

TOPIC B5a

The information given to patients (or their parents) about the risk of AIDS before their treatment with blood or blood products.

1. **The amount and content of information given to patients (or their parents) concerning the risk of AIDS as result of receiving blood products.**
2. **The amount and content of information given to patients (or their parents) of the risk of AIDS as a result of receiving a blood transfusion.**

Answer to 1 and 2

Patients were dependent on the information given to them by their clinician or information otherwise in the public domain. The Inquiry has clear evidence that in the critical period from the beginning of 1983 until the end of 1984 the risk posed by AIDS from blood and blood products was deliberately understated¹ by Ministers, by Officials responsible for advising those Ministers by the transfusion services throughout the UK and by clinicians. The paternalistic approach² adopted by clinicians limited the amount of information given to patients. In relation to the issue of what information was given to patients it is clear that the deliberate understatement both publicly and privately of the risk posed by AIDS supports the clear evidence of patients that they were not told of the risk when receiving blood or blood products during this period. Even at a very late stage after it was known that the Scottish blood supply had been infected the public were being told that “they do not have anything to worry about, whether they are getting blood transfusion or other treatment with blood products”³. This was misleading and known to be so.⁴ The Inquiry heard from Christine,

¹ This understatement was expressed succinctly by Dr Mark Winter. They were not told “There appears to be a new disease in America, which is affecting people with haemophilia. It looks as if you can get it from commercial concentrate. There is no test for it. If you get the disease, it looks like it will kill you.” That would not have been a very reassuring message to tell patients, but I accept it probably would have been nearer to the truth [Day 16 27/04/11 134 (21)] [See also Professor Ludlam Day 39 28/06/11 23 (1) to (7)]

² See for example Dr Wilkie’s evidence [Day 32 14/06/11 50(9) – 52(11)]

³ See articles in “Evening News” SNB0048744 and SGH0026515.

⁴ See Briefing note 5/12/1984 SGH.002.6513 “The general tenor of the articles is to give Scotland a somewhat cleaner bill of health than we know to be justified. We understand that Dr Cash is not entirely happy with the reporting of his remarks, but they do have the effect of preparing the ground for any subsequent reporting of the actual position that needs to be made. No statement can be made at the moment until the haemophilia directors resolve the very difficult ethical problem of what action to take with regard to their patients about the matter”

Amy, David, Elaine, Frances and Mark (and in addition has obtained numerous statements from patients)⁵. Christine, David and Elaine made it clear that they were not told about the risk of HIV. Christine summed up the position thus

“We didn’t know [her son] had been infected. We didn’t make a connection between haemophilia treatment with factor viii and HIV. We were pretty naive. The doctors were perceived by us to be gods. We trusted them and didn’t question the treatment they were giving. We accepted that they were giving him the best treatment available because that was what they told us. No one ever warned us about the risks associated with blood products. No one mentioned the risk of contracting either Hepatitis C or HIV or both. We were not warned about the implications of a positive diagnosis. We had no reason to think that the blood products that our son was getting would not be clean. We had no idea that blood was being collected from paid donors (drug addicts and prisoners) in America at the time, because in Britain we were used to blood being collected from unpaid volunteers. We heard from my brother (who is also a haemophilia patient with HIV) that some haemophilia patients in Oxford were refusing to be treated with American Factor VIII manufactured by Armour, but the doctors at Yorkhill reassured us that it was safe and that there was no chance of cross infection”

Frances (who could not give direct evidence) was unable to say what her father had been told in relation to the risks associated with factor viii treatment. Mark stated that in 1984 he was told there was a risk of HIV from blood products “but provided you stick to the factor viii we are providing (i.e. Non-commercial) the risk is very low”. David as a haemophilia B sufferer was not told that heat treated factor ix was not available for some months after heat treated factor viii became available. He seroconverted between January 1985 and November 1985⁶. On the evidence there is absolutely no justification whatsoever for him not being informed of the risk of taking untreated factor ix during this period and the alternative treatments discussed with him. He should have been informed of the risk and if possible protected against it. Amy (blood transfusion) was not told of the risk and was unable to say whether her husband was told. The Inquiry has clear evidence from blood transfusion patients that no one discussed with them the risks of infection from a blood transfusion⁷. It is

⁵ The Preliminary Report records that the great majority of witnesses asked about their prior knowledge of the risks associated with their treatment told the Inquiry that they were not warned about risks associated with their treatment [Paras. 4.34 and 4.35]

⁶ Day 30 9/06/11 107 (12) – (20)

⁷ [see Preliminary Report at para. 4.126]

submitted that it is clear from the evidence of Professor Lowe⁸ that very limited information was given to patients about the risk of AIDS from blood products.

3. Whether patients (or their parents) were given sufficient information to be able to make an informed choice relative to the treatment they received.

If it is accepted that most patients were not given information relative to the risks of HIV in the period from 1983 and 1984, it follows that they were unable to make an informed choice relative to the treatment that they received. In essence the decision was taken for them because of the paternalistic approach of the clinicians prevalent at the time. The decision whether or not to continue receiving treatment with blood products or whether to consider alternatives such as cryoprecipitate or DDAVP was not one which the majority of patients were in a position to make informed decisions about. The Inquiry was unable to discover why it was that children at Yorkhill were treated with commercial factor viii as opposed to local product well into 1983. There is no evidence that parents of such children were given sufficient information so as to be able to make an informed choice between SNBTS product and commercial product.

4. The nature and extent of information made available by the manufacturers of blood and blood products about the risk of infection with HIV from their products.

Dr Perry has prepared a paper outlining the content of package inserts⁹ and explaining the reasons why it was decided not to include a specific warning of the risk of infection from HIV from SNBTS products until 1985. From April 1985 the leaflet issued with the NY product stated that it was heat treated but could not be assumed to be “non- infective”. Dr. Perry explains that there was no specific reference to AIDS or HIV until HT DEFIX was issued in September 1985. He has indicated that the information provided in product leaflets, labels and packaging was primarily designed and intended for prescribing doctors. Patients were not the primary audience for the information intended. In his view discussion with patients of the treatment options and the associated risks is exclusively the responsibility of treating doctors. It follows that nothing in the material accompanying blood products gave any specific warning to recipients of the potential risk of infection with HIV before September

⁸ [Day 40 30/06/11]

⁹ PEN0180543

1985. It is noteworthy that whether or not to include such a warning was discussed by SNBTS in October 1983 – it being appreciated that such a risk was present.

5. The amount and content of the information given to patients (or their parents) about studies taking place involving samples of blood taken from them.

The evidence in the Inquiry is that patients were not advised when giving blood samples that these might be used for studies being carried out or to be carried out in the future¹⁰. Consent was not obtained from patients before the results of studies were published¹¹. The Inquiry also has evidence that studies took place in relation to these samples without the consent of the relevant patients. Patients were not informed of the results of the studies taking place¹². As a result of the lack of information some patients felt that they had been treated like guinea pigs.¹³ The Inquiry has clear evidence that patients were upset at what they perceived as research on samples provided by them without their knowledge¹⁴. It has been suggested that “blanket consent” had been obtained but even if that were so patients did not give any meaningful¹⁵ consent to the studies that subsequently took place in relation to stored samples. Professor Forbes stated¹⁶ that a decision was made to collect samples from patients with a view to storing them until a test for HTLV-III became available. He has stated that the initial samples “were taken over a period of several years”. It is clear from his evidence and the evidence of others that patients did not give consent for their samples to be used in subsequent studies¹⁷. Professor Forbes made it clear that by March 1983 most clinicians thought that AIDS would undoubtedly appear in time and they were starting to look at their patients rather differently to see if they had any features that might be an early warning of the condition¹⁸. Professor Ludlam gave evidence about the immune tests being carried out in and around the beginning of 1983 when there was beginning to be a concern

¹⁰ See Day 35 17/06/11 p78 (8)

¹¹ See Day 35 17/06/11 p79(9)

¹² [Day 39 28 June 2011 pp15-16 and 31 (6)]

¹³ See evidence of Alison Richardson and her statement at PEN016.1284 See Geraldine Brown Day 34 16 June 2011 73 (5) – (24) Her use of the term “acknowledgement” [by patients] that tests had been carried out without their knowledge was social work jargon for unhappiness on their part at this state of affairs Day 34 16/06/84 82 (13) –(15)

¹⁴ See for example WIT.0040007 “I was not aware that my blood sample would be tested for HIV and I did not give my consent for this testing. I am very angry that I was tested for HIV without being told or being asked for my consent”

¹⁵ They were not asked for permission to make a study of samples previously given by them in relation to a threat from a specific potential danger

¹⁶ See PEN0120411 at PEN.012.0412

¹⁷ See PEN.012.0411 at paragraph 9 PEN.0120413

¹⁸ Day 33 15/06/11 99 (18) – (22)

on a global sense about the threat from AIDS. To make sure that these immune tests were correctly carried out in the laboratory he labelled the blood forms “AIDS study”. Such evidence as he gave that it was explained¹⁹ to patients that immune testing was being carried out and that the new condition called AIDs might be spread by blood products did not appear to be based on any actual recollection on his part (understandable given the lapse of time) but upon a reconstruction of what “must have happened”. It is not supported by patients treated at Edinburgh at the time. Most patients were unaware that the study described as “AIDS study” was being performed. It seems reasonable to think that if a person was specifically told that blood was being taken from him with a view to carrying out a study of his immune system in relation to the new threat posed by AIDs he would remember. Professor Ludlam seems to have regarded this process as part of the “monitoring process”. It submitted that it is likely that by and large patients were not specifically told that this study was being carried out and many were unaware of it. No explicit consent was obtained from patients.²⁰ Professor Ludlam was reluctant to accept that his study was research preferring to describe it as “monitoring” or an “audit”. It is submitted that this work and its analysis and reporting should be regarded as “research”²¹.

However characterised, it is submitted that the patients concerned should have been specifically informed about studies and should have given explicit consent for their involvement in them. The particular analysis of samples already given was a new activity with a view to considering a new potential problem. By the medical ethical standards of the time it is debatable²² whether specific information should have been given and specific consent should have been obtained. Common practice of the time was not always the “best practice” of the time. But it is not a sufficient answer to this issue simply to say that medical ethical standards at the time did not “require” a certain course of action. Those medical ethical standards were constructed by doctors for doctors and because they did not take adequate account of patient interests had to be changed. The fact that patients were ignorant of studies, were not told of the results of the analysis of their blood²³ and did not give

¹⁹ The precise answers to questions from Inquiry Counsel on Day 35 17/06/11 pp7 to 86 require to be looked at closely. Professor Ludlam was not surprised that patients did not understand that they were being involved in an AIDS study, this kind of research at that time. He said that it is not always possible to convey information to people. “They may have forgotten what they had been told. We may not have told them. This was part of the monitoring of patients that was my responsibility” [see page 56 (14) to (25)]

²⁰ [Day 35 17/06/11 60 (14) – (24)]

²¹ Compare the approach to skin tests [Day35 17/06/11 66 (13) to 69(2)] see evidence of Vivienne Nathanson Day 37 23/06/2011 1662 (18) – (22) – she said that at the time she would have encouraged anyone asking her to regard it as research and thus requiring ethical approval

²² See Day 37 23/06/2011 pp93 (20) – 96 (12)

²³ [Day 35 17/06/11 77 (14) – 78 (15)]

consent to publication of the results²⁴ made a significant contribution to the breakdown of trust by patients in the medical professionals treating them. That such a breakdown of trust occurred is reason enough to conclude that there was a failure to pay sufficient regard to keeping patients informed of matters of intimate importance to them²⁵.

²⁴[Day 35 17/06/11 79 (9)]

²⁵ See the Evidence of Vivienne Nathanson Day 37 23/06/2011 pp162 to 165

TOPIC B5b

The tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products.

1. The amount and content of information given to patients (or their parents) about the diagnostic tests being carried out upon samples provided by them.

As indicated in the answer to paragraph B5a.5 (above) samples were taken from patients with a view to carrying out tests once a test for the HTLVIII became available. Once that occurred in the autumn of 1984 patient samples were tested for the presence of antibodies to the virus without any consent being given. Professor Forbes has stated that “I don’t think that we actually asked for the consent to be specifically tested but as in all these areas things tighten up and then consent was asked for and eventually (informed consent) written....By 1987 specific consent was asked for . Often before that it was not. It was a gradual process which came in.”²⁶ Professor Lowe was keen to emphasise that by the time he became a Consultant in October 1985 the vast majority of patients had been tested. Professor Ludlam made it clear that the patients whose samples were sent for testing in or about October 1984 were not told and did not give consent.²⁷ The first inkling that those patients would have had that they might have been tested²⁸ would have been if they attended the meeting on 19 December 1984. There is no reason to think that the position was any different throughout Scotland.²⁹

2. Whether informed consent for such tests was obtained and the content of information given to patients concerning the results of such tests.

²⁶ See PEN.012.0411 at paragraph 9 PE.012.0413. Dr Patricia Wilkie’s evidence supports this evidence as does the evidence of Dr Anna Pettigrew [Day 20 5/05/2011 53 (15)]

²⁷ See Day 35 17/06/11 92 (11) – (15)]

²⁸ Assuming that is they understood that was what they were being told

²⁹ See the evidence of Professor Cachia on Day 83 12/01/2012 27 (2) – He described the state of affairs as late as 1992 where HCV testing was being carried out on patients stored samples without informing them or obtaining their consent. Professor Cachia said he was “a bit horrified”.

3. **The response on the part of haemophilia clinicians in Glasgow and Edinburgh in the Autumn of 1984 to the results of tests showing that some of their patients had tested positive for the antibody to the HTLVIII virus.**
4. **The response on the part of SNBTS in the Autumn of 1984 to the information that patients who had been treated exclusively with SNBTS factor concentrates had tested positive for the antibody to the HTLVIII virus.**

Answer to 2, 3 and 4

It is clear that informed consent to diagnostic tests designed to establish whether an individual patient tested positive for HTLVIII was not obtained. Even after the results of initial tests became available and it was known that the Scottish donor population had become infected with the virus individual patients were not told that samples of their blood were going to be tested with a view to discovering whether they had anti-bodies to the recently discovered virus³⁰. The possibility that the Scottish donor population was at risk must have been appreciated before testing was requested and certainly after the first batch of results was obtained. The challenge posed by HIV was unprecedented and extremely difficult and it is highly regrettable that individual clinicians were left largely to their own devices as to how to manage the information to be made available to their patients about whether they were infected. There was no direction or leadership from SNBTS or SHHD on this aspect³¹. Once the results of tests became available a decision had to be made (1) whether to tell patients (2) when to tell patients (3) what to tell patients and (4) how to tell patients. Individual clinicians made different decisions when answering these questions. There was a significant delay between the discovery that the Scottish donor population was infected and any public recognition of that fact. The response of the SNBTS and the SHHD was reactive rather than pro-active³². It was only when it became apparent that a story was going to appear in the press³³ that steps were taken to inform haemophiliacs that Scottish donor population was infected with the virus. Information that blood products were to be heat

³⁰ Dr Patricia Wilkie thought that even in 1984 it would have been "ethical" to pause after the first positive tests came back Day 32 14/06/11 81 (18) et seq.

³¹ Management of information to be released to the public is apparent see for example the apparently reassuring message given by the Press Release SNF00104140

³² SGH002654. SHHD knew of the situation but a press briefing to the Minister dated 20/11/84 "It would not be appropriate at this stage to issue any statement on the discovery of antibodies in the Scottish haemophiliacs.

³³ See SGH0026503, SGH0026502AND SGH0026498. The Article in the Yorkshire Post SGH0026491 appeared the day after the meeting. Professor Ludlam accepted that the reason for the meeting was to let the patients know about the donor pool being infected before reading that in the press Day 39 28/06/11 (10) –(15)

treated was released³⁴. A blunt instrument in the form of a public meeting at the Royal Infirmary of Edinburgh on the evening 19 December 1984 was chosen for this purpose. The most reliable source of evidence as to what occurred at the meeting is the letter and statement with contemporaneous notes produced to the Inquiry on 19 January 2012³⁵. It is unclear whether patients from other parts of Scotland were invited or attended. Invitees were not told in advance that patients had been tested and found to be positive. Not all patients who were known to be infected or at risk of being infected attended the meeting. The meeting was conducted orally and without visual aids. No written information was provided or distributed at the meeting. Those attending would have a limited ability to grasp and absorb the information they were being given. The notes recovered make it clear that studies had been taking place for some time (presumably without informing patients up until this point). It was sought to convey a message concerning safe handling of blood products, the potential risk of cross infection and urging haemophiliacs and their families not to give blood. This last aspect of the meeting is referred to in a letter from Dr. Ludlam to Dr McClelland dated 31 December 1984³⁶. It is difficult to see why else Dr McClelland would have been asked to attend the meeting. Patients would not have appreciated and did not appreciate they had to come forward individually to find out whether they personally had been tested or to find out whether they as individuals had been infected³⁷. At some time after the meeting and almost certainly after the New Year an advice sheet³⁸ was sent to Edinburgh patients. Any patient reading the advice sheet would not appreciate that there was a possibility he had already been tested or that if he wanted to find out whether he had been tested and the result of the test he would have to come forward and ask for that information. Glasgow patients were sent a letter dated 8 January 1985³⁹. Unlike Edinburgh (or anywhere else in Scotland as far as is known) the patient was given an appointment, an indication that they would be tested and an opportunity to ask questions about the tests. While the letter is not candid as to whether a recipient of it had already been tested it is submitted that letter is more helpful and informative for patients. Professor Lowe's evidence in relation to the letter was unclear and difficult to follow⁴⁰. The problem for both Glasgow and Edinburgh is that stored samples were tested without consent and so positive patients had to be told their results without being advised that they had been tested without

³⁴ SNF0010414

³⁵ [PEN 0181404 and PEN 0181367] The notes are quite detailed and contain an entry "prepared to inform if have antibody" but there is no note that patients had been tested nor is there a note that if a person wanted to know whether he had been tested he would have to ask to find that out and the result.

³⁶ SNB0064686

³⁷ See Alison Richardson Day 29 8 June 2011 8 (2) –(10)

³⁸ [PEN0120495]

³⁹ LOT.0034244

⁴⁰ Day 40 30 June 2011 31 (3) – 54 (6)

permission. Edinburgh seems to have gone down the road of encouraging the patients to come forward to be tested using what appears to have been a rather subliminal approach while Glasgow went down the road of giving the patient a specific appointment. It is unclear to what extent in Glasgow, patients were told the results of tests which had already been carried out without their permission. The hearsay evidence of Professor Lowe to the effect that this occurred is unconvincing. There is some evidence from patients that this could happen for example Christine mentioned being told of her son's condition at a routine appointment. Either way the clinician has potentially lost the trust of the patient because of the failure to obtain permission to carry out the test in the first place. It is disappointing to say the least that Professors Forbes, Lowe, and Ludlam did not acknowledge that carrying out the tests for the antibody to HTLV-III on named patients without their consent was a mistake and something for which the patients concerned should have received an explanation and an apology.

5. Efforts made to trace patients infected with HIV through blood transfusion.

Dr Gillon⁴¹ explained the look back steps taken. It was organised on a regional basis. Unlike the present day there was no agreed national policy signed off by the national medical and scientific director and issued formally through the QA systems with appropriate document control. It was the responsibility of each regional transfusion director to ensure implementation. There was no national donor administration system in the early years.

⁴¹ [PEN012.0862] Day 38 24/06/11 106 -124

TOPIC B5c

The information given to patients who might have been infected, or who were found to be infected, and their families.

- 1. The amount, content and timing of information and counselling given to patients (and their families) found to be infected with the AIDS virus.**
- 2. The amount, content and timing of information given to patients (and their families) exposed to the AIDS virus but were not infected.**
- 3. The methods of communicating such information to patients (and their families).**

Answers to 1, 2 and 3

It was common for patients to be told that they were HIV positive without first being told that they had been tested. A patient could arrive for a routine appointment be taken aside and told that as a result of a test of a stored sample it was found that they he was HIV positive. The extent to which patients would be given further information was highly variable⁴². Christine told the inquiry⁴³

“I don’t know when they tested [my son] for HIV. I don’t know when he became infected. No one confirmed this to me. At the time that we found out that [her son] had been infected with HIV no one explained anything about HIV to us or how it would affect [his health]. We weren’t told to take any precautions. I went home in shock and told my husband. Our world crashed around us”

Steps were taken in both Edinburgh and Glasgow to manage the information given to patients with Patricia Wilkie assisting in Glasgow and Geraldine Brown in Edinburgh. Later on Alison Richardson became involved in Edinburgh.

⁴² See David WIT.004.0007 Para.4.

⁴³ Day 28 7/06/11

In her statement ⁴⁴Alison Richardson makes several important comments about the state of knowledge of patients and their anger. She states

“I remember best the dilemma about a person with haemophilia who was under sixteen years old. My impression was that this person was among an initial group who had been tested for HIV without his consent or his parents’ consent as part of a test of the HIV test itself. I remember debating over and over again do we tell the child, his parents or do nothing. I think Dr. Ludlam’s view was to keep trying to persuade them to have the test openly. I think that eventually, a few years later when the individual was 19 years old, he was tested for HIV. I subsequently saw this person, for treatment many years later”

Her evidence is supported by the affidavit of Billie Josephine Reynolds⁴⁵. She has deponed that a number of Edinburgh patients were not told of their HIV status long after their clinician knew them to have tested positive.

While many patients in Edinburgh and Glasgow were offered counselling this was sometimes not offered in the immediate aftermath of receiving the news of a positive diagnosis. Elaine’s husband was not told until December 1986. She was told in a letter from Professor Ludlam dated 3 June 2003 ⁴⁶that her husband tested positive in May 1984. The letter is misleading as the patient could not possibly have been tested in May 1984⁴⁷. She says her family was not offered advice, counselling or support until she was referred to Alison Richardson in 1987.

Mark’s evidence highlighted an important discrepancy in respect that his records contained an entry dated 20 March 1989 that “AWARE WE HAVE BEEN DOING HIV TESTS. DOES NOT WANT TO KNOW THE RESULT”. Mark’s position is that he thought that he would be told if anything was wrong. It is obvious that in his case health professionals treating him would have known since 1984 that he was HIV positive. He was told in 1991 when he was twenty one years of age⁴⁸. There is no reason not to accept Mark as a credible and reliable witness⁴⁹. He clearly thought that if it was known he was HIV positive he would have been told. It is not entirely clear on the evidence why he was told in 1991.

⁴⁴ Pen0161284

⁴⁵ Paragraph 13 PEN0180814

⁴⁶ WIT0010438

⁴⁷ As acknowledged by the Chairman – “we will be looking to find out what actually happened” Day 31 10/06/11 33 (5) –(9)

⁴⁸ See Day 32 14/06/11

⁴⁹ See Affidavit of Billie Josephine Reynolds PEN016.0810 at paragraph 19

David's clear recollection is that he was given the news of a positive test at an appointment made with Professor Lowe as a result of a telephone call. He is also clear that permission to test him for HIV was not sought or given. He was and is angry about the failure to seek and obtain his permission. Curiously the medical records refer to David being told that he was exposed to the virus but that is not necessarily carriage or infectivity. David's position is that he was told that he was positive. The evidence is that his mother and girlfriend were spoken to and given certain information about the virus. David was clear that he was not offered and did not receive counselling.⁵⁰

There is evidence that some patients were told at an earlier stage. Francis was clear that her father was told in 1984. She clearly remembers being fifteen years of age at the time and gave the date from her diary as 21 December 1984⁵¹. If accurate it would appear that her father was accorded a privilege not accorded to other patients. He was offered counselling but did not want it.

There is no evidence of patients who were the subject of testing in 1984 and who tested negative for the virus being told of that. It seems that patients exposed to implicated batches but who did not then go on to seroconvert were not told of that fact.

- 4. The ineffectiveness of communication between health service professionals and patients (and their families).**
- 5. The difficulties created by ineffective communication between health service professionals and patients (and their families).**
- 6. Recommendations designed to increase the effectiveness of communication between health service professionals and patients (and their families).**

Answers to 4, 5 and 6

Chapter 4 of the Preliminary Report sets out in detail aspects of the experiences of patients and their families. It is plain from what is contained in that chapter and from the evidence led during the public hearings that many patients consider that they were not

⁵⁰ Day 30 9/06/2011 116 (7) – (9) and 119 (7)

⁵¹ Day 30 9/6/2011 23 (8) There does not appear to be any record of the test result or its communication

- (i) warned of risks
- (ii) told about research
- (iii) asked for consent to testing
- (iv) told of their infection immediately
- (v) told of the consequences of being infected
- (vi) offered counselling

Clinicians have given evidence in the Inquiry tending to suggest that contrary to what is asserted by patients all of (i) to (vi) “would have occurred”. There is also other evidence that (i) to (vi) (or a selection) did occur in some cases.

Understandably an attempt to resolve the factual issue of what individual patients were or were not told on particular occasions has not been attempted in the public hearings. Nevertheless it is submitted that the weight of the evidence is such that the Inquiry is bound to find as a matter of fact that in many cases (i) to (vi) did not occur or did not occur effectively. Some explanations are offered for the conflict of perspective between doctors and patients-

Doctors limited the information given to patients

One reason for (i) to (iv) not occurring at all is because doctors limited the information given to patients. This limiting of information can be accounted for in part by the paternalistic approach spoken about by Vivienne Nathanson and Mark Winter and others in evidence. It was also partly because doctors were not just motivated by the interests of the individual patients. They were motivated by the urge to discover. Concentration upon the scientific quest meant that sight was lost of the need to keep the individual patient informed and to provide consent. The studies of stored samples, publishing the results and testing of identifiable samples without consent are examples of where the loss of a sense of this priority occurred. Another strand is that health professionals simply did not pay sufficient attention to keeping patients informed. There can also be no doubt that they were under so much pressure in the crisis that they were limited in the information that they conveyed.

Doctors did not go back to patients when they became aware of increased risks

A reason for (i) not occurring is that doctors were not aware of increasing risks as time went on or if they were did not go back to their patients to explain about these. This is perhaps more obvious with Hepatitis C but it occurred with HIV particularly around the middle of 1983 when a discussion of balancing the risk with other clinical options often did not occur.

Doctors could not be “upfront” with the patients

The failure to tell patients that testing had taken place without their consent meant that doctors were unwilling or unable to be open with patients in relation to their HIV status. It seems to have been thought that for ethical reasons once a positive result in relation to a patient had been obtained that patient has to be asked whether he wanted to know the outcome of the test. Quite why it was not appreciated that patients should not have been tested without their consent in the first place was not adequately explained. There can be no doubt that frequently doctors were not open with their patients because of the difficulty in telling them that they had had a test. Record keeping seems to have been such that years later clinicians could not give patients accurate information as to when they were tested.

Doctors communicated ineffectively

Many doctors are not effective communicators. Effective communication is a skill that requires to be learned. It can be improved and re-enforced. The choice of language, the tone adopted, the means used for conveying information, the number of times the message is conveyed are all important components of effective communication.

One aspect of effective communication that was highlighted several times in the evidence is the limited ability of the recipient to absorb the information conveyed. There is ample evidence that a person being given information at a time of severe stress may not absorb what they are being told particularly if that information contains a number of elements. This was not understood by health care professionals during the reference period.

Definition of “counselling”

One particular problem that arose in relation to (vi) is that doctors and patients differed in their understanding as to what amounted to “counselling”⁵². There can be no doubt that in certain cases patients were not “counselled” at all. In other situations a patient may have been spoken to but was not offered “counselling” as he would understand that term whereas as far as the doctor was concerned “counselling” was being provided.

⁵² The use of the term counselling is post-test counselling. “Pre-test counselling” for most infected patients simply did not occur because the doctors already knew that such patients had been infected. No doubt patients were encouraged to have a further test done but the motivation for that would be largely that the doctor would need to give them a test result already known

The difficulties created by ineffective communication

Ineffective communication throughout has created enormous difficulties for patients right up until the present. Much anger, frustration and distress would have been avoided had communication been more successful. The failure to communicate the risks heightened the sense of disappointment when things went wrong. The testing of patient samples without consent has had far reaching consequences. In some cases it has completely destroyed a trusting relationship between doctor and patient. It led to uncertainty on the part of patients as to their status. It resulted in misunderstanding and delay in the communication of results. It meant that patients felt that their families were unnecessarily exposed to cross infection. Patients felt that they were treated like “guinea pigs”

TOPIC B5d

The circumstances in which those patients known collectively as the Edinburgh Cohort became infected with HIV, the testing of such patients for HIV and the information given to them about their infection.

1. How did the Edinburgh Cohort come to be identified as a significant group worthy of study?

The Preliminary Report refers to the Edinburgh Cohort at paragraphs 8.205 to 8.215.

The value of study of the group (as at May 1988) was that

- (1) assessment was before exposure
- (2) the period of exposure was precise
- (3) all members of the group were presumed to be infected from the same source (probably a single virus strain)⁵³.

⁵³ In fact it is not absolutely clear that all were necessarily infected by “the implicated batch”. Certainly other batches of SNBTS factor viii were infected SM

Professor Ludlam started a collaboration in 1983 with Dr Steel (a colleague at the Western General in Edinburgh) to carry out research into immune function in patients with haemophilia. US studies had shown immune abnormalities in asymptomatic homosexual men similar but milder to immune abnormalities in homosexual men with clinical signs of AIDS. This led to immune status of apparently well haemophiliacs being undertaken showing similar immune abnormalities. This was perplexing and worrying and might be related to the widespread prevalence of an AIDS virus or be due to some other side effect of Factor VIII treatment or it might have been a previously un-described feature of haemophilia. The purpose of the study⁵⁴ was to look at immune function to see whether it was progressive and whether it might lead to AIDS.

Professor Ludlam explained⁵⁵ that the study showed immune changes were taking place in a similar way has had been reported in American studies. It was thought unlikely that the immune patients was caused by AIDS because the majority had received only Scottish product⁵⁶ and none had any symptoms or signs suggestive AIDS. He said it was imperative to continue monitor patients because if the immune changes were becoming progressively more abnormal there might be a risk of developing opportunistic infections characteristic of AIDS. Be that as it may the results were published⁵⁷ and offered as a means of distinguishing between two possible⁵⁸ explanations for immune abnormalities. At the same time Doctor Ludlam was always keen that his patients should receive exclusively Scottish product if at all possible. There was a clinical justification for this in that Scottish product was thought by him to be safer but there can be no doubt that such exclusive use also suited the purpose of conducting the studying which was ongoing. This other motive was not explained to patients. The studying continued after the point when it was realised that the AIDS virus had infected members of the cohort⁵⁹. In or about October 1984 samples of ten patients were tested and three were found to have antibodies to HTLV-III. These patients had been treated exclusively with Scottish product. Thereafter further testing took place. At all times

⁵⁴ See LIT0010425 for the published study

⁵⁵ Day 35 17/06/11 70 (5) – (14)

⁵⁶ Exclusively SNBTS in the last five years see LIT0010416

⁵⁷ LIT.001.0416

⁵⁸ Infusion of foreign proteins or a virus (AIDS)

⁵⁹ In the Lancet Article of 3 August 1985 [LIT.001.1669 it is stated that “An important feature of our study is that the patients’ lymphocyte subsets were measured during the spring of 1983 when all those who had received exclusively SNBTS factor VIII were negative for anti HTLV-III. We have thus been able to compare lymphocyte subset data before and after infection with HTLV-III. It is commonly assumed that the reduction in T-helper-cell numbers is a result of the HTLV-III virus being tropic for T-helper cells. Our finding in this study that T-helper-cell numbers and the helper/suppressor ratio did not change after infection supports our previous conclusion that the abnormal T-lymphocyte subsets are a result of intravenous infusion of factor viii concentrates per se, not HTLV-III infection. It is possible however that there will be progressive time-dependent fall in T-helper-cell numbers as a result of HTLV-III infection, but only long term follow up will reveal this.

the patients were identifiable. The identification of the source of infection and in particular the fact that it was thought to be a single batch was important to the ongoing study. The precise reason for selecting the particular individuals for the test was not absolutely clear. Professor Ludlam was asked what the purpose of testing patients for HTLV-III⁶⁰ in or about October 1984. He said that “It was to look at individual patients, so that we knew who appeared to have been exposed to the virus and those who had not. It seems that patients were tested was not just to find out whether that individual had been infected but also to further the study of what was going on generally⁶¹. According to the contemporaneous material, testing was performed as part of the “research project”⁶² being carried out by Doctor Ludlam.

2. The information given to “members” of the Edinburgh Cohort about its existence as a significant group worthy of study?

Patients did not provide explicit or informed consent for studies to be carried out in relation to blood or skin samples provided by them. This is despite an assertion when seeking ethical consent in relation to skin samples that informed consent would be obtained⁶³. Patients were not asked to give and did not give consent to results of the studies taking place being published. In his evidence to the Inquiry Professor Ludlam accepted, rather reluctantly, that the publication of years of birth of the eighteen seropositive patients in the 1988 Lancet article⁶⁴ was a mistake⁶⁵. Members of the Edinburgh Cohort were never told as individuals that they were part of significant group worthy of study.

3. How did the members of the Edinburgh Cohort become infected?

The Inquiry heard detailed evidence from Dr Perry⁶⁶, from Professor Ludlam and from Dr. McClelland as to the investigations into identifying which batch or batches of SNBTS factor viii was/were responsible for the infection of the patients who had been identified as anti-HIV positive on testing by Dr Tedder by November 1984. Batch NV 3-009 was identified as “the implicated batch” as a result of an analysis by Dr Ludlam and then at a meeting on 15

⁶⁰ Day 39 28/06/11 64 (19) – 65 (1)

⁶¹ Day 38

⁶² SGH0026491 The notes appended to the meeting of 19/12/84 refer in detail to the subject matter of the study and to “further study”

⁶³ Day 39 28/06/11 44 (21) -49 (10)

⁶⁴ LIT0010895

⁶⁵ Day 39 28/06/11 63 (4) – (16)

⁶⁶ Day 38 24/06/11

November 1984.⁶⁷ Professor Ludlam described the exercise which was undertaken (as far as he was concerned) as trying "to see if we could pin it down to a single batch".⁶⁸ If his approach was predicated upon an assumption that only one batch could have been implicated in the infection of those who had tested positive it was wrong. The exercise should have been approached with an open mind as to the batches which caused the infections. After all, the primary purpose of the exercise was to identify potentially infective batches which might still be in circulation.

Only fifteen out of the sixteen then identified were infected by the implicated. One of the patients then infected had definitely not received the implicated batch. This was recognised in the letter written by Dr McClelland to Dr Cash on 15 November at which time he suggested that further follow up would be necessary to work out how this sixteenth patient had become infected.⁶⁹ Some analysis of the position of this individual was described in an article written by Professor Ludlam & others in the aftermath of the infection of the members of the cohort⁷⁰. In the article another batch is identified which was received by the "sixteenth patient" and 8 of the other 15 who had been found to have seroconverted. It is likely that the sixteenth patient was also infected by an SNBTS factor VIII concentrate as he had not received commercial product.⁷¹ No factor VIII batches other than the implicated batch were ever recalled. No further follow up was ever carried out. Three other patients had been identified as also having seroconverted and having received the "implicated batch" by the time of a further article written by Professor Ludlam & Ors, published in the Lancet on 28 May 1988.⁷²

It cannot be asserted that the infection of the infected members of the Edinburgh Cohort (understood in the sense of the study group referred to above) was as a result of a single source of SNBTS product. At least one other batch and perhaps other unidentified batches (possibly the batch referred to in the 1985 Lancet article) were contaminated with HIV. It has not been possible to scientifically prove that the implicated batch was responsible for any of the infections of the Edinburgh Cohort by means of testing of that batch but it is likely that most of the infections of those in the wider Edinburgh cohort occurred because of it.

The source of the infection of the implicated batch is also something which should be of interest to the Inquiry. In the aftermath of the infections coming to light, it was thought that

⁶⁷ See SNF.001.3624 - letter from Dr McClelland to Dr Cash outlining the exercise undertaken on 15 November 1984

⁶⁸ Day 36 21/06/11; 23 (21 - 22)

⁶⁹ SNF.001.3624 @ 3625

⁷⁰ SNB.008.3434 @ 3435 (3 August 1985)

⁷¹ SNB.008.3434 @ 3435

⁷² LIT.001.0895

the batch may have been infected by a single positive donor who was "presumed to be a homosexual", had tested weakly positive for VD and lived in the west of Scotland.⁷³ After further investigation into his HTLV III status, this theory was found to be wrong. Dr McClelland accepted in evidence that the issue of the infected donor was not followed up by the SNBTS by way of donor testing, despite the fact that he had started to investigate that possibility with Dr Tedder.⁷⁴ The reason why the identity of the person whose donation infected the implicated batch would be of interest is that it would enable some further analysis of the likely reasons why the batch became implicated in the first place (for example the variations in the rigour with which high risk donors were excluded from donor sessions throughout Scotland).

4. The amount content and timing of information given to the members of the Edinburgh Cohort and their families concerning infection with HIV and the consequences of such infection.

Apart from the meeting on 19 December 1984 and the advice sheet it was up to individual patients to inquire whether they had been tested and to ask for information about the outcome later. Such medical records as have been produced do not contain a clear entry indicating the date of the 1984 tests, the result of the test and the communication of the test result to the patient. No clear explanation has been given as to why this information is not available in relation to the members of the Edinburgh Cohort. No records now exist of the work carried out in relation to the test results, the identities of the patients tested, the results and the work analysing the results⁷⁵

The evidence is that whether, when and how a member of the cohort was told of a positive test varied considerably. One member of the Edinburgh Cohort was told on 21 December 1984 that he had tested positive. Some may have come forward to ask for results following the meeting on 19 December 1984. Others were not told until they were persuaded to have a test at a later stage in some cases many months and in others many years later.

Such medical records of members of the Edinburgh Cohort as have been produced to the Inquiry do not contain any entry relative to the 1984 testing and the communication of those results (assuming that actually occurred in any case). No explanation has been provided as to why such information does not now form part of the patient records.

⁷³ As was noted at a meeting of the SNBTS directors on 11 December 1984 - SGF.001.0137 @ 0140

⁷⁴ PEN.012.1423 (28 November 1984)

⁷⁵ Day 39 28/6/2011 76 (13) – (24)

Frances, Elaine and Mark gave evidence as to the information given to them about the consequences of infection. The Inquiry has other statements from members of the Edinburgh Cohort detailing the information given as to the consequences of infection. Only three are still alive. The other fifteen of the eighteen infected died as a result of infection with HIV. As the Inquiry is well aware and as is clear from the evidence of Frances and Elaine the consequences of infection go far beyond the illness and death of the person infected.

RECOMMENDATIONS ARISING OUT OF B5 B6 C5 AND C6

From the perspective of patients the main shortcomings that arose during the reference period relate to patient autonomy, communication, public information, awareness and support.

Patient autonomy

It is essential that NHS in Scotland devises maintains and enforces strategies that ensure that all patients (and where appropriate carers) have autonomy over all care and treatment received. This includes any investigations carried out in relation to any samples of blood or tissue. The patient should be fully informed in relation to any proposed treatment. Informed consent must be obtained. Any request for a test should be accompanied with sufficient information to allow the patient to give consent and any result should be communicated to the patient. Detailed recommendations are necessary to ensure that patients are permitted to be in control of the care and treatment provided to them.

Communication with Patients

Communication is an essential requirement of successful treatment. The skills necessary to achieve effective communication are not obvious but can be acquired as a result of proper training. Even the most skilled medical practitioner requires has to be taught how to communicate with patients. What to tell a patient, how to tell them, when to tell them, where to tell them are all matters that require careful consideration if patient autonomy is to be achieved. Detailed recommendations should be made to ensure that all health professionals acquire and maintain the ability to communicate effectively throughout their careers.

Public Information

It is necessary to give information to the public at an early stage of the threat posed to public health by conditions such as HIV/Hepatitis C. There is nothing to be gained by understating a threat or giving false re-assurance. The management of such information requires to be directed nationally. The public in general and patients in particular should be given as accurate a picture as possible of the potential outcomes for them. If a threat is uncertain then that fact should be made clear. The use of language (by ministers, civil servants or their press officers) for public consumption⁷⁶ which although technically correct but which is in fact calculated to understate a threat is unhelpful. Detailed recommendations are required to ensure that accurate information is provided nationally in relation to threats to public health.

Awareness

There are three aspects to raising awareness. First, for patients in relation to whom it is known that they have any condition, it is axiomatic that they should be informed of that fact. Where knowledge develops over time in relation to the potential outcome of that condition then patients should be told about the changing picture. Where treatment becomes available that should also be shared with the patient. Second, awareness of a condition such as hepatitis C should be raised among all health professionals so that the presence of the condition can be recognised⁷⁷. False assumptions were and are repeatedly made about alcohol histories because of ignorance of the condition and its progression. Third, awareness requires to be raised among the public so that early intervention can occur in relation to patients unknowingly suffering from the conditions. Detailed recommendations would be welcome in relation to these matters.

Support

Patients and their families require to be supported through crises such as HIV and HCV. Resources are needed to provide support, counselling and other long term services designed to promote successful treatment. Organisations such as the Haemophilia Society require significant support to carry out their vital work. We hope that recommendations will be made with a view to the continued provision of support for patients and their families.

⁷⁶ Such as "there is no conclusive proof"

⁷⁷ It is important that GP's are aware of such things as the extra-hepatic manifestations of the condition