about the type of treatment.  For  
7       example, if there is a choice of treatment and things  
8       like home treatment and prophylaxis, these are all kind  
9       of consultant level decisions.

10  THE CHAIRMAN:  It sounds as if Professor Kennedy wasn't over  
11           generous in promoting your interests for a period.

12  A.  That's how I felt.

13  MR GARDINER:  With that background, Professor Lowe, can you  
14           recall if during this period you did discuss the risks  
15           of hepatitis with patients who had haemophilia and who  
16           were prescribed factor concentrates?

17  A.  Absolutely.  Right from the start, because I came to the  
18           unit at the end of 1974 and, you know, the haemophilia  
19           unit was sitting there.  It was obvious.  And the first  
20           thing I saw going into it was big red signs saying  
21           "Hepatitis".  So every room in the haemophilia unit had  
22           a big hepatitis warning.

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



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

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

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

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

1 getting the non-A non-B virus, with your patients?

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

15 Hepatitis A testing would be done if a patient had  
16 clinical jaundice, because that would be in the  
17 differential diagnosis. And I think the Inquiry has  
18 established in the literature that by the mid 1970s,  
19 reports from several units were that perhaps at least  
20 half of regularly treated patients with haemophilia had  
21 intermittently or occasional elevation of liver function  
22 test. Only a minority of those were Hepatitis B  
23 positive and that was when the term "non-A non-B  
24 hepatitis" was coming into use.

25 Q. You are describing tests there, professor. I'm

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

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

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

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

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

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

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

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

15                 What was the answer to that, Professor Lowe?

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

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

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

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

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

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

1 of cryoprecipitate as opposed to factor concentrate with  
2 your patients?

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

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

15 A. Yes.

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

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

23 Q. We are going to have a look at that. Question 3, which  
24 is over the page -- I think you have already answered  
25 this. I think we can take this short:

1           "Could Professor Lowe describe his approach to the  
2           treatment of patients with mild haemophilia ... prior to  
3           1986?"

4           You say there:

5           "The policy was to treat patients with mild  
6           Haemophilia A preferentially with DDAVP, where  
7           appropriate and tolerated, and mild Haemophilia B  
8           preferentially with fresh-frozen plasma."

9           Is that right?

10          A. That's right.

11          Q. Just moving on, I would like to ask you about some  
12           immune studies or immunological studies that you were  
13           involved in. Could we have a look at [\[PEN0121600\]](#)?

14          THE CHAIRMAN: Mr Gardiner, is there the remotest  
15           possibility of dealing with this in five minutes?

16          MR GARDINER: Actually, I think there is.

17          THE CHAIRMAN: Right.

18          MR GARDINER: This is a brief statement that you have given  
19           us in connection with immunological testing. The  
20           first study is [\[LIT0010215\]](#). We see that that's  
21           "Immunological abnormality in haemophilia." We see that  
22           your name is on that paper.

23          A. Yes.

24          Q. Briefly if you could, Professor Lowe, what was your  
25           involvement in this paper?

1 A. Well, not that much because this study was performed at  
2 the time that I was really moving on to another unit.  
3 Within the department of medicine we had our haemophilia  
4 group. We had a group of rheumatologists, headed by  
5 Professor Sturrock, and they had been involved with  
6 particularly the management and some papers on the main  
7 problems of haemophilia, which was joint damage, joint  
8 disease, arthritis, surgery, et cetera.

9 With the emergence of papers discussed earlier today  
10 about immunological abnormalities in haemophilia in  
11 America, then clearly in Glasgow, as well as in  
12 Edinburgh, we are concerned about, okay, do you see  
13 these immune abnormalities in patients in Scotland,  
14 treated by this time usually with NHS Scottish  
15 Factor VIII.

16 So --

17 Q. What was your involvement, professor?

18 A. Not much. Because during this time I wasn't really  
19 doing much in the way of clinics. I think the relative  
20 roles of the people concerned was that Dr Froebel was in  
21 charge of immune studies, she was a research scientist  
22 in the rheumatology group, Dr Madhok was, I think,  
23 a registrar in rheumatology with a particular interest  
24 in haemophilia and I think he took most of the samples  
25 from the patients.



1 Q. Just focusing on your input, professor, am I right in  
2 thinking that it was really critical review?

3 A. Yes, indeed. You see, I was a lecturer in the  
4 department and I was doing a lot of research studies,  
5 which you will see in my publications list, particularly  
6 on thrombosis and vascular disease. I was starting to  
7 get into epidemiological work and had done courses in  
8 statistics. I think my role in this was not directly  
9 involved in the studies but more in the interpretation.  
10 So I would advise on the statistical analysis. I'll  
11 say, "Did you have a study that had adequate statistical  
12 power to support your conclusions?" It was sort of peer  
13 review pre-publications. I would constructively  
14 criticise it and say, you know, "Can you defend your  
15 conclusions from the data presented?"

16 But I wasn't at the hot end in terms of saying to  
17 patients, "We would like to measure your immune  
18 function."

19 Q. Yes, thank you. So in a word you can't help us with  
20 whether the patients that were examined in this case  
21 gave their consent -- in a word.

22 A. No.

23 Q. Thank you very much.

24 THE CHAIRMAN: Did you do a viva on Karin Froebel to make  
25 sure that she had got it all right?

1 A. We were quite informal in the department of medicine.  
2 We would sit and have coffee. We would present the  
3 results to each other. We had a weekly seminar where  
4 everybody would present their research. But my role  
5 was, I think, critical adviser here.

6 THE CHAIRMAN: Mr Di Rollo, are you concerned with the role  
7 of a critical adviser or otherwise with Professor Lowe?

8 MR DI ROLLO: No.

9 THE CHAIRMAN: No? Mr Anderson.

10 MR ANDERSON: No.

11 MR GARDINER: Sir, I'm stopping because it's 5 o'clock, not  
12 because I'm finished with this witness.

13 THE CHAIRMAN: Oh, dear. I'm terribly disappointed, you are  
14 going to have to come back.

15 We will adjourn now until Thursday.

16 (5.01 pm)

17 (The Inquiry adjourned until 9.30 am on Thursday,  
18 30 June 2011)

19 I N D E X

20	PROFESSOR CHRISTOPHER LUDLAM .....	1
21	(continued)	
22	Questions by MR GARDINER (continued) .....	1
23	Questions by MR DI ROLLO .....	11
24	Questions by MR ANDERSON .....	123
25	PROFESSOR LOWE (sworn) .....	151

1	Questions by MR GARDINER .....	151
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
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