Witness Name: Dr Elizabeth Helen Moffat
Statement No.: WITN5508001
Exhibits: [XX]
Dated: 8 March 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ELIZABETH HELEN MOFFAT

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 11 February 2021.

I, Dr Elizabeth Helen Moffat, will say as follows: -

Section 1: Introduction

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

1.1. Name: Elizabeth Helen Moffat
Address: GRO-C
DOB: GRO-C 1954

1.2. Professional Qualifications: MB CHB (Glasgow), FRCP, FRC PATH

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. Employment History:

2.1.1. House Officer Falkirk & District Royal Infirmary 1977/78 in General Medicine & Surgery

2.1.2. Senior House Officer University Hospital of Wales, Pathology 1978 – 1979

2.1.3. Registrar Haematology UHW Cardiff Training Rotation in Cardiff Hospitals 1979/81

2.1.4. Senior Registrar in Haematology UHW Cardiff 1981/84 – training rotation in Cardiff Hospitals

2.1.5. Research Fellow in Haemophilia UHW Cardiff 1984 – 1988 Supervisor Professor AL Bloom

2.1.6. Consultant Haematologist Gwent Health Authority 1989 – 2009

2.2. I retired in June 2009 due to ill health with progressive multiple sclerosis. My duties as a consultant haematologist were general Haematology, clinical and laboratory, Haematology Oncology, Supervision of Blood Transfusion Practice & Policy in South Gwent and Lead for Coagulation disorders and anti-coagulant therapy in South Gwent from 1989 to 2007. I was a member of UK Haemophilia Centre Director's Organisation between 1999 and 2007, but never actually saw anyone with haemophilia in the hospital, as this was all managed through the Haemophilia Comprehensive Care Centre in Cardiff, UHW.

2.3. All patients with haemophilia in South Gwent were transferred to the care of Cardiff CCC before 1988, in other words before my tenure as Consultant Haematologist at the Royal Gwent Hospital.

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. If applicable, please ensure your answer addresses your involvement with the UKHCDO.

3.1. Membership of British Blood Transfusion Society (BBTS) 1989 to 2007 without any committee involvement. Member of British Society for Haemostasis & Thrombosis (BSHT) 1989 to 2007 with no committee involvement. Member of British Society for Haematology 1989 to 2007, with no committee involvement.

3.2. I was also the Clinical Tutor for Haematology with Cardiff University Medical School between 2004 and 2009, teaching and examining medical students. As

a member of UKHCDO I attended the annual scientific meetings and received regular updated guidelines on the management of haemophilia and haemorrhagic disorders. As a member of BSHT, BSH & BBTS I attended the annual scientific meetings for continuing professional development, registered with the Royal College of Pathology. I successfully completed annual appraisals and CPD standards from 1994 to 2007, receiving full accreditation and revalidation with the Royal College of Pathology and General Medical Council. I retired completely from clinical practice in January 2007, but continued to teach and supervise undergraduates and foundation year 1 and foundation year 2 medical trainees. I transferred my clinical and supervisory role to the Consultant Haematologist who remained in post and who was subsequently appointed before my retirement from clinical practice in January 2007. I continued in a non-clinical management role with the Gwent Healthcare Trust.

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 or reports which you provided.**

4.1. I have not provided evidence or been involved in any other enquires, investigations, criminal or civil litigation in relation to human immune-deficiency virus (HIV) and or Hepatitis B virus (HBV) and or Hepatitis C virus (HCV) and or variant CJD in blood or blood products. The Royal Gwent Hospital laboratory had a role in the diagnosis and management of new cases of haemorrhagic disorders, which included haemophilia and von Willebrand's disease. Any suspected cases were immediately referred to the Cardiff Comprehensive Care Centre (CCC) before 1988 and also from 1989 to present. My role was to liaise with the Cardiff CCC regarding any newly diagnosed cases of suspected haemophilia or haemorrhagic disorders and transfer their care and diagnostic work-up and registration at Cardiff CCC.

Section 2: Decisions and actions of the Haemophilia Centre at the Royal Gwent Hospital

5. **Insofar as relevant to the Terms of Reference, please:**
   a. **describe the roles, functions and responsibilities of the Haemophilia Centre at the Royal Gwent Hospital ('the Centre') during the time that you worked there.**
   b. **outline the facilities and staffing arrangements for the care of patients with bleeding disorders;**
   c. **identify senior colleagues at the Centre and their roles and responsibilities during the time that you worked there, insofar as they were involved with the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**

5.1. a) If any patient with mild haemophilia A or von Willebrand's disease required DDAVP treatment to cover dental extraction in the hospital at the Royal Gwent Hospital, this was done in liaison with the Haemophilia Centre in Cardiff and they received infusions of DDAVP and Tranexamic Acid to cover this. Only medical staff above FY2 level were involved in patient care and all patients carried cards indicating their diagnosis, coagulation factor levels and the name of the consultant responsible for their care at the Haemophilia Centre in Cardiff, where they were registered.

5.2. b) Haematology consultants at the Royal Gwent operated continuous on-call service and from 2004 onward there was also an on-call haematology registrar who was on the Cardiff and South East Wales Training Scheme.

5.3. c) This was all dealt with by Consultant colleagues at Cardiff Haemophilia Reference Centre.

Section 2: Decisions and actions of the Haemophilia Centre at the Royal Gwent Hospital

6. **Please describe:**
   a. **your role and responsibilities at the Centre and how, if applicable, this changed over time;**
   b. **your work at the Centre insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**

6.1. My role was to ensure hand-over and liaison with Cardiff Haemophilia Centre for haemophilia and von Willebrand's patients who presented at the Royal Gwent Hospital.

6.2. I was not involved with the care of patients with bleeding disorders and or patients infected with Hepatitis or HIV in consequence of infected blood or blood products.

7. **Approximately how many patients with bleeding disorders were under the care of the Centre when you began work there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).**

7.1. There were no patients with bleeding disorders under the care of the Centre at the Royal Gwent Hospital, they had all to be transferred to Cardiff HRC ten miles away.

8. **To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:**
   a. **How, and on what basis, and by whom were decisions made about the selection and purchase of blood products?**
   b. **What (if any) other bodies or organisations or individuals (e.g. other centres in the same region, or the Regional Health Authority) were involved in the arrangements for the selection, purchase or use of blood products?**
   c. **What were the reasons or considerations that led to the choice of one product over another?**

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

e. **What if any involvement did you have?**

f. **What products or treatments were generally used for treating (i) patients with severe haemophilia A; (ii) patients with moderate haemophilia A; (iii) patients with mild haemophilia A; (iv) patients with haemophilia B; (v) patients with von Willebrand's disease? Who had responsibility for the selection and purchase of blood products?**

8.1. a) I had no role in the selection or purchase of blood products or factor concentrates when I worked at the Royal Gwent Hospital. This was all procured by Cardiff Haemophilia Centre.

8.2. b) As above

8.3. c) As above

8.4. d) I had no involvement with commercial, financial considerations at the Royal Gwent Hospital, Cardiff Haemophilia Centre dealt with this.

8.5. e) I had no involvement in the procurement of Factor 8 or any other coagulation factors for patient use.

8.6. f) The only treatments used for mild haemophilia and von Willebrand's disease were pharmacological i.e. DDAVP and Tranexamic Acid. Any blood products were given at Cardiff Haemophilia Reference Centre.

9. **What was the relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre decisions and actions? In answering this question, please describe the kinds of interactions and communications (such as visits from sales representatives) you had with pharmaceutical companies which supplied factor concentrates.**

9.1. Royal Gwent Hospital Newport had no relationship with pharmaceutical companies, manufacturing or supplying blood products.

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

10.1. The purchase of blood products lay with the Welsh Blood Service who liaised with Cardiff Haemophilia Reference Centre.

11. What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders? What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Centre 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?

11.1. Alternatives to factor concentrates were cryo-precipitate for Haemophilia A and von Willebrand's disease and FFP for haemophilia B. The advantages were that there was more limited donor exposure and donors were unpaid and donated their blood voluntarily. Disadvantages were primarily the large fluid volume required to achieve therapeutic levels and a need for lengthy day care admission for patients. Factor concentrates could be self-administered promptly by the patient at the time of a bleed, and enabled patients to live lives, which were minimally disrupted by having to attend hospital.

11.2. Retrospectively commercial concentrates posed a risk of infection and as soon as the risk became known, there was a switch back to using cryo-precipitate and when they became available, heat treated factor 8 concentrate from BPL and subsequently recombinant factor 8 products.

12. What was the Centre's policy and approach as regards:

a. the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and if so, how?

b. home treatment? When was home treatment introduced?

c. prophylactic treatment? To what extent and when was treatment provided on a prophylactic basis?

12.1. Patients from Gwent were registered and cared for by the Cardiff Haemophilia Reference Centre. Patients on home treatment attended Cardiff Haemophilia

Reference Centre. No prophylactic treatment with factor concentrates or blood products was given at the Royal Gwent Hospital for haemophilia or associated disorders. This was all carried out in Cardiff.

12.2. Patients from Gwent were registered and cared for by the Cardiff Haemophilia Reference Centre. Patients on home treatment attended Cardiff Haemophilia Reference Centre. No prophylactic treatment with factor concentrates or blood products was given at the Royal Gwent Hospital for haemophilia or associated disorders. This was all carried out in Cardiff.

13. What was the Centre's policy and approach in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so, how?

13.1. All children were treated in Cardiff Haemophilia Reference Centre.

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

14.1. We have no records at the Royal Gwent Hospital of other blood borne viral transmission through the use of blood transfusion products.

Section 3: Knowledge of, and response to, risk

General

15. When you began work as a consultant haematologist at the Centre, 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 your knowledge and understanding develop over time?

15.1. I was fully conversant with the risks of transfusion related viral transmission, having trained at Cardiff Haemophilia Reference Centre as part of my rotation in the 1980's and having witnessed cases of HIV, HCV and associated clinical problems.

16. What advisory and decision-making structures were in place, or were put in place at the Centre, to consider and assess the risks of infection associated with the use of blood and/or blood products?

16.1. In relation to blood transfusion practice in general i.e. in red cell transfusion to patients with haematological malignancies, myeloid dysplasias and bone marrow failure and also haemoglobinopathies who required long term transfusion therapy. All blood was obtained as concentrated red cells and screened by the Welsh Blood Service. Patients were screened before treatment for HBV blood status and the liver function tests were monitored at least monthly and any subsequent major liver function test abnormalities were referred to a Hepatologist for assessment. Standard operating procedures were kept in the hospital blood bank and adverse events were reported to the Welsh Blood Service and the committee for Serious Hazards of Transfusion (SHOT).

17. What was your understanding of the relative risks of infection from commercially supplied factor concentrates and NHS factor concentrates?

17.1. My understanding was that NHS factor concentrates had a markedly reduced risk of transmitting infection in comparison to commercial concentrates.

18. How did you keep up-to-date with relevant scientific and medical developments in knowledge? What journals did you regularly read?

18.1. I attended annual national scientific meetings of BSH, BSHT, UKHCDO and BBTS. I attended local educational seminars in the Haematology Department at UHW Cardiff and I also read the New England Journal of Medicine, Blood and Lancet to keep up to date on a regular basis.

Hepatitis

19. When you began work as a consultant haematologist at the Centre, what was your knowledge and understanding of:

a. the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products?

b. the nature and severity of the different forms of blood borne viral hepatitis?

19.1. I was fully aware of the risks of transfusion related Hepatitis B and non-A, non-B or Hepatitis C as well as the nature and severity of these conditions.

20. What were the sources of your knowledge? How did that knowledge and understanding develop over time?

20.1. My knowledge was gained whilst training in Haematology at UHW Cardiff and from medical journals and seminars following on from my training.

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

21.1. We used only blood and blood products which had been screened for Hepatitis virus and donors who had been screened for HBV and abnormal liver function tests by the Welsh Blood Service. (Whilst I was working as a trainee Haematologist at UHW Cardiff).

HIV and AIDS

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

22.1. Association between AIDS and the use of blood products became evident in the early 1980's.

23. 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 during your time working at the Centre? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

23.1. Whilst a Haematology Trainee in Cardiff I experienced haemophilia patients and haematology patients with AIDS and studied blood cell markers of infection and correlated them with transfusion exposure and when HTLVIII was identified in 1983 and serological tests for the virus became available in 1985, I correlated patients' status with their clinical condition and other laboratory parameters.

23.2. I attended scientific meetings both to further my knowledge of AIDS in haemophilia and gave presentations of research findings to contribute to the body of knowledge at that time.

24. What (if any) actions did you and/or the Centre take to reduce the risk to your patients of being infected with HIV?

24.1. Patients with mild haemophilia A and vWd were assessed for response to pharmacological treatment with DDAVP and Tranexamic acid as an alternative to blood products. As far as I can recall when I was training in Haematology at UHW Cardiff patients with severe haemophilia A were switched back to cryo-precipitate therapy and when it became available heat treated Factor VIII from BPL, Elstree and SNBTS.

25. Did the Centre continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?

25.1. Whilst working in Cardiff Haemophilia Reference Centre as a trainee there were patients with Factor VIII inhibitors who could only receive commercial concentrate such as FEIBA. It was considered that the risk posed by haemorrhage outweighed the risk from concentrate infusion transmitting viral infection at that time.

Response to risk

26. Did you and/or your colleagues at the Centre take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

26.1. This relates to my time as trainee at UHW and not to my time as a consultant in the Royal Gwent Hospital. To the best of my knowledge at the time in UHW Cardiff Haemophilia Reference Centre, there was a major exercise to inform and educate patients and their families about HIV, AIDS and this was done through counselling by the consultant in charge and the haemophilia nurse specialist.

27. Did you or your colleagues at the Centre revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, when and how was it determined which patients would be offered a return to cryoprecipitate?

27.1. This relates to Cardiff Haemophilia Reference Centre and not to the Royal Gwent Hospital.

28. When did the Centre begin to use heat treated factor products and for which categories of patients? Please set out what steps were taken to obtain heat treated products. Please also set out whether steps were taken to recall any stores of unheated products which patients had.

28.1. Again, this relates to Cardiff HRC and not to RGH.

29. Looking back now, what decisions or actions by you, the Centre or any other relevant organisations or individuals, could have avoided, or brought to an end earlier, the use of infected blood products?

29.1. To my knowledge measures to stop the use of infected blood products were expedited as soon as possible.

30. 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?

30.1. Within my knowledge I cannot comment about the actions or decisions or policies made by other clinicians or organisations.

Section 4: Treatment of patients at the Haemophilia Centre at the Royal Gwent Hospital

HIV

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

31.1. I first discussed AIDS or HIV with patients when I was a trainee at Cardiff Haematology rotation in 1983.

32. The enclosed documents are letters to you regarding the first known haemophiliac to be infected with HIV in the UK; a Cardiff patient [CVHB0000157_184 & CVHB0000157_186].

a. Please confirm your position of employment at the time of receiving these letters.

b. As far as you can recall, when did you first learn about this patient?

c. What was the context of these letters?

d. What involvement, if any, did you have with his haemophilia and/or HIV care and treatment?

e. What steps, if any, were taken after learning of the patient's HIV positivity to investigate potential infections in other patients and to reduce the risk of HIV transmission?

32.1. a) Relating to the documents CVHB0000157_184 CVH 0000157_186: I was working as a senior registrar in Haematology in a training rotation at UHW Cardiff.

32.2. b) I first heard about this patient in early 1983.

32.3. c) This letter was correspondence from Dr Gerald Anderson, Chest Physician at the Royal Gwent Hospital in response to a referral to him by myself, of a patient from the Gwent area with suspected opportunistic infection such as pneumocystis pneumonia responsible for his pneumonia.

32.4. d) I reviewed the patient on the ward and in out-patients under the supervision of Professor A Bloom.

32.5. e) The patient would have been informed of the risks of transmitting HIV by sexual intercourse and through surgical or dental procedures, and he would have been counselled by the Haemophilia Nurse Specialist and responsible Consultant Professor Bloom regrading measures he should take to prevent this happening, and any treating clinicians would be informed with the patients consent, of his HIV status, so that the relevant precautions could be taken.

33. How many patients at the Centre were infected with HIV in consequence of the treatment with 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?**

33.1. To my knowledge one patient (who was registered at Cardiff CCC) was infected with HIV as a consequence of blood product treatment at the Royal Gwent Hospital in the early 1980's. Any other patients from Gwent were registered and under the care of the Haemophilia Reference Centre in Cardiff. To my knowledge the patient at the Royal Gwent Hospital who received the concentrate infusion was a child with mild to moderate haemophilia A. The boy's treatment at the Royal Gwent Hospital was in 1985 and preceded my employment there.

34. How and when did you learn that patients under your care/the Centre's care had been infected with HIV?

34.1. I learnt of the patient's infection whilst working at UHW as a trainee – the patient was not under my care at any time.

35. How and when were patients told that they had been, or might have been, infected with HIV? What (if any) involvement did you have in this process?

35.1. I had no involvement in the process of notifying patients of their HIV status.

36. Please describe the Centre's process for HIV testing, including pre-test and post-test counselling.

36.1. The processes were all undertaken at Cardiff HRC and not Royal Gwent Hospital.

37. What information was given to them about the significance of a positive diagnosis? Were patients told to keep their infection a secret?

37.1. As above.

NANB Hepatitis/Hepatitis C

38. How many patients at the Centre were infected with hepatitis C?

38.1. All patients from Gwent were transferred to Cardiff Haemophilia Reference Centre before my employment at the Royal Gwent Hospital in 1989.

39. Were patients infected with hepatitis C informed of their infection and if so, how and by whom? What information was provided to infected patients about the infection, its significance, prognosis, treatment options and management? What (if any) involvement did you have in this process?

39.1. See 38 above.

40. When did the Centre begin testing patients for hepatitis C? Please describe the Centre's process for HCV testing, including pre-test and post-test counselling. What involvement did you have in this process?

40.1. See 38 above.

Delay

41. Were the results of testing for HIV and hepatitis C notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

41.1. See 38 above.

Consent

42. How often were blood samples taken from patients attending the Centre and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so, how and where?

42.1. Patients from Gwent were under the care of the Cardiff Haemophilia Reference Centre and not at the Royal Gwent Hospital as of the early 1980's.

43. Did the Centre have a bank of stored samples? If so, was that storage undertaken with patients' knowledge and consent?

43.1. See above 42.

44. Were patients under your care/under the Centre's 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?

44.1. See above 42.

45. 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?

45.1. See above 42.

PUPS

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

46.1. See above 42.

Treatment of patients who had been infected with HIV and/or Hepatitis

47. How was the care and treatment of patients with bleeding disorders and HIV/AIDS managed at the Centre? 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 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?

47.1. a) All Gwent patients with bleeding disorders were registered with Cardiff Haemophilia Reference Centre from the early 1980's onward.

47.2. b) As above 47.1.

47.3. c) As above 47.1.

47.4. d) As above 47.1.

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

48.1. This happened in Cardiff Haemophilia Reference Centre.

49. How was the care and treatment of patients with bleeding disorders and hepatitis C managed at the Centre? 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 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 hepatitis C?

49.1. a) In Cardiff Haemophilia Reference Centre.

49.2. b) In Cardiff Haemophilia Reference Centre.

49.3. c) In Cardiff Haemophilia Reference Centre.

49.4. d) This happened in Cardiff Haemophilia Reference Centre.

50. What arrangements, if any, were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

50.1. In Cardiff Haemophilia Reference Centre.

51. Did the Centre receive funding from the Department of Health and Social Security or from any other source to help with the counselling of patients infected with HIV?

51.1. Not applicable.

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

52.1. Not applicable.

53. What (if any) involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

53.1. None.

Records

54. What was the Centre's policy with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis? Were you involved with any inquests in relation to patients who had been infected with HIV or hepatitis in consequence of their treatment? If so, please provide details.

54.1. Not applicable – no patients with blood product related HIV or Hepatitis were treated at Royal Gwent Hospital.

55. What were the retention policies of the Centre in regards to medical records during the time you were practising there?

55.1. All haemophilia, AIDS, Hepatitis B patients records were kept in Cardiff Haemophilia Reference Centre or University Hospital of Wales, Medical Records Department.

56. As far as you are able to recall, did you:

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

b. keep records or information (e.g. information used for research) about any of your patients at your home or anywhere other than the Centre? If so, why, what information and where is that information held now?

56.1. a) Not applicable. See above 55.

56.2. b) Not applicable. See above 55.

Research

57. Please list all research studies that you were involved with as a consultant haematologist at the Centre (or any other relevant positions of employment) insofar as relevant to the Inquiry's Terms of Reference, and please:

a. Describe the purpose of the research and your involvement.

b. Explain the steps that were taken to obtain approval for the research.

c. Identify what other organisations or bodies were involved in the research.

d. State how the research was funded and from whom the funds came.

e. State the number of patients involved.

f. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.

g. Provide details of any publications relating to the research.

Please provide the same details in relation to any other studies in which you were involved or articles you have published relevant to the Inquiry's Terms of Reference, including the the following studies:

Moffat, E.H., Bloom A.L. & Mortimer P.P. 'HTLV III antibody status and immunological abnormalities in haemophilic patients' The Lancet, 935, 1985. [DHSC0002267_045]

Moffat, E.H., Giddings, J.C., and Bloom, A.L. 'The effect of desamino-D-arginine vasopressin (DDAVP) and naxolone infusions on factor VIII and possible endothelial cell (EC) related activities,' Brit. J. Haem. 57, 651-662, 1984.

Moffat, E.H., Bloom A.L., Jones, J., Matthews, N. and Newcombe, R.G. 'A study of cell mediated immunity and humoral immunity in haemophilia and related disorders.' Brit. J. Haem. 61, 157-167, 1985. [WITN4029020]

57.1. a/b) I was involved in studies of haemophilia patients' blood parameters of immune function in 1984 and HTLV status in 1985, whilst working at UHW, Cardiff as a Senior Registrar and Clinical Research Fellow under the supervision of Professor AL Bloom. I was involved in the design of the studies, obtaining ethical approval and patient consent. The performance of laboratory

tests, examination of blood product transfusion records between 1974 and 1985. Subsequently I analysed and correlated the laboratory results with the HTLV 3 antibody status and then wrote these up for publication.

57.2. c) The PHLS virus reference laboratory London NW9 tested samples for HTLV 3 antibodies.

57.3. d) The Haemophilia Society funded the research project.

57.4. e) 46 patients were involved.

57.5. f) Patients in the form of consent was obtained by myself or Professor AL Bloom.

57.6. Publications:

57.6.1. HTLV 3 antibody status and immunological abnormalities in haemophilia patients. Moffat EH, Bloom AL, Mortimer PP, The Lancet April 20 1985 page 935.

57.6.2. A study of cell mediated immunity and humoral immunity in haemophilia and related disorders – British Journal of Haematology 61 157 to 167 1985. Moffat EH, Bloom AL, Jones J, Matthews N, Newcombe RG 57 patients studied. Patients' blood samples were tested for T cell helper suppressor, ratios and numbers, natural killer cell function and immunoglobulin levels and controller samples were obtained from normal individuals in the paper.

57.6.3. The effects of DDAVP and Naloxone infusion on factor 8 and EC related activities. Moffat EH, Giddings JC, Bloom AL. British Journal of Haematology 57 651 to 662 1984. This paper was primarily a study to find out how DDAVP mediated the release of Factor 8 and von WIllebrand's factor from endothelial cells in vivo and in vitro. There was no connection with transfusion related viral transmission.

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

58.1. Patients involved in the above studies all gave their informed consent.

59. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or shared with third parties without their express consent? If so, please explain what data was used, and how/why it was shared.

59.1. All patient data was de-identified before publication and any laboratory records which identified patients were stored securely in Cardiff Haemophilia Reference Centre for five years, then destroyed. Data was not shared out with Cardiff Haemophilia Reference Centre.

60. Please consider the enclosed letter from Stephen J May dated 21 June 1983 [WITN1656003]. The letter states that you were involved in a survey of severe haemophiliacs whose Factor VIII treatment was reduced in response to the potential risk of HIV transmission associated with blood products. As far as you can recall, please explain:

a. the aims and purpose of the survey,

b. the extent of your involvement, and

c. the survey's findings and if applicable, any steps taken in consequence of the survey in relation to the care and treatment of patients with bleeding disorders.

60.1. With reference to Doctor May's letter of 21/06/1983 I had been asked by Professor Bloom to correlate the amount of Factor 8 concentrate received by severe haemophilic patients with their immune status and clinical features of AIDS – this involved measuring their circulating helper and suppressor T cells, numbers and ratios and totalling the recorded type and the amount of Factor 8 concentrate infused between 1973 and 1983.

60.2. I was responsible for performing laboratory tests and scrutiny of the patients Factor 8 infusion records.

60.3. The survey showed a depression of the numbers of T helper and suppressor cells and ratios indicating cell mediated immunosuppression in these patients

which in turn correlated with the exposure to blood Factor 8 concentrate infusion. This could not be tied down to any specific type of concentrate or cryoprecipitate as many types and batches had been used over the ten year period. The survey confirmed that IV therapy was associated with an immunosuppressive effect.

Section 5: UKHCDO

61. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups). Did you usually attend the annual general meetings?

61.1. As a Consultant Haematologist at Royal Gwent Hospital from 1989 onward I attended the annual scientific meeting of the UKHCDO, I was not involved in any working parties, committees or groups.

62. During the period that you belonged to UKHCDO, please outline:

a. the purpose, functions and responsibilities of UKHCDO, as you understood them.

b. any involvement which you had in the development of policies or advice by UKHCDO which are relevant to the Inquiry's Terms of Reference.

c. how information or advice was disseminated by UKHCDO and to whom.

62.1. a) I understood UKHCDO to be responsible for the setting of guidelines and standards for the care of haemophilia patients. They were responsible for liaising with the Department of Health in the UK relating to national provision of clinical care and blood products in haemophilia.

62.2. b) I had no involvement in policy development in UKHCDO.

62.3. c) UKHCDO sent regular written bulletins with information on haemophilia care, hazard warnings and new policy initially by post and latterly by electronic communications.

Section 6: Pharmaceutical companies/medical research/clinical trials

63. 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 of 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 or non-financial incentives from pharmaceutical companies to use, purchase, or recommend certain blood products?

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

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

If so, please provide details.

63.1. a) I have never provided advice or consultancy services to any pharmaceutical company manufacturing or selling blood products.

63.2. b) See above. No financial gain.

63.3. c) No involvement.

63.4. d) No financial involvement.

63.5. e) No research on behalf of a pharmaceutical company.

63.6. f) No provision of research results to a pharmaceutical company.

64. What regulations or requirements or guidelines were in place at the time 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?

64.1. I had no involvement with pharmaceutical companies.

65. 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?

65.1. See 64 above.

Section 7: Interaction with the financial assistance trusts and schemes

66. Please explain as fully as you can any involvement you have had in relation to any of the trusts or funds (the MacFarlane Trust, the Eileen Trust, the MacFarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund) which were set up to provide financial assistance to people who had been infected[1]. Relevant involvement may include:

a. Occupying a formal position with any of the trusts or funds;
b. Providing any advice to any of the trusts or funds, including for the development of any eligibility criteria or policies;
c. Informing patients about or referring patients to the different trusts or funds;
d. Determining or completing any part of applications made by patients.

66.1. I had no involvement with any trust or funds set up to provide assistance to people who had been infected, this was all dealt with by Cardiff Haemophilia Centre.

[1] In answering this question, you may wish to consider the enclosed letter dated 10 August 1989 from you to Mr J WIlliams, Administrator of the Macfarlane Trust, regarding registration of HIV positive patients [MACF0000175_045].

Section 8: vCJD

67. 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?

67.1. I became aware of the theoretical risks of VCJD transmission through blood transfusion in 1996 through alerts from the UKHCDO and WBS.

68. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so, please answer the following questions:

a. What steps were taken/put in place a process at the Centre for informing patients about the risks of or possible exposure to vCJD?[2]

b. What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?

68.1. I had no involvement in decisions regarding patient information about VCJD.

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

69.1. Cardiff HC dealt with this.

Section 9: Look-back and tracing exercises

70. In as much detail as you are able to, please explain your knowledge and involvement in hepatitis (of any kind) look-back or tracing exercises.

70.1. I had no involvement in Hepatitis lookback or training exercises.

71. In as much detail as you are able to, please explain your knowledge and involvement in HTLV-III/HIV look-back or tracing exercises.

71.1. I had no involvement in HTLV3, HIV, lookback or tracing exercises.

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[2] In answering this question, you may wish to consider the enclosed document which records the number of vCJD Exposure Assessment Forms sent by you/the Centre in 2006 [HCDO0000572].

Section 10: Other Issues

72. The enclosed documents are reports from the National Audit of the Clinical Blood Transfusion Process [NHBT0042247 & BSHA0000061_017]. In as much detail as you are able to, please:

a. explain the aims and purpose of the audit, and your involvement;

b. outline its findings and if applicable, any steps taken in consequence of the audit in relation to the care and treatment of patients; and

c. highlight areas of specific relevance, if any, to the treatment and care of patients with bleeding disorders.

72.1. a) The aims and purpose of the audit were to ensure proper patient identification procedures were carried out and when blood was transfused that patients were monitored appropriately. It was an audit of process, a trust audit officer collected the data and the trust transfusion practitioner collated the data and returned it to SHOT. I supervised these members of staff.

72.2. b) The audit confirmed our compliance with SHOT guidelines on blood transfusion clinical procedures.

72.3. c) No issues were relevant to patients with bleeding disorders.

73. The enclosed document is a report on the 2003 Better Blood Transfusion Survey [DHSC0006181_043]. In as much detail as you are able to, please:

a. explain the aims and purpose of the survey, and your involvement;

b. outline its findings and if applicable, any steps taken in consequence of the survey in relation to the care and treatment of patients

c. highlight areas of specific relevance, if any, to the treatment and care of patients with bleeding disorders.

73.1. The survey was to ensure that SHOT guidance on the administration of red cell and blood product transfusion was being observed and documented appropriately.

73.2. The survey indicated a good compliance with SHOT guidelines.

73.3. No areas of specific relevance to patients with bleeding disorders in Gwent NHS Trusts were identified.

74. 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.

74.1. I have received no complaints or been subject to any investigation as relevant to the enquiry.

75. 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.

75.1. I offer no further information which I believe to be of relevance to the infected blood inquiry.

Statement of Truth

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

Signed: GRO-C

Dated: 8 March 2021