

**Notes of Meeting between Professor Ludlam, Gemma Lovell, Douglas Tullis, Tracey Turnbull and Kathryn McElroy on 19 April 2011 with corrections and clarifications added and responses to subsequently posed additional questions**

**Information about the risk of infection (hepatitis C and HIV)**

- 1. In the early 1980s when you were working as a consultant in Edinburgh did you discuss the risks of using factor concentrates (for example, infection with hepatitis B and, subsequently, NANB hepatitis) with your patients?**

It was well known amongst patients in the early 1980s that there was a risk of hepatitis from treatment with factor concentrates including cryoprecipitate. Patients on home treatment signed consent forms in which infection, was specifically mentioned as a risk. Copies of the consent forms are available. In the 1970s and 1980s there was literature available from the Haemophilia Society which addressed the issue of hepatitis. I did discuss the risk of hepatitis with many of my patients because they were at risk or had hepatitis and some became jaundiced. Hepatitis was not considered to be as serious problem at that time as it subsequently became.

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- 2. When the possibility that AIDS was a blood borne disease which affected haemophiliacs became apparent (around December 1982) did you discuss the implications with your patients before continuing to use factor concentrate therapy?**

At that time, most of my patients were being treated with NHS concentrates produced in Scotland. In December 1982, there was no evidence of AIDS in Scotland and we therefore perceived the risk of infection from NHS factor concentrates (which were

manufactured from blood collected in Scotland) to be small. I did not discuss AIDS with my patients at this time unless they specifically asked about it. I do not recall there being much concern about AIDS amongst the patients generally at this time.

**3. Did you consider switching your patients back to cryoprecipitate at this point? Did you discuss the option of switching back to cryoprecipitate with your patients?**

We did consider switching patients back to cryoprecipitate in around 1982/83 but the logistics of doing so were huge. In the late 1970s and early 1980s Scotland and Edinburgh in particular had been highly dependent on cryoprecipitate. A large effort had gone into scaling back cryoprecipitate production and scaling up the manufacture of factor concentrate which enabled patients to be treated at home. Concentrate was initially in desperately short supply. We did consider whether concentrate manufacture could be reversed but this seemed such a retrograde step. In 1982 it was not as simple as a clinician making a choice as to which product would be used. We did not have large supplies of cryoprecipitate available. The whole work stream had moved into production of concentrates. Switching patients back to cryoprecipitate would have required huge changes to the manufacturing practices and would have taken some time to accomplish. Some patients could not tolerate cryoprecipitate because of allergic reactions and had to take concentrate instead.

We were also aware that doctors in the USA had attempted to move patients back to cryoprecipitate when the risk of AIDS became apparent. This move was unacceptable to the USA patients who wished to continue taking factor concentrates even though there were many people with AIDS in the USA.

I do not recall discussing the option of switching back to cryoprecipitate with my patients. If a patient had asked me about the possibility of switching back I would have explained what is set out above. It would probably have been possible to change a small number of patients back to cryoprecipitate if this had been requested. I do not recall any enquiries of that nature from individual patients or the Haemophilia Society.

## **Testing and Consent (HIV)**

### **AIDS Study (1983–)**

- 4. When did you start to collaborate with Dr Steel at the Medical Research Council Unit (Western General Hospital in Edinburgh)? What records were retained in connection with the research? Are the records still available?**

I began to collaborate with Dr Steel in early 1983 (around Jan/Feb).

The results of the lymphocyte tests carried out by Dr Steel were initially recorded in paper records. The paper records were computerised. RIE has computerised records dating back to this period. The Inquiry has been provided with computer records of the test results for some patients.

Some of the request forms which accompanied the blood samples to haematology were added to individual patients' case notes retrospectively. These requests were unfortunately labelled "AIDS study". At the time they were kept out of patients' main case notes because they had "AIDS study" on them and we didn't want to alarm any clinical staff who may have come across the form in the notes. There was a huge amount of stigma around AIDS from 1983 onwards.

5. **In paragraph 11 of CAL21, you note that when patients attended the Edinburgh haemophilia clinic for review, blood was taken to enable a number of investigations to be carried out (see also paragraph 6). This helped you to monitor treatment related adverse events. Was blood taken from all patients each time they attended the haemophilia clinic for review? How often did patients attend for review?**

Blood was regularly taken from patients when they attended the clinic for review. It was part of the routine of coming to the clinic that blood was taken. Blood was not taken every time the patient attended but was done when tests were deemed necessary.

The frequency of a patient's attendances depended on their clinical situation. For example, patients on home treatment attended relatively infrequently (perhaps once every 3-4 months), others more often.

6. **Can you explain what happened (as set out in paragraph 11) more clearly?**

When patients attended the clinic patients were invited to give a blood sample for the investigations set out in paragraph 6 (as appropriate). In most instances the patient would be invited to lie on the examination couch. A blood pressure cuff would be placed round the upper arm and gently inflated to about 40 mmHg to make the veins visible. The skin in the antecubital fossa (flexor surface of the elbow) would be cleaned with antiseptic. A gauge 21 needle would be carefully inserted into the vein and the required volume of blood sample withdrawn into the syringe. The blood pressure cuff was deflated, the needle removed from the vein and the patient asked to hold a ball of cotton wool firmly on the site of needle entry for five minutes. The needle would be removed from the syringe

and blood dispensed into various tubes. The volume of blood would be approximately 15 mls i.e. 1 table spoonful.

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

The labelling of the request forms with "AIDS study" was unfortunate but was intended as a "shorthand" indication to the haematology laboratory that they needed to count twice as many white cells under the microscope and send the sample on to Dr Steel. When Dr Steel received the samples his research assistant counted the CD4 and CD8 lymphocytes. The number of each reflected the immune status. At the time, we noted gross abnormalities in the patients' immune systems but considered that this probably had nothing to do with AIDS. That was the presumption that we made at the time. We were correct at the time as the abnormalities were not due to HIV. The patients did not become infected until later.

- 7. Were samples from all of your patients sent to Dr Steel? If not, how many patients did you take blood samples from which were sent for analysis by Dr Steel to determine the proportion of CD4 and CD8 lymphocytes? How were these patients selected? Did you obtain consent from these patients?**

It is difficult to say that samples from all of my patients were sent to Dr Steel but samples from many patients were sent. I did not select particular individuals whose blood samples needed to be sent to Dr Steel for analysis. Rather, patients were "self-selected" by being attendees for treatment or review - people with severe or moderate haemophilia who attended the clinic regularly. I think that the tube was sent from the haematology laboratory to Dr Steel in all instances, where possible, if the haematology request form was labelled 'AIDS study'.

I did not obtain explicit consent for each individual test from the patients. The tests were seen as part of the general monitoring of patients who were used to blood tests being taken for different monitoring purposes. If a patient did not wish to give a blood sample then one was not collected. I wasn't trying to keep the immune tests secret but saw them as part of the general monitoring of patients for which we had implied consent. The patients were used to my monitoring whatever I considered appropriate.

By comparison, at around the same time we were carrying out skin tests on some of the patients as another immune function measurement. This involved use of a plastic device (CMI multi-test) with 8 tiny feet, each was about 2 mm in diameter and contained different antigens of commonly encountered infectious agents to which most individuals are exposed. After cleaning the skin the device was placed on the flexor surface of the patient's forearm. The patient was reviewed two days later to assess the response (if any). The response was assessed by measuring the diameter of reaction which was usually in the range 0-3mm. Any patients who were asked to do this test would have had the test explained in detail (as above) and would have been asked for consent as this type of testing was not part of their normal monitoring. The results of these investigations were important because they demonstrated that in HIV negative subjects those who used more factor VIII concentrate had a greater degree of immune suppression i.e. factor

VIII concentrate alone could possibly cause significant immune suppression. That this might be clinically significant was our observation of oesophageal candidal infection (an AIDS defining condition) in an HIV negative patient.

There was no record of any written consent for blood tests obtained at that time. In the 1970s and 1980s many of these patients were having to come up to hospital very frequently, sometimes 2-3 times per week and we got to know them very well. Against that background there was a lot of informal discussion about haemophilia, its treatment and complications. In the early 1980s patients would often sit round in a semi-circle together receiving infusions of cryoprecipitate. This close relationship, particularly with teaching hospitals consultants undertaking studies to try and improve treatment to those with haemophilia was highlighted by the Rev Alan Tanner in his evidence to Lord Archer's Inquiry. There was much more interaction between clinicians and patients than in many other areas of medicine. It is a completely different world now that the majority of patients are on home treatment.

- 8. After observing in your initial studies in 1983 that your Edinburgh patients had a pattern of lymphocyte abnormalities did you advise them of the results of the analysis of their blood?**

Patients were only advised of any lymphocyte abnormality if they asked.

We did not know how to interpret the results. The abnormalities were a surprise and the cause was uncertain. We thought that the abnormalities could have been due to a number of things. They could have been due to:

- (a) a feature of the condition of haemophilia which had not been described before because no one had previously looked at lymphocyte function in haemophiliacs;
- (b) impurities in the concentrates and a response to foreign proteins contained in those treatments. At that time most of any bottle of concentrate consisted of proteins that were not needed for treatment ;
- (c) a ubiquitous viral infection (not HIV) or to an hepatitis virus;
- (d) a specific AIDS causing virus (i.e. HIV), but this seemed unlikely because our patients were being treated with NHS concentrate made from blood donated in Scotland and there was no evidence of AIDS in the Scottish population who might have been blood donors.

- 9. In paragraph 13 of CAL21, you note that it seemed important to submit your data in respect of immune abnormalities in your haemophilia patients (i.e. the AIDS study data) for publication because it would offer alternative explanations (other than AIDS) for the immune abnormalities observed in US haemophiliacs. Your data was published in the Lancet in (1) May 1983 and (2) June 1984. Did you obtain consent from your patients before publishing the results of your investigations of their blood? Were all of these patients subsequently found to be antibody negative?**

I did not inform the patients or obtain their consent to publish data on them. I did not think that there was any need to do so as there was no patient identifiable information – it was all anonymised data. I thought the abnormalities were due to something other than a putative ‘AIDS agent’. This was subsequently shown to be the case. All patients were later found to be HTLV-III antibody negative in 1983 (when stored blood samples were anti-HTLVIII tested at the end of 1984 and beginning of 1985) at the time that the data was

published. Any patient interested in the results would have been told if they had asked.

- 10. In paragraph 15 of CAL21, you note that Dr Richard Tedder agreed in October 1984 to test serum samples from 10 Edinburgh haemophilia patients. He later agreed to test serum samples from other patients. How many patients were tested altogether? Were the samples sent in two batches only?**

You will need to ask Dr Tedder exactly how many samples were sent to him. I would guess it was between 50 and 70 samples. He was rationing the number of tests because he only had a limited amount of reagent which is why I only sent 10 samples originally.

I sent samples on more than two occasions. I do not recall how many batches of samples I would have sent after the initial batch but at that stage Dr Tedder had the only laboratory in the UK that was providing the 'service' on a research basis.

- 11. Please describe in detail how you arranged for the serum samples of the first ten patients to be tested by Dr Tedder. When were blood samples taken from these patients? Were they taken with the intention of HTLV-III testing? Did you obtain consent before testing?**

I phoned Dr Tedder and asked if he would test 10 samples for me. I explained that I had an unusual group of patients in that they had been treated predominantly with NHS concentrate manufactured in Scotland and that I anticipated that they would be negative. When Dr Tedder agreed to carry out the testing I would have arranged for the samples to be sent.

The samples were posted to Dr Tedder. They were carefully wrapped and sealed up so that if the tubes leaked blood it would

not come through the parcel covering. One of the haematology laboratory staff would have sent the samples for me.

The samples were chosen from patients with severe to moderate haemophilia because they were exposed to the largest amount of therapeutic products.

Most of the samples were not originally taken with the intention of HTLV-III testing. The samples were recent blood samples which would have been taken from the store in the deep freeze in the haematology department. I did not obtain consent from the patients for the samples to be sent to Dr Tedder for testing.

Blood samples were routinely taken for virological testing and stored in the virology department. A parallel store was kept in the haematology department because we also carried out clotting assays as part of routine monitoring of haemophilia and the samples were kept so we could check clotting factor levels further later if required. Samples were also kept in two departments in case there was a problem with the freezer in one department. It was not unknown for the freezer to break down over a weekend and for all the samples to be destroyed.

- 12. If the tests were done on stored samples were your patients advised that their blood samples would be retained in storage and would subsequently be used for testing at your discretion?**

My patients knew that I had an interest in blood safety and that samples of their blood were being stored. I made no secret of it. It was viewed as a very appropriate thing to do and was also done at a number of other hospitals across the UK, for example, the Haemophilia Centre at the Royal Free Hospital in London. It was seen as extremely good virological practice and was the envy of

many centres. My understanding is that all samples at this time sent to virology, for any and every test were stored 'indefinitely', not just those from people with haemophilia. It was all part of an organised programme for long term safety monitoring. The arrangements for storing samples were set up in Edinburgh in the 1970s by my predecessor and before my time. The patients must have presumed that the samples might be subsequently used, as had happened previously for hepatitis B infection, otherwise why would they be stored? So far as I recall no patient enquired about the circumstances under which additional tests would be carried out.

- 13. When were the serum samples of the first ten patients actually tested? (See DHF.002.5364 Central Committee for Research and Development in Blood Transfusion Minutes from 9 November 1984 which suggests August 1984).**

You will need to ask Dr Tedder but I think that testing was done in October 1984. I am pretty certain that the minutes mentioned are incorrect. Those minutes note that a batch of factor VIII had been discovered to contain HTLV-III antibody. That is incorrect. As far as I am aware, the batch has never been shown to contain HTLV-III antibody. Even retrospective tests done recently have failed to detect HTLV-III in the batch. It was the patients that were found to be have HTLV-III antibody not the batch of concentrate.

- 14. When were you advised about the results of the first batch of ten patients? How were you advised?**

Dr Tedder telephoned me at my home one evening at about 8pm. I think that this occurred sometime in October 1984. Evidence given by Dr Perrie shows that the date was the 26<sup>th</sup> October 1984. The initial notification to SNBTS was when I telephone Dr Brian McLelland on the evening of 26<sup>th</sup> October 1984 immediately after I

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spoke with Dr Tedder. The evidence given to the Lindsay Inquiry by Dr Tedder seems to concur with this.▼

**Deleted:** Dr Tedder to the Lindsay Inquiry was presented subsequently at the meeting (on 19<sup>th</sup> April) and it corroborated my recollection. The date recorded in the Lindsay Inquiry Report was 26<sup>th</sup> October 1984.

- 15. In Dr Tedder's evidence to the Lindsay Inquiry, he talks about giving you the test results (A8847 at pages 13-14). He states that you had a "clinical suspicion that something had occurred" i.e. before testing was carried out. Is this correct and can you explain the basis of this suspicion?**

I do not remember having a 'clinical suspicion that something had occurred' when I initially asked Dr Tedder if he would test samples. It was later when I found that some patients were anti-HTLVIII positive that I may have wondered whether the 'glandular fever' illness was due to HTLVIII infection because we discovered that the patient seroconverted in the middle of his illness. In the spring of 1984 (March/April), we operated on a young man who had recurrent bleeds into a knee. The surgeon undertook a synovectomy. What should have been a straight forward operation turned into a major medical difficulty in the post-operative period. The patient got recurrent infections in his operated knee joint. When we examined his blood it looked as though he had acute leukaemia. We had no idea of the cause of his illness. As 'glandular fever' due to HTLVIII had not been reported previously, a description of the clinical the episode was submitted to the Lancet in 1985. At the time in April 1984 we had no idea what was wrong with the patient. We stored blood samples from him and when the HTLV-III test became available a sample was sent to Dr Tedder who discovered that antibody to HTLVIII had developed during the illness. I think this is what Dr Tedder referred to.

- 16. Who did you in turn advise about the results and how was that done? When were senior SNBTS staff and haemophilia staff advised?**

I discussed the result directly with the SNBTS. I would have approached Dr McClelland shortly after Dr Tedder told me that 3 of my patients were HTLV-III positive. I think I may have phoned Dr McClelland the night that I received the results from Dr Tedder. I almost certainly would have discussed the matter with Professor Bloom, who was the Chairman of the UKHCDO, and with our local virologist, Dr John Peutherer. This was probably done verbally. I also informed Dr Craske and he wrote to me on 30<sup>th</sup> November setting out how the patients should be investigated including the continued assessment of their immune function including skin tests and the T-cell responses to mitogens. (PEN.015.0253)

**17. Was the testing done anonymously or were samples labelled with the names of the patients?**

The samples were almost certainly sent with the names of the patients. That was the usual way to send samples to the laboratory for testing. We were very worried about transcription errors. If a sample is sent with a number on it there is a significant chance that the number could be transcribed incorrectly which could have disastrous consequences.

**18. Please describe in detail how you arranged for further patients to be tested by Dr Tedder?**

A second lot of samples would have been sent down to Dr Tedder a few days after I got the results on the initial 10 samples. Further batches of samples were sent.

**Meeting of Haemophilia Patients in Edinburgh 19 December 1984**

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**19. What was the purpose of the meeting on 19 December 1984?**

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The purpose of the meeting was to inform patients that HTLV-III tests had been carried out and that some patients were positive for HTLV-III antibody and to tell patients what we knew about AIDS. My recollection is that all patients with haemophilia in Scotland were written to and invited to the meeting. I do not have any copies of the letter.

- 20. Why was there representation from Glasgow at the meeting (that is, why was Professor Forbes, West of Scotland Haemophilia Centre Director, in attendance and why did he chair the meeting)?**

All haemophilia patients in Scotland were invited to the meeting including Dr Forbes' patients. Dr Forbes was the more senior physician present. He had more experience in haemophilia than I did and he managed the largest haemophilia centre in Scotland. It was agreed that he would chair the meeting.

- 21. Do any records of what was said at the meeting still exist?**

I do not know of any physical records of the meeting.

- 22. What was decided before the meeting about what information was to be given to patients? Who was involved in the decision about the information to be given?**

We were keen to give patients all of the information that we had available regarding the testing that had been done, interpretation of the results and the difficulties of interpreting the results. We particularly wanted to emphasise that there was a possibility that many patients might have the virus (even those who were anti-HTLVIII negative) and that all patients should behave as if they might have the virus. There was an emphasis on what precautions should be taken e.g. all men should use condoms, rubber gloves

should be used by others when mopping up body fluids, surfaces should be cleaned with bleach etc. In the meeting Dr Forbes, Dr McClelland and I laid out what we knew. We did not keep back any information.

**23. Who was advised about the meeting? How was the date of the meeting and its subject matter communicated to patients? How many patients were advised of the meeting?**

AIDS was a topical subject. So far as I recall all patients in Scotland were written to and we thought that we would get a large amount of people coming along to the meeting.

Each centre arranged for its own patients to come to the meeting. Dr Forbes wrote to all of his patients and I wrote to all of mine. Copies of the letter were sent to colleagues in Aberdeen, Dundee and Inverness to distribute to their patients.

We estimated that there would be about 400 patients in Scotland and that if each came and brought a partner we could have about 800 people at the meeting. I booked two lecture theatres at the Edinburgh Royal Infirmary to accommodate everyone.

If all of the patients from Glasgow and Edinburgh alone had attended we would have expected about 250 patients.

In the end it is my recollection that about 30 – 40 people attended the meeting, including some spouses. The general view around at the this time was that the risk of AIDS was so small that patients thought it wasn't of concern and I think this is why the turnout was lower than we anticipated.

**24. Please describe the meeting in as much detail as you can recall. Where did it take place? How many patients attended?**

**How long did the meeting last? Who spoke to the patients at the meeting? What format was followed (for example, did Professor Forbes, Dr McClelland and yourself all speak one after the other)? Were there any one to one discussions?**

The meeting was held in a large surgical theatre at the Edinburgh Royal Infirmary. I had booked two lecture theatres but we only ended up needing the one. My recollection is that most of the people who attended the meeting came from the Edinburgh area.

The meeting took about one and a half hours and started at around 7.30pm. We were readily prepared to run similar meetings in other parts of the country but there were no requests to do so.

Dr Forbes, Dr McClelland and I all spoke to the audience. I think that Dr Forbes gave an introduction as Chairman and explained what was known about the HTLV-III antibody test and that some people in Scotland had been found to be positive. I almost certainly would have explained about what has become known as "the Edinburgh Cohort" although at the time of the meeting, we were still examining transfusion records and it was not clear who was therefore part of the Cohort and who was not. Dr McClelland would have talked about blood transfusion matters and may have also talked about the Cohort as well. Geraldine Brown sat near the front of the meeting. She was relatively new to the haemophilia world at that stage. I do not think that she spoke. We told the patients what we knew. There were no one-to-one discussions, even in a quiet corner after the meeting. The audience came in and we were at the front. We ran the meeting. Individual patient results were not discussed at the meeting.

- 25. At the meeting were patients advised that tests had been carried out on blood and that some patients had tested**

**positive for HTLV-III? If so what additional information was provided about who had been tested and who had not been tested?**

We made it clear at the meeting that we had tested quite a number of people and that some patients had been found to be HTLV-III antibody positive.

- 26. What information was given about (i) the treatment which patients had received (i.e. domestic or commercial concentrates); (ii) the risks involved in the different therapies; (iii) the accuracy of testing; (iv) the possible significance of a positive diagnosis? Were patients advised that HTLV-III infection could be terminal?**

Patients were told that the majority of patients were being treated with NHS concentrate manufactured in Scotland but that commercial concentrates had been used in the past.

As different centres had been using different products we did not have any general information about treatment. I knew about my patients and Dr Forbes knew about his. Some patients who had been found to be HTLV-III positive had been treated with both NHS and commercial concentrates and it was not clear where the infection had come from. You cannot make an assumption that just because patients received commercial concentrates they got HIV.

The test was a very new test. It was a research test. We explained to patients that the test was still under development and that we were not sure about the accuracy of the results.

We did discuss the significance of a positive result. If someone had a positive result (and it was a true positive) that meant that they had been exposed to the virus. It did not mean that they still had the

virus. With the majority of viral infections a positive antibody result does not mean that the person still has the virus. With HIV you get antibody and the virus together. There is a similar situation with hepatitis C. We did not know this at the time. A positive anti HTLVIII test meant that the person had been exposed to the viral antigens (either in the form of 'live' virus, or possibly 'inactivated or killed' – during the process of plasma fractionation). Initially we also wondered whether the antibody might have been acquired from the bottles of concentrate but further investigation did not reveal any detectable antibody in the concentrates. We could not tell patients whether they still had the virus or not. The fact that they had antibody could have meant that they were better off i.e. were immune to HTLVIII. We just did not know enough about it. We told the patients what we knew. At that stage (December 1984) about 1 in 1000 people with haemophilia who had the antibody had AIDS. Therefore the risk at that time seemed to be – 1 in 1000.

We did not tell the patients that HTLV-III infection could be terminal because (1) we did not know that the prognosis and (2) we were not sure that the patients were infected. We knew that they were antibody positive but did not know whether this meant that they were currently infected with the virus.

It is likely that we would have told the patients that immune tests had been done. This type of testing had been done at other leading haemophilia centres, for example The Royal Free, Birmingham, Glasgow were carrying out immune tests. It was not unique to Edinburgh. There was no need for us to be secretive about it. It is difficult to look after patients for a long time and keep secrets from them. I am sure that we would have told the patients at the meeting that we were going to continue to offer to monitor them

- 27. What was the patients' response to the information? What questions were asked? What further information was given by**

**the doctors in response to questions? Was there a discussion of the relative safety of Scottish blood products, commercial products, cryoprecipitate, heated commercial products etc?**

Patients were surprised but fairly matter of fact. It was a well ordered meeting and I don't recall distress being displayed.

For details of the meeting see paragraph 26 above. I do not recall discussion about the relative safety of the different blood products. There would certainly have been discussion about heat treatment because it had been decided to heat treat all factor VIII concentrate in Scotland and patients were invited to exchange unheated material which they had at home for heated material.

There was a question and answer session at the end of the meeting. I do not remember what questions were asked but we were happy to answer any questions as openly and honestly as we could.

**28. Which GPs were sent the advice letter mentioned in paragraph 20 of CAL23? Is LOT.002.2489 an example of that letter?**

All GPs of patients with haemophilia in Scotland were sent the advice letter. LOT.002.2490 is an example of that letter.

**29. In paragraph 21 of CAL23 you note that "GPs were not given the anti HTLV-III result unless the patients gave consent for this". What discussions took place before the decision not to advise GPs of the individual patient's result? Who was involved in those discussions and who took the final decision?**

The anti-HTLVIII result was considered very confidential information because of the stigma surrounding AIDS. Many patients lived in small communities alongside their GPs and their local medical centre staff. We were concerned about secretaries and

receptionists seeing the information. The decision not to advise GPs of results was made by the staff at the haemophilia centre probably in discussion with some of the patients. This may well have been discussed at the meeting on 19 December 1984. Patients were sent information sheets stating what was known about HTLVIII and AIDS, advising about safety precautions and recommending that those who wanted to know more should contact their haemophilia doctor. A copy of the information sheet is lodged with the Inquiry.

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The reason for the delay between the meeting on 16 December 1984 and getting letters to GPs and patients on 31 January 1985 was because Dr Forbes and I were compiling similar letters and documents to go out. It was also over Christmas and New Year. The information sheet that was sent to patients contained both the telephone numbers for both Glasgow and Edinburgh haemophilia centres.

**30. When patients were told of their test results from 1985 onwards, were you alone when you told them? If not, who attended the meetings? What exactly was said about prognosis and future treatment?**

The meetings were mostly one-to-one meetings. I saw the patients alone (or with their partners where appropriate). No one else from my department usually attended the meetings. If a patient wished to know the result of any investigation, including the result of an anti-HTLVIII I would tell them. I would have offered the patients a repeat anti-HTLVIII test because we would not want to rely on a single result. I do not recall that any of my patients expressed any reservations about having had their blood from the deep freeze store tested without discussion with them before hand.

**31. Why did you not just tell individual patients of their results?**

It took us a little while to come to terms with the results. The fact that some of the patients had been exposed to the virus was a surprise and a shock and I had to give some thought as to what to say to the patients. It was a time of great difficulty and turmoil. There was a lot of discussion at the time about whether clinicians should or should not tell patients and it took a while for all the information to sink in.

We did not just tell patients the results of their tests because they may not have wanted to know. What became very evident after the meeting on the 16<sup>th</sup> December and after the letters were sent out was that some patients wanted to know the results and others were hesitant about knowing the results. We made it clear that test results were likely to be available and that if a patient wanted to know their result they should get in touch with their haemophilia clinician. The vast majority of my patients came to see me within 1 – 2 months of the meeting to enquire about their results. A lot of those patients were HTLV-III negative but I could not say for certain that they did not have HTLVIII. We left it up to the patients to come in their own time.

There was so much stigma surrounding AIDS. Patients had to consider that when deciding whether or not to get their results.

I would see spouses/partners if they wanted me to discuss AIDS/HTLVIII generally and I would offer testing to partners, if appropriate. The blood sample for testing could be taken in the haemophilia centre and I would give the individual the result. Individuals had the option of visiting other clinics in the city where they could obtain a test, for example their GP, infectious diseases unit at the City Hospital and the Genitourinary Medicine Department at the RIE. I do not know of any of the sexual partners, of those patients who contracted HIV in Scotland, who have been infected.

So far as I know none of our patients have passed HIV on to their partners.

### **Immune status monitoring from 1985**

**32. Did you obtain consent from patients to “monitor their immune status” and to use their data to provide evidence of the safety of heat-treated concentrates from 1985 (paragraph 25)?**

From 1983 we had studied immune abnormalities but were uncertain what the cause of those abnormalities was. It was very important to know how they were changing and whether there was evidence of immune system decline. We monitored those patients who were antibody positive and those who were antibody negative. We did not know whether those who were negative had been latently infected with the virus.

We continued to monitor all patients who came to the clinic for review in the same way that we had always done.

I did not obtain written consent but made it very clear to patients that we were monitoring their immune status. I do not recall any patient expressing reservations about having the immune tests. If they had not wanted the immune tests the blood would not be sent for these. It would have been negligent not to offer to monitor their immune status.

It was extremely important to know if the heat treatment introduced in Scotland in 1984 was effective. The immune status monitoring carried out in Edinburgh was seen as a way of gathering evidence of the efficacy of the heat treatment process. We know from the lookback [\[LIT.001.0664\]](#) carried out by the SNBTS after the introduction of donor screening for anti-HTLVIII that there were plasma pools (prior to October 1985) that were likely to have

contained anti-HTLVIII positive donations from which concentrates had been made and given to patients. The fact that those patients did not develop anti HTLVIII was evidence that the heat treatment was effective in inactivating the virus.

**33. Was consent asked from HTLV-III positive patients to carry out investigations of archive samples of blood?**

I did not ask for specific consent. See above

**34. Did you obtain consent from the individuals who had received the “implicated batch” to do further tests on their blood? If so, was consent recorded somewhere?**

As indicated above many individual were monitored for immune function and HTLVIII because it was essential to know whether patients were infected with HTLVIII and whether there were changes in their immune systems (for those who were anti HTLVIII negative and positive). The individuals who received the implicated batches were managed no differently from any other patient. It was not usually necessary to take additional samples of blood for the immune tests (because they could be carried out on the sample collected for the full blood count, see above). At the beginning of 1985 it was my policy that patients would have been informed that we were keen to repeatedly test for anti-HTLVIII and if any individual had expressed a reservation the test would not have been requested from the laboratory. Later after it became generally accepted that patients should be counselled about anti-HIV testing and give explicit informed consent for anti-HIV testing, consent was sought and recorded both in the computer record and case notes. A protocol setting out the arrangements to be followed at the Haemophilia Centre has already been submitted to the Inquiry.

When information and technology advanced to a stage where the virus from individual patients could be studied this sometimes required a small amount of extra blood (about 10-15mls – 2-3 teaspoonfuls) which would be collected at the same time as the routine monitoring tests. Patients would be asked individually each time if this additional blood could be taken. These viral tests were to characterise further the degree of infection and the changes in the virus particularly in relation to the introduction of anti-HIV drugs, e.g. zidovudine, and the development of resistance to therapeutic agents assessed. This is now standard practice for patients on anti-HIV medication. The plan was to aim to test patient's viral status every six months from about 1988 onwards when the new techniques were established. A record was kept in the haemophilia centre of all blood samples collected from patients and what investigations were requested from each. Verbal consent was obtained for the investigations. If this was not given or the patient expressed a reservation then the blood for the investigation would not be sent. Consent or non-consent was therefore not recorded.

**35. Did you obtain consent for testing in connection with the Edinburgh studies which continued in connection with alloantigen or non-HIV viral exposure (referred to in paragraph 28(e) of CAL21)?**

The management of nearly all patients involved the immune tests initially in both anti-HTLVIII negative and positive individuals (as explained above) who had been exposed to a clotting factor concentrate. All such individuals had therefore been exposed to alloantigens and it was not known who had, and who had not, been exposed to HTLVIII. In the subsections of paragraph 28 in CAL21 I have set out the reasons for serially testing anti-HTLVIII patients.

- 36. Who was on the Lothian AIDS Advisory Committee? When did it meet? What was discussed? Do Minutes of the meetings remain?**

The AIDS Advisory Committee was set up in December 1984. It initially comprised a number of people primarily in hospital services. Dr Ray Brettle (infectious diseases), Dr John Peutherer (virologist), Dr Rob Cavelle (Scottish Office) were amongst some of the members. I was the Chairman.

The committee was set up to address the huge number of concerns in the hospital service about whether patients who were HIV positive posed a risk of infection to those treating them and how to deal with the risk. Monthly meetings were held for several years.

The Inquiry has been provided, some time ago, with all of the minutes of the meetings.

- 37. Please explain why it has not been possible to identify further the source of infection of the three patients in Edinburgh who became HTLVIII positive who did not receive the "*implicated batch.*"**

It is likely that the individuals got infection from treatment for haemophilia but we have not been able to identify a particular batch. There are a number of reasons for this: (1) the delay between being exposed to the virus and the antibody developing (2) the patients could have had several batches of product during the period when they were last tested negative and first tested positive. (3) Some patients may have received cryoprecipitate which might have contained infectious HTLVIII

### **Separate Files**

- 38. We wish to establish what files or other collections of papers you know of in relation to the patients known as the Edinburgh Cohort. To save time, we should say that we appreciate that each patient will have/have had his own set of hospital records, which we would call “the main records”. But we understand too that it was your practice to retain the records of these patients which related to their infection with HIV “separately from their centrally held main RIE records”. We call these “the secondary records”. What secondary records do you know of in relation to the Edinburgh Cohort?**

I did not keep separate clinical files for patients who were infected with HIV. We avoided writing anything about anti HTLVIII and AIDS in the patients' casenotes in 1985 because we were keen to keep the information very confidential. For a few patients I kept a brief record of consultations in relation to anti-HTLVIII status in a separate file in a locked cabinet in my office. These records have now been returned to the main files. This happened around 3-4 years ago. This was done for all patients.

Counselling records were held in the social work department.