Wednesday, 2 December 2020

(10.00 am)

SIR BRIAN LANGSTAFF: Good morning, professor. Can you hear me?

A. I can. Good morning to you, Sir Brian.

SIR BRIAN LANGSTAFF: Good morning, Ms Richards.

CHRISTOPHER ARMSTRONG LUDLAM, continued

Further questioned by MS RICHARDS

Q. Professor Ludlam, I am going to be asking you this morning questions relating predominantly to 1983/1984 and issues relating to AIDS. I'm not --

A. Could I, just before we start, bring to your attention our discussion yesterday about hepatitis outbreak in Edinburgh. You asked me about how I first heard about hepatitis, and I indicated that I had been a student at the time of the hepatitis outbreak and that I worked with one of the staff who died. And I indicated that I thought that four members of staff had died and four patients had died. You, I think, at that time considered there were 11 patients and one member of staff.

I went away and did a little homework last night, because it was a major event in my life that I do remember, and consulted a very good paper that Barrie Marmion wrote who was a professor of virology

in Edinburgh in the 1980s. It appears that from his reports, which I can forward to you, there were four members of staff who did die. One was a surgeon, one was a junior doctor, one was a receptionist in the Haematology Department at the Western, and one was the research technician I mentioned as well. There were apparently eight deaths of patients. I hope the Inquiry will find that helpful.

Q. Thank you, professor.

A. I will send in the -- Barrie Marmion's paper.

Q. Thank you. I also checked after yesterday the Rosenheim report, which is where my figure of 11 had come from, and I had -- you are right that there were more staff than that. The Rosenheim report gives the figures of eight patients and three staff, but it may be that the further death that you relate was not included in that. But thank you for that, and we'll ensure that we check both materials.

A. I think it will be three because it was three hospital staff, and the blood transfusion staff, a member of staff, was not considered hospital staff. I think that makes up the numbers.

Q. Thank you. Well, that would make sense of the numbers.

So, professor, I'm going to concentrate on

issues relating to HIV and AIDS this morning. I'm not proposing to ask you questions this morning about the AIDS study, the research, monitoring, surveillance -- however one is going to term it -- work that you were undertaking. I will be asking you about that probably tomorrow when we look at some other issues relating to research. I hope that assists in understanding the direction of travel this morning.

A. Thank you. That's helpful.

Q. When and how, as far as you can recall, did you first become aware of cases of AIDS in haemophiliacs?

A. I can't remember exactly when, but, as you know, the MMWR report was in July of 1982 of the three cases. That was not a journal that was on my reading list. It's a rather specialist journal for those interested in public health and infectious diseases. And it also takes a little while to travel, in those days, across the Atlantic from CDC.

I would think probably September or October. I'm sorry I can't be more precise. Maybe August, but that sort of time.

Q. Now, we know, and we'll come on to this later, that in September of 1982 there was some brief discussions amongst the Reference Centre Directors in relation to AIDS reports, and Dr Craske was tasked with providing

a report, or going away and researching the matters, and reporting back.

I'm going to ask you to look at one report from Dr Craske that did come your way in November of 1982. If we could have, please, Soumik, HCDO0000273_079, please.

We can see, professor, that this is a letter dated 11 November 1982 from Dr Craske addressed to you. It's entitled "AIDS and haemophiliacs", and he says:

"I enclose a copy of a paper I've prepared for the meeting of the MRC Hepatitis Vaccine Working Group which describes the most recent information available about this new syndrome."

In the second paragraph, he talks about his telephone conversation with CDC in Atlanta and the latest information he'd received which was that:

"Five haemophiliacs had been identified with the syndrome, two of whom had died. All these cases are without the usual association of homosexual practices, drug addiction or treatment with immunosuppressive drugs; factors which have been found in the other patients."

Then in the third paragraph, he says:

"The hypothesis at present being used to

explain the acquisition of these cases which are in areas of the USA, where the syndrome had not been hitherto described, is that one or two patients in the incubation period of the disease donated plasma which has since been used to prepare Factor VIII or IX concentrates. All the haemophiliacs who have had the disease have had severe coagulation defect requiring regular treatment with Factor VIII. The likelihood is, therefore, that other cases will be identified amongst severe haemophilia, though probably at a low prevalence."

Then he goes on in the next paragraph to say that there should be a meeting of the working party. Presumably, professor, that would be the Hepatitis Working Party?

A. I presume so, yes.

Q. And some dates suggested.

A. Yes.

Q. Now, we'll have a look at a copy of the report that he is sending you. It's a different reference so, Soumik, it's HCDO0000557. We can see this is, in fact, a letter to Ms Spooner at Oxford. It's the same date. The text of the letter is the same as the letter to you. And if we go to the next page please, Soumik, we'll see a copy of the report itself. I'll

check the date. Dr Craske has dated it; November 5, 1982.

If we just jointly have look at it, professor, we can see that in the first paragraph, he provides an outline of information received from the CDC in the States.

If we look at the second paragraph, he talks about the infections.

And then in the third paragraph, he talks about a delay between the occurrence of initial symptoms and diagnosis. He sets out signs and symptoms being, in most cases, insidious and non-specific.

Then if we go over the page to the top of the next page, he talks about the high mortality rate, age range 15 to 57, and then there is a discussion of laboratory data. Then if we look to the bottom of this page, under the heading "aetiology", he says this:

"Several theories have been advanced. It seems likely that this is a new syndrome."

Then we'll see he sets out three theories. One is effect of drugs such as amyl nitrate. He says:

"This is not a factor as the disease has been described in patients who do not use the drug."

Would you agree with me, professor, that

Dr Craske is identifying that as a theory that's been advanced but discounting it in this paper?

A. He is discounting it for the patients with haemophilia who have developed AIDS.

Q. Yes. Then he goes on -- his second theory, the immuno-suppressive effect of cytomegalovirus infection. He goes on to say:

"This seems unlikely as CMV infection is rarely the primary cause of profound immunosuppression ..."

Go to the next page please, Soumik:

"... in patients with CMV-associated infectious mononucleosis, et cetera."

Then his third theory that he's setting out:

"The association with sexual promiscuity, intravenous drug abuse and possibly the transfusion of commercial blood concentrates, together with evidence of clustering and a prodromal phase suggest an infectious agent with similar epidemiology to that of hepatitis B, possibly specific for human T cell populations."

Then he goes on to say:

"If three is the most likely cause, then it seems possible that such an agent might be present in the plasma of hepatitis B carriers used to prepare hepatitis B vaccines."

And then goes on to set out a number of matters that would no doubt have been relevant for the purposes for which this report was prepared, which was the MRC's hepatitis vaccine working group.

Would you agree that, looking at this paper, the theory that Dr Craske is advancing as the most likely is the third theory, an infectious agent with a similar epidemiology to that of hepatitis B?

A. I think this letter demonstrates the uncertainty that there was at the time about the cause of AIDS. We haven't had a discussion about the definition of AIDS. We'll perhaps come back to that later. But the question of the aetiology of immune suppression and AIDS in haemophilia -- the aetiology, it might be a virus it might be something else. As you know, there is this theory that blood products themselves altered the immune status of recipients and there was a suggestion and some evidence, that I'll perhaps come on to later, to demonstrate that the immune status, in fact, of HIV negative haemophiliacs was, in fact, suppressed and in this time, the late 70s/early 80s, there had been a big increase in the amount of clotting factor used to treat haemophilia and there was the suggestion that there could possibly be two, if I can put it this way, parallel aetiologies for the

AIDS that was appearing, that in homosexual men and that in people with haemophilia might have different aetiology.

I'm not saying they didn't think it possible or even likely that there might well be a virus that could spread in the clotting factor concentrates. Clearly, as soon as the first three cases were described in July '82 and the possibility -- it was well established that amongst homosexual men it might be a virus that's causing the syndrome that was well described in them at that time. So there was clearly the possibility of a virus and the virus could have got into the concentrates as described here.

But there was a lot of uncertainty at this time about -- and puzzlement and the puzzlement in some people's minds about the viral aetiology of AIDS extended until at least 1992 when I had to reply to an article in The Lancet suggesting that AIDS was not due to a virus.

So I think at this time there was much uncertainty but a viral aetiology was perhaps the most likely.

Q. Now you became aware, I think, of the reports that were in the MMWR in December 1982 of three cases, transfusion-related cases, including the case of

a 20-month old infant in California. You became aware of that in either late 1982 or early 1983.

A. Yes, that will be early 1983.

Q. We'll look at a handful of documents that relate to that. Before we do so, can we just look at the New England Journal of Medicine for 13 January 1983. PRSE0002410, please, Soumik. I think you have already explained to us that the New England Journal of Medicine wasn't on your regular reading list. We'll see how this would have been drawn to your attention at meetings in January 1983 in a moment. But in relation to this particular article in the New England Journal of Medicine, AIDS and Preventative Treatment in Haemophilia, if we go to the second page please, Soumik, and if we look at the last paragraph on the left-hand column, we can see there, this is the article by Jane Desforges, the opening sentence:

"The fact that haemophiliacs are at risk for AIDS is becoming clear."

Then she goes on to talk about the need for physicians involved in the care of haemophiliacs to be alert to the risk, talks about the possibility of revising home treatment programmes and, in the last sentence, says:

"Preventing the complications of the present

treatment may have to take precedence over preventing the complications of haemophilia itself."

Do you know whether you read this article at the time?

A. I was certainly aware of it early in 1983. It would be obviously after 13 January but I was aware of it, yes.

Q. We'll come on to the question of whether greater use could or should have been made of cryoprecipitate at a later stage this morning, professor, but did you agree with, at the time, the opening sentence of that final paragraph, "The fact that haemophiliacs are at risk for AIDS is becoming clear"?

A. Yes, I think that's fair.

Q. Now, we then in January 1983 have three meetings which you attended. The first is a meeting of the Hepatitis Working Party on 19 January 1983. That's HCDO0000 --

A. Just before we move on from that document, did you want me to comment on it further?

Q. I have no particular further question at this stage but you are welcome to comment on it, professor, if you wish.

A. Is it possible to go back to it?

Q. Do you want the first page or the second page, professor?

A. The second page. It's merely --

Q. Do you want us to zoom in on the last paragraph again?

A. The last paragraph. Yes, that would be helpful.

The question has been raised as to, in a sense, why more wasn't done to think about moving back to cryoprecipitate, as suggested by Jane Desforges. I think the answer for me is that I'm not sure that Jane Desforges really understood about haemophilia. I'd never come across this individual before. I'd been, as you know, interested in haemophilia for quite a long time. She is, in fact, as far as I can gather, a staff writer for the New England Journal of Medicine. So I think what her suggestion is -- I can see why she's made it. The paper she refers to later on in the journal by Lederman and Menitove are correct, but the number of patients who showed normal T Helper/Suppressor ratios in the cryoprecipitate group was very small indeed, compared to the constant number of patients in the concentrate group, and to suggest on the basis of that that it might be prudent to move towards cryoprecipitate, seemed a little premature.

That was my take on this and why I think it didn't gain much traction. Had it been written by a well-known name in haemophilia, an eminent

haemophilia physician people might have -- and it said the same text, then maybe it would have carried more traction.

Q. Thank you, professor, I will come back further to the issue of cryoprecipitate in a little while.

A. Thank you.

Q. Just continuing with the chronology through January 1983, Soumik, could we have HCDO0000558, please. So you'll see here, professor, that this is the meeting of the Hepatitis Working Party 19 January 1983 at which you are present, along with Professor Bloom by invitation, I think, as he wasn't normally a member of the Hepatitis Working Party, and the usual members.

If we go to, I think it's the second page, Soumik. Sorry, if we keep going down the page. Next page.

So we can see bottom half of the page under the heading Acquired Immune Deficiency Syndrome, we can see that on 19th January Dr Craske is updating members of the working party. He refers to having written to Dr Lawrence at the CDC in Atlanta. He provides details of there now being ten cases of AIDS in haemophilia A patients with none of the pre-disposing causes, such as heroin addiction, homosexuality,

treatment with immunosuppressive drugs. All except one patient were patients with severe coagulation defects on regular Factor VIII therapy. He explains that the youngest is seven, that five had since died and says:

"It seemed possible that Factor VIII or other blood products administered to these patients might be implicated."

He goes on to explain that:

"The CDC AIDS Task Force were working on the hypothesis that an infective agent was involved, possibly a virus specific for human T-cells in the same way that EB virus was specific for human B-lymphocytes."

Then he goes on to provide an update about the three cases associated with whole blood or platelet transfusions, provides details of those and then of the third case, and this is the last five lines or so of the page:

"... [the] 20-month old boy from California who had been transfused with blood platelets at birth ... 14 months later he developed an AIDS-like syndrome ... One of the donors of a unit of platelets was a young homosexual who subsequently developed classical AIDS and died in August 1982."

Then:

"Incubation period of the [if you go to the top of the next page, please] cases was between six months and two years."

So pausing there, Professor Ludlam, it would seem from that apparent that by 19 January at least, you are aware, because Dr Craske is specifically updating you and your colleagues on the Hepatitis Working Party and Professor Bloom, about those platelet transfusion cases and, in particular, the Californian baby case.

A. Yes, I was, as you say, at the meeting and I don't remember that particular case being discussed but the case was eventually published in March or April 1983 and the title of the paper was possible transmission of an AIDS virus.

It was one possible explanation for immune deficiency arising in this infant. I'm not a paediatrician but I do know that there are a range of immune deficient -- congenital immune deficiencies that can arise in small children, which makes them very susceptible to opportunistic infections and they would present, I think, in a similar way to a patient who had been infected with an AIDS virus.

So it was circumstantial evidence. It didn't,

in any way, begin to fulfil Koch's postulates for demonstrating that an agent causes a disease.

Q. Is it fair to say, looking at this account, there's no suggestion from Dr Craske of there being any other suggested cause? These cases are being drawn to the attention of the Hepatitis Working Party precisely because it supports the concerns and the most likely theory of there being an infectious agent and an association between blood and blood products and transmission of AIDS?

A. Yes, I'd agree with that.

Q. Then we can see if we look further down the page the long paragraph beginning "The Americans were keen", there's a discussion about reporting, there's reference to the New England Journal of Medicine or to two papers in the New England Journal of Medicine. Everything that is set out in this working party paper, can we agree is material that you would have known either on or before 19 January 1983?

A. Yes, I think that's fair.

Q. We then can see that you attended a meeting --

A. Just before -- sorry, just before we move on, could we go back to the document. I'm sorry, I need to see a bit further down the document that's on my screen. So I want to talk about, just draw your attention to

the last paragraph:

"It was also reported there had been an outbreak of Mycobacterium tuberculosis infection ..."

I'm sorry, it seems to have --

Q. It's still there.

A. Oh, I'm sorry:

"... in young severely affected haemophiliacs at the Birmingham Children's Hospital."

Thank you:

"Skin legions appeared to be the main lesion involved. In view of the altered response to [other] tests of CMI reported in haemophiliacs, it was important to determine whether haemophilia A patients on freeze dried concentrates [might be] more susceptible to tuberculosis than healthy children not treated regularly with blood products."

I may come back to that later but I am interested that at that stage we were noting this. A very astute observation by Professor Hill in Birmingham.

Q. 21 January, there's a meeting in Scotland you attended. Soumik, it's PRSE0001736.

We can see this is a meeting of the directors of the SNBTS and haemophilia directors

21 January 1983. Again, you were present. If we go on please to page 7, and we zoom in on paragraph 6 please, Soumik, under the heading "AIDS" 6(a), it said this:

"Dr Cash drew members attention to recent articles in the United States, and also in the Observer and the Lancet, about this problem. MMWR extract (CDC, Atlanta) had been circulated with his paper. Dr Ludlam informed members that in the UK a letter and questionnaire had been sent out to haemophilia directors."

Now, we don't, I think, have, at least not currently, Dr Cash's paper itself that appears to be referred to here, but is it reasonable to assume that the MMWR extract is likely to be the December MMWR?

A. I'm sorry, what was the date of the meeting?

Q. 21 January 1983.

A. I'm sorry, I'm not at all certain that it would be the December. It would have come by post over Christmas time and the holiday period. I'm sorry, I can't -- it might be the July version, the first three cases.

Q. We can no doubt ask others who were present at the meeting. It may be a feature of the compressed nature of minutes, but there doesn't seem to have been much of a discussion about the implications, either for

Haemophilia Centre Directors or for SNBTS, of the developing knowledge in relation to AIDS at this meeting. Do you recall anything about it?

A. I'm sorry, I don't remember the meeting. I'm sure there was a short discussion and I think I would have said that this was being thought about by the Hepatitis Working Party and UKHCDO. I'm sorry, I can't speculate more than that.

Q. We then come on to a meeting on 24 January 1983. Soumik, that's PRSE00002647. It should be in the general bundle that's common to all the witnesses, Soumik. It's not specific to this witness.

SIR BRIAN LANGSTAFF: Is it 0000 or 000?

MS RICHARDS: Ah, you are absolutely right, sir, and the fault is entirely mine. I have put in an extra zero, Soumik. My apologies. PSRE0002467.

So we can see, Professor Ludlam, we think these are notes from Dr Boulton of a meeting with Immuno at London Airport on 24 January 1983. If we just go, first of all, to page 4 and we look at the list on the bottom half of the page please, Soumik, we can see that there were a number of attendees including yourself, yours is the fifth name listed. There were various Reference Centre Directors there but also other Haemophilia Centre Directors. We can see, for

example, Dr Colvin, Professor Hardisty, Dr Aronstam, Dr Hill, as well as, for example, Professor Zuckermann whose interest, no doubt, would have been in hepatitis.

Other documents tell us that this was a meeting that probably took place at the Excelsior Hotel at Heathrow Airport in London on 24 January 1983. Do you have any recollection of that meeting and the circumstances in which it was called?

A. I don't. I have a recollection that the meeting took place and I mentioned that I think in my long statement to the Inquiry, beyond that, I have little recollection of the contents of the meeting.

Q. I appreciate it was a long time ago, but it would seem at first blush to have been quite an unusual meeting. It's out of the ordinary. It's not part of the usual chain of UKHCDO meetings, for example, and it's a meeting specifically attended by this large number of interested clinicians with Immuno. Was that not something unusual, or was that a regular occurrence?

A. In my experience, this was not a regular occurrence. This was a one-off meeting. I don't think I've been invited to a meeting like this before. May not be entirely accurate, but certainly these sort of meetings weren't regular meetings in any sense.

I think the purpose of the meeting, having seen this record from Frank Boulton, was primarily to tell the audience, this list of people, the work that Immuno were doing to try and improve the viral safety of their concentrate, Factor VIII concentrate. And I think this was really a way of advertising the research they were doing, hoping to get the interest, I imagine, of the attendees.

Q. Yes. You are absolutely right that the first part of the meeting seems to have been occupied by discussion of what's referred to as hepatitis-reduced Factor VIII and Factor IX concentrates.

But if we go to the third page, please, Soumik -- so that's the page before this -- we can see under the heading "acquired immunodeficiency syndrome" -- it's the bottom half of the page, please -- that there's a further update from Dr Craske. I won't go through the detail of all of it because we have seen similar updates from him already from the Hepatitis Working Party document. But if we look under the heading "AIDS", the fourth paragraph, it talks about:

"Up to 10 December '82, some 800 people have been reported as having suffering from AIDS; 45 per cent mortality."

There's then reference to, again, the figures of:

"Ten haemophiliacs in the US: 5 have died, youngest 7. All cases have had prolonged treatment with Factor VIII. There's no specific implication of one particular product or batch."

Then there's reference to the three platelet transfusion cases, including the young child.

If we go on to the top of the next page, we can see reference to the incubation period. It refers to one or two cases having been reported from the communicable diseases centre so far in the UK.

There's then a discussion of protocols from the United States, including in relation to donor screening. It's said that those are being considered by the Hepatitis Working Party.

There's then reference to the editorial in the New England Journal of Medicine on 13 January and the issue in relation to cryoprecipitate.

And then we see:

"Final comments on the possible nature of the transmissible agents indicated that there may not be just one agent but a mixture, i.e. a barrage of viruses, including hepatitis B, non-A, non-B, CMV and many others, possibly transmitted from asymptomatic

healthy blood donors."

Professor Ludlam, would you agree that whilst obviously there is still much that is not known, maybe a considerable number of uncertainties, there is no suggestion here that the cause in either haemophiliac patients or transfused patients is anything other than the receipt of blood or blood products?

A. I agree that is as set out by Dr Craske, but of course, Dr Craske is a virologist and would see things from a virological perspective.

Q. Yes. There are many others attending, however, who are -- include amongst their number many haemophilia specialists. We don't see recorded in this note -- and of course, it's just one note, and you have no independent recollection of the meeting -- any alternative theories being put forward by haemophilia directors.

A. I would need to see the rest of the document to see how it records the discussion because I can't see it on the screen at the moment.

Q. In terms of --

A. Or maybe there is no discussion recorded.

Q. There is discussion recorded at various points in the notes in relation to hepatitis-reduced Factor VIII and Factor IX concentrates. So the note doesn't simply

record, for example, Dr Eibl from Immuno's presentation but records the interventions of Professor Zuckerman, and it's said there was considerable discussion.

In relation to AIDS, if we go back to the previous page, Dr Boulton's note in the first line under "acquired immunodeficiency syndrome", report says:

"This was discussed in the after-lunch period."

We then -- it refers to Dr Craske's summary.

If we go over then to the fourth page, the last paragraph before the list says "final comments". That might suggest that those are comments from those attending the meeting, but certainly Dr Boulton's note, read as a whole, incorporates comments from attendees in relation to hepatitis. Does that assist at all with your memory?

A. Not particularly because I don't remember the meeting. This is -- these are notes. I think the document is headed "notes from the meeting", not a minute or a record of the meeting. In other words, there may have been -- and it's clear there was discussion that isn't recorded here. So I'm not prepared to speculate as to what was discussed beyond what's stated here.

Q. Do you have any recollection yourself of any

discussions either at the Hepatitis Working Party meeting that you attended on 19 January, or any other meetings around this time at which haemophilia directors were discussing alternative theories other than a causal link with factor concentrates?

A. Yes. In the meeting of 19 January, the Hepatitis Working Party, there is some discussion about looking at the possibility of assessing immune function. And having noted that it was abnormal in asymptomatic people with haemophilia in the US, as reported in 11 January New England Journal, there was discussion about what that might mean. And the minute records the suggestion that it would be interesting to look and see what the results of lymphocyte subset tests were in patients who had been treated purely with NHS Factor VIII concentrate because it was rather less likely that those recipients would have been infected if there was an AIDS virus by an AIDS virus that was circulating in the United States at that time.

Q. Other than what you recall, or what you said you've drawn out of the minutes of the Hepatitis Working Party, can you recall any other discussions that took place amongst Haemophilia Centre Directors in early 1983 about the causes or potential causes of AIDS in haemophiliacs?

A. I think there was much puzzlement. And although 10 cases had been reported in the United States, that's out of a population of 320/330 million, five times that of the UK, so the equivalent of two patients in the UK -- so in overall terms, it was a small number, and we were very puzzled by the cases. There appeared to be a few at that stage, and the cause was much thought about.

SIR BRIAN LANGSTAFF: Just a moment on the maths there. The 10 cases are cases of haemophiliacs, aren't they?

A. That's correct, yes.

SIR BRIAN LANGSTAFF: So the relevant population is not the total population of the States, is it? It must be the population in the States of haemophiliacs.

A. Oh, yes. I was -- but the number of haemophiliacs is proportional to the total population.

SIR BRIAN LANGSTAFF: Yes.

A. And in the UK, it's roughly 5,000, and the United States, it's probably about 25,000 --

SIR BRIAN LANGSTAFF: Yes.

A. -- people with haemophilia. So that's -- I'm suggesting that the US population of people with haemophilia was probably about 25,000. And it's five times the British number, and, therefore, on a per head basis of haemophiliacs, it would be a fifth if it

was the UK.

SIR BRIAN LANGSTAFF: Yes. Thus far, yes.

A. Yes. Oh, yes.

MS RICHARDS: If we can then look at one further publication from January, professor. It's RLIT0000201. We can see that this is an article in The Lancet, January 29 of 1983; so an article you would be likely to have read. Is that fair?

A. That's true, yes.

Q. "Acquired immunodeficiency-like syndrome in two haemophiliacs". We can see from the summary there's an evaluation of:

"The immunological status of two multiply transfused patients."

And then if we look at the last sentence of the summary:

"Transmission of an infectious agent in blood products seems likely."

So, again, professor, whilst accepting, of course, there are uncertainties and lack of proof, the likeliest cause being advanced here and in all of the documents we've looked at is transmission of an infectious agent, is it not, as the cause of AIDS in haemophiliacs?

A. I would agree that, in the discussions, an infective

aetiology was the most likely cause, yes.

Q. So would you accept that by the end of January of 1983, you as a Haemophilia Centre Director would have appreciated that the probable route of transmission for haemophiliacs was blood products, although you might not yet understand what the aetiology is and there may be a range of different theories. In all likelihood, the most probable cause was transmission through blood products; is that fair?

A. I think it's fair to say that people with haemophilia appeared to be acquiring AIDS as a result of their treatment with clotting factor concentrates.

Q. And you would also have known by the end of January 1983, again whilst recognising there was still much to learn about AIDS, that it had a very high mortality rate?

A. Once an individual developed an AIDS-defining illness which, in the early days of AIDS, was predominantly Kaposi's sarcoma in homosexual men and pneumocystis carinii pneumonia in others, you only get, or you tend only to get pneumocystis in people who are very severely immunocompromised. In other words, they've been -- whereas we now know -- infected probably for quite a long time. And by the time they are diagnosed by this clinical means of getting PCP, then their

outlook was not good, and that's how it came to be. Once you crossed the threshold of AIDS particularly being defined by PCP, then your outlook was poor, and the figure you quote is reasonable.

Q. You've touched on what may have been a third important feature at the time, that it was at least beginning to be understood, or if not already clear, that there could be a significant lapse of time before the onset of symptoms and a further significant lapse of time before diagnosis.

A. That's correct.

Q. So the fact that currently the numbers of cases might be said to be comparatively low as hard figures, that wouldn't necessarily be a reliable guide as to how many might be infected?

A. That is true.

Q. Can I ask you to look at your statement, please. Soumik, it's WITN3428001. Could we go to page 80, please, Soumik. Can we put page 80 and 81 side by side?

So I just want to ask you a little more about what you've said in some parts of your statement here. You have said in paragraph 209 (a), which asks what actions you took to reduce the risk to your patients of being infected with HIV, you have said at 209 (a):

"Assume that AIDS might be caused by a transmissible agent."

If we look across the page to paragraph 211, in answer to the question "did you continue to use blood products after becoming aware of the possible risks of infection and why", the first reason you put forward is you continued to use blood products after it became apparent that AIDS in 1982 might be caused by a transmissible virus because:

"(a) Initially, there was no definitive evidence that AIDS could be caused by a transmissible agent, apart from the reports of AIDS being reported in a few individuals with haemophilia."

Which approach shaped your approach to treatment: an assumption that AIDS might be caused by a transmissible agent, as you described in 209 (a), or the view that there was no definitive evidence and therefore no need to take any steps at that time?

A. No, I would take the view that there's a possibility, as set out in 209 (a), and therefore it was reasonable and appropriate to review treatment on that basis.

Q. So what, if any, steps or changes were taken at Edinburgh in 1983 in response to the understanding that there was a risk to haemophiliacs from AIDS?

A. At that time, as you know, we were treating virtually

all our patients with either cryoprecipitate or NHS Scottish-produced, PFC-produced, Factor VIII concentrate. And there were -- and we were taking measures to reduce the risk or keep as low as possible the risk of hepatitis being contracted in patients, particularly those who weren't infused very often or, if possible, in small children.

I was aware and made enquiries that there were -- no cases of AIDS had been reported in the Scottish population, and so I made the assumption that the likelihood of there being a transmissible agent was low in Scotland. I contacted the infectious diseases unit at Ruchill that collected the data, rather like Dr Galbraith's centre in Colindale at the BHLS, and they had no knowledge of cases. And I made a number of other enquiries, and I'd not heard of any cases.

So, on that basis, I thought that the risk was small but not zero.

Q. Does it follow, from the answer you have just given, that there was no significant change of approach to treatment in 1983 and 1984 on your part because you assumed, for the reasons you have given, that the concentrates you were using were safe?

SIR BRIAN LANGSTAFF: Reasonably safe, I think.

MS RICHARDS: Yes.

A. Yes. Relatively or reasonably -- relatively safe. I think that's fair, yes.

Q. Did you consider, in the course of 1983 or 1984, a much greater use of or reversion to cryoprecipitate?

A. I'm sure we must have done. I don't recall discussion, but there would have been some discussion, I'm sure, with the Blood Transfusion Service as just -- if we were to go back, as we were discussing yesterday, they had turned their whole system over to producing as much Factor VIII as possible for my apparently insatiable demands. And I'm sure we had some discussions. And I know from documents that have been produced subsequently that it was a view that it would technically have been actually very difficult to have gone back, and it had all sorts of other implications I'm happy to talk about if you would like.

But there wasn't a decision made. I'm sure it was discussed, but we felt it reasonable to go on with using cryoprecipitate in decreasing amounts and using local concentrate for treating the patients.

Q. We'll look at one record of a discussion along those lines, if we may, PRSE0001556. You'll see, professor, these are the minutes of a meeting of SNBTS and

haemophilia directors, 2 February 1984. Again, you are present along with other director colleagues and SNBTS representatives. If we go on to the second page, approximately halfway down there's (ii):

"Members discussed the suggestion that the production of cryoprecipitate could now be reduced. Dr Ludlam said that cryoprecipitate was preferred in the treatment of children at present, because of the new danger of AIDS. Dr Hann concurred. A policy seemed to be emerging however to use less cryo for haemophilia A patients. It was agreed that a certain minimal amount of cryo was required an Dr Cash pointed out that TDs could produce it in emergencies."

So it would appear that by February 1984, leaving aside the position of children, which you and Dr Hann have there identified as recorded in these minutes, the approach appears to be, notwithstanding the danger of AIDS, using less cryoprecipitate for haemophilia A patients rather than more, which might be thought to be a somewhat surprising response to the new danger of AIDS. Are you able to assist with why that was the approach that was taken?

A. Well, I think the way we were trying to manage at that time was in keeping with the guidance issued by UKHCDO on -- in June -- is it 23 June 1983, which suggested

that NHS concentrate would be an acceptable form of therapy for patients with haemophilia.

Q. Would you agree that the natural understanding of what's being said here, not least by you, is that cryoprecipitate was seen as a safer treatment than NHS concentrates. That's the very reason that you are preferring it and Dr Hann is preferring it for children?

A. Yes, I've obviously not scrutinised these minutes carefully and nor does it probably record or almost certainly doesn't record all that was said, but it doesn't say also using cryoprecipitate for children because of the hepatitis risk.

Q. No, it specifically singles out the danger of AIDS as a reason for preferring cryoprecipitate for treating children. Why would those same considerations not also apply to adults with haemophilia?

A. Because adults require larger doses of treatment and therefore there's much greater donor exposure, and that's one of the reasons why adults treated with cryoprecipitate are at greater risk than children.

Q. Surely, for that very reason, adults treated with concentrates who are being exposed to thousands and thousands and thousands of donations and are heavily treated are at greater risk from concentrates than

from cryoprecipitate?

A. Well, they might be. The infective risks of cryoprecipitate are not negligible, even for viruses that are screened, I can give you an example: I was doing a ward round one day and someone came running up from the local blood bank to ask us to take down a bag of cryoprecipitate that was being given to a patient because he had just discovered that it was -- a hepatitis B antigen positive donation had gone into it by mistake. Unfortunately, by the time we got to the patient's bed all the cryoprecipitate had run through. So there was a patient exposed to a large dose of hepatitis B antigen, as a result of an administrative error, presumably, in the Blood Transfusion Service. So that if you get an infection from a unit of cryo that's infected, then you get, potentially, a big dose of it. I was quite concerned that this patient might develop immune complex disease because he had a very high level of antibody to hepatitis B.

But let me move to the risk of concentrate and pool size. There is the assumption made that if one donation in a pool is infected with a virus, that the whole pool is contaminated, which is true, and that will automatically result in infection in the

recipients. During the manufacture of a clotting factor concentrate, particularly Factor VIII, there are a number of steps, and during those steps the virus can either be inactivated or destroyed, or it can be neutralised by antibodies present in other donors. It is actually established that in the preparation of clotting factor concentrate, so Factor VIII concentrate, that there is a destruction, a tenfold destruction, of HIV. This is all known obviously retrospectively. So there is some destruction of virus. It is also diluted in the concentrates -- in the pool that's contributed of the donors.

There is -- when patients are exposed to a virus they need to be exposed to what's called an infectious dose. That is the dose that infects 50 per cent of the recipients, is my recollection from many years ago of this. So what I'm trying to say -- I'm sorry I'm a bit slow -- that one donation to a large pool that is then processed, vis clotting factor concentrate, doesn't mean that every bottle that's produced of that concentrate will infect a recipient.

I'm sorry that's a slightly long answer to -- I'm not sure I've fully addressed your question but

I tried to show that it's not quite as simple as just assuming that cryoprecipitate will be safer than concentrate.

Q. Can I take you back to February 1984, which is the date of this meeting, and it's obviously a not insignificant date, given the dates of seroconversion of your patients who were subsequently infected with HIV from concentrates, not from cryoprecipitate.

In February 1984, what was your understanding of the relative risks of cryoprecipitate and factor concentrates in relation to the risks of transmission of AIDS?

A. Are you asking about the risks as I perceived them in Scotland or in England or in the United States?

Q. In the United Kingdom and then specifically in Scotland.

A. In England, by 1983, there were individuals who had AIDS in the general population. So there was a risk that some of those potentially could present as blood donors and, therefore, there was a risk, I can't put a figure on it but there was a risk, that NHS concentrates and cryo and other blood products could be infected.

In Scotland, as I mentioned a moment ago, I wasn't aware, nor were the authorities I consulted,

and no-one drew to my attention, any individuals, any known cases of people developing AIDS who could have been blood donors.

Q. So in February 1984, did you think that NHS concentrates that you were using were safer than cryoprecipitate or less safe than cryoprecipitate?

A. At the moment I find that a difficult question to answer because I thought it likely that the risk of infection, if you like, in the donor population was low. Cryoprecipitate, for other reasons -- if you like, the hepatitis B is an example of a virus that is very infectious, if I can put it that way. You need only a very small dose. The number of virus particles to infect an individual is very low; in other words, it's highly infectious and that's why it spreads so well.

Q. Could we go back to the document please, Soumik. PRSE0001556, second page. If we just zoom in on the same paragraph, sub-paragraph (ii), "Members discussed the suggestion", just slightly further down the page. Thank you.

I'm going to press you on this Professor Ludlam because it would seem that the reason you are saying here that cryoprecipitate should be used for children and Dr Hann is agreeing, and obviously I can ask

Dr Hann this week, is because cryoprecipitate is seen as safer in relation to AIDS. Do you accept that's what you're saying?

A. That's what's recorded, yes.

Q. Are you suggesting that wasn't your view in February 1984?

A. I'm sorry, I feel a little bit tired. I'm not trying to be difficult. Because I don't recall the discussion, it's possible that I said that and it could be argued that the risk is -- would be smaller with the use of cryoprecipitate.

Q. Would you agree that there doesn't appear to be recorded here -- maybe you will tell me it's recorded elsewhere -- discussions about any practical obstacles to using cryoprecipitate more?

A. Yes. There were difficulties in the Blood Transfusion Service because, as I mentioned a few minutes ago, although I couldn't recall the discussions, there are documents put together by, I think, Professor Cash, which I think I have sent to the Inquiry or the Inquiry has -- perhaps in my statement -- indicating that it would be very difficult for the Blood Transfusion Service actually to increase its cryo production at a time when they were on the verge of being able to introduce a virucidal process into the

manufacture of concentrates.

Q. We can ask that question of Dr Cash or other SNBTS witnesses.

Did you at this time, or indeed any other time in 1983/1984, discuss with patients the risks of AIDS and offer them specifically the choice of reverting to cryoprecipitate?

A. I have to say at this distance I don't remember discussion -- patients asking me about the risk of AIDS. You've received a statement, I think you requested a statement from Dr Carr who worked with me, and I understand you've received that. He states he has a clear memory of patients asking about the issue of AIDS.

I was thinking about it in relation to something we may come on to later. I was a bit surprised that it hadn't been raised but that's -- I'm sorry, that's the best my memory is. There may be some more in the transcripts of my evidence to the Penrose -- there will be more because my memory was considerably better then than it is now.

MS RICHARDS: Sir, I note the time. We can take a break there.

SIR BRIAN LANGSTAFF: Yes, we'll take a break. I'm sure you could probably do with one. You said you were

getting a bit tired a few minutes ago.

Just one thing would like to ask you before we stop, since we have been discussing it. If we can go back please to your witness statement, 3428001, and go, please, to page 81. Thank you. It's paragraph 211(a). You were asked by counsel about the contrast between that and what you had said at 209(a) but I want to focus here just for a moment on the language that is used. Now, it may simply be casual use of language, although you don't strike me as a particularly casual user of language. What you say is "there was no definitive evidence that AIDS" not was caused, which I would understand but "could be caused". So no definitive evidence that it was a risk being caused by transmissible agent is how it actually reads as a matter of literal text. Did you mean that, or did you mean no definitive evidence that it was caused?

A. Yes, I'm sorry. It's -- your wording is more accurate.

SIR BRIAN LANGSTAFF: Because there couldn't be any doubt -- there's plenty of evidence, whether you define it as definitive or not does not much matter, plenty of evidence of the risk that it was caused, could be caused, wasn't there?

prepared from large plasma pools; especially important for those countries where self-sufficiency has not yet been achieved.

"To inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks."

And then:

"To provide all blood donors with information on AIDS."

Now, as I understand it from a later document, you were not aware of this at the time; is that right?

A. That's correct. I think the first time I saw it was in connection with the Penrose report. I don't recall ever seeing it or ever finding it in my -- when I looked back through my records of minutes and other documents.

Q. It may have been slightly earlier than that. I don't think we need to go to it, but there's an exchange of correspondence that you had with an MSP, Ms Leckie in 2005 in which you said:

"The existence of the recommendation was not known to me, nor was it discussed at any of the meetings I attended."

A. I'm sure that's correct, yes.

A. Yes.

SIR BRIAN LANGSTAFF: That was all that I ask. Thank you very much.

So we'll take a break now until -- we'll make it 10 to 12, shall we?

A. Thank you.

(11.19 am)

(A short break)

(11.50 am)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Professor Ludlam, before we turn in more detail to what happened in Edinburgh in relation to AIDS, I just want to ask you about some elements of national decision-making, first of all, and information sharing.

Soumik, could we have on screen, please, PRSE0000372. You'll see here, Professor Ludlam, this is a Council of Europe recommendation from June of 1983. And if we go to the second page, we zoom in on the top part, thank you, we can see the Council of Europe's recommendation is to governments of Member States to:

"Take all necessary steps and measures with respect to AIDS and in particular to avoid, wherever possible, the use of coagulation factor products

Q. Would you agree that this is a piece of information that should have been brought to the attention of, at the very least, the UKHCDO's Reference Centre Directors so that they could reflect on its significance?

A. Entirely. I don't understand why it never reached us.

Q. At this time in 1983/1984, to what extent was there interactions between either UKHCDO and the Chief Medical Officer in England or the Chief Medical Officers in relation to Wales or Scotland?

A. In England, the Department of Health had a representative at the Reference Centre Directors' meetings, and they acted as a conduit for bringing information from the Department of Health and for relaying to the Department of Health views that had been discussed and decisions taken at the Reference Centre Director meetings.

So far as Scotland was concerned -- I'm sorry, can you repeat your question?

Q. Yes. I was wondering whether the Chief Medical Officers in Scotland had had any involvement with representatives of haemophilia centres in Scotland to discuss issues relating to AIDS in '83 or '84.

A. No. The discussions that did take place were the discussions that had been minuted and I think we've

mostly talked about. There were some later on in 1984 that we'll perhaps come to later. But the Scottish Home and Health Department was -- they took the lead in bringing together, as I mentioned yesterday, haemophilia doctors and blood transfusion in Scotland in the early '80s, and they were kept in touch with these sort of matters that way.

I think there probably also had been communication between the Department of Health for England and the Scottish Home and Health Department. There was a conduit of information travelling up and down that route as well. Sorry, I can't speak for Wales or Northern Ireland.

Q. In relation to the Council of Europe recommendation, it would seem to follow from your evidence that the obvious conduit for providing that information to Haemophilia Centre Directors would have been through the Department of Health's attendance at the Reference Centre Directors' meetings?

A. Yes.

Q. Can we then look at another letter from 1983. This is the letter from Dr Galbraith. It's CBLA0000043_040, please, Soumik.

We've looked at this within the Inquiry before. It's Dr Galbraith's letter of 9 May 1983, addressed to

Dr Field at the Department of Health. He draws attention to the case of AIDS in a haemophiliac in Cardiff, to a report of three cases in The Lancet of AIDS in haemophiliacs in Spain, and an update on cases in the US. And then he sets out his recommendation that blood products made from blood donated in the USA after 1978 should be withdrawn, and there's a paper which sets out the reasons.

The evidence that you provided to the Penrose Inquiry indicates that this was a document that you did not see at the time; is that right?

A. That's correct, yes.

Q. Would you agree that it's a document that should have been brought to the attention of Reference Centre Directors?

A. I believe it would have been very helpful if it had been brought -- I note it's written on 9 May, which is a very significant date, and I suppose I'm just -- I've wondered why it wasn't written before 9 May.

Dr Galbraith worked in CDSC in Colindale, part of PHLS. He would have received MMWR weekly reports. It would be his bread and butter, much like the Financial Times is for a stockbroker. So he would have seen the cases of AIDS back in 1982, and he would know about non-A, non-B hepatitis. That was a general

public health issue in his field, and so he would know, I assume, about importation of blood products in that context. And he, I would have thought, would have been alert to the fact the haemophiliacs reported from CDC in July and December had been treated with concentrates and, for all the reasons we were discussing before coffee, he might well have thought that the infectious agent could be found in concentrates and should the consideration about stopping their importation have been made much earlier. But that, if you like, is with the benefit of some hindsight.

Q. You suggested in one of the documents you provided to the Penrose Inquiry that you thought Dr Galbraith might be wrong in stating that the case at that time in the UK was a Cardiff case. Do you want me to show you that, or do you recall that?

A. I'm quite prepared to talk about the Cardiff case because I think it -- the way it has been documented and portrayed, I think, from my perspective anyway -- I've done a little research into it, and I think the way things rolled out in relation to this case are not quite as they might seem, if I can put it that way.

Q. Professor, my questions to you about the Cardiff case are going to be based upon what you did or didn't know

at the time, rather than anything subsequently, because we do have information that you may not have in relation to the individual case itself.

If we look at PRSE0000353, please, Soumik. Just to give us an idea of timing, and it may explain the timing of Dr Galbraith's letter, this is the Communicable Disease Surveillance Centre's weekly report. And you'll see under the heading "Acquired Immune Deficiency Syndrome: Cardiff" there for the week ending 6 May is a report of a case of AIDS in a patient with haemophilia in the United Kingdom. And, no doubt, that's the basis for Dr Galbraith's letter.

What I wanted to ask you, Professor Ludlam, is this: what did Professor Bloom say, if anything, about the Cardiff case at the time to you or your fellow Reference Centre Directors?

A. I'm sorry, I can't remember him describing to me or at a meeting about the details of his case. I'm sorry, I have no memory of that.

Q. Do you recall whether he, and if so when, he informed you and your Reference Centre Director colleagues of the fact of there being a case of a patient under his care?

A. Well, I think this diagnosis, if I can put it that

way, definitive diagnosis, was made by Dr Galbraith I think, rather than Professor Bloom. I'm happy to go into my reasons for thinking that if it would be helpful and to what Professor Bloom said or knew about it.

Q. I think what we'd be interested in, Professor Ludlam, subject to any questions that the Chair himself might wish to ask you, is: what was said or known at the time?

In May of 1983, there is reported the case of a patient in Cardiff with AIDS, or fulfilling the criteria for AIDS. Was that something that was discussed amongst Reference Centre Directors in May of 1983 or thereabouts is my question.

A. I don't recall it being discussed in a meeting around that time of May, although Professor Bloom had told The Haemophilia Society annual general meeting at the end of April that he may have a mild case of AIDS. So he was aware that he might have a case of AIDS.

Q. I want to move forward to -- again, before we come back in more detail to -- specifically to Edinburgh, to the meeting that took place in December 1984, 10 December, at Elstree, and the production of the AIDS Advisory Document that followed.

Now, if we look at the minutes of the meeting

on 10 December, HCDO0000394_117. With the exception of Dr Preston, you are the first attendee at the meeting to give evidence on this, so I just wanted to ask you -- and, indeed, maybe the only attendee, or one of few attendees who give evidence.

So I just wanted to ask you, first of all, what your recollections are of how this meeting came about. It was the Reference Centre Directors had had their regular meeting in I think it was September of that year. How did this meeting come about?

A. I think there are a number of factors. One was the knowledge, or rather the reports, that HTLV-III was heat-sensitive from J Levy's work and from the Cutter work in October 1984. There had been a death of a further patient with AIDS, a patient with haemophilia in the UK, and I think one of the factors was my discovery that some NHS -- a batch of Factor VIII NHS had infected a group of patients in Edinburgh.

I think this was the first definitive evidence that the UK blood supply was, in fact, contaminated or had resulted in an infection of patients. So I think there are a number of reasons for holding this meeting.

Q. If we could just go down the page please, Soumik, we

can see at item 1, "Introduction to the meeting" the way it's put by Professor Bloom:

"The Chairman outlined that the resulting publicity surrounding the events in Newcastle and Australia, and the continuing work on HTLV-III, has precipitated today's meeting."

So the continuing work on HTLV-III may be the issue to which you've referred a few moments ago. What can you recall about publicity surrounding events in Newcastle and Australia, if anything?

A. I'm sorry, I have no recollection. I could speculate about Australia but that might not be helpful.

Q. I'm not going to go through the details of the minutes with you, Professor Ludlam, but if we go to page 5, please, Soumik -- sorry, can we pick it up at page 4, first of all. I want to ask you about the discussion that took place on the question of whether or not to inform patients of their test results.

If we see under the heading "Advice to patients and donors" there are interventions recorded from Dr Jones, and then it says:

"A long discussion took place on whether persons found to be [positive] were to be informed. Several differing views were expressed. It was agreed that each clinician would decide for each case

depending on the facts of the case but in general to provide information if asked for."

Then if we go to the next page, top half of the page we can see if we look, fourth paragraph down, there's a comment from Dr Kernoff:

"... as some 70 per cent of haemophiliacs are [positive] it may be considered irrelevant if one tells or doesn't tell the results of testing.

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

We'll come on to your own practice in Edinburgh in a few minutes, but what, if anything, can you recall about the discussion on the telling of patients of their test results?

A. I'm sorry, I can't at this -- I used to have a good memory of this meeting because it was an important and it was a traumatic meeting and it was stressful and I had -- because of that, I had a good memory. I'm sorry, I can remember one or two things from the meeting but my memory has faded and so I would be speculating as to what was discussed.

Q. If we go to the last page, the paragraph towards the bottom of the page, under the heading "Advisory

Statements", it says:

"... recommendations would be issued on the days proceedings these would be widely circulated."

Then there's a suggestion made by Dr Lane that haemophilia directors be allowed to have a private meeting with only themselves present. We don't have a UKHCDO minute of this meeting. This is Mr Pettet of BPL's note. Do you recall anything about why there was a private meeting and what the content of that private meeting was?

A. I wish I could help you. I've never seen any record, which rather surprises me, if we did have a meeting. So I'm sorry, I can't help you. I have no record of that.

Q. We'll see there that the paragraph above that refers to recommendations being issued, "these would be widely circulated", and we know that that became the AIDS advisory document. If we look at the final version of it, first of all, HCDO0000270_007, please, Soumik.

We can see, and again I'm not going to go through the detail of it, but we can see this is the final version. If we go to the last page, please, I just wanted to draw your attention to two matters. The first is under the heading "Antibody Testing", the

Professor Bloom dated 18 December saying:

"I am enclosing my version of the discussions last Monday 10 December. I would plan to send the document or something like this out to the Haemophilia Centre Directors and would be grateful for your comments as soon as possible. I understand that articles in newspapers are due and the Lancet Editorial should be out on 29 December. If you have any comments please let me know by letter or telephone as soon as possible."

So we can see here Professor Bloom sending you on 18 December what would appear to be a draft of the document we've just looked at in final form. If we go to HCDO0000273_053, please. This appears to be the document that was sent to you. It's also dated 14 December 1984, so the same date as the final version. Am I right in thinking -- please tell me if I'm not -- if we go to the second half of this page, the handwritten notes are yours?

A. It looks like my writing. I'm having difficulty, as I sometimes do, in reading my own writing.

Q. If we just look at the very bottom of the page you'll see it says, last paragraph:

"It seems probable that HTLV-III has been incorporated into at least one BPL and one Scottish

third paragraph says:

"Ab positive people should be informed, reassured and counselled regarding transmission to spouses, et cetera, including the possible use of barrier contraception."

So it would appear that, following a discussion at which it was more equivocal as to whether patients should be told their test results, according to Mr Pettet's note, the final recommendation is that patients should be informed. Do you have any recollection of any further decision-making or discussion about the formulation of this final recommendation?

A. No, it's as seen.

Q. Then if we look just the very bottom of the page, I just want to draw your attention to the date. So we can see that this final document is dated 14 December. I'm going to try and ask for your assistance as to when it might actually have been finalised and shared with other directors who weren't present. It may be relevant for later clinicians, Professor Ludlam, to understand how and when this document was sent out.

Could we look, please, Soumik, at HCDO0000273_052.

We can see that this is a letter to you from

batch of Factor VIII. Recipients have been informed are and are being followed up."

Someone has written, with reference to "recipients have been informed", "No", and of course we know that recipients hadn't been informed. I am going to explore that with you in a moment, professor.

The final version takes out the reference to "recipients had been informed". So it would seem likely that's you making the correction because you know that your patients haven't yet been informed.

A. Yes, it's possible I wrote "No". It doesn't look quite like the way I would write "No". I don't know whether someone else has looked at this. I'm sorry. I might have written that on the 18th, "had been informed" -- no, that's -- probably I might have written that.

Q. Do you know, and maybe at this distance of time you can't help, but do you know whether you sent this back in the post to Professor Bloom or you telephoned Professor Bloom?

A. I'm -- this was December 1984.

Q. Yes, so the letter to you was 18 December 1984 and presumably would not have been received by you until the 19th, at the earliest?

SIR BRIAN LANGSTAFF: It is Christmas, as well, the

Christmas post.
A. Yes. I'm sorry, I think it likely I received it before Christmas, it is dated 18th it must have been -- perhaps hit the mail on the 19th and I might have received it on the 20th or 21st. I don't know whether there was a weekend in the middle or -- I've probably seen it before Christmas.
SIR BRIAN LANGSTAFF: The other aspect is perhaps this. If we just go back, for a moment, to 273_052, and just curious looking at the typeface there. It's a different font size giving your address, Professor Ludlam. The date is in the larger font size, so also is the body of the text. It looks as though it was sent round to all the directors. Do we have other examples of this?
MS RICHARDS: I don't know without checking, sir. We may do. This has been provided to us by UKHCDO.
SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: There may be other examples.
SIR BRIAN LANGSTAFF: So it may well be that all the directors who took part in the discussion got a letter like this saying this is what I'm going to send round and any comment.
MS RICHARDS: Yes. I mean, you will understand, sir, there are later witnesses to whom the question of when

this document was finally received is highly relevant.
SIR BRIAN LANGSTAFF: Yes.
A. Yes, I think that's a very astute observation. I wasn't the only recipient, I think, of this letter.
MS RICHARDS: It doesn't sound like you will be able to assist us there about timings, which is perhaps unsurprising.

Can I then come on to, first of all, the question of what patients in Edinburgh were told about AIDS and then, secondly, I want to come on to your discovery of the infection of a number of your patients in the autumn of 1984.

If we look at your witness statement again, WITN3428001 please, Soumik, and if we go to page 90, please, paragraph 237, bottom of the page, you've said this:

"The view has been expressed by patients to the present Inquiry that they should have been informed about the risk of AIDS from blood products in 1983 and 1984. Whilst I was aware from The Haemophilia Society that there was anxiety in UK patients expressing concern and seeking information (particularly about the use of imported concentrates), as I have recorded elsewhere, I do not recall such inquiries from patients in Edinburgh. I think this was probably

because patients were being treated with local NHS prepared therapy. Had I been asked by them, I would have explained the current information in relation to AIDS and indicated that it was possible that an infective agent might get into the blood supply, but that I considered the risk to be small. I would not have recommended any change of therapy."

Professor Ludlam, this paragraph would suggest that you did not take any proactive steps to advise your patients in 1983 or 1984 of the possible risks of AIDS, from Factor concentrates; is that correct?
A. That, I think, is correct, as best I can remember.
Q. In --
A. I would have answered questions but I didn't, as it were, proactively raise the subject with patients.
Q. If we go to a document you prepared for the Penrose Inquiry, it's PRSE0004704. You can see it's headed "Information about HIV" -- sorry, it's "Information about HIV available to patients and families" and then there's a subheading, "Information about HIV for patients in Scotland prior to 1 December 1984".

You've identified on this page a number of pieces of information which are all Haemophilia Society documents. You refer to three bulletins, an interview from Dr Kernoff, reference to a talk

given by Professor Bloom, an Article by Ken Milne and then the Haemofact May 1983 publication from Professor Bloom. Then you go on to discuss those in more detail and refer to The Haemophilia Society documents in more detail over the pages.

Can I ask you this: did you read those publications at the time and conclude that they gave sufficient information to patients and that you therefore didn't need to say anything, or is this document an *ex post facto* attempt to identify information patients might have seen?
A. This was -- we regularly received from The Haemophilia Society their bulletins and we made them available in the haemophilia centre, so patients could pick them up and take them home or read them there. So that's how -- of course, some of the patients or many of the patients belonged to The Haemophilia Society and would have got a copy through the post as a member.
Q. You would accept, presumably, that there may have been patients who weren't members or who didn't read the bulletins?
A. Yes, there would be.
Q. I'm not suggesting you didn't make these documents available within the centre to be picked up if patients wanted to look at them, but did you look and

see what was being said in them about HIV or about AIDS, HTLV-III and the risks to patients and decide at the time that, because The Haemophilia Society was passing information on, you didn't need to?

A. I have to say that I probably didn't read them because I had a pile of post to deal with every morning, quite a large in-tray and there would be a bundle of these and I'd say to my secretary "Oh, can you put these in the haemophilia centre, please, give them to the sister for patients", and I'd move on to the next item in the in-tray.

Q. Would you accept, as a matter of principle, that it's the professional responsibility of a clinician to give a patient information about the risks of treatment, rather than relying upon what patients may or may not read or be told elsewhere?

A. Yes, I would agree, but it depends on the risk and what might -- whether one should take different action as a result of that risk.

Q. Would you agree that the question of whether to take different action as a result of risk -- so, for example, the decision not to continue receiving factor concentrates -- is a decision for the patient, ultimately, not the doctor, because it's their choice as to what magnitude of risk they are willing to run?

A. It comes down to a matter of what is the level of risk. It's always been accepted that clotting factor concentrates may transmit viruses or other infective agents, and there's a question as to at what level it's appropriate and to whom to make that risk known.

Q. You may have thought, professor, that the risk was a small one, but it was a risk if it eventuated of being infected with a very serious and likely fatal disease. Wasn't that highly relevant for the patient to know, again, to enable them to take a decision for themselves?

A. You raise a very interesting point about, if I can put it this way, the severity of HIV or HTLV-III infection because what wasn't at all clear at this stage was the severity of the consequences of HIV or HTLV-III infection. That only became known gradually in 1986/87, perhaps, but virtually no other viral infections that cause almost 100 per cent mortality. Most viral infections result in a spectrum of clinical presentations, and the degree of mortality is usually very low. And I'm a bit reluctant to talk about Covid because of all the great parallels there are between it and other epidemics. But with Covid, as we know, the mortality is somewhere between 1 in 100, and 1 in 1,000 or even less, depending on a number of clinical

factors.

What wasn't appreciated at this stage, in 1983 and '84, was that if you got infected that you were almost certainly going to get severe clinical consequences.

Q. Professor Ludlam, the documents we've looked at from 1983, and they're a snapshot at various points in time so the figures change, but some of the ones we've looked at this mornings show of the 10 haemophiliacs reported at a point of time in 1983, 50 per cent had died. The mortality rate generally in relation to AIDS patients reported from the States is variously described by Dr Craske -- 40 per cent is a figure given in some of his reports; the precise figure varies.

But it was very clear, was it not, that this was a disease with high mortality rate. Not necessarily a certainty of death but a high mortality rate. Would you accept that?

A. I see where the confusion has arisen. There's a difference between being infected with a virus and developing AIDS. After you've been infected, as I think we're agreed, with HIV, there's a long latent period before you get sufficient immune suppression, depression, for opportunistic infections to occur, and

at that point (for example when the patient gets pneumocystis), they have AIDS and their life expectancy, on average, after developing AIDS is shorter; there's the 40 per cent that you have been talking about.

If we go back to the initial infection and the antibody positive results that we had in 1984, at that time it was thought by many individuals, well-informed individuals, that the risk of developing AIDS (in other words, clinical consequences of HIV infection) was small because at that stage only between 1 in 100, and 1 in 500 people who were antibody positive had developed the clinical syndrome of AIDS, mostly by demonstrating -- by presenting with PCP.

Q. Given the high mortality rate of those who develop AIDS, was it not important that your patients should be given that information so they could take their own decisions, professor?

A. Well, if -- if the risk of them developing AIDS was only 1 in 100, or 1 in 500, that is a relatively -- relatively -- small risk, considering the risks of bleeding and death from bleeding, which in the years we're considering, 1983 and '84, it seems there were possibly, by the end of 1983, two cases of AIDS in the UK. There were five times that number of deaths from

bleeding, let alone all the other causes of morbidity and mortality.

So I would put it in that context. It's a matter of relative risk, and one's doing that the whole time in thinking about these issues.

Q. Could we look at your statement, WITN3428001, please. Go to page 93. If we look at paragraph 245, you talk there about DDAVP, and you say you would explain to a patient about its potential side effects which include nausea, flushing and water retention.

Do we correctly understand from that that your practice in '83/'84 would have been to explain to your patient that if they used DDAVP, they might get nausea, flushing or water retention, but you wouldn't explain to them that factor concentrates might infect them with a virus for which there was no treatment and a high mortality rate?

A. Well, I have set out here the reactions that occur in virtually all patients, particularly if you give the desmopressin infusion quickly. So these, if you like, were common reactions.

The other, in relation to HIV, were of a different frequency. I agree the consequences of HIV infection, as we now know it, and I think this is -- this is one of the difficulties of trying to

look back with hindsight, knowing what we know in 2020. I'm trying to do the best I can for you.

Q. In August of 1983, so not in December of 2020 but in August of 1983, or very soon thereafter, you would have become aware that a patient in Bristol who was a haemophiliac died of AIDS. Is that information which you shared with your patients?

A. I don't remember doing that, no.

Q. If we look, please, at NHBT0020668, Soumik, you will see, Professor Ludlam, this is a National Blood Transfusion Service letter with a leaflet, July 1983. If we go to the next page, please, you may or may not have seen it at the time -- you may well not have done. If we look towards the bottom of the page, we can see the question:

"Can AIDS be transmitted by transfusion of blood and blood products? Almost certainly, yes. There is only the most remote chance of this happening with ordinary blood transfusions ..."

And then it goes on to talk about haemophiliacs and explains in the last sentence:

"Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease."

So you'll see the approach taken by the Blood

Transfusion Service in England in July 1983, or perhaps a little later than that in terms of dissemination of the leaflet, was donors -- not themselves at risk -- were to be told that almost certainly, yes, AIDS could be transmitted by the transfusion of blood products. But your patients, as recipients of factor concentrates, were not being given that information. Does that strike you as the correct outcome?

A. Looked at in retrospect and hearing what the patients are now saying and if we had received the Council of Europe document, then maybe we should have explained this to patients. I think it was fairly well understood by patients that there was a risk, and I think that comes out in some of the statements that Scottish patients have given to the Inquiry, that they thought the risk was small because of our self-sufficiency and so on.

Q. Can I move then to the testing of patients for HTLV-III in the autumn of 1984.

First of all, as I understand the evidence that you gave Penrose and that you have provided to this Inquiry, in the autumn of 1984, you used stored samples without patient consent and without telling your patients to test or to have tested by Dr Tedder

for HTLV-III; is that correct?

A. That's correct, yes.

Q. In relation to the stored samples, for how long had a library or bank of samples been built up at the Edinburgh centre?

A. It was standard practice, going back into the 1970s, that the virology department, if you sent a sample to them, they did the investigations, and they then stored the sample in a long-term store, in a deep freeze. That was their standard practice. That was good practice and one supported by various authorities.

We started collecting them in the Haematology Department in parallel because one weekend in the early 1980s a deep freeze failed and all the samples melted and were lost, and so we kept a sample, a parallel sample, as it were, as a backup to virology. But virology continued to collect, at least to store, samples that we sent for routine testing for hepatitis or other investigations. That was part of their standard arrangements.

Q. When did the centre's own practice, triggered, as you described, by a deep freeze failing, when did that commence?

A. I think it might have been about 1982, perhaps.

I forget exactly when but I remember there being this failure of the equipment in virology.

Q. If we look at PRSE0000828 -- I'm turning now to your interactions with Dr Tedder, professor -- this is a memo. It's between Dr McClelland and Dr Perry, cc to Dr Cash, 20 November, but it may help us give some dates. It tells us in paragraph 1 that on 26 October you telephoned Dr McClelland at home to tell him that six haemophiliac patients had developed antibody to HTLV-III. Then we can see in paragraph 4 on 2 November, so the following Friday, you telephoned Dr McClelland to explain that you'd received further data from Dr Tedder relating to a total of 16 of his haemophilia patients. Is this likely to be a reliable guide to the dates?

A. I think so, yes.

Q. As far as you can recall, how many samples did you first send off to Dr Tedder?

A. My recollection was sending about ten samples. My recollection also is that Dr Tedder had a slightly different memory when he provided evidence to the Penrose Inquiry. I don't think it was a major difference in numbers but it was a small number.

Q. I think your evidence to the Penrose Inquiry suggested there was an initial batch and then a follow-up larger

batch.

A. That's correct, yes.

Q. I'm going to ask you to look at something Dr Tedder said to the Lindsay Tribunal. It's LIND0000310, please. If we go to page 13, we can pick it up at the bottom of the page, the last few lines Dr Tedder is discussing "in late autumn '84 ... we did the first testing for him", and he refers to:

"... going through this litany of positive, positive, positive. And Christopher Ludlam obviously getting more and more pensive and me feeling less and less kind, as this evolution of damage done to a cohort evolved. That was the very early testing when he had sent us cohorts of samples which he already had a clinical suspicion that something had occurred, and that was the beginning of the evolution of knowledge on the Edinburgh cohort."

So Dr Tedder's recollection was that you had a clinical suspicion that something had occurred. Is that correct?

A. No. I had no clinical suspicion. No, I had no clinical suspicion. I notice on the previous page reference is made to the glandular fever episode, which he puts as, I think, 1985. I don't know if you can go back a page.

Q. Go back to the bottom of the previous page, Soumik.

A. I'm sorry, I'm not quite sure what's up on the screen at the moment:

"When did this first come to light, this outbreak, as a result of Scottish product; I think you give March 1985?"

Dr Tedder answers:

"I think it was earlier than that. I mean, March '85 was the description of one of the young men who developed glandular fever-like illness ..."

The individual who developed glandular fever-like illness was March 1984, and I had no suspicion that that was due to HTLV-III at the time. Because we kept the weekly samples on him, we were retrospectively able to discover that the horrendous clinical course this young man had was as a result of HTLV-III infection. But I had no idea. It never occurred to me because it hadn't been described.

This, I think, was the first -- one of the first cases in the world that was described once testing became available. But in March 1984, we had this terrible clinical episode. We had no idea what was wrong with the patient. He had had a simple -- what appeared to be a simple synovectomy for a very, very troublesome knee joint that he'd a lot of trouble

with bleeds in.

So your question is that I had no prior inkling that any of our patients had been infected.

Q. If you didn't have any such prior inkling and you had a firm belief in the safety of the Scottish product, why had you taken the step in the first place of asking Dr Tedder to use what we know from elsewhere were scarce resources to test samples of your patients?

A. Well, to be honest, I nearly didn't. I was pretty confident that they would be negative. There were -- as we discussed yesterday, there were two or three patients, a small number of patients, who had received commercial concentrates, and as much on the basis of testing those individuals that I sent the samples to Richard Tedder. But I nearly didn't send any samples at all. Had I not done that, then it wouldn't have been clear that this terrible episode of the batch of Factor VIII had happened and that potentially, as I was saying earlier, was one of the events that led to the meeting on 10 December.

If one of the reasons was my discovery of these patients being positive was for the meeting being called, then that was very fortunate because the meeting had been delayed. Or if I had not tested my

patients and there had still been the meeting, there might not have been a recommendation to heat treat NHS concentrates. So -- and if the meeting had been delayed for other reasons -- in other words, I hadn't made these observations; the meeting had been held in January or February, then that would have delayed the introduction of heat treatment and the benefits of that in the UK.

Q. Professor, my question implied no criticism of having the samples tested. The question was: why, given that you had, you say, no reason to suspect that there was anything untoward, why did you send 50 to 70 samples (was your estimate to Penrose) to Dr Tedder, the vast majority of whom had only been treated with NHS concentrates?

A. Oh, I sent them because Dr Tedder and his colleagues had published a paper in the Lancet in, I think, September of that year, describing anti-HTLV-III testing of patients in different groups, and one of the groups was people with haemophilia, of which 34 per cent were positive. Now, this was a research test for anti-HTLV-III and, therefore, perhaps viewed with a certain degree of uncertainty about interpreting the results. But it also included 1,000 North London blood donors, none of whom were positive.

So it was the availability of the test, the anti-HTLV-III test, that alerted me to be available in the UK. And I thought, well, I should at least find out whether the patients who got commercial concentrate were antibody positive or not and, along the way, why not send some people who had only received Scottish Factor VIII, as I say, expecting them to be negative.

Q. I want to --

A. That was the reasoning, and there were only about ten samples sent to start with.

Q. I want to look with you at the steps you took after receiving the results. We've got the dates from that memo, 26 October, and then 2 November for the further results.

If we have up on screen, please, LOTH0000097_007, please, Soumik. If we go to page 3, please. So we can see this is headed "Confidential summary of meeting on 7 November 1984. Subject: laboratory and clinical management of patients with evidence of HTLV-III infection and from groups known to be at risk". And there are a number of attendees from the GUM clinic, the diagnostic lab, et cetera, and you and a colleague, Dr Parker, from haematology.

If we look at the next paragraph down, under

the heading (1), it says:

"This new human retrovirus is now believed to be the aetiological agent of AIDS. Virus is present in and can be transmitted by close contact with patients' blood saliva and probably other secretions (similar to hepatitis B). The groups of patients known to be at risk are promiscuous male homosexuals and recipients of blood products, especially Factor VIII concentrates. Antibody to HTLV-III can be measured and is present in the pre-clinical stages."

Then this:

"It is important to appreciate that patients with antibody are infectious and can transmit the virus."

Then we go on to see, if we look at the rest of the document, paragraph 2:

"General guidelines have been circulated for the management of AIDS patients and their specimens. [They] should be managed as for patients with hepatitis B."

We can see under the heading "Local Problems", (a) there's reference to a limited research study in 20 haemophiliac patients having antibody to HTLV-III, associated with the particular batch of Factor VIII concentrate. Then we can skip the next paragraph.

If we go to the preceding page, Soumik, because this document appears out of order, zoom in the top of the page, "Proposals", it says:

"The following groups of patients must be treated as High Risk:

"(a) Haemophiliac patients who are known to have antibody to HTLV-III and all other patients whose have received Factor VIII or Factor IX concentrates prepared from large numbers of donors."

Then there's various discussions of implications. If we go further down, we can see at (d), the top of what we can see on the screen:

"Laboratories must be informed that specimens are from high risk patients and processed according to established High Risk procedures."

Then:

"Implications

"(a) Clinical Management: information must be given to surgeons and dentists or any others who may be required to examine and/or investigate the patient ..."

Then there's a description about facilities, accidental exposure of staff and diagnostic service.

If we then go back to page 3, please, Soumik, if we look again at that sentence, "It is important to

appreciate that patients with antibody are infectious and can transmit the virus", there doesn't appear to have been any great uncertainty or misunderstanding at this meeting as to the significance of a positive result, does there?

A. I think this is very interesting. I note the date of the meeting and it, I think, has arisen because of the samples I sent to Dr Tedder, because I think my patients were the first to be diagnosed with anti-HTLV-III in Edinburgh, and I found myself at the centre of very many things related to HTLV-III in the hospital and in the Health Service.

The difficulties mounted up very quickly and to try and address these we got together a group of appropriate experts and I was asked to chair the group on behalf of the Health Board and we had frequent meetings dealing with a whole range of issues within the hospital, particularly in relation to managing patients from at-risk groups.

We took a very cautious view about samples and about people, not only, as you see here, who were anti-HTLV-III positive but we made the assumption that, in relation to haemophilia, that anyone who had recently received clotting factor concentrate from whatever source, whether it was NHS or commercial,

might be infected because we had no idea what the false negative rate was for Professor Tedder's test; in other words, patients who might test negative on his test but might still be infected with the virus.

So we adopted that approach. It had a number of advantages, I'm happy to go into if you would like, from the point of view of managing patients and the advice that we gave to patients was irrespective of their anti-HTLV-III status.

Q. The particular sentence I invited your attention to, professor, was "important to appreciate that patients with antibody are infectious and can transmit the virus."

That was the understanding of this meeting, was it not?

A. Yes, that's fine, yes.

Q. Because of that, although you then broadened it out for the reasons you have given, that the arrangements might cover, for example, all haemophilia patients who had received concentrates, the implications were, amongst other things, all specimens to be treated as high risk and surgeons, dentists, other clinicians would be told that they needed to implement high-risk operative procedures. At this point, as at 7 November, no discussion here of any steps to tell

the patients themselves?

A. That's correct. We were quite taken aback -- I was quite taken aback by the results that I had received and it was only on five or six patients and this meeting was -- certainly occurred because of my observations. As I say, we were taken aback and taking stock of the situation and, if you like, it was out the blue, and we had to actually think about what the implications were.

Q. I think we've already established, by reference to Dr McClelland's note, that it was 2 November you were told it was a larger number than the five or six: 16 patients. So by the time this meeting is occurring on 7 November you already have the second suite of results?

A. I'm not in a position at the moment to quibble over the dates but the first results were phoned to me on 26 October. I think -- did Professor Tedder not say it was a Friday?

Q. If we look at Dr McClelland's memo, if we go back to that, PRSE0000828, we can see, paragraph 1 Friday, 26 October, that's the six results, and then there's further discussion that Dr McClelland describes, and then there's a further phone call related in paragraph 3 between you and Dr Boulton. Then

paragraph 4, Friday, 2 November:

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

A. Thank you, that's helpful. I hadn't retained that. So I must have sent some samples down to Dr Tedder on Monday, the following -- whenever it would be, 31 -- or, no, 30 October, and he must have processed them fairly quickly and let me know the results.

Q. We've looked at the meeting of 7 November. There's just three pieces of correspondence I want to look at for November and then we'll turn to the meeting of 19 December, and that will probably be where we get to for today. If we could look at, please, LOTH0000097_007, we can see on 16 November you wrote to Dr Sutherland, Community Medicine Specialist. You told him in the first paragraph that some patients have antibody to HTLV-III virus. You refer in the second paragraph to classification of haemophiliacs who received concentrates as "high risk", and then you say this, in third paragraph:

"We hope that at the clinical end of our

service that this will not cause too much disruption although it is going to be necessary to offer a reasonable explanation to some of the patients."

Then you go on to talk about implications for the laboratory and refer to another meeting.

What did you mean by "it is going to be necessary to offer a reasonable explanation to some of our patients"?

A. Well, explain the results or that we had results if they wished to know them.

Q. That still wasn't done as at 16 -- or hadn't been done as at 16 November, had it?

A. No.

Q. If we then look at a letter from the day before. LOTH0000005_052, please. If we go to the first page of that. Thank you.

This is a letter from Dr McClelland to Dr Cash, 15 November. It's cc'd to you. We can see -- and we don't -- I'm not proposing to go through the detail of all of it, but we can see from the first paragraph that there have been clearly a number of discussions between you and Dr McClelland about the discovery of patients having been infected with HTLV-III due to PFC product.

We can see from further down this letter,

there's been an analysis undertaken by you and Dr Tedder -- this is the third paragraph -- suggesting one batch of product had been received by all but one of the 16 patients and was highly suspect.

And then a description of there being a further analysis -- this is the numbered paragraphs towards the bottom of the page.

And then if we go over the page, we can see the conclusions, second half of the page. It is that the -- a batch ending 090 is probably responsible for seroconversion, then there's a discussion about what to do with other batches.

Then in the last paragraph, Dr McClelland thanks you for your data analysis. Then it says this:

"Dr Ludlam has specifically requested that the information relating to the batch associated with seroconversion be treated in confidence."

Why did you want that information to be treated in confidence?

A. Because I wanted to inform the patients in a controlled way. I didn't want the patients learning, if you like, by rumour that there were results available.

Q. We can see that those discussions and that analysis that you and Dr McClelland had undertaken must have

been completed by 15 November, that's the date of the letter.

We can then see you attended a meeting on 29 November. This is at PRSE0002066. We see the date at the top of the page. We see the attendees, which include you. We can see in paragraph 2 it's a meeting convened to discuss the implications of the recent finding of HTLV-III antibodies in Scottish haemophiliacs:

"Measures being taken by SNBTS to prevent transmission of AIDS by blood products and the media attention associated with these developments."

Then there's a reference to the Elstree meeting that we know took place on 10 December.

The second paragraph -- sorry, the third paragraph refers to you explaining the circumstances in which it's been discovered that 16 patients had developed antibodies to HTLV-III.

Then if we go over the page, please, discussion about heat treatment, though I'm not going to ask you about for present purposes.

If we look at paragraph 8 towards the bottom of the page:

"Views were exchanged on the very difficult ethical questions which had arisen. These included

whether patients and patients' relatives should be informed and perhaps subjected to needless worry; whether publicity additional to that already provided should be given, and how directors should respond to direct enquiries or requests for advice. The Chairman advised members that ministers had been informed. The SIO had been briefed. While a press statement would not be issued by the department at present, any enquiries would be answered. It was agreed that every effort should be made for patients to have the situation explained to them before the impending publicity."

We can see that by 29 November, then, Professor Ludlam, a number of organisations or individuals, including ministers, had been told of the situation. Patients at this stage are still in the dark, aren't they?

A. Yes.

Q. Why was it a very difficult ethical problem to decide whether to tell a patient that they have antibodies to HTLV-III?

A. At this time, I think because of the -- there was a lot of activity, a lot of discussion, and I was waiting for the meeting on 10 December to happen to get the view of my colleagues and for a full

discussion about the issues. We could have -- we could have informed patients sooner. We could have indicated to patients that results were available sooner, but we were considering actually how the best way was to manage the situation and to think what we should be saying to patients and what patients would want to know. This took us, I have to say, very much by surprise, as you will have gathered, and a lot of activity going on, and we needed to, as it were, get our minds in order and our systems -- decide what our systems should be. So that's where we were. There was -- I didn't want information being spread by rumour because that didn't help.

Q. Can we look at one further letter from November which is at HCDO0000273_058, please. This is a letter from Dr Craske to you on 30 November. And we can see from the first paragraph that you've had telephone conversations, plural, with Dr Craske about the issue of suspect batches and infection.

If we go over the page, we look at the bottom half of the page under the heading "Methods of investigation", you can see there's a strategy there proposed by him:

"Identify all patients, and then follow them up at least four monthly intervals for six years."

Top of the next page, there's a discussion about record forms JC1, JC2, JC3 to be completed and returned to Dr Craske.

Then if we go to the next page, we can see under the heading "Should the patient be told?" The view of Dr Craske:

"Ideally, I think he should, but this will depend on many factors, including the amount of anxiety concerning AIDS already present in the centre and the degree to which the patient is capable of understanding the situation. Every effort should be made to encourage the patient to discuss the problem with his spouse and help them to face the problem together. The GP should also be informed by letter."

What was it that had prompted you, at a stage when, as I say, none of your patients yet knew the results, to contact Dr Craske and have a series of conversations with him?

A. Could you go back to the top of the letter, please?

Q. Yes. The first page?

A. Yes, please.

Q. Top of the first page please, Soumik.

A. I don't think I contacted Dr Craske. I think he telephoned me, and we must have had a discussion, and he then wrote this letter and sent it to me. The

interesting ... yes, that, I think, is the sequence of events.

Q. Do you recall whether you completed the JC1, 2 and 3 forms for the patients, and if so, when?

A. I don't think we did, no. I don't remember doing -- it's possible one of my staff did, but I don't have any recollection of that.

Q. We know from your and other evidence that eventually, on 19 December of 1984, a group meeting took place at the Edinburgh Royal Infirmary. By that time, is this right, you had known the results for 16 patients, as well as a larger number of negative results, for nearly two months and had not told a single patient?

A. That's correct, yes.

Q. Even though, as we saw from the meeting on 7 November, patients were known to be infectious, and this was a disease known to be sexually transmissible. Why the delay, Professor Ludlam?

A. I think the implications of it all were so enormous, actually, that it took us a bit of time to -- for it all to sink in and for us to think of the best way of responding. And, as you see, there were a series of meetings, and I was keen to gather as much wisdom and help and advice as I could so that I could help the patients as I thought was best.

Q. Did that delay not place at risk not only those in sexual relationships with the infected patients, but bearing in mind that we're talking about a cohort of severe haemophiliacs, family members or other contacts who might come into contact with their blood?

A. Well, as far as family members were concerned, they were all very aware that the blood, any blood spillages, potentially contained infectious viruses. That was well established and we tried to persuade or arrange that patients treated themselves and they knew about avoiding blood contact with other family members.

So far as connection with possibility of sexual transmission, yes, there was a two-month delay. The risk -- we know actually that the risk was very small but it was a small risk and, looked at in retrospect, if I had sent out some information on the -- very early in November, we would have had a lot of patients who were suddenly on our doorstep wanting further information and distressed and might have been too much for us to cope with. The stress -- it's easy looking back at -- with, literally, 20/20 vision, and although we knew that there was a risk, if you like, from sexual transmission, we had no idea how great the risk was, though we thought it was relatively small

and it turned out to be vaginal intercourse, anyway, was a small risk.

But it was a very difficult time and certainly I do see that, in retrospect, maybe we should have done things differently and we certainly learnt a huge amount from the way we responded to the whole of this episode in relation to AIDS. For example, when it came to considering issues related to new variant CJD, we took a different approach and we had learnt from the very stressful events surrounding HTLV-III, and particularly as things rolled out the end of 1984 and into 1985.

Q. Why did you organise a group meeting in a lecture theatre at the Royal Infirmary, rather than invite 16 patients to come and see you confidentially and privately one by one? Why did you think a group meeting was a good idea?

A. Well, I went to the meeting on 10 December in London at Elstree. It was a big meeting, we discussed it, it was important. It was a stressful meeting and I was keen to get other people's views. I turned up at work the following morning to receive a phone call from the Yorkshire Post, a reporter had said he had heard about the Edinburgh episode. I think -- the implication, my memory is, as a result of the meeting the previous

day, and he wished to publicise this in the Yorkshire Post the following day, and I was absolutely furious with him that -- because this sort of publicity is not the way that patients should be informed about the situation, whether they are antibody positive or negative.

So he agreed to come up and see me. I think he came up, perhaps, the following day and I begged him to delay -- he was desperate to publish his story, in case someone else, some other newspaper, published it first, and I was very upset and very cross, and I was left -- he said, "Well, I really want to publish this", and so I eventually persuaded him to wait about a week before publishing it, and he told me he would publish it on I think it was 20 December, which left me a handful of days to decide what to do.

There was no way that I could -- my staff could see everyone. So the next best thing was to write to all the patients and say that we were holding a meeting about AIDS and HTLV-III on the evening of -- I think it was the 19th -- if they'd like to come we would tell them more. If they weren't able to come but wished to discuss the situation to get in touch with me.

That's how the meeting came to be held. It

wasn't my idea of the way of informing patients about what had happened but I was, as it were, door stepped by the Yorkshire Post and what I think was not good behaviour.

Q. If the threat of impending publication had not been made and precipitated the meeting in the way you describe, is it likely then that 1984 would have come to an end with your patients none the wiser?

A. I think I would have written to the patients saying results have become available, if they would like to know the results please make an appointment to come and see me, and I would have -- as you know, we sent out an information sheet. I would have sent that out, or something similar to it, to all patients and then, as it were, monitored, as we did anyway, who responded who came to see me, or who would have come to see me. That's what I would have done had the Yorkshire Post not intervened.

Q. Can we just look at the letter that was sent on 12 December 1984, WITN3428009, please. This is your letter of 12 December to patients and parents:

"... much publicity in the press and television about the HTLV-III virus and AIDS. Dr Forbes ... and I are holding a meeting to discuss with patients some of the anxieties and issues that have been raised.

You ... are cordially invited.

"... I will ... speak for a few minutes on AIDS, Haemophilia and Blood Transfusion. We will then open the meeting to questions and general discussion. If you do not wish, or are unable to attend ... but would like to talk to me ... we should be delighted to see you by appointment ..."

There's nothing in that letter, is there, that would inform the recipient that there is a problem with Scottish Factor, or that patients have been tested, or that there are positive results that have come back?

A. No, but I open the letter with saying "there's been much publicity", so there was a lot around in the general news about AIDS, and so patients were aware of the virus. I agree I didn't want, at this stage, to -- I suppose I could have said that we had results from some patients but I didn't, but the implication was that if you were interested please come and see me.

Q. The problem with sending a letter in these terms, Professor Ludlam, although you may not have wanted to cause undue anxiety, is that the recipient might think, "Oh, well this is just a meeting designed to reassure", the recipient who for years has received

concentrate that they have been assured is Scottish and safe may think that there's no point in them attending this meeting.

As your evidence to Penrose explained, that in fact you sent the invitation to every patient in Scotland, expected hundreds and only a few tens turned up.

A. I'm sorry, can you repeat your question?

Q. Yes, of course. Because this letter is written in the terms that we see on the screen, recipients of it might have simply thought this was a meeting designed to reassure and that they weren't personally at risk because they'd received safe Scottish factor for years and, therefore, there was no need for them to turn up.

SIR BRIAN LANGSTAFF: That's really a comment but it's framed with a question mark at the end.

MS RICHARDS: It is.

A. I assumed that people with haemophilia would have a fairly low threshold for being concerned about AIDS and, in a sense, I didn't need to say too much to encourage people -- people would have a low threshold to attend the meeting and, as you see, that was my view. I'd set aside two large lecture theatres because I thought we'd sent this letter out to all people with haemophilia in Scotland, was my

time to think about whether they wished to know their result or not. It was very interesting seeing patients in early 1985. And I used to see them mostly in my room in the Haematology Department, rather than the out-patient clinic, medical out-patient clinic, because it was a quieter place; less likely to be disturbed, and I could see patients outside the clinic time.

Patients really appreciated the opportunity just to reflect, to talk about themselves, because the implications of knowing that you were antibody positive led to another series of questions. And with the outside world not being very sympathetic, to put it mildly, to people with haemophilia, once it became common knowledge that a number were anti-HTLV-III positive, patients wanted and their families wanted a bit of time before they came to see me.

Q. Professor Ludlam, I may need to pick up with you tomorrow events in early 1985 and what you say patient reaction was. Before we do that, just two short matters arising out of the meeting, or related to the meeting.

You've exhibited to your witness statement the information sheet that you say was sent out after the 19 December meeting but not the letter which was sent

understanding with Dr Forbes and the other east coast centres. There may have been some misunderstanding about that. Certainly, it went out to all those in south east Scotland.

Q. What is your recollection of what you said at that group meeting about the issue of testing and test results?

A. Oh, I explained that we had tested from stored samples in Richard Tedder's test and that some of them had been reported as being positive and that we had -- a preliminary look at the results suggested that there had been at least one batch of PFC concentrate that had caused infection.

Q. Is this correct, that after that meeting, you left it to patients to make contact with you or the centre to find out what their -- if they'd been tested and what their test results were?

A. Well, we wrote to all patients and enclosed the information sheet that you have which describes the situation in relation to HTLV-III, including the safety precautions, and there was the invitation in the covering letter to come and find out more by making an appointment. And that arrangement actually worked reasonably well for the majority of patients.

They were appreciative, actually, of a bit of

to patients which you say accompanied it and invited them to come and find out more.

Is there a reason for that? Do you have a copy of the letter available to you?

A. I'm sorry, I don't have a copy. As you know, I have a fairly extensive archive related to all of this which I have been very careful to preserve because of the severity of the episode and the catastrophic consequences of the episode. I'm sorry, I don't have a copy of the letter.

Q. Then finally for today, if we just look at an observation you make about your approach in your witness statement. So it's WITN3428001. Go to page one hundred and -- no, I'm sorry. That's the wrong reference.

In that case, sir, it may be more sensible that I pick it up in the morning with the correct reference.

SIR BRIAN LANGSTAFF: Yes. Well, we will take a break now. I'm sure you could do with one, but can I just, before we break, just pick up on a couple of points which arise out of this last exchange and some of the evidence which you gave earlier.

You've told us how really stressful a time it was, having sent off your blood samples to

Richard Tedder, having got back, about 26 October, at least 6 positive results, and then a few days later a total of 16. You've essentially, I think, given a description of not quite knowing where to turn; just trying to work out, come to terms with the situation. Am I right in that?

A. No, you are correct. I was very much taken aback.

SIR BRIAN LANGSTAFF: So, obviously, you thought it was very, very serious indeed. Am I right?

A. Yes, that's correct.

SIR BRIAN LANGSTAFF: At this time, you did not know, you told us -- you drew a distinction between HIV, or HTLV-III as it was then, and AIDS, and you had a belief -- indeed, it's what Craske told you on 30 November -- that the chances of developing AIDS were somewhere between 1 in 100 and 1 in 500, but that still struck you as being very, very serious.

A. The seriousness was related to the fact that people appeared to have become infected. That was serious enough, if you like, and the consequences of that were, to some extent, unknown, and that is also unsettling.

SIR BRIAN LANGSTAFF: Was it because they were not only, to some extent, unknown but it well appreciated, both by you and plainly by the popular press if they were

chasing the story, well appreciated that it might be very serious; indeed, possibly deadly?

A. I think it was the uncertainty that was stressful. I entirely agree that if I had known what we subsequently learnt, that if you're antibody positive the chance of getting AIDS was pretty or very high indeed, yes, that would have been stressful, difficult, but at least that would have been, if you like, a known fact. What was so difficult in this instance was trying to cope with the uncertainty. Was this actually a situation where 100 per cent of those infected were going to get AIDS or was it a case of only 1 per cent? Trying to cope with that and explain to patients and ourselves that degree of uncertainty for a serious disorder was taxing.

Is that -- does that help?

SIR BRIAN LANGSTAFF: It is helpful to an extent. Yes, thank you very much.

We will take a break now and it's 10 o'clock, of course, tomorrow morning and I look forward to seeing you again then. Thank you very much. 10 o'clock tomorrow morning.

(1.42 pm)

(Adjourned until 10.00 am the following day)

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