Witness Name: Dr Michael McEvoy
Statement No.: WITN4742001
Exhibits: N/A
Dated: 25 February 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR MICHAEL MCEVOY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 10 November 2020.

I, Dr Michael McEvoy, will say as follows: -

Section 1: Introduction

1. Please set out your name, address, date of birth and professional qualifications.

1.1 Dr Michael William McEvoy FRCPath.
Date of Birth is GRO-C 1941.
My address is known to the Infected Blood Inquiry.

2. Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.

2.1 1966/7 H.O. posts, medicine, neurosurgery, paediatrics (including haemophilia therapy pre-cryoprecipitate)
1967 School Med. Officer, Dudley.
1967 SHO Path. E. Birmingham Hospital

1968 Registrar Pathology EBH

1969 Registrar Pathology/Haematology. United Birmingham Hospital (UBH) Primary MRCPath.

1970 Senior Registrar Haematology UBH rotation scheme.

1 year Birmingham Children's Hospital (Professor John Stuart) specialising in childhood malignancy, haemophilia, including haemarthrosis rehabilitation, surgery cover, haemostatics. Use of cryoprecipitate when available.

1971 1 year at West Midlands Blood Transfusion Service (Dr. George Bird) specialising in cryoprecipitate production. Undertook some research into F. 1X concentrate production.

1972 1 year Coventry Hospitals (Professor Keith Shinton) specialising in general haematology, laboratory and clinical work, laboratory management, haemoglobinopathies, haemophilia.

1973 Queen Elizabeth Hospital Birmingham specialist in general haematology, haemophilia, Final MRCPath.

1974 Locum consultant posts around the region

1974 (September) Appointed Consultant Pathologist (Haematology) Harrogate Hospitals. This was a new appointment to comply with the then policy of the government to develop "District General Hospitals" that would offer a full range of secondary services to the local area. Thus Harrogate Hospital had single handed services in the minor specialities (ENT Haematology etc.). My remit was to provide clinical and laboratory services for the district. In addition, I was Director of Pathology, shared the autopsy load with the histopathologist, and had administrative charge of microbiology. I held this post until I retired in April 2003.

2.2 Whilst I have endeavoured to answer the questions that have been asked, some of these questions relate to matters which occurred 40 or so years ago. For the past 17 years, since my retirement, I have not practised as a doctor and so my answers to these questions should be seen in this context.

3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

3.1 I was not a member on any committee or held any office.

4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements, reports or documents that you provided.

4.1 To the best of my recollections I have had no involvement in any of the areas described above.

5. The following questions are focused on your role as a consultant haematologist and centre director at Harrogate General Hospital, but please refer to the Leeds Haemophilia Centre where appropriate as an umbrella centre for Harrogate General Hospital

Section 2: Decisions and actions of the Harrogate General Hospital ("the Hospital")

6. Please describe the roles, functions and responsibilities of the Hospital (insofar as relevant to the Inquiry's Terms of Reference) during the time that you worked there.

6.1 At the time of my appointment, I was one of the first clinically trained haematologists in the region. As we were defining our own roles and agreeing on the complexity of cases that it was appropriate for us to treat, we met weekly at Leeds General Infirmary (LGI) to review cases, slides, and hold a joint ward round. Unfortunately, at that time, there was no *clinical haematology* team at St James's Hospital (St James's) where the Haemophilia service was based. This was run by an *Immunologist* (Dr Layinca Swinburne) who did not attend these meetings. However, I was in regular contact with her and also with Dr Peter Jones (Newcastle) and both of them informed the patients who lived nearer Harrogate that I was prepared to treat clotting disorders. I thereby amassed a total of some 20-30 patients with clotting disorders of varying severity who chose Harrogate as their treatment centre. Of these about a dozen were haemophiliacs of a moderate to severe status of which two thirds needed regular treatment and 6/7 had developed HIV. The remainder had other clotting disorders. Being single handed precluded my attendance at many meetings, though I attended Haemophilia Centre Directors meetings and British Society of Haematology meetings when possible and all relevant regional meetings.

7. Please identify senior colleagues at the Hospital involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products, and their roles and responsibilities during the time you worked there.

7.1 Patients with haemarthrosis were referred occasionally to an orthopaedic surgeon but usually treated conservatively by me and the senior physiotherapist, Mrs Liz Kelley who had undertaken specialist training. Cryoprecipitate was prepared in the transfusion laboratory and given by me or an A&E doctor. Dental care was provided by Mr C Mellor at his surgery with me providing appropriate cover medical cover for these patients at the Hospital. When blood borne infections were relevant, I received considerable support from my close colleague Dr Mike Barnham, consultant microbiologist.

8. Please identify how you interacted with the Leeds Haemophilia Centre as the umbrella centre for Harrogate, and identify senior clinicians at the Leeds Haemophilia Centre and their responsibilities.

8.1 Initially, I sought advice from Dr P Jones (Newcastle) or Dr Swinburne (St James's) but, in about 1985 Dr Tony McVerry was appointed as Haemophilia Centre Director at St James's and he became my point of contact.

9. Please describe your role and responsibilities as consultant haematologist at the Hospital and how, if applicable, this changed over time.

9.1 These were as described in the forgoing paragraphs. Latterly, the swathe cut by HIV, together with the increase in home administration and the development of a comprehensive centre at St.James's reduced the need for the Harrogate haemophilia service and it became subsumed. My role in the first 10 years was running regular review clinics for patients with clotting disorders. With the increased availability of the service at St James's we found that patients preferred to go to the clinics at St James's, but we facilitated the patients' local collection of factor concentrates from the Hospital and also answered questions that they had about their treatment. If patients required surgery they would be seen at St James's. Therefore over time I had less of a role with patients. We did not have any new patients after Dr McVerry started at St James's.

10. Please describe your work at the Hospital insofar as it involved the care and treatment of patients with bleeding disorders; the care and treatment of patients infected with hepatitis and/or HIV in consequence of infected blood or blood products; and the care and treatment of patients with blood or blood products other than for the treatment of bleeding disorders.

10.1 Prior to the service being subsumed with that of St James's the main function was the therapeutic administration of factor 8. No elective surgery in haemophiliacs was performed. Routine dental care was covered. Other patients with suspected bleeding disorder were investigated and treated if required. All registered patients were reviewed on six monthly basis with me, Mrs Keilley and Mrs Margaret Hanson (medical social worker) present.

11. Approximately how many patients with bleeding disorders were under the care of the Hospital when you first started working there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so). What proportion were children and what proportion adults?

11. For accurate figures please contact Harrogate Hospital. However, my estimate was that we built up the number of patients to between 20 and 30 one being a child. Of that I think that there were approximately a dozen that required Factor 8. Please see my answer to question 6 for more detail.

12. What decisions and actions were taken, and what policies were formulated, by you and by the Hospital, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you were there? In addressing this question please answer, to the extent that you are able to, the following questions:

a. How, and on what basis, were decisions made about the selection and purchase of blood products?

b. What were the reasons or considerations that led to the choice of one product over another?

c. What particular products were used for treating patients, over what period of time and for which categories of patients?

d. From where were the factor concentrates used at the Hospital sourced?

e. What role did commercial and/or financial considerations play?

f. What involvement did you have?

12.1 I chose the haemostatic products. First choice was the NBTS product either cryoprecipitate or factor concentrate. When these were not available, I chose Armour Pharmaceuticals USA sourced factor 8. My reasons for choosing Armour was because others were using it (I think that Dr Swinburne used this product), Armour provided a good local contact, it was a reliable supply (which was important to service the needs of our patients) and Armour were able to sell this to us in the small quantities that we needed. As far as I can now recall there was no general source of advice to determine which commercial blood products were to be preferred. I received no inducement of any kind to select this product. My preference for the BPL (NHS) product was based on donor selection and loyalty to a service in which I had trust.

13. What was the relationship between the Hospital/you and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Hospital's and your decisions and actions?

13.1 None in answer to both. There was no relationship between me, the Hospital and the pharmaceutical company supplying these products.

14. If the responsibility for the selection and purchase of blood products lay with an organisation other than the Hospital, please specify which organisation and provide as much information as you can about its decision-making.

14.1 It was my decision on the basis set out in the answers to questions 12 and 13.

15. How did you decide which products to use for particular patients? To what extent, if at all, were patients offered a choice, or given a say, as to what products would be used?

15.1 As I have said previously, the first choice was for NBTS products and then if not the Armour Pharmaceuticals product.

16. On 17 September 1991 you wrote to Dr Cash of the Scottish National Blood Transfusion Service and commented that you have been "coming under pressure" from the Haemophilia Society and sales representatives regarding use of high purity factor products. Please describe the views of Dr Cash that you agreed with. Please describe in further detail the pressures that you refer to in the letter [SBTS0000024_086].

16.1 In an opinion piece in the BMJ the week before I wrote my letter, Professor Cash had said that he was aware that some of the US pharmaceutical companies were suggesting that the high potency products (which they were promoting) were more beneficial to patients that had already contracted HIV. He suggested that these companies were pressurising the Haemophilia Society to use their products when the only evidence for what these companies were saying was from their own material and that there was no independent evidence to support what they were saying.

17. What alternative treatments to factor concentrates were available for people with bleeding disorders in the 1970s and 1980s? What were, in your view, the advantages and disadvantages of those alternative treatments? What use did you make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

17.1 There were limited alternatives which were, bed rest, analgesia, ice-packs, fresh frozen plasma. None of these were as effective as the factor concentrates and so although these were alternatives they were not viable alternatives. It was possible to revert to cryoprecipitate but this cannot be standardised and some patients need to have antihistamine cover to guard against potential allergic reactions. In summary once a patient has been transferred to factor concentrates it is difficult to revert to previous sources of treatment and maintain the standard of care.

18. What was your policy and approach at the Hospital in relation to home treatment for patients with bleeding disorders? Did that policy and approach change over time and, if so, how?

18.1 I was in favour providing home treatment provided that the circumstances and venous access was satisfactory for the patient. We had a relatively small patient base and so we followed the practice of the larger centres such as St James's. In time the care of these patients was largely taken over by St James's as referred to in my answer to question 9.

19. What was your policy and approach at the Hospital in relation to prophylactic treatment for patients with bleeding disorders? Did that policy and approach change over time and, if so, how?

19.1 Although I was initially hesitant, fearing over use and potential development of inhibitors, we came to follow the practice of the larger centres such as St James's, as I refer to in my answer to question 9.

20. What was your policy and approach at the Hospital as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and, if so, how?

20.1 The variability of the product (cryoprecipitate), the potential for allergic reaction and the practical difficulties that cryoprecipitate poses in

administering the product to patients meant that at the time of the initial introduction of blood concentrates, we were keen to switch.

21. To what extent, and why, were patients with mild or moderate bleeding disorders treated at the Hospital with factor concentrates?

21.1 As far as I can now recall none of our patients suffering from mild to moderate bleeding disorders needed blood products.

22. What, if any, viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at the Hospital in consequence of the use of blood products?

22.1 None

Section 3: Knowledge of, and response to, risk

23. At the time you took up your position as consultant haematologist at the Hospital (and please state when that was), what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

23.1 I became a consultant in September 1974. My knowledge was from my experience in Birmingham and with the Blood Transfusion Service (BTS). At that time we did not have the ability to screen for the infections that subsequently became a problem. At the time the most important factor was donor selection. As HIV became more apparent, donor selection and screening was introduced. Further knowledge came from regular regional meetings at the Blood Transfusion Service, Medical Journals and regular formal discussion with colleagues in the field.

24. What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products, and (ii) the use of NHS blood products?

24.1 The US products relied on paid donors which potentially raises the risk profile of these products whereas the NBTS had a recruitment protocol which was superior as it used unpaid, screened donors.

25. What advisory and decision-making structures were in place, or were put in place at the Hospital and and/or within the area covered by the Leeds Comprehensive Care Centre, to consider and assess the risks of infection associated with the use of blood and/or blood products?

25.1 I refer to my answer to question 23 with regard to how my knowledge was informed and updated. There were no formal decision making structures at the Hospital, but I followed the treatment used at the Leeds Comprehensive Care Centre.

Hepatitis

26. At the time you took up your position as consultant haematologist at the Hospital, what was your knowledge and understanding of the risks of the transmission of hepatitis, including HBV and NANB hepatitis (HCV), from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

26.1 I cannot recall dates. I think that cross infection of Hep B and NANB was recognised a little later than 1974. My knowledge at the time would have been from similar sources as described in the answer to question 23. From around 1977 policy was developed with Dr Barnham (consultant microbiologist) and we had daily meetings to share new information and review any changes that may have been required for our process.

27. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

27.1 It was a similar process to that described in the answer to question 26 above.

28. What, if any enquiries and/or investigations did the Hospital and/or you carry out or cause to be carried out in respect of the risks of the transmission of hepatitis? What, if any, information was obtained as a result?

28.1 I do not have any specific recollections. However, once we established our relationship with Dr Barnham, our cross-infection process was rigorously reviewed, revised where necessary and complied with.

29. What, if any, actions did you and/or the Hospital take to reduce the risk to patients of being infected with hepatitis (of any kind)?

29.1 Please see my answer to 28 above.

HIV and AIDS

30. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

30.1 I cannot be specific about dates of knowledge, but in general terms, due to the interactions that I have previous described in answers to questions in this section (3) of my statement, I knew of reports in the USA, that Communicable Disease Reports indicated that there was a new illness in the homosexual community of New York and California and links with Haiti. Once the association with recipients of blood/blood products was made, the network of

meetings and journals spread the word and I took care not to deviate from the current advice.

31. How and when did you first become aware that there might be an association between AIDS and the use of blood products?

31.1 Please see my answer to 30 above.

32. What steps were taken by you and/or at the Hospital in light of that awareness?

32.1 Please see my answer to 30 above. National and regional advice was followed.

33. What, if any, enquiries and/or investigations did you and/or the Hospital carry out or cause to be carried out in respect of the risks of transmission of HIV or AIDS? What information was obtained as a result?

33.1 In line with regional and national policy we counselled tested and gave post-test counselling to all patients that had received blood concentrate products.

34. What, if any, actions did you and/or the Hospital take to reduce the risk to your patients of being infected with HIV?

34.1 For a short period we reverted to the use of cryoprecipitate whilst we sourced heat treated and microbiologically inactive products. We stressed the potential dangers of blood and blood products and the need for diligence in their use to all colleagues. Together with Dr Barnham and the cross infection sister, we reviewed the venepuncture techniques used by our phlebotomists and alerted all staff to the potential dangers of infected blood and body fluids.

35. Did you continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

35.1 Please see my answer to 34 above.

Response to risk

36. Did you or the Hospital take any steps to ensure that patients (or their parents) and/or the public were informed and educated about the risks of hepatitis and HIV? If so, what steps?

36.1 I assumed the role of "lead consultant" in the spread of information within the Harrogate district. For some months, I was accepting invitations to talk to public meetings, church groups and schools (from the diocesan bishop to the teenage lad who stayed behind to chat after my sixth form talk} and, for a time, I was a trustee of a local charity set up by some local homosexual men in order to inform people at risk within the community. Once the information about HIV had been incorporated into more conventional programmes of health education, I withdrew from this role. Most of the severely affected (haemophilia) patients were members of the Haemophilia Society. The Haemophilia Society provided current information that I shared with all patients. The opprobrium of the public towards the sufferers of this disease made confidentiality essential. Local and regional professional meetings considered all aspects of the known disease.

37. Did you or the Hospital revert to treatment with cryoprecipitate for some or all of your patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

37.1 Please see my answer to question 34 above.

38. When did you begin to use heat treated factor products and for which categories of patients?

38.1 I do not recall beyond what I said above as I have no access to these records.

39. **On 27 February 1985 you wrote a letter to Dr Snape (Head of Quality Control, BPL) noting your intention to use a mixture of heat-treated commercial and 'raw' Elstree factor products when treating patients until the full stock of BPL products was heat-treated [CBLA0002071]. Please explain why this had been your intention and why you changed your mind.**

39.1 The principle was to try and ensure that patients who were HIV negative received the heat-treated concentrate. This was in limited supply and the patients had to be registered to receive it with Elstree. It was therefore our intention to use the raw concentrate for HIV positive patients. However, after further consultation and consideration I determined that this was not appropriate and so the raw concentrate was not used and I was able to register patients, who were HIV positive, with Elstree so that they could also receive the heat treated products.

40. **Do you consider that heat-treated products should have been made available earlier? Please explain your reasons.**

40.1 Heat treated concentrate was considered safer but I had no knowledge of whether BNTS could have made more heat-treated products available and so I cannot answer this question.

41. **On 3 June 1985 you wrote to Dr Smith at BPL about the protocol for the use of heat-treated factor products and changing HTLV-III positive patients from a BPL heat-treated product to an Armour heat-treated product [CBLA0002174]. Please explain the background to this letter and describe in detail the procedures at the Hospital regarding the use of heat-treated products. Please also answer the following questions:**

a. **What were the arrangements for the allocation of heat-treated product to the Hospital?**
b. **What were the "protocol demands of regular blood tests"?**

c. What was the advice of Dr Stevenson to which your letter refers?

d. From where had you obtained the heat-treated Armour product that you had previously been using?

41.1 This letter was in response to the use of Elstree Factor 8 for home treatment, and as such would be administered by the patient or the patient's carer. This means that the administration is not medically supervised. However, I became aware that Elstree only wanted their products to be used where it could be medically supervised which would have meant it only being used in the hospital. Unfortunately, initially, I was not aware that this was their requirement. Elstree's reason for requiring medical supervision was that they wanted these patients to be monitored for allergic reactions which would not be possible at home.

41.2 I therefore asked Elstree if they wanted me to change the home treatment to Armour products. I do not recall receiving an answer. However, events superseded this as the BNTS heat treated Factor 8 became registered for general (rather than just "hospital") use which included home treatment.

42. Do you consider that your decisions and actions and those of the Hospital in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

42.1 I do not think that any further precautions were required for patients, however, procedures were reviewed and revised when we became aware that we were treating patients with an infectious disease.

43. Looking back now, what decisions or actions by you and/or by the Hospital could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

43.1 As far as I am aware we followed the guidance at the time and switched to alternative products when they became available to us.

44. **What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?**

44.1 My view is that this question requires an answer from a specialist and so I do not feel competent to answer this question.

45. **Do you consider that greater efforts should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?**

45.1 Again my view is that this requires an answer from a specialist and so I do not feel competent to answer this question.

<u>Section 4: Treatment of patients at the Hospital</u>

Provision of information to patients

46. **What information did you provide or cause to be provided and/or what information was (to your knowledge) provided by others at the Hospital, to patients with a bleeding disorder:**

a. **about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates), prior to such treatment commencing?**
b. **about alternatives to treatment with factor concentrates?**
c. **before they began home treatment/home therapy?**

Please detail whether and if so how the information provided to patients changed over time.

46.1 At this stage we would have been thinking about infections that we knew about such as syphilis and malaria, which we did not discuss with the patients as these were already screened for by the BTS. We would not have spoken about NANB/Hepatitis C as these were not recognised at this time as transmissible. There were general six monthly reviews. I also saw patients when they attended for their treatment and when their condition deteriorated requiring further care.

46.2 40 years ago, the consent process was not the same as it was even at the time I retired in 2003. I cannot now recall the process that we used 40 years ago, but I anticipate that the process was influenced by the knowledge that these patients had previously received many and varied products and that these were patients that had been on cryoprecipitate. Therefore they would have been aware of possible issues associated with this type of therapy. My knowledge and understanding of the risks associated with blood products developed with the publication of medical literature on this subject.

46.3 We did advise about the environment necessary for injecting factor concentrates and they would inject at the clinic until such time as I was satisfied that they were able to do this safely.

HIV

47. When did you first discuss AIDS or HIV (HTLV-III) with any of your patients at the Hospital?

47.1 I cannot recall the date when this would have first occurred. Patients and carers were seen individually, consent for testing for HTLV-III was obtained and subsequently the results were explained. The hospital notes of all my patients were retained in a filing cabinet in my room. I do not have these records or have access to these records now.

48. Please describe how and when you learned that patients under your care had been infected with HIV. How was the testing of patients arranged and by whom was it undertaken?

48.1 Please see my answer to question 47 above. I had developed a secure system for ensuring confidentiality and was developing some experience in treating the disease.

49. How, when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by telephone? Were they seen individually or in groups?

49.1 Please see my answer to question 47 above. They were told individually in person by me.

50. What information was given to them about the significance of a positive diagnosis? Were they told to keep their infection a secret? What information was provided about the infection, prognosis, treatment options and management?

50.1 Please see my answers to question 47 to 49 above. There was a significant issue with publicity and therefore patients did generally keep the diagnosis to themselves. They were reassured that their diagnosis would be kept absolutely confidential and their notes were kept separately in my room to ensure this confidentiality was maintained.

51. What, if any, arrangements were made for pre-test counselling and for post-test counselling?

51.1 This was done within the context of the possibility of a diagnosis. Initially I performed pre and post-test counselling in person as we did not have a counsellor at that stage. However, we created a team of professionals to deal with the care needs as soon as possible.

52. What was the Hospital's/your policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?

52.1 I discussed this with the patient and in all the cases that I recall the partners/family were tested and I think that none were positive.

53. What, if any, information or advice did the Hospital provide to partners or family members of people that were at risk of infection with HIV or were infected with HIV?

53.1 I cannot recall beyond the usual cross infection advice such as protected sexual intercourse with a condom, mopping up blood safely wearing gloves, not sharing razors etc. The patients and carers/partners were taught safe techniques for venepuncture, avoidance of spillage, disposal of sharps/swabs.

54. How many patients at the Hospital were infected with HIV in consequence of infected blood/blood products? Of those infected,

a. How many had severe haemophilia A?
b. How many had moderate haemophilia A?
c. How many had mild haemophilia A?
d. How many had haemophilia B?
e. How many had von Willebrand's disease?
f. How many were children?

54.1 My best recollection is that there were 6 or 7 severe haemophilia patients and one child within the cohort referred to in the answers to questions 6 and 11 who were infected with HIV. These would have been patients infected with HIV before HIV had been identified. However, please contact the Hospital for the data required in a-f as I cannot recall this detailed information.

55. Was work undertaken at the Hospital to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached.

55.1 As far as I can recall, no patient seroconverted after first testing negative.

56. To the best of your knowledge, how many partners (or other family members) of patients became infected with HIV?

56.1 None that I recall

Hepatitis B

57. Were patients infected with HBV informed of their infection and if so how? What information was provided to them about the infection, its significance, prognosis, treatment options and management?

57.1 I do not now recall whether any haemophiliac patients became infected with HBV.

58. How many patients at the Hospital were infected with hepatitis B?

58.1 None that I recall

NANB Hepatitis/HCV

59. Were patients infected with NANB hepatitis informed of their infection and, if so, how? What information was provided to them about the infection, its significance, prognosis, treatment options and management?

59.1 I am not aware that there were any haemophiliac patients infected with NANB from the use of infected blood or infected blood products. However, there may have been some non-haemophiliac patients who became infected

through blood transfusion and these would have been referred to Professor Lisowsky who was an hepatologist at St James's.

60. When did you begin testing patients for HCV? How, when and by whom were patients informed of their diagnosis of HCV? Were they told in person, by letter or by phone?

60.1 I am sorry I cannot remember.

61. Please describe the process of testing patients for HCV. When a test for HCV became available, what if any steps were taken by the Hospital and/or by you to ensure that all patients who had received blood products were traced and invited to be tested?

61.1 I am sorry I cannot remember.

62. What information was provided to patients infected with HCV about their infection, its significance, prognosis, treatment options and management?

62.1 I am sorry I cannot remember.

63. How many patients at the Hospital were infected with HCV in consequence of infected blood/blood products?

63.1 As far as I can recall there was no clinical infection of patients as described in the question.

Delay/public health/other information

64. Were the results of testing for HIV and hepatitis (of all kinds) notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

64.1 As far as I am aware all results would have been notified appropriately.

65. To what extent, if at all, did you or your colleagues at the Hospital take into account the public health implications of HIV, AIDS, HBV, NANB hepatitis and HCV, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?

65.1 There were regular contacts with senior colleagues such as the microbiologist Mike Barnham which would have covered any relevant issues in relation to public health.

66. What information was provided to patients about the risks of other infections that could be transmitted through blood or blood products?

66.1 I cannot now remember specifics but all relevant information would have been shared with patients. Please see my answer to question 53 above.

67. What information was provided to patients about the risks of infecting others?

67.1 The patients and carers/partners were taught safe techniques for venepuncture, avoidance of spillage, disposal of sharps/swabs. The infective risks of saliva, semen and blood was stressed.

Consent

68. How often were blood samples taken from patients when attending the Hospital for treatment for their bleeding disorder and for what purposes? What information was given to them about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of those samples? Was their consent recorded and, if so, how and where?

68.1 Samples were obtained at the 6 monthly reviews. I cannot now recall the detail of the process.

69. Were patients under your care treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? Was their consent recorded and, if so, how and where?

69.1 My recollection is that the cohort of haemophilia patients that I was treating and who transferred to factor concentrate were consented and transferred on the basis of our knowledge at the time. Following this cohort (which is referred to in the answer to questions 6,11 and 54) I believe that there were no new haemophiliac patients.

70. Were patients under your care tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent for testing? Was their consent recorded and, if so, how and where?

70.1 At the time verbal consent was obtained before testing.

PUPS

71. Please detail all decisions and actions taken by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

71.1 As far as I can recall there were no previously untreated persons.

72. Did you use the term PUP or PUPS when speaking about or referring to any of your patients? If so, what did you mean by the use of the term?

72.1 As far as I can recall there were no previously untreated persons.

Treatment of patients who had been infected with HIV or Hepatitis

73. How was the care and treatment of patients with HIV/AIDS managed at the Hospital? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years to those infected with HIV?
c. What information was provided to patients/their parents about the risks and benefits of specific treatments and about side effects?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

73.1 There was no infectious diseases or genito-urinary medicine consultant available in Harrogate so I formed an association with Dr Charles Lacey, Consultant Physician, in genito-urinary medicine at the LGI genito-urinary medicine service. He reviewed the treatment available for my patients. He guided me in the treatment that I provided to them at the Hospital. I also joined the sub-group at LGI in order to ensure that we were providing a suitable initial service. We discussed management and reviewed treatment. Single rooms on medical wards were used and appropriate staff training provided. Dr Barnham (microbiology) and Dr Warren (palliative care) were involved and the local hospice offered end of life care. This service covered all patients with HIV needing admission.

74. How was the care and treatment of patients with HBV managed at the Hospital? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients/their parents about the risks and benefits of specific treatments and about side effects?

d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HBV?

74.1 Please see my answer to question 59. I did not have general responsibility for the care and treatment of patients with hepatitis (I looked after haemophiliacs and HIV patients). General hepatitis patients would have been the responsibility of the general medical department and they may have referred patients to Professor Lisowsky.

75. How was the care and treatment of patients with NANB hepatitis managed at the Hospital? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients/their parents about the risks and benefits of specific treatments and about side effects?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with NANB hepatitis?

75.1 Please see my answer to question 74.

76. How was the care and treatment of patients diagnosed with HCV managed at the Hospital? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients/their parents about the risks and benefits of specific treatments and about side effects?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HCV?

76.1 Please see my answer to questions 74.

77. What arrangements were made for the care and treatment of children infected with HIV and/or hepatitis, and how did those arrangements differ (if at all) from the arrangements made for adults?

77.1 As far as I recall these were the same for adults. We also had a close rapport with the treating GPs.

78. What involvement did you, or patients at the Hospital, have with clinical trials in relation to treatments for HIV and/or HCV? Please provide full details.

78.1 None.

79. What (if any) difficulties did you/the Hospital encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or HCV?

79.1 None.

80. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support? What kind of counselling, if any, was made available to patients at the Hospital?

80.1 Initially there was no counsellor and so I undertook this role. However, a suitable counselling service was developed, which included the use of a counsellor.

Research

81. Please list the research studies that you were involved with during your time as consultant/director at the Hospital insofar as relevant to the Inquiry's Terms of Reference, and please:

a. describe the purpose of the research;
b. explain the steps that were taken to obtain approval for the research;
c. explain what your involvement was;
d. identify what other organisations or bodies were involved in the research;
e. state how the research was funded and from whom the funds came;
f. state the number of patients involved;
g. provide details of steps taken to inform patients of their involvement and to seek their (or their parents) informed consent; and
h. provide details of any publications relating to the research.

81.1 I was not involved in any research

82. What do you understand to be the ethical principles that should guide research? Did you apply those principles to the research studies referred to above and if so, how? If not, why?

82.1 I was not involved in any research

83. Were patients involved in research studies without their express and informed consent? If so, how and why did this occur?

83.1 I was not involved in any research

84. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express and

informed consent? If so, what data was used and how and why did this occur?

84.1 I was not involved in any research

85. Was patient data (anonymised, de-identified or otherwise) shared with third parties (e.g. UKHCDO or Oxford Haemophilia Centre) without their express and informed consent? If so, how and why did this occur, and what information was provided to whom?

85.1 I do not recall any data being shared with third parties. I was not involved in any research

86. Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference.

86.1 I was not involved in any articles or studies relevant to the terms of reference.

Records

87. What was the Hospital's policy or practice as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?

87.1 As I have said in answers to questions 59 and 74 I did not have responsibility for hepatitis patients that did not have bleeding disorders and so I cannot comment in relation deaths of these patients. From my cohort that I refer to in answer to questions 6, 11 and 54, the death of the patient would not have taken place in the Hospital under my care and would usually have taken place either at home or in the hospice, and so I would not have certified death and do not know what the policy was for recording this information. I am not aware of any death certificates quoting Hep B and I neither diagnosed nor treated any patient with blood borne Hep B or NANB that I recall.

88. **What were the retention policies of the Hospital in relation to medical records during the time you were director?**

88.1 I no longer recall.

89. **Did you maintain separate files for some or all patients? If so, why; where were those files located; and where are those files now?**

89.1 No.

90. **Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the Hospital? If so, why, what information and where is that information held now?**

90.1 No.

91. **Do you still hold records or information about any of your patients? If so, explain why and identify the records or information that you still hold.**

91.1 No.

Section 5: Blood services

92. **Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, in your capacity as consultant haematologist at the Hospital.**

92.1 I had the normal relationship as a haematologist would for receiving deliveries of products etc. I was not on any committee that related to the provision of blood services.

93. What if any consideration was given to increasing production of cryoprecipitate, or producing a product with lower risk, in response to the risks associated with factor products, and what, if any, involvement did you have with any blood service (regionally or nationally) in relation to this?

93.1 Please see my answer to question 92, I had not involvement with this.

94. What, if any discussions or meetings or interactions did you have with any blood service (regionally or nationally) in relation to: the risk of infection with hepatitis from blood products; the risk of infection with HIV/AIDS from blood products; and the steps to be taken to reduce the risk of infection?

94.1 Please see my answer to question 93.

95. What if any involvement did you have with any decisions or actions taken by any blood service (regional or national) in response to the risks arising from blood and blood products?

95.1 Please see my answer to question 93.

Section 6: UKHCDO

96. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups) and the dates of your involvement.

96.1 I received information from the UKHCDO, but did not participate actively. I think that I may have attended 2-3 meetings over the years but I have no recollection of when these occurred or what was discussed.

97. During the period that you were involved with UKHCDO, please outline:

a. **the purpose, functions and responsibilities of UKHCDO, as you understood them;**
b. **the structure, composition and role of its various committees or working groups;**
c. **the relationships between UKHCDO and pharmaceutical companies;**
d. **how decisions were taken by UKHCDO;**
e. **how information or advice was disseminated by UKHCDO and to whom;**
f. **any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to: the manufacture, importation, purchase, selection or use of blood products; alternative treatments to factor products for patients with bleeding disorders; self-sufficiency; the risks of infection associated with the use of blood products; the sharing of information about such risks with patients and/or their families; obtaining consent from patients; heat treatment and other measures to reduce risk; vCJD exposure; and treatments for HIV and HCV.**

97.1 Please see my answer to question 96.

Section 7: Pharmaceutical companies/medical research/clinical trials

98. **Have you ever:**

a. **provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?**
b. **received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products?**

c. **sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?**

d. **received any financial incentives from pharmaceutical companies to use certain blood products?**

e. **received any non-financial incentives from pharmaceutical companies to use certain blood products?**

f. **received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?**

g. **undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products?**

h. **provided a pharmaceutical company with results from medical research studies that you have undertaken?**

If your answer to any of the above questions is Yes, please provide details.

No.

99. What regulations or requirements or guidelines were in place during your employment concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take to comply with them?

99.1 I do not know as I had no such involvement with these companies.

100. If you did receive funding from pharmaceutical companies for medical research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

100.1 Please see my answer to question 98.

Section 8: vCJD

101. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products?

101.1 When reports appeared in the medical press, I am sorry that I cannot be more precise.

102. How and by whom were decisions taken as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?

102.1 As far as I can recall there was no formal consent process for the *giving of blood* to a patient. We were already very careful in the use of blood but the awareness of vCJD may have influenced the practise of other doctors in their use of blood in the care and treatment of patients. There were no vCJD cases.

103. What was the process at the Hospital for informing patients about possible exposure to vCJD?

103.1 Please see my answer to question 102.

104. How and when were patients first told of possible exposure to vCJD? What subsequent notifications were provided to patients?

104.1 Please see my answer to question 102.

105. What information was provided to patients about the risks of vCJD?

105.1 Please see my answer to question 102.

106. What counselling, support and/or advice to be offered to patients who were informed that they might have been exposed to vCJD?

106.1 Please see my answer to question 102.

107. What measures were put in place, from a public health perspective, in relation to the care and treatment of patients?

107.1 Please see my answer to question 102.

Section 9: Involvement with the financial support schemes

108. What involvement did you have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation and the Skipton Fund) which were set up to provide financial support to people who had been infected?

108.1 This was attended to by our Medical Social Worker, Mrs Hanson. I have no recollection of the processes undertaken by Mrs Hanson. She was a close colleague who acted as MSW to the Haemophiliac patients and, if she had asked for a signature, then I would have signed. There were no points of conflict about eligibility that I recall.

109. To what extent did the Hospital and its staff (including you) inform patients about the different trusts or funds?

109.1 This was attended to by our Medical Social Worker, Mrs Hanson. Please see my answer to question 108.

110. Did the Hospital have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

110.1 This was attended to by our Medical Social Worker, Mrs Hanson. Please see my answer to question 108.

111. What kind of information did the Hospital (whether through you or otherwise) provide to the trusts and funds about or on behalf of patients who were seeking assistance from the trusts and funds?

111.1 This was attended to by our Medical Social Worker, Mrs Hanson. Please see my answer to question 108.

112. Did the Hospital, or any of its staff (including you), act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

112.1 This was attended to by our Medical Social Worker, Mrs Hanson. Please see my answer to question 108.

113. Was the Hospital or any of its staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

113.1 This was attended to by our Medical Social Worker, Mrs Hanson. Please see my answer to question 108.

114. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of the Hospital's patients in relation to the trusts or funds, do you consider that the trusts and funds were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

114.1 This was attended to by our Medical Social Worker, Mrs Hanson. Please see my answer to question 108.

115. On 14 December 1987 you wrote a letter to Robert Banks MP requesting an extension of compensation to those infected with HIV via transfusions.

a. Please explain your reasons for writing this letter.

b. Please describe (without identifying patients by name) the circumstances (as far as you are aware) in which two patients in the Yorkshire region were infected with HIV through a contaminated blood transfusion.

c. Please describe the response you received to your request [DHSC0006860_004].

115.1 I can recall one patient who was West African and was working in a skilled job. He received a blood transfusion in West Africa for surgery and was subsequently diagnosed with HIV. Patients who were haemophiliacs and contracted the disease through blood transfusions were included in the compensation scheme but non-haemophiliacs who contracted the disease in the same way were not included and so my letter concerned an extension to non-haemophiliac patients. My request was rejected.

Section 10: Other issues

116. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

116.1 None.

117. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

117.1 None.

Statement of Truth

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

Signed GRO-C Dr. H.W. McEvoy

Dated 25 February 2021

Table of exhibits: N/A

Date	Notes/ Description	Exhibit number