Witness Name: Prof Christopher Ludlam
Statement No.: WITN3428027
Exhibits: WITN3428028-37
Dated: 25 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHRISTOPHER LUDLAM

I provide this statement in response to requests under Rule 9 of the Inquiry Rules 2006 dated 20 June 2019 and 15 August 2019.

I, Professor Christopher Ludlam, will say as follows: -

Section 1: Introduction

1) My full name is Christopher A Ludlam. My date of birth is GRO-C 1946. My address is known to the Inquiry. My professional qualifications are B.Sc, M.B.,Ch.B, MRCP, MRCPath, Ph.D, FRCP, FRCPath.

2) I have set out the positions I have held as a haematologist in the curriculum vitae held by the Inquiry (WITN3428002).

3) All past and present memberships of committees and groups relevant to the Inquiry's Terms of Reference are set out in my curriculum vitae (WITN3428002).

Section 2: Responses to criticism of W2189 and W2190

Background

4) I am distressed by the criticisms of the haemophilia service that Mr and Ms Mackie have set out in their written statements and Ms Mackie's oral evidence to the

Infected Blood Inquiry. Some of these criticisms appear to arise out of misunderstandings, particularly in relation to the interpretation of the clinical case notes. Additionally I have learned that Mr Mackie never received a detailed response to the issues he raised with the GMC (see below). I therefore fully understand Mr and Ms Mackie's frustration at the absence of information and explanation.

5) Mr and Ms Mackie consider that they may not have received a complete copy of his medical records. I do not know what records have been provided. It may be that they have not been provided with some data held on hospital computer systems or treatment records held separately in the Haemophilia Centre.

6) My relationship with Mr Mackie over many years has had its difficulties and as Ms Mackie indicates in her oral evidence he did not like routine morning clinic appointments and would often arrive on occasions in the early afternoon without an appointment. The majority of the medical staff at the Haemophilia Centre were employed during the mornings when most of the clinic appointments were scheduled. The Centre was always able to provide acute medical help at such a time, e.g. to treat a bleed. As I was often on other duties and clinics elsewhere in the hospital during the afternoons it was not always possible to see him personally. This did not help us being able to offer optimal care.

7) In response to some of the difficulties Mr Mackie was experiencing with the haemophilia arrangements in the Spring of 2003 two meeting were held with Mr and Ms Mackie in which I agreed to see Mr Mackie at lunchtime appointments. These different clinic arrangements resulted in apparent improved and more acceptable review appointments and, from my perspective, significantly improved our working relationship over a six month period.

Referral to the GMC

8) At this point in 2003 Mr Mackie's complaint to the GMC was delivered to me at a time when relations between us were improving. I had to respond formally to the complaint and it would have been quite inappropriate for me to have had a meeting with Mr Mackie to discuss his criticisms. Had I been able to do so and review the case records with him I could have explained the nature and reason for the

investigations we had undertaken. I could also have reviewed with him the completeness of the records that he had been provided with.

9) At this time the GMC did not, so far as I know, inquire as to whether the hospital had previously considered his complaints and arranged what would have been a formal meeting between myself and Mr Mackie. Had such a meeting taken place some of what I perceive to be misunderstandings, on both sides, might have been addressed.

Detailed Response to the GMC

10) Until recently I assumed that my detailed response in writing to the GMC in response to Mr Mackie's complaint had been forwarded to him. I have recently learned that the IBI requested an explanation from the GMC as to how the complaint had been handled. On reading this it appears that, because of the GMC protocol for the process for handling complaints, my detailed response was never forwarded to Mr Mackie. (The protocol concerned being that the GMC would only forward to the complainant the doctor's initial written response and not subsequent correspondence. The initial response made on my behalf was to claim that the substance of the complaint occurred over 5 years previously and should therefore not be considered (a standard rule of the GMC at that time)). The GMC, however, decided to set aside the 5-year rule and I, therefore, submitted a detailed response.

11) This was not sent to Mr Mackie because it was not the first response from me. Thus, apparently Mr Mackie never received my detailed response to his criticisms. I understand his resultant frustration. I very much regret this and to try to put the record straight I attach a copy of my original response to the GMC along with its attachments (WITN3428028).

Outcome of GMC complaint

12) The delivery of the complaints by the GMC brought to a halt an improving clinical relationship without the GMC first considering whether there were at least initial ways in which the complaints could be considered at a meeting overseen by the hospital. Had this taken place Mr and Ms Mackie would have had the opportunity to put their questions and criticisms to me and learn of my responses. If this

meeting, or potentially series of meetings, did not address all their concerns then this would have been an appropriate time for the GMC to seek a formal response from me.

13) On receipt of the detailed response from me, the GMC closed the complaint without action.

Referral to Lothian and Borders Police

14) In around 2009, I was interviewed by Lothian and Borders Police as a result of Mr and Ms Mackie's concerns being brought to their attention. No subsequent action was taken.

Section 3 - Responses to Rule 9 requests dated 20 June 2019 and 15 August 2019

15) This response is provided without reference to the principal case notes, my answers are based on information available to me through the GMC complaint and in response to his initial court action in the late 1980s.

A. Responses to questions in Rule 9 request dated 20 June 2019 in relation to Mr and Ms Mackie's written witness statements

Ms Mackie in paragraph 3 of her statement wonders about the purpose of the 'letter' I gave to Mr Mackie to show at other haemophilia centres where he might receive treatment requesting that he be treated with NHS concentrate. She expresses concern that this was done for research purposes.

16) Ms Mackie states that I gave Mr Mackie a letter after the reaction he had to BPL 8Y after 1987 to ensure that he did not receive anything other than Scottish Factor VIII if attending another hospital. She records other patients being given a similar letter.

17) I provided a short written statement to all patients with haemophilia early in the 1980s to request that if they were attending another Haemophilia Centre that they should receive cryoprecipitate or NHS concentrate rather than commercial concentrate, if possible. I think this is the 'letter' that Ms Mackie is referring to. I do

not recall issuing Mr Mackie with an additional letter detailing his reaction to some blood products.

18) The reason for this short statement being provided to all of my patients was principally for the patient safety reason of not exposing patients to a different donor population base, e.g. North American donors. The general view in the 1970s and 1980s was that NHS derived products were likely to be safer than commercial ones, for example in relation to hepatitis. There was also a possibility that recipients might have a degree of immunity to local viral infections that might occur in the local donors. Additionally because the majority of Edinburgh patients had only been treated with Scottish derived NHS products as a group they were almost unique as a group in the UK and might be useful as a valuable comparison group to those who had been exposed extensively to commercial products. The value of this arrangement was appreciated by the UK Haemophilia Society. Dr S H Davies, my predecessor, initiated this policy which I was keen to continue.

19) The above reasoning was explained individually to the patients who were encouraged to carry the short statement in their Haemophilia Card (which gave details of their bleeding disorder and could be shown when visiting another Haemophilia Centre).

20) Ms Mackie inquires about Mr Mackie being changed from cryoprecipitate, which Dr Davies had recommended, to Factor VIII concentrate. The change was made because Mr Mackie had reactions to cryoprecipitate in the early 1980s and he did not react to NHS factor VIII concentrate. Subsequently when the supply of NHS factor VIII concentrate increased he was able to have treatment at home. This allowed early treatment of bleeds and avoided a long journey into Edinburgh. The change of product was for clinical therapeutic reasons not research.

Ms Mackie in paragraph 6 notes that Mr Mackie repeatedly inquired about the risks of hepatitis and AIDS. He and Ms Mackie were aware that hepatitis was a risk of treatment. She reports that when Mr Mackie first started taking factor VIII in the early 1980s he was told by me and other doctors that 'hepatitis' was not a problem.

21) Mr and Ms Mackie indicate that they were aware of the risk of hepatitis. Until the mid-1980s there was no firm evidence that hepatitis (non-A non-B hepatitis) reflected progressive or serious liver disease in people with haemophilia. It was

manifested by mild abnormalities of the laboratory liver function tests with the bilirubin rarely being significantly raised. Thus jaundice (a clinically apparent raised bilirubin) was uncommon in individuals such as Mr Mackie. It is therefore unlikely that I would have said he could turn 'a bit yellow for a day or two'. I do not believe I did so. I would have told him that his liver tests demonstrated that he had hepatitis, that it was prudent to monitor this and this would be done routinely at clinic visits. I would also have told him he had evidence of previous hepatitis B infection.

22) I have no recollection of Mr or Ms Mackie asking about the risk of HTLVIII/AIDS in the period 1980 to 1984. If he had inquired, I would have discussed with him my perceptions of the risks. I do not have any recollection of being asked about risks to his wife prior to 1984.

23) Had he asked in the period prior to December 1984 I would have said that he was not at risk of passing on hepatitis B (because he had immunity to this having been infected in the past) and it was not generally considered that non-A non-B hepatitis was sexually transmissible.

24) After December 1984 our advice changed (because of finding that some patients had been exposed to HTLVIII). We recommended that all patients who had received blood products should use condoms irrespective of their HTLVIII antibody status. This was because we were uncertain about the sensitivity and specificity of the HTLVIII antibody test, e.g., some patients might have a negative test but still be infected with the HTLV III virus. This information about condom use was emphasised in the December 1984 meeting in the Royal Infirmary of Edinburgh, was sent to all patients in January 1985, was given verbally by all staff to patients, was part of the counselling of patients by the Social Worker and condoms were given out with Factor VIII concentrate to patients at the Haemophilia Centre when patients attended to collect home treatment (in addition patients could uplift them in brown paper bags in the waiting room).

Ms Mackie in paragraph 6 and Mr Mackie in paragraph 6 of their statements set out that when they inquired about risks to Ms Mackie and children of Mr Mackie taking Factor VIII concentrate they were told 'that there was nothing that we should worry about there was nothing he could pass on to me'.

25) When Mr Mackie was commenced on home treatment it would have been indicated that he should treat himself as a result of which there would be no exposure to the product by anyone else. This was routine advice given to patients on home treatment.

In paragraph 13 Ms Mackie claims I provided no information about the risks of "infected blood products till the end of 1984". She refers to a meeting of "over 100 haemophiliacs" and describes her recollection of the meeting and leaving under the impression that all individuals who were anti-HTVLIII positive had been informed prior to that meeting. She also claims I failed in my duty of care by not informing patients about infections individually.

26) Ms Mackie's statement specifically refers to HTLVIII and not to other infections. Mr Mackie was well aware of the risk of hepatitis when he went on to home treatment and signed the appropriate consent form.

27) The meeting to which Ms and Mr Mackie refer was held on 19th December 1984 and all patients (and parents of children) attending the Edinburgh Haemophilia Centre were invited by letter to attend. The meeting was chaired by Dr Charles Forbes (Director, Glasgow Haemophilia Centre) and Dr McClelland (Director, Edinburgh Blood Transfusion Centre) were present as well as myself. Mrs Geraldine Brown (Social Worker, Edinburgh Haemophilia Centre) also attended the meeting. About 50 people were present.

28) Dr Forbes opened the meeting and presented an introduction on the latest information available about HTLVIII, anti-HTLVIII, AIDS and haemophilia including UK and international data. He told the meeting that some patients with haemophilia were anti-HTLVIII positive and this was evidence of exposure to the AIDS virus. Because of uncertainties in interpreting the results of HTLVIII tests, particularly negative results, he emphasised the importance for all patients to consider it possible they might have been exposed and to take safety precautions. This included advice that all men should use a condom during sexual intercourse. I gave a short presentation to explain that in Edinburgh some patients had been found to be anti-HTLVIII positive and we considered that some had been exposed by a single batch of SNBTS factor VIII concentrate used in the spring of 1984. I repeated the information about the safety precautions that all patients should take. Ms Mackie sets out in her statement her memory that it was only HTLVIII positive

patients who should use condoms when in fact the message was that all patients, irrespective of the test result, were encouraged to use condoms. All patients were strongly encouraged to make an appointment to see their haemophilia doctor to find out about their individual situation in relation to the anti-HTLVIII test. Dr McClelland spoke about the steps SNBTS had taken to reduce the risk of infected donations and about the immediate introduction of heat treatment for all factor VIII concentrate. All patients were being asked to return unused bottles of factor VIII concentrate held at home and to exchange them for heated concentrate. Dr Forbes then opened the meeting to questions and the speakers responded. This part of the meeting continued until all there were no further questions.

29) One of the family members who attended the meeting made notes which record what was presented. These record the issues presented and advice given. I have referred the Inquiry to a statement provided to the Penrose Inquiry which contained an informal minute of that meeting (PRSE0002471).

30) To further inform all patients registered at the Edinburgh Haemophilia Centre that some had been exposed to the AIDS virus an information sheet was sent in January 1985 to everyone registered with the Edinburgh Centre (PRSE0002785). This was sent with a covering letter inviting patients to make an appointment to see me to learn of their individual situation. A letter was also sent to all general practitioners of patients with haemophilia (WITN3428009).

31) That the message that patients should make an appointment to see me was clearly received by those attending the meeting was evidenced by many individuals making an arrangement to see me; the first within a few days of the meeting. As a result of the meeting and the circulated information sheet many patients made appointments to see me early in 1985. At these appointments if the patient wished to know the result of their anti-HTVLIII test I would tell them (if available) and ask for their agreement for a further fresh blood sample to confirm the initial result.

32) In the haemophilia team we discussed about what measures should be taken to inform patients, especially those who were anti-HTLVIII positive. At this time there was no specific treatment that could be recommended for those who were anti-HTLVIII positive and all patients were being recommended to use safety precautions. Furthermore there was considerable uncertainty about the significance of a positive result. It was clear that many patients wished some time

to consider whether or not they wished to know the result of their anti-HTLVIII blood test. We decided to wait for patients to ask about their results.

33) At this time there was much in the press about AIDS some of which was very unsettling so it was not a topic that could be ignored. Additionally there was a very hostile atmosphere in many communities to those who might be exposed to the AIDS virus. When patients attended the Haemophilia Centre with a bleed, or for a routine appointment, if appropriate, they would be reminded that I was ready to talk to them about AIDS and whether they would wish to know their blood test result. To emphasise the importance of condom use these were issued discreetly along with factor VIII concentrate when it was given out for home treatment.

34) I do not agree that I failed in my duty of care by not informing patients immediately of their anti-HTLVIII results. Not all patients wanted to know their anti-HIV results immediately. All patients were given firm and clear advice about safety precautions at the meeting, in the letter sent to all patients to protect spouses and other family members and the routine issuing of condoms. This information was reinforced by the staff at the Haemophilia Centre.

In paragraph 7 of Mr Mackie's statement he asks why prophylaxis was not stopped in 1983 when he was getting quite a lot of bleeds.

35) Mr Mackie had considerable trouble with recurrent bleeds into his left elbow and right shoulder. He was recommended prophylaxis to reduce the frequency of these bleeds. Had he not had short periods of prophylaxis he would have had more joint bleeds which would have required additional treatment. The treatment itself would have been Factor VIII in greater amount than the prophylaxis. Although the prophylaxis apparently reduced the frequency of bleeds they still occurred and required treatment.

36) At this time Mr Mackie was on home treatment with SNBTS factor VIII concentrate. By the end of 1983 there were probably two cases of AIDS known in the UK out of about 5,000 individuals with haemophilia. It is likely that both had been treated with US-derived Factor VIII concentrate.

37) UKHCDO guidance was issued in June 1983 which considered it was appropriate to continue treatment with both NHS and US concentrates. There was no

suggestion that prophylaxis should be stopped. At this time in the US there were 21 known cases of AIDS in people with haemophilia out of a population of about 20,000 and even within the US the National Haemophilia Foundation recommended continued use of Factor VIII concentrate. In Scotland SNBTS was collecting blood from an apparently AIDS free donor population. I therefore concluded that the risk of a putative virus infecting Edinburgh patients was much lower than the risk from Factor VIII manufactured in the US or from blood collected in England (where there were a total of 14 people with AIDS including one with haemophilia in July 1983).

Paragraph 15 of Ms Mackie's statement indicates that at the time of the meeting on 19th December she did not appreciate that the meeting was to inform individuals that some had been exposed to HTLVIII. She understood that thereafter all SNBTS Factor VIII concentrate was heat treated in anticipation that it would reduce the future risk of HTLVIII exposure. She describes a cut to the skin from which Mr Mackie bled and for which no special safety precautions were taken. She also sets out that neither I, nor the other doctors, mentioned HTLVIII or HIV or AIDS after that meeting.

38) I have set out above what was set out about HTLVIII in my above response. I am very sorry that Mr and Ms Mackie appeared to misunderstand the information that was laid out

39) It is correct that we mentioned at the meeting that all Factor VIII concentrate prepared by SNBTS was being heat-treated and we hoped this would prevent further infections in future. We did not state that heat-treatment was certain to prevent all transmission as the evidence was not available. Subsequent studies in Edinburgh, however, did demonstrate that heat-treated SNBTS Factor VIII concentrates did not result in any further HTLVIII infections (Cuthbert et al Vox Sang 1988; 54:199-200).

40) At this time in December 1984 when the decision was made to heat treat Factor VIII concentrates in Scotland patients were asked to return unused vials of (unheated) concentrate and were issued with replacement heat-treated concentrate.

41) Subsequent to the December 1984 meeting patients were encouraged by nursing and other medical staff to seek an appointment with me to discuss their own situation in relation to the anti-HTLV III test.

42) It is regrettable that it was not appreciated by Mr and Ms Mackie at the December 1984 meeting that attendants should use gloves to protect from infection. This was stated at the meeting and reinforced in the circular sent to all patients.

43) By 1983 the Haemophilia Centre in Edinburgh had its own dedicated nurse who oversaw the arrangements for patients to get therapy at home. My clear recollection is that she was obsessional about safety in the use of such treatment. All necessary and appropriate equipment would have been available from her.

Mr Mackie in paragraph 17 and Ms Mackie in paragraph 15 make reference to a potential newspaper article as being the reason for the December 1984 meeting.

44) It is correct that Edinburgh and Glasgow Haemophilia Centres decided to hold the meeting in Edinburgh because a reporter from the Yorkshire Post had learned of the HTLVIII exposure to Edinburgh patients. It is likely this information had been passed to the press as a result of discussions at a meeting held on 10th December 1984 in London with UKHCDO, senior blood transfusion personnel and representatives of the NHS protein fractionation centres.

45) The Yorkshire Post reporter contacted me shortly after the 10th December meeting. He was very keen to publish the information about the situation in Edinburgh immediately. I did not want patients to learn about HTLVIII exposure from the newspaper. I indicated to him that it would be seriously detrimental to patients if he were to publish his report as he intended. I had some considerable difficulty in persuading him to delay publication until after the meeting but he eventually agreed. In conjunction with Dr Charles Forbes (Glasgow, Haemophilia Director) we decided that we should hold the meeting in Edinburgh. All patients were sent a letter inviting them to the meeting. It was agreed that we would write to all patients after the meeting about HTLVIII setting out the safety measures which were necessary for all patients. All patients were encouraged to seek an appointment with their haemophilia physician to discuss their situation.

In paragraph 6 of Mr Mackie's statement and Ms Mackie's statement (paragraph 15) they indicate concern that I was putting her life, and that of their son, at risk by my not informing them of Mr Mackie's anti-HTLVIII status and necessary safety precautions.

46) The necessary safety information had been provided at the December 1984 meeting, in the circular to patients and by the issuing of condoms from the Haemophilia Centre. Non-sexual other household members, e.g. their son, were not thought to be at risk of infection from ordinary social contact.

Mr Mackie in paragraph 6 and 11 and Ms Mackie in paragraph 17 indicate that Mr Mackie repeatedly asked about the risk of treatment particularly in relation to AIDS from 1983 onwards.

47) I do not have any recollection of either Mr or Ms Mackie inquiring about risks of AIDS from 1983 onwards.

48) If Mr and Ms Mackie had made inquiries about the safety of Factor VIII concentrate I would certainly not have reassured him that there was 'nothing to worry about' and 'everything is safe'. He was aware that there was a risk of hepatitis from their reading of the patient insert leaflet with the factor VIII concentrates, from the home treatment consent forms, from attendances at review clinics, when blood was taken for liver function tests, from Haemophilia Society bulletins etc (which were placed in the Haemophilia Centre waiting room), from the patient statements to accompany the patient's Haemophilia Card asking other centres to give NHS products in the event of a bleed (paragraph 19 above). We hoped that the heat-treating would reduce the risk of further HTLVIII exposure. We did not have any evidence that the heat-treatment then used would abolish the risk of non-A non-B hepatitis transmission.

49) By the end of 1983 in the UK there were two people with haemophilia who had been diagnosed with AIDS out of approximately 5,000 patients in total. By July 1983 in the US there were reported 16 patients with haemophilia and AIDS out of a total of approximately 15-20,000 patients (MMWR July 1983). It was quite unclear what the risks were to UK patients as there were no reliable markers of HTLVIII exposure. I would have been quite prepared to discuss the developing situation with him had he asked. It was an important topic and I considered that I

was as well informed as I could be. There were no reported cases of AIDS in the Scottish population.

50) After the December 1984 meeting I do not have any recollection of Mr Mackie asking about the safety of factor VIII concentrate that he was receiving. Had he asked about safety I would have used it as an ideal opportunity to ask whether he might want to discuss the matter further and at that time would have inquired whether he would want to know his ant-HTLVIII result.

Mr Mackie (paragraph 8) and Ms Mackie (paragraph 21) report that the information that he was anti-HTLVIII positive was given in an insensitive manner. They set out the circumstances in which they were told in their statements.

51) I did write to Mr Mackie inviting him to come and see me. I arranged to see him in my room in the Department of Haematology because I considered this would be a quieter and more confidential environment and there would be less chance of interruption or distraction. At the beginning of the meeting I indicated that I had some private information for Mr Mackie and I wondered whether he would want his wife to be present. I did leave them alone in the room for a few minutes so they could discuss this in private. I did not, as Ms Mackie reports 'asked me (Ms Mackie) to leave the room.' When I returned to the room Mr Mackie was adamant that his wife should stay and be present. There then followed my telling him that he was anti-HTLVIII positive and I did ask about whether there were any other possible risk factors.

52) Ms Mackie states in paragraph 21 that 'Robert did ask how he became infected but Dr Ludlam did not answer the question.' I had strong evidence that he had been infected by the 'implicated' batch of SNBTS Factor VIII concentrate in the spring of 1984 and I told him this. There was no reason not to do so.

53) Mr Mackie states in paragraph 8 that I 'had met the donor of the infected blood donation, that the donor had been a homosexual man and that he was dead'. This is wholly inaccurate. The HTLVIII infected donor(s) to the presumed infectious batch of Factor VIII concentrate has never been identified as far as I am aware.

54) I will have advised that they should think very carefully about who they told about his anti-HTLVIII situation. This was at a time when there was much hostility in the

general community to people considered to be infected with HTLVIII. I do not remember him asking about whether he should talk about HTLVIII to other members of his family who had haemophilia.

55) Mr Mackie states that 'Dr Ludlam also asked if I wished for another doctor to treat me from now on, and since I believed he was ignorant of the threat of AIDS and that it why he had not told me anything about the risks or about my infection sooner, I just decided to keep him my treating consultant'. I did not offer Mr Mackie the option of another consultant to take over his care at that time, nor did he ask for this.

56) I have some difficulty understanding Mr Mackie's statement in paragraph 8 'he (Dr Ludlam) knew the mortality rate in haemophiliacs was high, in fact it was discussed in July 1983 about the predicted mortality being 100% in 25 months for haemophiliacs, meaning that since I was infected in May 1984 I was now out of time'. I do not understand the reference he makes to prognosis. It might be true that someone with clinical AIDS in 1983 had a prognosis of 25 months but Mr Mackie had only been found to be anti-HTLVIII positive and at the time of the December 1984 meeting the chance of such an individual developing ADIS was considered to be between 1/00 and 1/500.

57) At the end of the meeting I told them I had arranged for them to see Mrs Geraldine Brown immediately after the meeting so that she could begin to offer them further counselling and other help. I did leave the room so that Mr and Ms Mackie could have some time together in private before leaving. So far as I know they were seen by Mrs Brown.

Mr Mackie in paragraph 9 and Ms Mackie in paragraph 21 express concern that I should have asked about other AIDS risk factors for infection when he had received the presumed infected batch of concentrate.

58) As indicated above I did inquire about other possible risk factors for being exposed to HTLVIII. Although he did receive the presumed anti HTLVIII infectious batch of factor VIII, this did not preclude him being infected from another source. These inquiries were entirely appropriate.

Ms Mackie in paragraph 21 records that I was not 'open' to questions in the meeting and that she felt I wanted them to leave my office as soon as possible.

59) I was prepared to discuss Mr Mackie's situation for as long as he and Ms Mackie wished. I was quite prepared to answer any questions that Mr and Ms Mackie wished to ask. Understandably they were taken aback by the news. I do not recall it being me who brought the meeting to a close. In these circumstances I leave it to the patient or relative to indicate that the meeting should finish. At the conclusion of the meeting I did leave the room to offer them some privacy to discuss what they had just been told.

Mr Mackie in paragraph 8 and Ms Mackie in paragraph 22 (not 21 as referenced) indicate that no counselling nor an offer to test Ms Mackie was made.

60) Prior to the meeting with Mr and Ms Mackie I had arranged that our Social Worker, Mrs Geraldine Brown, would be free and available to see them immediately after our meeting. They lived some distance from Edinburgh and this would be an opportunity to meet her and consider their situation. Mrs Brown, by this time had worked in the Haemophilia Centre for over two years and was very experienced and competent in counselling people with haemophilia, spouses and others about HIV. A short summary of the then current aspects of HIV counselling was produced which is exhibited to my statement (WITN3428029). Part of the early review of their situation would have been consideration as to whether Ms Mackie should be tested for ant-HTLVIII.

61) Following knowledge of anti-HTVLIII positivity in some people with haemophilia in Edinburgh we established arrangements for the psychological support for those affected and their families. Initially Mrs Brown led the counselling arrangements and the nurses were also active in keeping in touch with the patients. When patients came to collect their factor concentrates for home treatment there was often an opportunity to talk to staff.

62) In 1987 Dr Alison Richardson, Clinical Psychologist, was appointed with a specific remit to HTLVIII infected patients and their families. She worked closely with Mrs Brown. Weekly meetings were held for the staff to share, as appropriate, individual patient's situations. Because of the sensitive nature of some of the difficulties being experienced a high degree of confidentiality was required. Dr Masterton,

Consultant Psychiatrist, was very supportive not only in seeing individual patients, but also in assisting the haemophilia team cope with the stresses of helping people with haemophilia and their families. Dr Masterton made a submission to the Penrose Inquiry describing and assessing our counselling arrangements for patients (PRSE0004379). The Haemophilia Sister at the time wrote to me about the large amount of counselling that was being requested and seeing patients out with the usual working week required additional staffing (WITN3428032).

63) There was therefore a well-established and effective counselling service which was offered and available to the Mackie family.

In paragraph 21 Ms Mackie states that Dr Ludlam 'went on to tell us not to tell anyone' about the HTLVIII.

64) At the meeting with Mr and Ms Mackie in January 1987 I would have raised the issue about what might or should be said to other people, including members of his family. As Mr Mackie indicates elsewhere in his statement he had a number of other family members with haemophilia and he subsequently learned that some were infected with HIV. My advice was that it would be best not to mention HIV to other family members meanwhile until they had had a chance to think about it themselves and perhaps with Mrs Brown. The importance of considering carefully who to let know was painfully described later in her statement where Ms Mackie describes a distressing incident where Mr Mackie's anti-HTLVIII status becomes known and they were asked to leave a friend's house (paragraph 38).

Mr and Ms Mackie in paragraphs 7 and 21 of their statements indicate that my chance of dying of a heart attack was greater than Mr Mackie's chance of dying of AIDS.

65) Mr Mackie states that I stated that 'I (Dr Ludlam) have more chance of dying of a heart attack than you have of dying of AIDS'. I did not respond in that way. Such a comment would be wholly inappropriate, and it is not something I would have said. Quite apart from it being a flippant and inappropriate comment, this is not a comparison that I would have used because it would not be clear to Mr Mackie what my chance was of dying of a heart attack. I would have been quite uncertain as to what my chances were of dying of a heart attack.

Ms Mackie records asking in paragraph 21 that about the number of individuals who were infected and she reports I stated that 'just a few' haemophiliacs had been infected. She goes on to say that I indicated the infection could not have been avoided and was just one of those things.

66) I don't recall being asked at the meeting how many people with haemophilia were infected. Had I been asked I would not have said 'just a few'. I knew that about 20 people with haemophilia in Edinburgh had been exposed to HTLVIII, the majority by the implicated HTLVIII infectious batch. I would have told them of this number. This information had been given at the meeting in December 1984. I was always keen to give the best most accurate available information.

67) There was no way in 1984 of knowing in advance that the batch of factor VIII that was presumed to have infected Mr Mackie contained HTLVIII.

Ms Mackie in paragraph 21 indicates that 'Robert was not told the date he was infected, or when the test was carried out and we thought that Dr Ludlam has just received the results, he was not offered any treatment.'

68) I would have told Mr Mackie that he became infected in the Spring of 1984. I do not recall whether I had the exact dates of the last negative and first positive anti-HTVLIII result at the meeting. In response to a subsequent inquiry I wrote to Mr Mackie with this information.

69) At that time (January 1987) there was, unfortunately, no specific treatment for HTLVIII. Subsequently, for those who had laboratory evidence of their lymphocyte CD4 count (a measure of immune function) declining below a threshold, they would be offered pentamidine inhalations (and later, cotrimoxazole tablets) to help prevent pneumocystis carinii pneumonia, but this was not known to be useful until a later date.

In paragraph 53 Ms Mackie indicates that neither she nor her son was not offered an anti-HTLVIII test shortly after Mr Mackie had been informed of his situation.

70) When Mr and Ms Mackie met with Mrs Geraldine Brown one of the topics which would have been discussed early would have been whether Ms Mackie would like to be tested for anti-HTLVIII. It was not usual practise to offer an anti-HTLVIII test

to other members of the family or household members as it was considered that the risk of infection was exceedingly small.

Ms Mackie in paragraph 26 indicates that Mr Mackie was never told there was a blood test for hepatitis C and he was not told anything about the condition when he was seen at the clinic in 1993. She also sets out that Mr Mackie was advised to undergo an endoscopy to determine if he had hepatitis C.

71) In 1990 Mr Mackie had received a letter from Dr Chapman indicating that a new test for hepatitis has become available and we were trying to assess its usefulness (paragraph 24 of Mrs Mackie's statement). This test was for hepatitis C.

72) Hepatitis C was discussed with Mr Mackie when I saw him at a clinic visit on 3rd May 1993. This would have included a discussion about the hepatitis C blood test and what was known about the condition at that time. It is likely to have been explained that the hepatitis C test was another way of describing non-A non-B hepatitis. Mr Mackie agreed to have an abdominal ultrasound but he declined the offer of an endoscopy. He was subsequently seen by Dr Hayes (hepatologist) and me jointly again on 25th May and was offered an endoscopy, laparoscopy and interferon therapy. He agreed to the endoscopy which was booked but his wife phoned on 27th May to cancel the investigation. He was sent a further appointment for the combined liver clinic for the 22nd June which Mr Mackie did not attend.

73) Although Ms Mackie states that Mr Mackie needed an endoscopy and liver biopsy to diagnose hepatitis C she appears to have misunderstood the situation. The diagnosis of hepatitis C was made with the anti-HCV and HCV PRC blood tests; the endoscopy and liver biopsy were to assess the extent of any liver damage.

Ms Mackie claims in paragraph 26 that she was not informed of the seriousness of hepatitis C and that counselling was not offered.

74) If Ms Mackie attended the two appointments mentioned in 3.18 above I and Dr Hayes would have explained to her about hepatitis C and answered questions. It would have been explained that it would only be possible to tell if Mr Mackie had significant liver damage if he had the investigations (as set out above). The diagnosis of hepatitis C had already been made.

75) Hepatitis C was discussed fully by Dr Hayes and me in the clinic appointments. This discussion was the counselling provided to patients who were also provided with information sheets (WITN3428011).

Mr and Ms Mackie in their statements indicated that Mr Mackie participated, without his consent, in research into AIDS and HIV from 1983 onwards. Ms Mackie also suggests enquiries as to the need for blood samples were ignored.

76) I should like to address the issues raised by outlining how and why patients' haemophilia and the side effects of treatment were monitored and how the investigations were tailored to the changing circumstances during the 1980s. I outline several instances when Mr Mackie explicitly knew of and very kindly helped with research.

77) When I took up my appointment as a haematologist in Edinburgh in 1980 one of my principal concerns was to ensure that patients received the safest blood products and that their well-being should be appropriately assessed and monitored. To do this the investigations used were those that addressed the known risks to people with haemophilia. These had been routinely carried out by my predecessor Dr S.H. Davies. The routine blood tests included a full blood count, clinical chemistry including liver function tests, assessment of potential infectious agents e.g. hepatitis B, blood clotting factor level and a test for the presence of anti-Factor VIII inhibitors. Routinely all samples (from all clinics in the hospital and General Practitioners) sent to virology were stored after analysis in a deep freeze. This was considered a mark of good practise for a virology laboratory and was applied to samples from all clinical areas.

78) These stored samples were valuable clinically on occasions when specific infections were being considered because it was sometimes helpful to compare the results from two blood samples taken at different times. Continuing Dr Davies' practise these samples were potentially used for further retrospective virological investigations for example as new infections were identified as a risk, or new tests or tests of greater sensitivity became available. Unfortunately in the early 1980s one of the deep freezers in virology broke down one weekend and all the samples were destroyed. For this reason, as a precaution against a similar failure, subsequently a small aliquot of blood was also stored in the haematology department from people with haemophilia.

79) It was important that the clinical monitoring investigations undertaken kept pace with developments in the field of haemophilia. In the early 1980s, because of the relative paucity of NHS Factor VIII concentrate availability for home therapy, the majority of patients attended the Royal Infirmary for treatment of their acute bleeds with cryoprecipitate. As a result, I and the other doctors, saw the patients frequently (sometimes at least once per week). As a result I and other doctors got to know the relatively small group of patients well. We had a very open policy for talking with patients about their own situation and the routine monitoring investigations.

80) My interest in the safety of blood was well known. To monitor safety periodic blood samples were requested when patients attended the centre either to collect their home treatment supplies or at review clinics. When blood was being taken for the routine assessments inquiry was often made as to whether a little extra could be taken for Dr Ludlam's research. I don't recall being told of any patient who expressed a reservation or who declined.

81) From 1985 onwards most patients, both anti-HTLVIII positive and negative, attending for review would be considered for the extended monitoring, including HTLVIII virology and immune assessment. This was because of uncertainty around the interpretation of an anti-HTLVIII result but also the uncertainty about abnormal lymphocyte subset results in anti-HTLVIII negative patients. Certainly sometimes patients inquired how each sample would be used and a full explanation was always given. If patients attended in the afternoon it might not be possible to collect a sample for some of the virology investigations because some needed a lengthy period of processing. For the most part the investigations being undertaken were those for direct monitoring of patients' clinical situation.

82) At the Haemophilia Centre a diary record was kept of all individual blood samples taken from patients including all investigations. Blood was only taken with patient consent and therefore this diary was evidence of such consent and exactly what samples had been collected.

83) During the 1980s the investigations that were necessary to monitor the clinical situation of patients developed to keep pace with evolving knowledge about the immune status of those with haemophilia and subsequently what was known about HTLVIII. As I set out in the narrative below I was proactive in establishing

investigations that were not available from routine hospital laboratories at the time, e.g. lymphocyte subsets and HTLVIII virus monitoring, which I considered important. Following the discovery of the HTLVIII tragedy in Edinburgh the very least I could do was to try and provide optimal monitoring of all patients for their benefit. At the time we set out to undertake what we considered were the most important investigations into immune function and the evolving virology.

84) The only way I could arrange the appropriate monitoring of immune function and HTLVIII at that time was to seek research funding. The NHS laboratories did not provide these investigations at that time. Although the funding for the investigations was from a research source the use to which it was put was to monitor what I considered to be in the patients' best clinical interest. Because of the observation that many HTLVIII negative individuals with haemophilia had abnormalities of immune tests there was a need to monitor the immune function of those who were anti-HTLVIII negative as well as those who were positive. Assessment of the virology including monitoring the developing virus status of the patients also became important with the development and detection of resistance to anti-HTLVIII treatment.

85) At a later date, the investigations I had instituted as set out above, were eventually provided by NHS Laboratories as part of the routine assessment of patients. Standard practice for monitoring all patients (in other centres and risk groups) infected by HTLVIII became very similar to the initial arrangements I established.

86) I had a responsibility to record what we were learning about the completely new area of immune assessment and HTLVIII so that the wider haemophilia, and medical, community could be informed. This was a completely new and rapidly developing area of great concern for patients and their physicians. Because of the paucity of knowledge there was a requirement to make what was being observed and learned available for others to assess. To do this medical and scientific papers were written and published so others in the wider haemophilia community could learn of our experience.

87) The following description is of the early evolution of information about immunity and AIDS in haemophilia and describes some aspects of how I responded.

88) AIDS was first reported in 3 people with haemophilia in the US in May 1982 and shortly thereafter it was reported that many asymptomatic people with haemophilia

in the US had abnormal circulating blood lymphocyte subsets numbers. These changes, first reported in January 1983 (Lederman et al and Menitove et al) were very similar (but less pronounced) to those seen in individuals with a clinical diagnosis of AIDS. The implication was that these changes may have been secondary to whatever was causing AIDS – they were in a sense seen as possible surrogate markers for a predisposition to developing AIDS and might reflect the presence of the causative agent.

89) At this time the cause of AIDS was unknown and it was uncertain whether the cause in homosexual men was the same as in haemophilia. There were certainly different clinical presentations between AIDS in haemophilia and in homosexual men. Before this time lymphocyte subsets had not been assessed in people with haemophilia. As these subset abnormalities had been found in apparently well people with haemophilia in the US I considered it important that these should be assessed as part of the monitoring arrangements for patients under my care. At this time I thought it unlikely that Edinburgh patients would have been infected by an AIDS agent transmissible by blood as they had been almost exclusively treated with clotting factor concentrates derived from donors in Scotland where there were no known individuals with AIDS.

90) In the spring of 1983 when patients attended the clinic and blood was being taken for other routine investigations a small aliquot was sent for lymphocyte subset determination (labelled as 'AIDS study' on the request form). This specialist investigation was not one that was available routinely in hospitals but my colleague Dr Michael Steel set up the technique at the Western General Hospital to help with my assessment of local patients.

91) The results of the investigation of local people with haemophilia were unexpected. I had anticipated that the lymphocyte subset counts would likely be in the normal range. In summary the results revealed similar lymphocyte changes to those being reported from North America. I concluded that these changes were almost certainly not due to a possible infective aetiological agent for AIDS but likely had other causes, for example they were secondary to non-clotting factor components in the clotting factor concentrates, e.g. immunoglobulin, they might be a previously undescribed immune disturbance that was part of the 'haemophilic' condition or they might be due to a non-AIDS associated widely disseminated viral infection. At the time the cause(s) of these changes was unknown but subsequently

evidence has been published supporting all these possible causes (Bayry et al Blood;101:758-65, Jardim et al Br J Haemtol 2017;178:971-78, Hartling et al Scand J Gastroenterol. 2016; 51:1387-97) (WITN3428035, WITN3428036, WITN3428037).

92) Having observed these lymphocyte changes it seemed only responsible to continue to monitor them.

93) It was at this point that Dr Gordon's letter appeared in the Lancet inquiring about lymphocyte subset numbers in subjects unlikely to have been exposed to a possible AIDS aetiological agent. As the results of monitoring patients in Edinburgh it seemed only responsible that I should, and did, respond with the preliminary information (which had emerged and I subsequently published a fuller description of the results of monitoring). (Ludlam et al, Lancet 1983;1: 226) (PRSE0001303) (Carr et al, Lancet 1984; 1: 1431-4) (OXUH0002842).

94) To try and investigate the immune changes in people with haemophilia further as a research endeavour we undertook some skin tests. In summary the results demonstrated a degree of immune depression which appeared to be related to the amount of Factor VIII concentrate used, suggesting that there was something 'immunosuppressive' in the therapy. At this time the NHS concentrates were relatively impure and contained many non-Factor VIII proteins, e.g. immunoglobulins. With today's knowledge there is now evidence that infusion of immunoglobulin can alter immune function (e.g., Bayry et al, Blood 2003: 101:758-65) (WITN3428035) and this is a possible explanation for some of the immune changes which we observed.

95) In September 1984 a paper appeared in the British Medical Journal reporting anti-HTLVIII prevalence in people with haemophilia in London. This was the first I learned that Dr Tedder, Virologist, had set up an anti-HTLVIII test as a research project. I got in touch with him and he agreed to test a small number of samples. He was getting many requests and could only offer to assess a small number. I arranged to have *10* serum samples taken from the deep freeze and sent to him. He phoned me one evening with the results and I was very surprised and shocked to learn that 3 people who had been treated exclusively with NHS products were anti-HTLVIII positive. He agreed to test some further samples and the results demonstrated that exposure to HTLVIII had probably mostly occurred by a single

batch of Factor VIII concentrate (what has become known as the 'implicated' batch).

96) This was one of the first instances when it was clear that the NHS blood supply had become contaminated by HTLVIII which could infect recipients. I reported this immediately to SNBTS and Prof Bloom as Chairman of UKHCDO. The result was a high-level meeting in London on the 10th December 1984 at which the decision was taken to recommend preferential use of heat-treated concentrates (as some evidence had emerged a short while previously that HTLVIII was heat-labile). As SNBTS had undertaken some preliminary assessment of heat-treating NHS factor VIII concentrate it was possible to offer it to all patients in Scotland in December 1984. As a result Scotland was the second country in the world to enable all patients with haemophilia A to receive heat-treated factor VIII concentrate. Subsequent studies demonstrated the HTLVIII safety of heat- treated Scottish factor VIII concentrate (Cuthbert et al Vox Sang 1988; 54:199-200) (STHB0000159).

97) Mr Mackie was aware that I undertook assessment and research into the safety of blood products. He will have been asked on appropriate occasions if a little extra blood could be taken concurrently with samples being taken for conventional and long standing investigations (an additional venepuncture would not be necessary). The volume of blood taken on any one occasion for non-immune and HTVLIII test would be about 20 mls and with lymphocyte and virology an extra 10 mls (total up to 6 teaspoons). For conventional investigations 4-5 tubes of blood would be necessary and for lymphocyte and virology tests an extra two tubes were filled. It is difficult to take more than about 30 mls of blood on any one occasion (especially using a thin needle as was customary for people with haemophilia) because the process is slow. It is therefore unlikely that more than 50 ml (10 teaspoons) of blood would have been collected on any one occasion.

98) Mr Mackie will have been aware of my research interest in the safety of blood products by a variety of means, for example he will have been asked on occasions if a little extra blood could be taken for research, he received a letter from me about hepatitis research and the use of stored blood samples (and agreement by Ms Mackie was given). I wrote asking Ms Mackie if we could have a research blood sample from her for some genetic tests and she kindly agreed to help (WITN3428033).

99) Mr and Ms Mackie highlight the publications that arose from my safety investigations. The vast majority of the results reported are from laboratory investigations used to monitor patients' clinical medical status. Ms Mackie states in paragraph 89 of her statement that she discovered research papers setting out dates of birth and death. I do not recall ever using such data in any published papers.

At paragraph 30 Ms Mackie inquires about why I would have asked Mr Mackie if he would be kind enough to donate some factor VIII free plasma at the Blood Transfusion in 1983. She was also invited by letter to give a blood sample for genetic research.

100) The Blood Transfusion Service, the Protein Fractionation Centre and the blood coagulation laboratory in Edinburgh needed to have plasma free of Factor VIII in order to measure Factor VIII during the manufacture of NHS Factor VIII concentrate and the Factor VIII level in patients' plasma. The service depended upon the generosity of patients to help in this way.

101) Paragraph 31 inquiries about Ms Mackie being asked to give blood because we were assessing the utility of new genetic tests we had established for tracking haemophilia genes in families. At this time it was not possible to characterise the individual genetic change causing haemophilia in a particular individual. The best that could be achieved was to track genetic markers close to the Factor VIII gene. These markers had one or more alleles (variations) and they were often only useful when individuals had different alleles. My recollection is that the one we were assessing was ST14 and Ms Mackie's blood would be used for this purpose (Gitschier et al Nature 1985;314:738040) (DHSC0002249_042).

102) Subsequently I wrote asking if it could be used for hepatitis research (WITN3428033). Neither this sample nor any other stored sample, as far as I recall, was ever used to test Ms Mackie for HIV.

Ms Mackie in paragraph 32 indicates that Mr Mackie had never given consent or agreed to a hepatitis C test.

103) It was well known to Mr Mackie that he had a form of hepatitis, other than hepatitis B. This would be known as non-A non-B hepatitis but it might have been known just as hepatitis to Mr Mackie. Non-A non-B hepatitis became known as hepatitis C after the identification of the virus in 1989. It was thus not a new diagnosis. Mr Macke was informed in 1990 by letter from Dr Chapman that a new hepatitis test had become available and was under evaluation. In 1993 he was seen in the clinic and told of the result of the hepatitis C test. It would have been explained that hepatitis C was a more specific name for non-A non-B hepatitis.

Ms Mackie claims to have been repeatedly ignored when raising issues around the negative side effects of medication in paragraphs 69-71. She attributes Mr Mackie's difficult behaviour to his medication.

104) I do not remember anyone suggesting that Mr Mackie's behaviour was caused or exacerbated by his medication. At this time he was under care for his HIV at the infectious diseases until at the Western General Hospital. Dr Brettle as the consultant in infectious diseases was responsible for prescribing and monitoring his therapy for HIV. Mr Mackie was also seeing Dr Ann Tait, Consultant Psychiatrist at the Western General Hospital.

105) The meeting Ms Mackie describes with me and Staff Nurse Shea did take place although it was not just about his behaviour as she sets out. Rather it was a much wider meeting, around treatment options as well as Mr Mackie's difficulties in attending the haemophilia centre. The meeting referred to (on 24 March 2003) was the second of two meetings, which were attended by other staff from the hospital. The positive outcome of these meetings was that I arranged to regularly review Mr Mackie at a lunchtime clinic appointment (as he had difficulty attending a morning clinic, and I had other clinical commitments in the afternoons.) These new arrangements worked well and this was a very positive outcome of the meetings. I have appended minutes of two meetings (WITN3428030, WITN3428031).

Ms Mackie indicates that every time she requested a copy of Mr Mackie's case notes from the Royal Infirmary there was a difficulty in obtaining them. She also sets out that when she received them the period after 1984 was missing along with entries relating to HIV and AIDS.

106) So far as I recall I was never consulted by the hospital when Mr Mackie, or any other patient, requested case notes. Thus when patients were given their case notes I neither knew they had been requested nor asked about what records might be available. Ms Mackie wonders where the records are in relation to HIV/AIDS.

107) As I do not know what medical records have been given to Ms Mackie, and therefore cannot evaluate whether a complete set was provided. I wonder whether the haematology/haemophilia computer records have been provided.

108) The hospital developed a haematology record keeping computer system in the early mid-1980s. This recorded basic demographic information, diagnosis and laboratory data, and for those with haemophilia in addition their immune and virology results. The haemophilia information was stored in this way separate from the case notes partly to preserve confidentiality and also because the immune and virology results were sent from the laboratories on specifically designed forms for the purpose of reporting the specialist results.

109) Most routine hospital laboratory report forms were designed to be filed in patients notes. Some of the investigations we carried out on people with haemophilia were very specialised and those investigations were specifically set up for monitoring this group of individuals. As the results of these investigations were not standard laboratory reports and they were not filed in the paper case notes but instead the results were entered into the haematology/haemophilia computer system.

Ms Mackie states that she learned I kept a 'separate file' on Mr Mackie which contained all the HIV/AIDS notes. She sets out that she asked me for those notes in 2003 but I did not provide them.

110) For those patients who were anti-HTLVIII positive I kept short 'thumbnail' sketches of pertinent clinical information along with laboratory findings. These were very useful when consulting Dr Brettle (Infectious diseases consultant, City Hospital Edinburgh). In the mid-1980s those who were anti-HTLVIII positive were keen to continue to be seen primarily at the Haemophilia Centre and not travel to another hospital for review. When treatment options first became available, e.g. pentamidine inhalations or AZT, these were managed at the Haemophilia Centre. Dr Brettle kindly came to the Haemophilia Centre and we discussed each of the patients in some detail – these short resumes about each patient were very useful

for informing the discussion. Later when additional specific anti-HIV medicines became available treatment became more complex and the patients HIV management I was keen that care of this aspect was taken over directly by Dr Brettle at his clinical unit.

111) I kept a small number of notes (no more than a single sheet of paper for each patient) separate from the main hospital case records in relation to people with haemophilia who came to see me early in 1985 in response to the December 1984 meeting, the circular letter written to all patients and the encouragement of the haemophilia staff to inquire about their anti-HTLVIII status. These notes were kept separate because as a team we decided at this time that we would not make any record related to HTLVIII or AIDS in the patients' notes because of discrimination against positive patients even within the hospital. From a safety point of view for hospital staff etc all people with haemophilia who had received factor concentrates were considered as a 'risk of infection'. This ensured that individual patients were not disadvantaged or discriminated against.

112) When I told Mr Mackie of his HTLVIII status in January 1987 the hospital was much more accommodating to HIV positive individuals and by this time we were able to write about HIV in case notes. Therefore I do not think I would have held any information on Mr Mackie in the small file described above.

Ms Mackie indicates in paragraph 76 and Mr Mackie in paragraph 14 that I was not prepared to tell her about the 'AIDS study' at a meeting in 2003 but instead said "That's all in the past."

113) I do not recall the meeting at a clinic in 2003 at which Ms Mackie states in paragraph 76 of her statement that she inquired about the 1983 AIDS Study. I note that she states that there is a record in the case notes that we had discussed this. Although I cannot recall the occasion I would have offered a full explanation about our investigation of lymphocyte subsets and why the assessment had been undertaken. I would not have said 'That's all in the past'. I would have answered all questions and explained how the 'AIDS Study' fitted into the overall programme of monitoring patient safety particularly in relation to viral infections.

Ms Mackie states in paragraph 88 that I ignored the risks of AIDS infection to her, Mr Mackie and their son for the sake of my 'own non-consensual scientific research and own personal kudos'.

114) The risk of people with haemophilia developing AIDS infection even in 1984 when treated exclusively with Factor VIII prepared by SNBTS is Scotland was considered low and less than those using Factor VIII prepared by the Blood Transfusion Service in England and lower than recipients of commercial Factor VIII for reasons explained elsewhere. I was cognisant of the then current thinking in terms of risk (set out in detail above).

115) My principal responsibility was the care of patients and to ensure they were managed in the most appropriate way. At all times national guidelines were followed in relation to treatment.

116) Until I received the result of the first anti-HTLVIII results from Dr Tedder I considered the risk of infection by HTLVIII in patients attending the Edinburgh centre and receiving NHS concentrates to be low.

117) In paragraph 88 Ms Mackie refers to the 'AIDS Study' and goes on to state that 'Dr Ludlam chose to ignore the risks….for the sake of his own non-consensual scientific research and his own personal kudos.' As set out in my response in paragraph 3.2 (above) the 'AIDS Study' came about precisely because I was aware of the potential risks of AIDS in those with haemophilia and considered it important to try and monitor the state of health of those with the condition. I am sorry that Ms Mackie sees my efforts being towards my 'personal kudos' when I considered that I was helping patients under my care and contributing to the wider understanding of alterations to the immune system in those with haemophilia.

Ms Mackie in paragraph 88 claims that Mr Mackie 'took so much care in his younger life to enable him to lead a normal life and Dr Ludlam took it all away'.

118) Severe haemophilia is a major life-long clinical disorder that has many manifestations and complications and treatment is not always straight forward. My responsibility was to lead a team of specialist healthcare staff to help those with haemophilia to lead as normal a life as possible. This has always been my aim and I am distressed to read that Ms Mackie considers I prevented Mr Mackie from

leading a 'normal life'. We did our best to address his evolving life over many years and his very extensive case records provide evidence of our care of him.

119) Mr Mackie was infected by the "implicated" batch of therapeutic Factor VIII concentrate, a tragic medical accident that occurred at a time when I and my peers considered the risk from Scottish NHS blood products to be low.

In paragraph 22 Mr Mackie considers he was used as a 'guinea pig, lab rat, for research.' Later in paragraph 56 he states that 'haemophiliacs at the Royal Infirmary of Edinburgh would have been better served if Dr Ludlam had informed us of the risks of AIDS' and 'perhaps if he had acted more like a treating doctor than a scientist then at least 16/18 of his patients would not have been infected with HIV/AIDS.'

120) My first priority was to provide up to date clinical care for people with haemophilia both at an individual patient level and also in a clinical setting that would provide the best care within the resources I could acquire. My role and responsibilities as a clinical scientist and the research undertaken are directed by clinical practice and the needs of patients. Being a good clinician and a good clinical scientist are not mutually exclusive but rather each complements the other to the benefit of both.

121) By far and away the majority of investigations undertaken, even those which were research funded, were with the aim of ensuring that patients were monitored and therefore managed optimally. This is considered more fully in paragraph 3.20 (above).

122) I also had a wider responsibility particularly to convey to the medical community what was being learned from the monitoring of patients so that the information could be used to help improve the care of others. This was magnified in light of the very new and aggressive infection we were faced with. To not do so would probably lead to serious criticism, especially when working in a teaching hospital.

123) As a clinician I would suggest that it was my endeavours to prioritise patients to local NHS produced clotting factors that substantially reduced the risk of HTLVIII infection. Had I responded to strong patient demand for home therapy in the early 1980s by purchasing commercial clotting factor concentrates (as happened in

many parts of the UK) it is possible many more patients in Edinburgh would have been infected by the AIDS virus.

124) I have come to appreciate that the group of patients exposed to the 'implicated batch' being referred to as the Edinburgh Cohort does make some patients feel stigmatised. And I am sorry about this. It was a way of helping those reading the publications to understand the context of the results being reported.

B. Responses to issues raised in the extensive paragraph 95 of Ms Mackie's and paragraphs 38-53 of Mr Mackie's statements which are not raised as criticisms in the Rule 9 request of 20 June 2019

'AIDS Study'

125) The investigations labelled as 'AIDS Study' have led, I believe, to misunderstanding and in retrospect this would perhaps have been avoided if the investigations had been labelled a 'lymphocyte immune tests.' These investigations were undertaken because of AIDS arising in people with haemophilia in the US and not because I considered that those with haemophilia attending Edinburgh were at high risk of infection. Mr and Ms Mackie's statements indicate that I was aware of the risks of AIDS in people with haemophilia in the Spring of 1983 and I should have alerted Mr Mackie to the possibility. I was certainly aware that a small number of individuals with haemophilia in the US had developed AIDS but I considered the risk of a possible blood transmissible agent contaminating the Scottish plasma supply was small. The lymphocyte immune tests undertaken at that time were because I perceived the risk of contamination was small and the test results would not be a response to a possible transmissible AIDS agent. I anticipated that the lymphocyte test results would be normal and was very surprised that abnormalities were present. Having detected these abnormal results it was only responsible that I should monitor them particularly as the reason of the abnormalities was uncertain.

Publications

126) The statements quote from some of the publications arising as a result of investigations of patients attending the Edinburgh Haemophilia Centre. The vast majority of the investigations were undertaken as part of the appropriate

monitoring of patients' clinical assessment. Some of these assessments were selected for documenting in the publications of the consequences of the very unfortunate HTLVIII infection. The aim was to provide an observational narrative of a group of patients, some of whom, but not all, had become exposed to HTLVIII.

Ethical Approval

127) The original studies in 1983 were undertaken without ethical approval because they were to monitor the clinical status of the patients for their benefit. Ethical approval was sought and granted in 1985 as a consequence of the funding of the subsequent investigations being raised from a source of research support. These were investigations which I considered necessary from a clinical perspective but which I could not carry out in the NHS (and I have discussed these extensively above). Patients were asked if a little extra blood could be collected for research studies when samples were being taken for routine monitoring tests. As described above the extra amount was small. The storage of samples was considered good laboratory practice and on occasions allowed results of investigations to be checked.

Virulence of the HTLVIII infection

128) Mr and Ms Mackie suggest that because it appeared that the HTLVIII infection was relatively virulent that this information should have been acted upon by informing Mr Mackie earlier about his infection. The relative apparent virulence of the infection only became apparent in 1988 as part of our monitoring of the patients and we therefore learned of this some considerable time following Mr Mackie being informed of his infection.

Comparison of HIV progression in patients treated with different Factor VIII concentrates.

129) In paragraph 50 of Mr Mackie's and extended paragraph 95 of Ms Mackie's statement reference is made to a retrospective observational study to assess whether the type of Factor VIII concentrate affected HIV progression. This study was undertaken because some weak evidence was published suggesting that use of 'purer' Factor VIII concentrates might result in a slower decline on immune function in those with HTLVIII. Our retrospective study was possible by comparing

patients treated with ion-exchange prepared SNBTS concentrate and those with monoclonally purified English BPL product. The result of the investigation was that there was no difference detectable between the two groups. (Hay et al British Journal of Haematology 1998 10632)

In paragraph 5 of Ms Mackie's statement she criticised the arrangements in the Haemophilia Centre in Ward 23. The response below substantiates and expands what Ms Mackie records in paragraph 7 of her statement about the treatment arrangements and their improvement in about 1983.

130) The Haemophilia Centre in 1980 only consisted of a room approximately 20 feet x 10 feet in the entrance corridor to Ward 23. Patients could come to this room at any time with a bleed and be seen by a doctor and receive appropriate treatment. There was no privacy for the patients and often, especially in the mornings, several would be present and were obliged to give details and be examined in front of others. Treatment was mostly with cryoprecipitate and the patients who were able often set up the intravenous infusions themselves by acquiring the necessary equipment from the ward stores as this was often the quickest way to get the therapy. On many occasions the drip sets and other items were not cleared away before the patients left. This situation, in my view, was entirely unsatisfactory and what was needed was privacy for the patients and a nurse to help with their assessment and treatment.

131) I was eventually able to secure funds from the hospital to partition the room into a small waiting and treatment room and very small consulting room just large enough for an examination couch, a sink unit and work surface and a place for two filing cabinets to store the latest volume of each patients' case notes. This allowed the patients to be seen in privacy and their case notes to be immediately available for consultation and for adding a clinical record of the visit. The larger task was to secure the position of a haemophilia nurse – this posed two difficulties; one it was a relatively high recurrent expense for the hospital, and the other was getting acceptance that the nurse could take blood samples and administer intravenous treatment (this being an almost novel responsibility for a nurse at the time). Once the two challenges had been overcome a very competent person was appointed to the post of Haemophilia Sister. At this point by about 1983 the arrangements in the Haemophilia Centre in Ward 23 had been transformed in that it was then overseen by a fulltime Haemophilia Sister who could attend and treat the patients.

C. Responses to questions in the Rule 9 request dated 15 August 2019 in relation to Ms Mackie's oral evidence on 4 July 2019

In Ms Mackie's oral evidence (page 32) she states that Mr Mackie was always asking about the safety of treatment and if he continued to do so he would be banned from the hospital.

132) I do not understand the suggestion that 'if he did not stop asking questions about the safety of Factor VIII he would be banned from the hospital'. The haemophilia medical staff who attended Mr Mackie would have been quite able to address his questions about Factor VIII safety. This was after all my principal clinical and research interest in the 1980s and my staff were therefore knowledgeable on the then current issues. I would have been quite prepared to answer his questions and would have valued the opportunity to explain my assessment of the safety issues. I cannot imagine any of the doctors working with me saying that Mr Mackie would be barred from the hospital if he asked questions.

133) I do not have any recollection of Mr Mackie inquiring about the safety of Factor VIII concentrates during the first half of the 1980s. Nor do I recall any of the staff letting me know he had inquired nor asking me for advice about questions he allegedly posed.

Ms Mackie indicates on pages 32 and 97 that Mr Mackie wished to receive cryoprecipitate rather than factor VIII concentrate. She also stated that Mr Mackie was told that cryoprecipitate was no longer manufactured and therefore not available

134) I have no recollection of Mr Mackie asking to change back to receiving cryoprecipitate. I certainly would not have told him that it was no longer made because the SNBTS was continuing to produce it.

135) Had he asked I would have reminded him that he had previous repeated bad reactions to cryoprecipitate infusions. Cryoprecipitate use would therefore have been contraindicated as reactions can be severe and occasionally fatal. Even if he did not have reactions, Mr Mackie benefited from the Factor VIII therapy by being able to treat himself at home for early bleeds rather than on each occasion having

to make a long journey into Edinburgh for treatment. Such prompt treatment of joint bleeds would have helped reduce the progressive damage to his joints.

136) Leaving aside the issue of Mr Mackie's reactions, if he had asked for cryoprecipitate, I might have agreed because I was always seeking additional supplies of NHS Factor VIII concentrate from SNBTS, and the supply available for Mr Mackie might have been offered to another patient to enable someone else to benefit from home therapy.

Ms Mackie considers on pages 38 and 39 of her evidence that I knew about her husband getting infected in the spring of 1984 at the time because he presented with a sore throat.

137) At the time Mr Mackie reported the sore throat in the Spring of 1984 he was appropriately investigated and offered antibiotic treatment at that time. It was not known at this time that HIV infection could be associated with a sore throat.

138) So far as I recall that a sore throat could be a feature of acute infection by HIV was first reported in 1985 (Cooper et al, Lancet, March 9 1985 page 537-40). Mr Mackie was seen by Dr Wensley in Manchester in 1988 and by that stage it was generally known that a sore throat could occur with HIV infection.

Ms Mackie indicates on pages 42 and 43 of her evidence that she believes that in March 1983 32 patients were being studied and that 50 percent became infected from the 'implicated' batch. She alleges that I knew at this time these haemophiliacs were going to get infected with this batch and heat treatment efficacy would be assessed by seeing how many patients became infected

139) Ms Mackie appears to consider that I knew that the 'implicated batch' of factor VIII contained HIV in the spring of 1984 and it had been heated treated and given to patients to see who might get infected. She appears to consider that this batch was used as a way of testing the viricidal efficacy of heat treatment.

140) I am appalled by the suggestion that I would have knowingly allowed a batch of factor VIII concentrate that I knew contained HIV (even with heat-treatment) to be given to patients. I categorically deny that I had any indication that the 'implicated'

batch was probably infectious until November 1984 when the results of the first ant-HTLVIII results because available from Dr Tedder.

141) As I understand her evidence it is because the blood request forms in 1983 were labelled 'AIDS study' (which was to arrange assessment of lymphocyte subsets) and because the batch number of the 'implicated batch' was written out in full, rather than the three or four digits for other batches.

142) The reason for the 9 figure number being written out in full has only recently been discovered. I asked for some background research to be done on the use of the 9 figure reference number. We have recently discovered that the implicated batch (023110090) was the first batch labelled with the 9 figure number in December 1983. It was not the very first batch so labelled, other earlier batches had been sent to Glasgow, Aberdeen and Belfast. It was however the first batch sent to Edinburgh.

143) Prior to this being received, the batches were prepared with only 3 or 4 figure references which is why earlier records show a shorter reference number.

144) I can only think that the first 9 figure reference was recorded in full to ensure the reference was correct, and it was only when we realised that the reference could be condensed to a rather more manageable 4 figure reference that we shorted it. There appears to be no significance at all in the use of the 9 figures in the records. I have provided an explanation sent to me by SNBTS in 2019 after I made further inquiries (WITN3428034).

I note that Ms Mackie states that at the December 1984 patient meeting in the Royal Infirmary that 'when Robert went to ask a question Ludlam turned round and says to Dr Forbes, "just ignore him. He's a troublemaker, and they closed the meeting down, and we couldnae ask any more questions after that".

145) This does not accord with my recollection of the meeting. I would never have said to Dr Forbes what is alleged above. Dr Forbes was a senior colleague experienced in chairing and running large meetings. Even if he had been presented with difficult or challenging questions he would have been more than capable of addressing them. My recollection of the meeting is that after initial presentations by Dr Forbes, Dr McClelland (Blood Transfusion) and myself we answered questions from the

audience. The meeting continued until all the questions had been answered before being closure by Dr Forbes.

Ms Mackie on page 71 of her statement indicates that Mr Mackie came to see me in relation following receipt of a letter about vCJD and I indicated that he could be infected by eating meat.

146) Ms Mackie says in her statement is that Mr Mackie came to see me about the vCJD issue. From what she says if appears that I told Mr Mackie that he had not had any of the batches of Factor VIII that had retrospectively been identified as having received a donation from a donor who subsequently developed vCJD. What I would have said in this instance is that there was still a possibility that he might have received a batch of Factor VIII which was infectious for vCJD but none of the donors had been identified as developing vCJD (they may have been either incubating it and were 'infectious' from their blood). I might well have indicated that vCJD was thought to be due to eating some meat or meat products. I believe amongst those who developed vCJD in the general population at least one was a vegetarian.

147) If Mr Mackie had developed vCJD there would have been an investigation to try and ascertain whether he might have acquired it from his diet or Factor VIII treatment. At that time there is no way I could have balanced the likely source between diet and Factor VIII concentrate.

Ms Mackie in her statement on page 74 states that 'they treat haemophiliacs not even as patients, not people, they just treat them as experiments'.

148) I can understand Ms Mackie's view of what appears to be a feeling of abandonment by doctors when the issues raised by Mr Mackie's medical situation are complex, difficult and ready solutions are not apparent. At such times I appreciate that the results of blood tests may not provide the help that is needed and insight from research tests may not at that moment be helpful and as a result these are seen as an unhelpful intrusion.

Ms Mackie states on page 98-100 that she does not like my attitude to her when we meet. She also refers to an occasion when I concluded a meeting by pushing in my chair and stating "That's all in the past."

149) I always try to be welcoming to Ms Mackie when we meet. I am sorry that she has felt ignored, I was always happy to include her in the consultation when she came with Mr Mackie.

150) I wonder whether we perhaps did not get off to a good start when we first encountered each other. I well remember an occasion when I saw Mr Mackie (a little while after he had got married) when he presented with a medical problem in the clinic room. After I had seen him and organised treatment I left the room and walked through the waiting room. I think Ms Mackie was sitting in the corner. I had not met her previously nor been introduced to her. I hesitated, wondering whether I should say something to her, but not being certain who she was I went on my way. I have always regretted not going back to ask Mr Mackie if she was his wife in the waiting room and to ask if she would like me to speak to her. Had I done so I wonder if our future rapport might have been better.

151) As I have set out elsewhere I have never concluded a meeting in the way described. I would not have refused to answer questions by stating 'that's all in the past'.

Ms Mackie on page 100 of the transcript states that Mr Mackie was told that it would be necessary 'to watch Dr Ludlam because he was employed as a scientist and not as a treating doctor' when he was appointed.

152) I was appointed by the Lothian Health Board as a consultant haematologist primarily to provide care for people with haematological disorders and to help provide a laboratory service for the Royal Infirmary and South Edinburgh. I was also offered a part-time Senior Lecturer position at the University of Edinburgh to assist with teaching and research.

153) The functions of a 'treating doctor' and a 'clinical scientist' are not mutually exclusive. I would suggest that a doctor with experience of treating patients is in a good position to know what studies as a clinical scientist are likely to be most useful. Conversely what is learned and evaluated as clinical scientist is brought to bear on clinical practise. Each role complements the other to the benefit of both.

Response to Ms Mackie's statement about treatment which was not highlighted in the Rule 9 request of 15th August 2019.

Treatment of Mr Mackie on 7th June 1981 with Armour factor VIII concentrate as described on page 24-25 of the transcript of Ms Mackie's appearance on 4th July 2019.

154) At the Inquiry session Ms Mackie describes Mr Mackie attending for treatment of a bleed on 7th June 1981 which is described in the case record as being a 'severe left elbow bleed of one hour's duration.' The record of the treatment indicates that it was manufactured by Armour, i.e., it was a commercially manufactured factor VIII concentrate. Unfortunately Mr Mackie suffered a reaction to this therapy of sufficient severity that it appears he was treated with cortisone.

155) Mr Mackie was normally treated with SNBTS factor VIII concentrate at this time and on this occasion he should have received this therapy. It would appear that an error was made in issuing him with the Armour concentrate. I hope we apologised to Mr Mackie at the time. I would certainly want to do so now.

Other Issues

156) There are no other issues I wish to raise in response to Mr and Ms Mackie's evidence, either oral or written. I hope my explanations help them understand I only ever tried to do my best for my patients.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 25/11/20

Table of exhibits:

Date	Notes/ Description	Exhibit number
6 April 2005	Letter from Professor Ludlam to the GMC Fitness to Practise Directorate	WITN3428028
Undated	Edinburgh Haemophilia Guidance for HIV counselling	WITN3428029
18 March 2003	Record of meeting with at Haemophilia Centre	WITN3428030
24 March 2003	Record of meeting with at Haemophilia Centre	WITN3428031
1 October 1987	Letter from nursing sister	WITN3248032
27 January 1986	Letter from Professor Ludlam	WITN3248033
Oct/Nov 2019	Emails to the SNBTS	WITN3428034
2003	Bayry et al, Blood 2003: 101:758-65	WITN3428035
2016	Hartling et al Scand J Gastroenterol. 2016; 51:1387-97	WITN3428036
2017	Jardim et al Br J Haemtol 2017;178:971-78	WITN3428037