Witness Name: Professor Peter William Collins

Statement No.: WITN4029001

Exhibits: WITN4029002 – WITN4029031

Dated: 2 September 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR PETER WILLIAM COLLINS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 8 July 2020.

I, Professor Peter William Collins, will say as follows: -

Section 1: Introduction

1. My name is Professor Peter William Collins. My work address is c/o Cardiff and Vale University Health Board, Heath Park, Cardiff CF14 4XW. My date of birth is GRO-C 1961.

2. My professional qualifications are BA Hons Cantab, MBBD Lond, MD, MRCP, FRCPath.

3. I trained in medicine at Cambridge University and St Bartholomew's Hospital, London. I qualified in 1986.

4. The following is an overview of my employment history:

Dates	Location	Role(s)
August 1986 to January 1987	St Bartholomew's Hospital and Homerton Hospital (London)	House Officer in Medicine
February 1987 to July 1987	Homerton Hospital	House Officer in Surgery
August 1987 to January 1989	Oldchurch Hospital, London (now closed)	Senior House Officer in Medicine
February 1989 to January 1990	The Royal London Hospital	Senior House Officer in Haematology
February 1990 to August 1991	The Royal London Hospital	Honorary Lecturer Haematology
September 1991 to June 1993	The Royal London Hospital	Leukaemia Research Fund Clinical Training Fellow
July 1993 to July 1995	Royal Free Hospital London	Lecturer and Honorary Senior Registrar in Haematology
August 1995 to July 1996	Great Ormond Street Hospital, London	Lecturer and Honorary Senior Registrar in Haematology
September 1996 to August 2001	Cardiff Haemophilia Centre, University Hospital of Wales	Consultant Haematologist
September 2001 to date	Haematology, School of Medicine, Cardiff University Cardiff Haemophilia Centre, University Hospital of Wales	Professor (previously senior lecturer and reader) of Haematology Honorary Consultant Haematologist

5. I have been a member of the UK Haemophilia Centre Doctors' Organisation ("UKHCDO") since 1996. I have sat on various committees in different roles over this period including the following working parties: Inhibitor, Von Willebrand Disease, Genetics, Paediatrics, Rare Disorder and Data Management. I have been the Vice Chair of the Executive Committee of UKHCDO since 2016.

6. I have also been involved in the following organisations/ processes over the periods and in the capacities set out below:

Organisation	Period	Capacity
International Society on Thrombosis & Haemostasis	1996 to date	Co-Chair of Factor VIII/ IX Scientific Sub-Committee (2016-2018)
Haemophilia Alliance	2000-2007	Member
National Institute for Health Research	2009 to 2015	Chair of Non-malignant Haematology group
Pan Thames Haemophilia Consortium Review	2007-2008	Member
Welsh Ministerial Review of Inherited Bleeding Disorders	2011-2012	Contributor
Wales Inherited Bleeding Disorder Group	2012 to date	Clinician representative
UK Procurement Group	2010 to date	Clinical representative for Wales

7. I have not provided evidence to or otherwise been involved in any other inquiries, investigations or litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus and/or hepatitis C virus infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

Section 2: Decisions and actions of those treating patients with bleeding disorders at the Cardiff Haemophilia Centre

Facilities

8. I started as a Consultant in Haematology at Cardiff Haemophilia Centre (the "Centre") in September 1996. At this time, the Centre consisted of a waiting area, one treatment room and an office. The decision had been made prior to my arrival to close these facilities and provide treatment for bleeding disorders in a joint Haematology Day Unit. This happened in 1998.

9. In around 2000, a new Haemophilia Centre was built which is the same structural unit that is used today. This consists of one treatment room and a shared treatment room, a consultation room, a waiting area jointly used by adults and children, a room to store treatment, an office for the nurses and registrar and a reception area which holds the notes of people attending the centre. Across the corridor is a room for the data manager and research nurses and an office.

Organisation

10. The Centre is organised as a multi-disciplinary team within the Haematology Directorate. As explained below, in 1996, it consisted of two doctors, one nurse, a physiotherapist and a social worker. Over time, additional members of medical, nursing and physiotherapy staff have been appointed, together with a data manager and a play specialist. And, in 2012, a psychology service was established.

11. The Centre functions as a comprehensive care centre and supports the haemophilia centres in Swansea and Newport/ Abergavenny. The Centre provides advice on the management of bleeding disorders to all hospitals in South and West Wales. Since 2005, an outreach clinic has been provided in Swansea once a month and, since 2014, a clinic in Abergavenny is held once every two months. Some patients based in England choose to be treated by the Centre.

Roles and responsibilities, generally

12. The roles and functions of the Centre are to manage people with inherited bleeding disorders of all age groups. This covers all aspects of treatment and prevention of bleeding

including at the time of surgery and during the perinatal period. The Centre also co-ordinates family studies and genetic testing.

13. Initially, the Centre managed HIV and Hepatitis but, over time, this has been passed to the Infectious Disease Service.

14. The Centre also co-ordinates the management of immune thrombocytopenia purpura and thrombotic thrombocytopenia purpura. The Centre's Consultants provide treatment of deep vein thrombosis through a nurse-led clinic and consultations for complex thrombotic disorders. They also provide an antenatal haematology clinical service.

Senior colleague role and responsibilities

15. At the time I joined, the Centre had the following staff:

    a. Dr Has Dasani was a staff grade doctor. Dr Dasani's role was as a physician to the Centre. In the six months before my arrival Dr Dasani had been the acting consultant of the Centre. He specialised in the treatment of HIV/AIDS and hepatitis and had extensive knowledge of bleeding disorders having previously worked at Lord Mayor Treloar Hospital in Hampshire and Oxford Haemophilia Centre. He retired in 2007.

    b. Sister Jennifer Jones, a senior nurse, co-ordinated treatment for patients of all ages. She established patients on home treatment, visited schools and carried out community visits. Sister Jones retired in or around 2003.

    c. Mr Timothy Hunt was the senior social worker in 1996. His role was in counselling and support of patients and their families affected by HIV and hepatitis. He left the Centre in 1998.

16. Mrs Fiona Hall, a senior physiotherapist, was at the Centre in 1996 and remains in post today. Her role is to prevent and treat musculoskeletal symptoms and support rehabilitation following orthopaedic surgery.

17. Ms Christine Loran started working in the Centre shortly after I did, and she took over as lead nurse when Sister Jones retired. Ms Loran retired in 2018.

18. Dr Rachel Rayment was appointed as a Consultant in the Centre in 2004 (although she went on maternity leave shortly thereafter and so started her position in earnest in 2005). Her role was to provide care for people with inherited bleeding disorders as well as establishing an

obstetric haematology clinic. Dr Rayment is the lead clinician for immune thrombocytopenia purpura and thrombotic thrombocytopenia purpura in Cardiff. She took over the role of Haemophilia Centre Director in 2017. She also led the working group that established the South and West Wales bleeding disorder network which is the current service model for the area.

19. Dr Raza Alikhan was appointed as a Consultant in the Centre in 2008. In addition to providing care for people with inherited bleeding disorders, he has led on the management of venous thrombosis in Cardiff.

20. Most recently, in 2019, Dr Heledd Roberts was appointed as a Consultant in the Centre – as part of the South and West Wales inherited bleeding disorder network. Dr Roberts is the lead clinician for Swansea Haemophilia Centre. In the same year, Dr Samya Obaji was also appointed as Consultant at the Centre (also as part of the inherited bleeding disorder network).

My role and responsibilities, and how they have changed

21. In 1996, my role was that of clinical lead for bleeding and thrombotic disorders. This included treatment of adults and children with inherited bleeding disorders and patients bleeding after operations, trauma or childbirth. I provided clinical services for patients with venous thrombosis including diagnosis of the cause of thrombosis and anticoagulation through an INR (international normalised ratio) clinic. In addition, I had responsibility for running of the Centre.

22. Between 1996 and 2005, I provided a one-in-one out-of-hours service for the Centre and clinical haemostasis and thrombosis referrals in Cardiff. Since 2005, the out-of-hours commitments have been shared with Dr Rayment and other colleagues.

23. In 2001, I was appointed as a senior lecturer at Cardiff University and my job became 50% clinical for the NHS and 50% research and teaching for the University.

24. In 2005 Dr Rayment commenced working at the Centre and we shared clinical responsibilities. Dr Rayment took over responsibility for running the Centre in 2017.

25. In 2008, Dr Alikhan was appointed to lead thrombosis services and I now have almost no role in the management of thrombotic diseases.

Number of patients with bleeding disorders

26. In 1996, there were 328 people with an inherited bleeding disorder registered in Cardiff. 239 over the age of 18, and 87 under the age of 18.

27. In 2000, there were 427 people registered: 118 children and 309 adults.

28. In 2010, there were 629 people registered: 135 children and 494 adults.

29. In 2019, there were 802 people registered: 162 children and 640 adults.

30. This information has been supplied by the National Haemophilia Database ("NHD").

Selection of blood products in the 60s to 80s

31. I do not know the arrangements for selection and purchase of blood products used at the Centre in the period 1966 to 1985 – when patients were infected with HIV, hepatitis C and hepatitis B. Professor Arthur Bloom would have obviously played an important and leading role in the selection of blood products.

32. When I started working in Cardiff in 1996 blood products were purchased by the Blood Transfusion Service (now the Welsh Blood Service) and passed on to hospitals in South and West Wales.

33. I also do not have any direct knowledge as to *how* decisions were made about/ the rationale for the selection of blood products over the relevant period.

34. The blood products used to treat patients between 1969 and 1986 were reported to the NHD. I am aware that this information is being collated for all UK Haemophilia Centres by UKHCDO and will be forwarded to the Inquiry (including detailed data for Cardiff). I understand that UKHCDO is cross-checking the accuracy of the data held on the NHD before finalising the report.

35. To the best of my knowledge, the Centre used a mixture of NHS/BPL/Oxford factor VIII and IX, commercial factor VIII and IX, cryoprecipitate and fresh frozen plasma during the period 1969 and 1986.

36. The brands of commercial factor VIII that were used during this period that I am aware of are: Immuno factor VIII (Kryoglobulin), "Travenol/Hyland/Hemofil", Alpha FVIII profilate, Armour FVIII factorate, Cutter FVIII Koate, Humanate, Autoplex, FEIBA, porcine FVIII, PFC

factor VIII. I also understand that the brand of commercial factor IX used during this period was Profilnine.

37. I have no knowledge about what treatments were used for which category of patients in the years before 1983.

38. I have seen a Protocol apparently written in May 1983 which provided that **[WITN4029002]**:

    a. Mild haemophilia and von Willebrand disease should be treated with DDAVP, cryoprecipitate or NHS [underlined] concentrate.

    b. Children with severe haemophilia should be treated with cryoprecipitate or NHS concentrate. Adults with severe haemophilia should be treated with cryoprecipitate for in-patients where feasible: patients who have never received imported concentrate should receive NHS concentrate; and patients that previously received imported concentrates should continue to receive these imported concentrates.

    c. All patients with haemophilia B should receive NHS factor IX concentrates.

    d. Patients with inhibitors should be treated with imported factor VIII or FEIBA.

    e. A 'general point' is made to maintain a patient on the same batch where possible to reduce donor exposure.

    f. The point is also made that NHS factor VIII transmitted non A non B hepatitis and DDAVP and cryoprecipitate should be used for mild patients who were susceptible to hepatitis.

    g. And combining a commercial concentrate and NHS concentrate for the same episode should be avoided.

39. The Protocol for choice of blood products was updated in October 1985 **[WITN4029003]**. It is followed by a list of patients treated in Cardiff, dated November 1985, stating what product they should be treated with. This provides:

    a. DDAVP should be used for mild haemophilia A and heterozygous type 1 von Willebrand disease.

    b. FFP should be used where concentrates and other treatments were not available.

c. Cryoprecipitate was to be used for von Willebrand disease and mild haemophilia A when exposure to non A non B hepatitis and HTLV III was to be avoided and DDAVP could not be used.

   There is a reference to donors being tested for HTLV III from 14 October 1985.

d. Intermediate BPL factor VIII (heated 60-68^{O}C for 10 to 72 hours) was described as "probably safe" from HTLV III but could transmit non A non B hepatitis. It was to be used for the routine management of haemophiliacs who had been exposed to concentrate previously, described in the document as "non-virgin". These were people who had been previously exposed to concentrates that transmitted hepatitis.

e. High potency factor VIII, Profilate (Heated) was to be used for the routine treatment of haemophilia A and for "virgin" haemophilia A if DDAVP was not indicated.

f. BPL 8Y (heated 80^{O}C for 72 hours) was considered to be "probably safe" for non A non B hepatitis but that this needed to be assessed. It was to be used for children and young adults especially those that were HTLV III negative. There was a note to "use follow up NANB hepatitis protocol". It was stated that "this is probably the safest and best FVIII concentrate available". The protocol implies that supplies of the product were limited, and it should not be used for people already virally exposed if this was the case.

g. Koate HT (heated 68^{O}C for 72 hours). This was thought to be safe from the point of view of HTLV III but there was no evidence to show that it did not transmit NANB. It was to be used in "non-virgin" patients already exposed to NANB.

h. Factor IX. Profilnine (wet heat treated 70^{O}C). This was stated to be HTLV III secure and probably safe for NANB. The implication of the protocol is that all patients with haemophilia B should be treated with this product.

i. Factor IX BPL (non-heated) was considered not acceptable because of the risk of HTLV III.

j. Heat treated FEIBA was also not considered acceptable. Also see **[WITN4029004]** below.

40. I am also aware of three letters written by Professor Bloom in 1985 regarding choice of products:

a. A letter to Sister Jennifer Jones dated 12 February 1985 **[WITN4029004]** which explains that the effect of heat treatment on the efficacy of FEIBA was unknown and unheated FEIBA could be infected with HTLVIII, and that NHS factor IX should be used for treating bleeds in patients with a factor VIII inhibitor.

b. A letter dated 12 April 1985 to the Acting Chief Pharmacist **[WITN4029005]** which requests the use of the more expensive Alpha product Profilate HT which he describes as having a more effective heat-treatment than the cheaper Koate product. I do not know how this letter was responded to but the individualised list of treatments in October 1985 suggests that, by that time, Profilate was being used and Koate was not.

c. A letter dated 21 August 1985 (to blank/ unknown) **[WITN4029006]** where he says that the cost of the safer heat-treated concentrates was "now phenomenal". In the letter he proposes reducing the dose of factor VIII and factor IX to be given and this suggests that there were financial pressures at that time.

Relationships with pharmaceutical companies over the relevant period

41. I have no knowledge about the relationship between the Centre and pharmaceutical companies during the relevant period.

Blood products used during my tenure

42. I have been involved in the selection of blood products and recombinant coagulation factor concentrates to treat inherited bleeding disorders since September 1996.

43. When I started working in the Centre, almost all patients with bleeding disorders were being treated with plasma derived factor VIII or factor IX. At the time, these concentrates were sourced from UK plasma and purchased from Bio Products Laboratory ("BPL"). Patients with haemophilia A were treated with factor 8Y and Replinate and patients with haemophilia B were being treated with Replenine.

44. When I arrived in Cardiff, a small number of people were being treated with recombinant factor VIII (Kogenate). Dr Dasani told me this was because they had been involved in a clinical trial of recombinant factor VIII and the treatment had continued after the trial ended.

45. Some people with haemophilia A or von Willebrand disease were treated with desmopressin if they had an adequate clinical response to this treatment.

46. One of the first priorities I had when starting in Cardiff was to advocate for universal access to recombinant coagulation factor concentrates. This was to reduce treatment with coagulation factor concentrates manufactured from blood products. This was achieved through engagement with the directors of Public Health and NHS Finance throughout Wales. In 1997, it was agreed that all people in Wales with haemophilia A should be switched to recombinant factor VIII from plasma-derived factor VIII. The switch to recombinant factor VIII took place over the next two years and Wales became the first country in the world with a policy of offering recombinant factor VIII to all people with haemophilia A.

47. The recombinant factor VIII products available in 1997 were Kogenate and Recombinate. These first-generation products contained human albumin and were subsequently replaced by second- and third-generation products that did not contain human albumin. The second- and third generation products were called Kogenate FS, Refacto AF, and Advate. More recently another recombinant factor VIII called NovoEight has been introduced.

48. When enhanced half-life factor VIII products became available these were introduced and offered to patients. The products used in Cardiff are Elocta, Esperoct and Adynovate.

49. Over the last two years, the non-factor VIII replacement product Emicizumab has become available for people with severe haemophilia A without inhibitors and some people have chosen to switch to this product.

50. People with haemophilia A and an inhibitor have been treated with recombinant factor VIIa (Novoseven) and/or the plasma-derived product Factor Eight Inhibitor Bypassing Activity (FEIBA). Emicizumab has been offered to people with inhibitor since it became licensed in 2018. Some people with high titre and resistant factor VIII inhibitors have been offered treatment with a plasma-derived factor VIII with a high von Willebrand factor content. The product used has been Fanhdi.

51. In 1998, recombinant factor IX (Benefix) became available and all patients with haemophilia B were offered this product and switched to recombinant factor IX. However, some patients switched back to use plasma-derived factor IX because their experience was that plasma derived factor IX worked better for treating their bleeds. More recently enhanced half-life factor IX has become available and some people with haemophilia B have decided to switch to these products. The enhanced half-life factor IX products used have been alprolix, Idelvion and Refixia.

52. Throughout the time I have been working in Cardiff, plasma-derived von Willebrand factor concentrates have been used to treat von Willebrand disease for people who do not have an adequate response to desmopressin. The products used have been factor 8Y, Haemate P and Voncento.

53. When I first started working in Cardiff, Dr Dasani and I made joint decisions about what blood products to use but I was ultimately responsible for this choice. When Dr Rayment was appointed in 2004 (although she went on maternity leave shortly thereafter and so started her position in earnest in 2005), she became involved in discussions about the choice of blood products and recombinant coagulation factor concentrates. Over time, Dr Rayment and I became jointly responsible for the choice of blood products and recombinant coagulation factor concentrates.

54. The hospital's finance team have been responsible for purchasing blood products and recombinant coagulation factor concentrates and I have had no involvement in that side of things.

55. Decisions regarding the choice of factor VIII and factor IX used in Cardiff since 1996 has been based on the safety and efficacy of the products, availability of products, and the outcomes of UK-wide national tenders.

56. The switch to recombinant blood products was made because these are safer than plasma-derived products because of the risk of currently unknown infectious agents entering the blood supply. As recombinant coagulation factor concentrates that did not contain human albumin became available these were introduced to further reduce the potential risk of infectious agents.

57. Some people with high titre and resistant factor VIII inhibitors have been offered treatment with a plasma-derived factor VIII which contain von Willebrand factor because these concentrates may help to suppress or eradicate the inhibitor. People with inhibitors have been treated with Novoseven and/or FEIBA because these products act in different ways and have different efficacy between individuals.

58. For many years, the UK has undertaken national procurement tenders for factor VIII and factor IX. As a result, haemophilia centres have been required to use minimum amounts of specific recombinant concentrates. This has often required asking people to switch recombinant product to achieve these targets. The Centre has complied will all requirements

relating to these national tenders and this has played a significant role in the choice of which brand of recombinant factor VIII to use.

59. People with von Willebrand disease have been treated with plasma-derived von Willebrand factor concentrates. When I arrived in 1996, people with von Willebrand disease were being treated with factor 8Y. The decision to change to Haemate P and Voncento was made because I thought these products had better efficacy to treat and prevent bleeds.

60. Financial considerations have played a role in the choice of products to treat bleeding disorders and continue to do so. The switch from plasma-derived to recombinant blood coagulation factor concentrates required a substantial investment in funding by the NHS in Wales and could only take place once the funding had been agreed.

61. Tenders for UK-wide procurement for recombinant concentrates and blood products have been in place for many years and price plays an important role in the ranking of these products and hence the use of products. The Centre has selected which brands of recombinant factor VIII and factor IX to use based on the outcome of the national tenders and the relative cost of equivalent products.

Relationships with pharmaceutical companies during my tenure

62. Since 1996, representatives from pharmaceutical companies have visited Cardiff and spoken to members of staff to promote their specific brand of FVIII or FIX on numerous occasions.

63. Pharmaceutical companies donated money to the hospital that contributed to the cost of building of the Centre in Cardiff. The following companies donated money for this purpose: Bayer, Baxter and Wyeth. The Centre has participated in many clinical trials sponsored by pharmaceutical companies and continues to do so. Pharmaceutical companies have funded members of staff to attend education meetings and have supported patient activity days.

64. The relationships with pharmaceutical companies have not influenced the selection of products to treat bleeding disorders in Cardiff.

65. I have been referred to an email trail in February 2003 **[HCDO0000109_031]** between myself and colleagues. I cannot remember the exact details surrounding this email trail. It appears to be about whether to accept sponsorship to publish UKHCDO von Willebrand

disease guidelines in a journal supplement, which would have required funding, or submit them to be published in the main journal.

66. I do know that the decision was to submit the guidelines for publication in the main journal. The guidelines were not sponsored, and no funding was received.

67. I am not aware of a pharmaceutical company sponsoring any UKHCDO guideline. I am not aware of any involvement or influence of a pharmaceutical company on any UKHCDO guideline.

Virus/ infection transmission since 1996

68. I am not aware of any viruses or infections that have been transmitted by a blood product to a person treated at the Centre since 1996. However, many people treated with plasma-derived concentrates made from UK plasma have been designated as being 'at risk' for vCJD for public health purposes (I refer more particularly to this below).

69. I am not aware of any infections other than HIV, hepatitis C and hepatitis B being transmitted to a person treated at the Cardiff centre as a consequence of exposure to blood products before 1996.

Section 3: Knowledge of, and response to, risk

70. I started work as a senior house officer at the Royal London Hospital in February 1989. At the time I had a limited understanding of the risks of infection related to blood products, but I was aware that HIV, hepatitis B and non-A non-B hepatitis could be transmitted. I was aware that haemophilia products had caused transmission of HIV. My knowledge about hepatitis came from medical school training. I cannot remember from where my knowledge about HIV transmission came.

71. When I started work in Cardiff in 1996, I had a much better understanding of the risk of transmission of infectious diseases by blood products and, in particular, the implications of pooling plasma from a large number of donors. I was aware of the methods of viral inactivation that were available and which methods were used for specific concentrates. By 1996, I was aware that the hepatitis C virus had been identified.

72. The source of this knowledge had come from my training at the Royal London, Royal Free and Great Ormond Street Hospitals. I had also gained knowledge from reading papers and attending academic meetings.

73. Subsequently, I have continued to develop knowledge related to the risk of infection from blood products through continuing professional development. In addition, I have become aware of the issues relating to the potential risk of transmission of vCJD. This knowledge has been derived from academic meetings, reading journals and discussion with colleagues.

74. At the time of my arrival in Cardiff, I was not aware of any advisory or decision-making structures that covered the Centre to consider the risk of infection from blood products in relation to inherited bleeding disorders.

75. Structures or decision-making bodies that considered the risk of infections associated with blood and blood products would have been led through the Blood Transfusion Service rather than the haemophilia centre.

76. I was aware around this time that people with inherited bleeding disorders had been infected with HIV, hepatitis C and hepatitis B as a consequence of treatment with blood products but I was not aware of the individual clinical circumstances. As such, I have not investigated the clinical circumstances that led to infections in individual cases. In some cases, individual patients or their relatives have told me about the circumstances surrounding the transmission of these infections.

Hepatitis

77. When I began work at the Centre, I was aware that the risk of transmission of hepatitis B and C through pooled blood products had been very high until viral inactivation had been introduced. I was aware that the risk of transmission of hepatitis from plasma-derived coagulation factor concentrates was very low following the introduction of viral inactivation procedures. In addition, it was standard practice at that time to offer hepatitis B vaccination. I was aware that the use of recombinant coagulation factor concentrates reduced the risk of infectious disease further.

78. I was also aware that the risk of transmission of hepatitis from red blood cells, fresh frozen plasma, platelets and cryoprecipitate was low but not zero due to the lag between a donor contracting hepatitis and this being evident on testing.

79. The source of my knowledge was the training I received at the Royal London, Royal Free and Great Ormond Street Hospitals, reading textbooks and journal article and attending academic meetings.

80. The Centre would have been aware that pooled coagulation factor concentrates were associated with a high risk of transmitting hepatitis B and non-A non-B hepatitis before 1985, as it was common knowledge to haemophilia doctors at the time. This knowledge would have evolved through the 1970s.

81. The Centre offered hepatitis B vaccination when it became available to reduce transmission.

82. I do not know what actions, if any, were taken at that time to reduce the risk of transmission of non-A non-B hepatitis before 1985.

HIV and AIDS

83. In 1996, my understanding was that plasma-derived coagulation factor concentrates had transmitted HIV and AIDS in the past but that, since the introduction of viral inactivation steps in 1985, no further infections had occurred. I understood that red blood cells, fresh frozen plasma, platelets and cryoprecipitate continued to be associated with very low risk for transmission of HIV. I was aware that virally inactive fresh frozen plasma was available and should be used for treatment of some inherited bleeding disorders.

84. I do not have first-hand knowledge about the understanding the Centre/ its staff may have had in relation to the risk of transmission of HIV and AIDS during the time when the infections occurred. The relevant period pre-dated my time at the Centre by around a decade. I would expect that Professor Bloom would have been up to date with issues relating to the risk of AIDS and his knowledge would have evolved from 1983 onwards. It is not possible for me to know what the state of knowledge was at any specific time.

85. I have some second-hand knowledge about steps taken to reduce the risk of transmission of HV/AIDS in the 1980s. I have been told by Dr Dasani and Sister Jennifer Jones that coagulation factor concentrates sourced from UK plasma were used for children and patients not previously exposed to concentrates because these were thought to be safer than imported concentrates. I was also told that the Centre had a policy of exposing people with haemophilia to as few batches of concentrates as possible to the reduce risk of transmission of infection.

86. As explained above, a protocol produced in May 1983 **[WITN4029002]** described which patients should receive which types of blood products. The role of desmopressin and cryoprecipitate is highlighted. This protocol demonstrates attempts to reduce the risk of transmission of HIV/AIDS to certain groups of patients such as those not previously exposed

to blood products. The date of the protocol in May 1983 demonstrates that actions were taken soon after AIDS became recognised as a major concern for people with haemophilia. The document also appears to confirm the policy of exposing people to as few batches as possible. The protocol was updated in October 1985 **[WITN4029003]**.

87. The latter protocol included a list of people who attended the Cardiff centre at this time and indicated which blood product each person should be treated with. This document indicates that young children and patients who had not previously been exposed to blood products were being treated with products thought to be of lower risk of HTLV III.

88. Heat treated factor VIII concentrate - a BPL product - was introduced in Cardiff in early 1985 and later that year the heat-treated Profilate HT was introduced. Heat treated factor IX (Profiline) was introduced in late 1985 as soon as it became available (as can be seen by the October 1985 Protocol). In a letter dated 19 March 1985 **[WITN4029007]**, BPL describes the distribution of heat-treated NHS factor VIII. The letter states that "Limited supplies of concentrate are now being made available from BPL on a regional pro-rata basis: the amount being 50% of what would otherwise have been supplied of unheated concentrate".

89. I am afraid that I am not able to comment on whether any decisions or actions could have been taken by the Centre to avoid or reduce the use of infected blood products beyond what I have noted above. This is because I do not know what the specific level of knowledge was at the relevant time and/or the specifics as to what decisions were made at that time and why.

90. I was not qualified in medicine at the time patients were infected with HIV and hepatitis and cannot comment on whether decisions and policies of clinicians or organisations taken at this time (timing of knowledge – individual and generally – is obviously critical) could have contributed to the scale of infections.

Section 4: Treatment of patients at the Centre

Provision of information to patients

91. When I started work in Cardiff, all people who were about to start treatment with coagulation factor concentrates were counselled about the potential risk of infection associated with these products. This counselling was provided by either Dr Dasani or me and reinforced by Sister Jones. People were told about the previous transmission of HIV and hepatitis and the

steps taken to reduce this risk with viral inactivation. The potential risks of unknown infectious agents were explained.

92. The same information continues to be given today for patients starting on plasma-derived products. In particular, the history of transmission of HIV and hepatitis is explained and the potential risk of *as yet unknown* infectious agents.

93. Since the introduction of later generation recombinant coagulation factors the risk of transmission of infections has been removed because these concentrates do not contain human blood products. Despite this, when a patient first starts treatment with a recombinant product the past history of HIV and hepatitis is explained, and this is still my practice today.

HIV

94. In order to assist the Inquiry, I have obtained the following information regarding the Centre's patients from the NHD:

    a. The total number of people who were infected by HIV in Cardiff and reported to the NHD was 45. In addition, a partner of a person with a bleeding disorder was infected. It is worth noting that I have previously written documents which state this number is 54, but this includes people looked after in Cardiff who were infected elsewhere (see g. below).

    b. The number of people with severe haemophilia A that were infected with HIV was 28. The number with severe haemophilia B was 3. A total of 31.

    c. The number of people with moderate haemophilia A who were infected with HIV was 6, and the number with moderate haemophilia B was 1. A total of 7.

    d. The number of people with mild haemophilia A who were infected was 6. No people with mild haemophilia B were infected with HIV.

    e. The total number of people with von Willebrand disease who were infected with HIV was one.

    f. Of the 45 people infected with HIV in Cardiff, 10 were below the age of 18 years when first diagnosed.

    g. In addition, when I arrived in Cardiff, there were 9 other people with HIV who were being or had been treated at the Centre.

95. I am aware that blood samples were stored and subsequently tested for HIV when the test became available. The earliest HIV test result I can find reference to is 1978 **[WITN4029021]** and so these samples were being stored before HIV/ AIDS was a recognised disease. The time period for seroconversion can be established for many patients from these samples. To the best of my knowledge this information has never been collated at a Centre level.

96. In addition, a study was performed by Professor Bloom and Dr Elizabeth Moffat that investigated parameters of the immune system in people with bleeding disorders who attended the Centre in 1984. Dr Moffat was a research registrar in the Centre during this period. The study gives some information about reduced CD4 counts amongst the patient cohort during 1984. I have seen papers written about the study and the references are: *A study of cell mediated and humoral immunity in haemophilia and related disorders* Moffat EH, Bloom AL, Jones J, Matthews N, Newcombe RJ. Br J Haematol. 1985 61:157-67 **[WITN4029020]** and *HTLVIII antibody status and immunological abnormalities in haemophilia and related disorders* Moffat EH, Bloom AL and Mortimer PP Lancet 325: 8434,p 835, 20 April 1985 **[WITN4029021]**.

Hepatitis B

97. It is not possible to state the number of people who were infected with hepatitis B at the Centre because these numbers have never been collated by the Centre. The individual patient records are insufficient or unavailable to provide this information in a systematic or readily accessible way. It is likely that most people treated with pooled coagulation factor concentrates before hepatitis B screening of plasma was introduced were infected. People exposed to blood products such as red blood cells, fresh frozen plasma, cryoprecipitate and platelets were also at risk of hepatitis B but, again, unfortunately it is not possible to give numbers.

Hepatitis C

98. When I started work in Cardiff in 1996 Dr Dasani told me that he and Dr Simon Davies (a locum consultant at the Centre after Professor Bloom died in 1992, who now works in Taunton Hospital) had undertaken hepatitis C tests on all the people who were attending the Centre and were thought to be at risk of exposure to hepatitis C.

99. Dr Dasani told me that he or Dr Davies told patients about their results face to face soon after the results became available; however, I cannot give an exact timeline or verify that this information is correct in all cases.

100. I remember one person treated at the Centre whose hepatitis C diagnosis was made after September 1996. I informed this patient of the result in person as soon as it was available.

101. By 1996, all patients with a positive hepatitis C test had been informed about the diagnosis of hepatitis C. When I started, I established regular out-patient clinics and people with hepatitis C were regularly updated about the infection and potential for progression to chronic liver disease. Hepatitis C was discussed with all infected people as a routine part of these clinics. Advice about moderating alcohol consumption was given regularly. Treatment options were discussed as they became available. This was initially with alpha-interferon and subsequently with pegylated alpha-interferon and ribavirin. These discussions were primarily undertaken by Dr Dasani. Some people had been treated with interferon by Dr Dasani before my arrival.

102. Dr Dasani had offered hepatitis C testing for partners and household contacts of people with hepatitis C before I started in Cardiff and had advised people about the risks of transmission within households. Dr Dasani published a paper about this work in 1997: *Absence of intrafamilial transmission of Hepatitis C in patients with inherited bleeding disorders* Dasani H, Jackson H, Jones HA and Howlett J. Haemophilia 3: 199-200, 1997.

103. This paper describes that counselling was given by Dr Dasani before these tests were performed. The paper states that 215 partners and household contacts of 118 people with inherited blood disorders who attended the Centre were tested.

104. In 2003, a joint liver clinic was established with Dr Godkin, a hepatologist (who also works at Cardiff University and has an honorary contract with Cardiff & Vale) and he continued to provide up-to-date information for people with hepatitis C attending that clinic.

105. When new treatments for hepatitis C became available these were introduced through the Blood Borne Virus clinic in Cardiff. This service was led by Dr Brendan Healey who is a Consultant in infectious diseases/ microbiology. The Centre referred all patients with hepatitis C who attended the Centre to Dr Healey, and they were assessed, counselled and offered treatment through the Blood Borne Virus clinic.

106. In 2016 a joint liver clinic was started with Dr Srivastava, a hepatologist appointed in Cardiff in 2016. These clinics continue to provide information about the significance of liver disease and its prognosis.

107. As mentioned in paragraph 103 above, the number of people reported as having been infected with hepatitis C and were being treated at the Centre was 118. This is the number of people who were tested and found to be antibody positive. It is, however, inevitable that many more would have been infected by hepatitis C but died before a test became available.

108. I have been shown a letter dated 19 August 1996 written by Jane Martin of BPL to me (albeit sent prior to my tenure) about a voluntary recall of a batch Factor VIII and three batches of Albumin due to traces of hepatitis C genomic material in one of the donations to the pool **[BART0000553]**. I do not remember Dr Dasani informing me about this letter when I started working in Cardiff a few weeks later. I do not remember discussing the issue with any of the patients.

109. I have also been shown a letter from Dr Dasani to Clive Dash of BPL a couple of days later **[BART0002050]** which states that Dr Dasani discussed this issue with the five patients who had been supplied with the specific batch of Replenate. He describes the *"long counselling and reassurance"* by telephone demonstrating the patients involved were contacted promptly and told about the recall.

110. Dr Dasani's first concern in that letter appeared to be the way the information was sent and the fact that he was not informed directly. Looking at this letter, I share his concern. He noted: *"Receiving this information two hours earlier would have saved at least one patient being exposed to this batch"*.

111. His second concern that was that there was no apparent plan to monitor people who had been exposed to the batch and were hepatitis C negative. I agree that these people should have been monitored for hepatitis C seroconversion.

112. I have also been shown correspondence between 1996 and 1997 relating to an investigation **[BPLL0016072]**, which was triggered by an article published by Dr Dasani and others around this time into the transmission of hepatitis C from heat-treated factor concentrate produced by BPL **[BPL0016072(2i)]**. My observations on this are as follows:

a. The initial letter was addressed to Dr Dasani and he showed it to me when I started working in Cardiff. I took the lead in the written responses to BPL's inquiries because

I had become the Centre Clinical Director. However, Dr Dasani led the process because he had written the case report and knew the cases in much more detail than I did, and I was guided by his views on this matter.

b. I have not received any similar requests to investigate other patients. I have not assisted with any similar investigations.

c. I do not remember seeking the consent of the two patients before agreeing to their records being reviewed. Dr Dasani took the lead in liaising with the BPL representative during the visit and I do not know whether he obtained consent for the notes to be reviewed.

d. I do not remember informing either of the patients about the results of the investigation. I do not know whether Dr Dasani informed the patients about the results.

e. The source of the hepatitis C infection in one case was not disputed and was due to a non-virally inactivated pooled coagulation factor concentrate. Dr Dasani reported the other case as being that of transmission of hepatitis C associated with a virally inactivated concentrate in 1985. The discrepancy of opinion was never resolved. I do not think there were any clinical implications resulting from this discrepancy of opinion. I do not remember informing the patient about this. I do not know whether Dr Dasani did so.

Delay/ public health/ other information

113. When I started working at the Centre, all patients with a positive HIV or hepatitis C test had already been informed about the results.

114. During my time in Cardiff, HIV tests have been performed regularly for partners of people who were HIV positive. All of these tests have been negative. The results of these tests were notified to the individuals involved promptly. Dr Dasani and Sister Jones took the lead in performing these tests and notifying individuals of the results.

115. People who transferred to the Centre from another centre or from abroad had baseline HIV and hepatitis bloods performed. My memory is that all people who transferred from another UK centre already knew their status in advance of the test. Some people

transferring from abroad did not know their status and they were informed of the result promptly.

116. When I started in Cardiff, people who were HIV and hepatitis C negative who were being treated with pooled, plasma-derived coagulation factor concentrates were tested for HIV and hepatitis C on a regular basis. This practice continued after I arrived. There were no positive results.

117. With the introduction of recombinant coagulation factor concentrates the risk of transmission of HIV, hepatitis C and hepatitis B was reduced and routine blood tests for these infections was phased out.

118. I am not aware of any delays in informing people about a diagnosis of HIV, hepatitis C or hepatitis B during my time in Cardiff.

119. Since 1996, the public health implications of the treatment for haemophilia were very important when considering what information to give to people and what treatment to offer. All patients, or the parents of young children, who were starting treatment with a pooled plasma-derived coagulation factor concentrate were informed of the potential risk of transmission of an infectious agent.

120. At this time, all staff at the Centre were aware that treatment available at the time was virally inactivated and that the risk of transmission of HIV, hepatitis C and hepatitis B was very low; this was explained to patients. The past history of transmission of HIV and hepatitis C by non-virally inactive concentrates was discussed. The potential risk of an *as yet unknown* infectious agent was explained. This is still the practice for people starting a plasma-derived concentrate.

121. The practice of the Centre was to maintain individuals on the same batch of concentrate, where possible, to minimise donor exposure.

122. Further, vaccination against hepatitis A and B was routinely offered to people receiving a pooled concentrate and an explanation about this was given. It was explained that, although the risk of transmission of hepatitis A and B from virally-inactivated concentrates was very low, people with bleeding disorders were more likely to need treatment with red blood cells of blood components and these products continued to be associated with a small risk of transmission of these infections.

123. As explained in paragraph 46 above, one of the first actions that I took when I took up my post in Cardiff was to advocate for the use of recombinant coagulation factor concentrates because I was aware of the public health implications of plasma-derived concentrates. In Wales, the directors of public health agreed to support the universal introduction of recombinant coagulation factor concentrates in 1997. Wales was the first country in the world to offer recombinant coagulation factor concentrates, if available, to all patients.

124. Although there is no risk of transmission of an infectious agent with modern recombinant concentrates, patients and their families receiving these products for the first time still have the issue of transmission of infectious disease discussed, including the past transmission of HIV and hepatitis, and an explanation given as to why this is not relevant to recombinant products.

125. People who were treated with plasma-derived coagulation factor concentrates were informed about the potential risk of *as yet unknown* infections and this advice continues to be given. As people were switched to later generations of recombinant products this advice became unnecessary and was no longer given.

126. With regard to the information given to patients about the risks of infecting others, when I first arrived in Cardiff, Dr Dasani informed me that everyone who had been infected with HIV had been counselled about the risks of infection to other people and been given advice of how to reduce this risk. Mr Timothy Hunt, the Centre's social worker, continued to provide ongoing advice. Sister Jennifer Jones was involved in counselling patients and families about how to administer treatment and dispose of needles safely.

127. Children who were infected with HIV were informed of the risk of transmission through sexual activity at an appropriate age and this process had been led by Professor Bloom and Dr Dasani. My understanding is that this had taken place before I started in Cardiff.

128. Before my time at the Centre, Dr Dasani had undertaken a systematic process of offering hepatitis C testing to the partners of people who had been infected with this virus. All of these tests were negative. It was the practice of the Centre to counsel people that the risk of transmitting hepatitis C through sexual contact was low. People were counselled about not sharing items such as toothbrushes. Patients and families were educated about how to administer treatment safely.

Consent

129. In 1996, blood samples were taken from people with HIV infection every 1-3 months, depending on their clinical situation. Samples were taken to monitor the CD4 count, full blood count and liver function tests. Very soon after I started in Cardiff HIV viral load tests were introduced. The purpose of these blood tests was to monitor the HIV infection and the response to treatment. At a later stage, tests for HIV virus resistance were introduced to help decide which anti-retroviral agents would be most likely to be efficacious in an individual case.

130. Patients were informed about the purpose of the blood samples and understood the implications of results. The reasons for performing a CD4 count and the implications of the result had been explained to all patients before I arrived. The implications of CD4 counts were regularly re-iterated after I arrived.

131. When the HIV viral load and HIV viral resistance tests were introduced the reasons for performing these tests were explained. The implications of the results of the tests were explained to individuals by Dr Dasani, Dr Freedman and me.

132. Tests for hepatitis C genotype and PCR (polymerase chain reaction) were introduced when these became available. The reasons for these tests and the implications of the results were explained to individuals by Dr Dasani, Dr Freedman and me.

133. Blood samples taken from people receiving pooled plasma-derived concentrates were stored in the virology department. The reason for this was that, if a new infectious agent was discovered, the date of the infection could be established in retrospect and the possible cause of infection investigated. The reasons for storing the blood samples were explained to individuals but written consent was not sought.

134. When the Centre switched to recombinant products the practice of storing samples was phased out around 2000. These samples are no longer stored in the virology department.

135. During my time at the Centre, no one has been tested for HIV or hepatitis without their express and informed consent. Patients who were being tested for HIV or hepatitis C for the first time were counselled about the implications of the tests, for example, on life insurance or applying for mortgages, and the tests were not performed unless express consent was provided.

136. People treated with plasma-derived concentrates and who were HIV and hepatitis C negative were routinely tested for HIV and hepatitis C every 6 to 12 months. This practice had been ongoing for many years before I started and the reasons for this practice had been explained to people by Dr Dasani before 1996. Separate consent was not sought from individuals on each occasion that these tests were performed.

Previously untreated patients ("PUPs")

137. During the late 1960s and 1970s, when hepatitis C and hepatitis B were transmitted, I do not have any knowledge of how treatment was selected for people who had never been previously exposed to coagulation factor concentrates. From the relevant Protocols referred to above, it appears that, in 1983, the policy was to treat children with severe haemophilia with cryoprecipitate or NHS factor VIII. This group would have included most previously untreated patients. And, in 1985, the policy was to treat previously untreated patients with either heat treated profilate HT or BPL factor 8Y.

138. After I started work in Cardiff in 1996, all people who had never been previously exposed to coagulation factor concentrates have been treated with recombinant factor VIII or factor IX.

Research

139. I have considered the Inquiry's Terms of Reference and believe the following studies may be relevant to the same:

a. In 1998, the Centre collated routine information about (33) patients treated exclusively with the plasma-derived product, Factor 8Y, since 1985 when it was introduced. The purpose of this analysis was to report on the long-term safety and efficacy of the concentrate. Dr Dasani and Dr Brown collated the information and wrote the first draft of the manuscript, I advised on what data should be included in the report and commented on the manuscript. At this time, Drs Dasani and Brown and I did not consider that this process constituted research and so did not required ethical submission or individual consent because it was based on routine information collected about standard care. No other organisations were involved in this work. The work received no funding.

The publication reference for this work is Brown SA, Dasani H & Collins PW. *Long-term follow up of patients treated with intermediate FVIII concentrate BPL 8Y* Haemophilia 4:89-93, 1998 **[WITN4029008]**.

b. In 1999, routine clinical information was collated from seven haemophilia centres in the UK. The purpose was to report on whether people receiving protease inhibitors for treatment of HIV experienced more bleeding that expected. My understanding was that this work did not constitute research and so did not require ethical approval and individual patient consent because it was based in routine information about standard care. My involvement was to submit anonymised data and Dr Dasani assisted me in collating and sending this information. Other organisations involved were Queen Elizabeth Hospital Birmingham, Royal Free Hospital London, Churchill Hospital Oxford, Kent and Canterbury Hospital and Manchester Royal Infirmary. The work did not receive any funding to the best of my knowledge. There were 67 patients involved from 6 haemophilia centres, but I do not remember how many of the 67 were from Cardiff.

   The publication reference is Wilde JT, Lee CA, Collins P, Giangrande PLF, Winter M and Shiach C. *Increased bleeding associated with protease inhibitor therapy in HIV-positive patients with bleeding disorders*. Br J Haematol 107:556-559, 1999 **[WITN4029022]**.

c. In 2008-2009, Cardiff contributed to the CHAVI 14 study coordinated by Oxford University and Duke University. The purpose of the study was to identify human genetic variants that influence susceptibility or resistance to HIV infection. The study was submitted for ethical approval (REC reference 08/H0606/85) **[WITN4029023]**. My involvement was to recruit patients from Cardiff, seek informed consent and send blood samples to Oxford for analysis. I do not know how the study was funded. I cannot remember how many patients were recruited from Cardiff. Patients had the purpose of the research explained and written informed consent was sought. I am not aware of any publication related to this work.

d. The only other publication I think worth mentioning in the context of the Terms of Reference is: Kell WJ, Dasani H and Collins PW. *Aggressive treatment of HIV-associated microangiopathic haemolytic anaemia is associated with good outcome*.

Am J Nephrol 18:260, 1998 **[WITN4029024]**. This case report was written and published after the patient had died.

140. During my time at the Centre, patients have not been involved in research studies without giving their express consent. And no anonymised patient data has been used for research purposes in Cardiff without the express consent of the patient. I discuss the data submitted to NHD more particularly below. Anonymised patient information has been reported in academic journals without the express consent of the individuals involved. These reports are based on information collected about routine care and have been collated by members of the Centre. My understanding, based on current lexicon, which was not necessarily the same lexicon as 20 years or more ago, is these reports are not research studies but fulfil criteria for service evaluation and so do not need to be submitted for ethical approval and informed consent does not need to be sought. The relevant papers are:

a. *Mycophenolate mofetil as adjunctive therapy in acquired haemophilia A*. Obaji S, Rayment R, Collins PW. Haemophilia 25:e59-e65, 2019.

b. *Unclassified bleeding disorders: Outcome of haemostatic challenges following tranexamic acid and/or desmopressin*. Obaji S, Alikhan R, Rayment R, Carter P, Macartney N and Collins PW Haemophilia 22:285-291, 2016.

c. *Selective angiographic embolization for recurrent elbow and knee haemarthroses in haemophilia: A retrospective case series*. Obaji S, Jones C, Yates A, Gordon A, Wood A, Collins P. Haemophilia 21:e226-e228, 2015.

d. *A population based, unselected, consecutive cohort of patient with acquired haemophilia* A. Collins P, Macartney N, Davies P, Lees S, Giddings J and Majer R. Br J Haematol 124:86-90, 2004.

e. *Recombinant factor IX (Benefix®) by adjusted continuous infusion. A study of stability, sterility and clinical experience*. P Chowdary, H Dasani, JAH Jones, CM Loran, A Eldridge, and PW Collins. Haemophilia 7:140-145, 2001.

141. My current understanding of the ethical principles that should guide research is as follows: Research should be based on a protocol that has been passed by an ethics committee. Participants should provide consent to take part in the research which is freely given after a full explanation of the research. The research should take into account the balance between potential benefits and harm and that potential benefits outweigh the

potential risks. The researcher should be competent to perform the research. The safety, dignity and well-being of the participants should be protected. Research should be conducted with honesty and integrity. Conflicts of interest should be declared. Data collected as part of a research project should respect a participant's confidentiality.

142. All data requested by UKHCDO during my tenure has been submitted to the NHD. This information is neither anonymised nor de-identified. The type and amount of data submitted has changed over time and mainly describes the brand of treatment issued to individual patients, reports about side effects of treatment and information about infectious diseases. Some patients choose to submit information about individual bleeds and treatments through a system called Haemtrack.

143. When I started working in Cardiff the information was submitted to UKHCDO annually on paper forms. More recently the information has been submitted electronically every 3 months. The submission is co-ordinated by the Centre data manager under the supervision of the lead clinician and nurse.

144. It has been, and still is, my understanding that the NHS requires Haemophilia Centres to submit the data to the NHD (by way of illustration, I have supplied a copy of a letter to the Welsh Assembly Government from 2002 – although I have not been able to track down whether I received any reply at the time **[WITN4029009]**.

145. UKHCDO has prepared a series of patient information leaflets about what information is collected by the National Haemophilia Database **[WITN4029025] [WITN4029026] [WITN4029027]**. The leaflets also outline what the information is used for. The first patient information leaflet was distributed in 2001 and explained that individual patients had the right to ask for their data to be removed. Over the years, this leaflet has been through various iterations and these have been distributed to the patients in Cardiff.

146. I have been shown a letter dated 14 July 1998 from the Public Health Laboratory Service (and enclosed report) **[CVHB0000002_162 and CVHB0000002_163]** regarding the data provided by the Centre for the CD4 surveillance scheme.

147. Dr Dasani submitted data on behalf of the Centre about CD4 counts because he took the lead on issues related to HIV/AIDS. As far as I am aware, individual patient consent was not sought to use the information reported in this surveillance exercise. My understanding was

that patient consent would not be required for a national surveillance exercise led through the Public Health Laboratory Services Communicable Disease Surveillance Unit.

148. In the late 1990s, I was a junior member of the UKHCDO advisory committee and had minimal involvement in decisions about whether the UKHCDO was entitled to hold information about people with bleeding disorders.

149. As mentioned above, an information leaflet about the NHD and the information that it held was produced by UKHCDO in 2001. The Centre sent this information leaflet to people registered on the database. The patient information leaflet was updated a number of times over the years and each update was mailed to all patients who were registered or, for children, to their parents.

150. After the patient information leaflets were distributed, I do not remember anyone who attended the Centre raising any concerns about their data being submitted to UKHCDO.

151. I have been shown the minutes of the 17 July 2006 meeting of the UKHCDO Advisory Committee **[HCDO0000745_001]** which record a discussion of the Data Protection Act (1998) and the NHD. The minutes record that I said: *"thought must be given as to what is required for using the database for research"*. My comment was about whether any specific steps needed to be taken if data held by the UKHCDO was used for research as opposed to being held for other purposes. I do not remember this being discussed further.

152. I was supportive of the apparent majority view that the system of informing patients about the information held on the NHD and an explanation about what the data was used for through the patient information sheets, with the option to opt out of the database or ask for some or all of their data to be removed, was sufficient.

153. The patients in Cardiff were kept informed through the patient information leaflet distributed in 2001 and subsequent iterations of this document. I remember having a discussion with a small number of people about the information held on the NHD, this mainly revolved around how to access they own data.

154. No one attending the Centre has expressed any concerns to me about their data being held by the NHD. To my knowledge no one attending the Centre has asked to opt out of having their data held on the NHD or having some of their data removed.

Treatment of patients who were infected with HIV and/or hepatitis

155. When I arrived in Cardiff, people infected with HIV were being managed by Dr Dasani. In some cases he involved the Infectious Disease team led by Professor Leszek Borysiewicz. Dr Dasani was a specialist in the management of HIV and AIDS and undertook continuing professional development to keep up-to-date with advances in the field. Dr Dasani had offered anti-retroviral treatment for patients whose CD4 counts had fallen and this treatment had been initiated for those who wanted it. At the time, this treatment was with drugs such as zidovudine, didanosine and lamivudine.

156. Very soon after I had started to work in Cardiff, I approached Dr Andrew Freedman, a consultant in infectious diseases, to set up a formal system of inter-disciplinary working. The patient group in Cardiff expressed a strong desire to continue to be treated through the Centre and by Dr Dasani.

157. Patients with HIV were seen in joint clinics with Dr Freedman and either Dr Dasani or me. In addition, patients were seen through the Centre on an *ad hoc* basis. The patients knew that they could attend the Centre at any time.

158. Over time, patients became established on stable HIV treatment regimens and consistently had undetectable HIV viral load and a well maintained CD4 count. At this time patients were seen in Centre clinics for regular follow up and monitoring and three-monthly multi-disciplinary meetings were held with Dr Freeman, a HIV specialist pharmacist and a HIV specialist dietician to discuss individual patients' results and treatment plans. If any issues emerged, such as side effects of treatment, a detectable viral load or a falling CD4 count, patients were reviewed by Dr Freedman in the Centre jointly with Dr Dasani or me. Dr Freedman advised on all drug regimens to treat HIV and these treatments were prescribed through the Centre with support of the specialist HIV pharmacist.

159. The HIV specialist pharmacist and dietician held separate consultations with patients to discuss treatment related issues such as potential side effects and how these could be minimised and for dietary advice.

160. Regular HIV tests were offered to partners of patients infected with HIV and advice was given to couples who wished to consider having children. This was co-ordinated by Dr Dasani.

161. After Dr Dasani retired in 2007, the Centre continued to hold regular multi-disciplinary meetings with Dr Freedman and a HIV specialist pharmacist and, over time, the follow-up and treatment of this group of patients was transferred to the Blood Borne Virus clinic in Cardiff. Appointments are arranged so that people have their routine haemophilia review in the Centre on the same day as their Blood Borne Virus clinic appointment. Any blood tests that were necessary for monitoring HIV were taken in Centre by the haemophilia nurses at the same time as blood tests to monitor haemophilia care. This reduced the number of times an individual needed to attend the hospital and maintained a strong link between the patients and the Centre.

162. Dr Freedman and his colleagues in the Blood Borne Virus clinic continue to monitor the patients with haemophilia who have been infected with HIV. Some people have transferred their care to the clinic in Swansea because this hospital is closer to their home. The Swansea clinic is managed by Dr Yoganathan.

163. Patients with HIV have been offered up-to-date treatment throughout the time I have worked in Cardiff; with access to new drugs and laboratory assays as these became available. The treatment options to be offered were agreed jointly by Dr Freedman and Dr Dasani. Protease inhibitors were introduced in early 1997 and other drugs were offered as they became available. Laboratory tests such as HIV viral resistance testing was offered as soon as it became available. These tests were offered to patients by Dr Freedman and the implications of the results and treatment choices were discussed by Dr Freedman.

164. At all stages, information about the risks and benefits of treatment for HIV has been explained to patients. This information was initially given by Dr Dasani, Dr Freedman and the HIV specialist pharmacist. It is now given through the Blood Borne Virus clinic multi-disciplinary team, including the HIV specialist pharmacist and nurses.

165. No patients have been infected with HIV during the time I have worked at the Cardiff Haemophilia Centre.

166. I remember taking part in the review of HIV/AIDS services in the late 1990s which was chaired by Mr Clive Rees, but I cannot remember any details of the issues under review or the discussions that took place. I cannot find any minutes related to these meetings. I am not able to comment on whether the review led to any changes to the treatment for people attending the Centre.

167. I understand from Inquiry communications that the review considered therapy options for people with haemophilia co-infected with HIV and hepatitis B or C. I do not remember any details of these discussions. I am not aware of any difficulties accessing treatment for people co-infected with HIV and hepatitis who attended the Centre during the late 1990s.

168. People attending the Centre had been screened for hepatitis B before I arrived in Cardiff. Screening continued to be performed through the Centre after I started. This included identifying people with active infection. People who have been infected with hepatitis B were managed jointly by Dr Dasani and Dr Freedman.

169. People with active hepatitis B infection were seen in a joint haemophilia/liver clinic with Dr Andrew Godkin. Treatment advice was also given by Dr Freedman of the Infectious Disease team at the regular multi-disciplinary meetings. More recently people with active hepatitis B are seen and treated in the joint hepatology/haemophilia clinic with Dr Srivastiva, a hepatologist. Throughout the time I have been in Cardiff, people with hepatitis B have been screened for chronic liver disease and had surveillance for hepatocellular carcinoma with liver ultrasounds and alpha fetoprotein tests through the Centre and more recently through the joint hepatology/haemophilia clinic.

170. People with hepatitis B have been offered all treatments options that were available at the time. In most cases, people were co-infected with hepatitis C or a combination of hepatitis C and HIV. The treatment of the combined infections was coordinated by Dr Freedman. The risks and benefits of treatment for hepatitis B was supplied by Dr Dasani and Dr Freedman.

171. No patients have been infected with hepatitis B during the time I have worked at the Cardiff Haemophilia Centre.

172. When I started to work in Cardiff treatment of hepatitis C was being coordinated by Dr Dasani. At that time Dr Dasani was offering treatment with interferon and ribavirin through a clinical trial. Patients were being followed up for the development of chronic liver disease through the Centre and this was coordinated by Dr Dasani. He had referred patients for second opinions in England and some patients had undergone liver transplantation before I arrived. These transplants had taken place in London and Cambridge.

173. When I took up my post, I established a formal link with Dr Freedman to ensure that the treatments offered by the Centre for eradication of hepatitis C were optimal. These treatments were prescribed and managed through the Centre.

174. In about 1998, I established a link with a gastroenterologist, Dr Gareth Thomas, who had undertaken speciality training in hepatology in Birmingham. Patients were screened for signs of liver decompensation or hepatocellular carcinoma through the Centre with regular blood tests, liver ultrasounds and alpha fetoprotein tests. Dr Thomas was available to discuss patients and would see them as required. Because of his links with Birmingham, referrals for second opinions and liver transplantation, if necessary, were made to Professor David Mutimer and his team in Birmingham.

175. In 2002, a hepatologist, Professor Andrew Godkin, was appointed in Cardiff. In 2003, a joint haemophilia/liver clinic was established. Professor Godkin came to the Centre for the joint clinic and saw the patients with me or another member of the Centre staff. This clinic was not part of Professor Godkin's routine clinical activities and was performed during his time for supporting professional activities. These clinics occurred every 4-6 months and reviewed patients with more progressed liver disease. Professor Godkin made referrals to Birmingham as required. Routine surveillance for liver disease was performed by the Centre. If required, liver biopsies were performed by Professor Godkin with haemostatic cover provided by the Centre. Professor Godkin was available to discuss individual patients between clinics and would see patients in his own clinic if necessary.

176. The joint haemophilia/liver clinics could not be sustained because they were not part of Professor Godkin's clinical job plan. The joint clinics ended in about 2009. After the haemophilia/liver joint clinics had ended patients with hepatitis C were followed up through the Centre and surveillance liver ultrasounds and screening for hepatocellular carcinoma were organised through the Centre. The Centre team contacted Professor Godkin or one of his colleagues if there were concerns about a patient with progressive liver disease and clinical advice was given. If necessary, patients were seen urgently by Professor Godkin or one of his colleagues in their clinic and referral was made to Birmingham in some cases.

177. Fibroscans were introduced through the blood borne virus clinic in 2012.

178. When new therapeutic options for the eradication of hepatitis C became available these were discussed with patients through the Blood Borne Virus Clinic, led by Dr Brendan Healey. Treatment was prescribed and managed by the multi-disciplinary team attached to

that clinic. The Centre played no role in providing this treatment. Some patients who attended the Centre accessed hepatitis C eradication treatment through their local health boards. Hepatitis C eradication treatment was offered to all patients attending the Centre who were PCR positive.

179. In 2016, Dr Brijesh Srivastiva was appointed as a consultant hepatologist. The joint haemophilia/liver was re-established and took place in the Centre. Dr Srivastiva reviewed all the patients attending the Centre from the perspective of chronic liver disease. This included regular fibroscans that were performed in the Centre on the day to the joint clinic. Individual management plans were discussed and follow up arrangements were made. This joint haemophilia/liver clinic continues to be undertaken on a regular basis. Dr Srivastiva is available at short notice if the Centre has any concerns about a patient with liver disease.

180. When I started to work in Cardiff Dr Dasani was already offering treatment with interferon, pegylated interferon and ribavirin. This continued to be offered after I arrived, and many people opted to receive a course of treatment. Management of side effects and support were provided through the Centre.

181. The risks and benefits and side effects of all treatment options were discussed with patients. The interferon-based treatments were discussed by the Centre staff and this was mainly done by Dr Dasani and me. Further information was given by Professor Godkin and Dr Freedman. Information about tablet-based treatments was given through the Blood Borne Virus clinic.

182. Lifestyle advice was initially provided by Dr Dasani before I arrived. He had spoken to patients and their families about the risk of transmission by blood for example through shared toothbrushes and razors. He had spoken to patients about the low risk of sexual transmission. Alcohol consumption was discussed initially by Dr Dasani and continued to be discussed at clinics throughout the time. Dr Srivastiva continues to provide advice about alcohol and other lifestyle issues such as the impact of increased weight on liver disease.

183. No patients have been infected with hepatitis C during the time I have worked at the Cardiff Haemophilia Centre.

184. The treatment of patients with hepatitis C attending the Centre has been more limited perhaps compared to other parts of the country in respect of access to specialists in hepatology. This means that, for periods of time, follow up for chronic liver disease and

surveillance for hepatocellular carcinoma was dependent on haematology services. Liver specialists were contacted if the Centre staff had concerns and clinical advice was given or patients were seen in the next available liver clinic. Some patients needed to access hepatology services at other hospitals. In my view, patients with progressed liver disease would have been more appropriately followed up in a specialist liver clinic so that signs of deterioration, if any occurred, could be identified more reliably.

185. The reason for the difference in access to care, in my opinion, was that insufficient numbers of clinical sessions for hepatology were available within the hospital. Ultimately, this came down to a choice about which services should receive investment.

186. The clinical response of the Centre to the issue of limited access to specialist hepatology has been to maintain surveillance for chronic liver disease through the Centre to the best of our ability and to seek specialist advice when needed. The Centre has referred patients to the liver unit in Birmingham if necessary.

187. I advocated for increased access to specialist hepatology services through routes such as the Ministerial Task and Finish Group for Inherited Bleeding Disorders in 2011 and ensured the issue was one of the top priorities in that review. I also advocated for better access to specialist hepatology though the Welsh Health Specialised Services Committee and the All Wales Inherited Bleeding Disorder Group.

188. Since 2016, when the joint haemophilia/liver clinic was re-established with Dr Srivastiva, I do not think that treatment has been more limited than other areas of the UK.

189. In my view, access to drugs and treatment for the eradication of hepatitis C has been at least as good as anywhere else in the UK throughout the time I have worked in Cardiff.

190. The Centre has been involved in a number of clinical trials for the treatment of HIV and hepatitis C.

191. I am aware that, prior to my time in Cardiff, there had been at least two trials and a long-term access study into the management of HIV. I was not involved in these trials, but my understanding is that one trial was a randomised controlled trial of Zidovudine (AZT) versus placebo and the second was a trial of didanosine. To the best of my knowledge, both these trials were co-ordinated by the Medical Research Council. A study that allowed long-term access to 3TC (Lamivudine) was open when I arrived in 1996. During the time I worked in

Cardiff, Dr Dasani took the lead in running these trials, consenting patients and providing data. I do not remember any other trials relating to the treatment of HIV.

192. I am aware that Dr Dasani had been involved in clinical trials relating to the treatment of hepatitis C before I arrived in Cardiff. Dr Dasani had various contacts with hepatologists in the UK and became involved in studies through this network. I do not know the details of these studies, but these trials would have involved treatment with interferon and pegylated interferon and ribavirin.

193. After I started in Cardiff, the Centre was involved in one clinical trial related to hepatitis C that I can remember. This was a trial of pegylated interferon and ribavirin with or without the addition of amantidine. The study started in 2000 and Dr Dasani took the lead in recruiting patients to this study and ensuring appropriate follow up.

194. In 1996, a social worker, Mr Timothy Hunt, was in post and attached to the Centre. His main role was to provide services for people infected with HIV/AIDS and that included counselling of infected people and their families. He played a particularly important role in supporting relatives if a loved one had died including when it came to coroner inquests and funeral arrangements. I was aware that he ran group sessions to support bereaved relatives.

195. The social work post attached to the Centre had been established in the 1980s and was originally funded by the Welsh Office. I do not know the exact date that is post was initiated. The post included a counselling role.

196. The social work post was filled continuously during that time that I have worked in Cardiff and counselling was, and continues to be, an important aspect of the role. The job description was expanded to cover hepatitis in addition to HIV in about 2000.

197. A psychology service for people infected and affected by HIV and hepatitis has been available through the haemophilia centres in Wales since November 2012. This service was established after a Ministerial Task and Finish group into Inherited Bleeding Disorders chaired by Dr Christopher Jones the deputy chief medical offer for Wales. Welsh Government provided additional funding to the Welsh Health Specialised Services Committee to establish the All Wales psychology service for Inherited Bleeding Disorders. The remit included counselling and psychology services for people infected with HIV and hepatitis and their families. The service model was of psychologists, who are specialists in

the field of bleeding disorders, working as an integrated part of the multi-disciplinary teams in the Haemophilia Centres across Wales.

198. At the present time, the psychological service in South and West Wales provides a service to individuals with an inherited bleeding disorder, carriers of an inherited bleeding disorder and those connected to the Inquiry. This includes supporting any individuals who may be experiencing distress by taking part in the Inquiry and who could be reliving stressful and traumatic past experiences.

199. In Wales, the following posts were established in 2012:

a. South Wales

Band 8c 0.2 WTE: Consultant clinical psychologist (based in Cardiff)

Band 8b 0.2 WTE: Principal counselling psychologist (based at Singleton)

Band 8a 0.6 WTE: Highly specialist clinical psychologist (based in Cardiff)

b. North Wales

Funding was made available by Welsh Government to appoint a band 8a 0.5 WTE highly specialist clinical psychologist (based in Bangor). I do not know whether this post has been appointed.

200. In addition to the above posts, further psychological services have been provided through the Welsh Infected Blood Support Scheme since January 2020. These posts are not associated with the Centre and I do not know details about the services provided.

201. My understanding is that the Welsh Office funded the Centre social worker in the mid- to late 1980s but do not know details about this.

202. The All Wales psychology service for people with inherited bleeding disorders was funded by Welsh Government in 2012 with an allocation of £96,363 per annum recurrently.

203. Welsh Government has funded psychology services through Welsh Infected Blood Support Scheme since January 2020. I do not know the details of the funding arrangements.

204. I am aware that Welsh Government funded counselling support for people with hepatitis through the Liver Trust, but I do not know any details about this.

205. The psychology service provides support to those accessing the Centres with a particular emphasis for patients and their families affected by HIV and hepatitis. The kinds of counselling and interventions offered include help with:

a. Adjusting to a diagnosis and the impact on the family.

b. Coping with the demands of treatment.

c. Coping with difficult feelings such as: low mood, fears and worries, stress, and guilt.

d. Coping with change. This could be treatment changes or family circumstances.

e. Making decisions about treatment.

f. Experiencing pain.

g. Experiencing trauma linked to their health condition

206. In addition, the psychologists within the service run groups (e.g. mindfulness, pain management), support young people on normalising living with bleeding disorders and provide consultation and psychological advice to staff.

207. The Centre has never encountered any difficulties obtaining funding to treat people with HIV. The Centre did not encounter any difficulties accessing funding to treat for hepatitis C with drugs such as interferon and ribavirin whilst this treatment was prescribed through the Centre.

208. When the more recent tablet-based therapies were introduced for hepatitis C eradication, people with bleeding disorders were referred to the Blood Borne Virus clinic. I am aware that money was made available for these treatments but that, initially, this was insufficient to treat all patients straight away and, as a result, those with more severe liver disease were prioritised. I am not aware of the details about how funding was sought or any difficulties obtaining adequate resources.

209. Over time, all patients who needed treatment were offered the tablet-based therapies and I am not aware of any difficulties with funding now.

210. I was part of a working group that developed and wrote the National Service Specification for Haemophilia and Related Conditions ("NHSS"). This involved attending

various meetings in London to develop the service specification and commenting on the text as it evolved.

211. The service specification was introduced in Wales in 2003 when The Specialised Health Services Commission for Wales took over the commissioning of services for inherited bleeding disorders in Wales.

212. The main advantage of the NHSS was that it laid out minimum standards of care for people with bleeding disorders including those with HIV and hepatitis. It formed the basis on which commissioning decisions for bleeding disorder services could be made. This was the first time a forum was available to start to address issues such as the need for enhanced hepatology services in Cardiff.

213. I was involved in the Ministerial Task and Finish Group in 2011 **[WITN4029010, WITN4029011]**. I attended meetings that were chaired by Dr Christopher Jones, the deputy chief medical offer for Wales, and commented on documents that were produced. The group was re-convened in 2015 to review progress. The terms of reference of the group were

> *"To review the planning and delivery of diagnosis, treatment and support services, including physiotherapy and social services support, for people with haemophilia in Wales. This review will also consider services for those people with haemophilia who have been infected with hepatitis C as a result of contaminated blood, including access to counselling services."*

214. The final report was submitted in December 2011. The summary of findings stated:

> *"The effective management of patients with inherited bleeding disorders is complex and involved the provision of comprehensive care by a team of health care professionals with diverse skills. The Review has identified a number of service gaps that need to be addressed. Priorities including addressing the service issues in North Wales, access to counselling and social work support, increased hepatology input into the service in Cardiff and providing greater equity of access to services for patients in Mid and West Wales."*

215. The main recommendations were to:

a. Establish an All Wales multi-disciplinary National Advisory Committee. This committee was established in 2012.

b. Patients at risk of vCJD should have access to appropriate diagnostic testing such as endoscopy. The Health Boards confirmed to WHSCC (Welsh Health Specialised Services Committee) that arrangements were in place to allow access to endoscopy.

c. Ensure that appropriate consultant and specialist hepatology nurse input into the treatment of patients with inherited bleeding disorders must be provided in Cardiff. A consultant hepatologist was appointed in Cardiff in 2016 and a joint haemophilia/liver clinic was set up at that time.

216. I have been shown emails I sent to Department for Health, Social Services and Children ("DHSCC") in November 2011 **[CVHB0000006_014]**, where I expressed two concerns:

a. The first was about the need to appoint a hepatologist to provide specialist care for people with bleeding disorders infected with hepatitis and especially those with advanced liver disease. The hepatologist was appointed in 2016 and so the concern was addressed at that time. The relevance of this response was that the patients attending the Haemophilia Centre continued to have a limited hepatology service for 5 years after the Ministerial Task and Finish Group. The subsequent step of appointing the hepatologist in 2016 meant that the patients attending the Centre could access appropriate care for liver disease from that time.

b. The second was about increasing access to physiotherapy. This was addressed through the commissioning process. New physiotherapy posts were funded with a full-time post in Cardiff and two days a week post in Swansea appointed in 2014. The physiotherapists in Cardiff and Swansea have made a substantial impact on the quality of patient care across south Wales. The additional posts have allowed increased access to physiotherapy and more opportunity for patients to be treated in their own homes.

217. I have also been referred to the minutes of the 28 September 2012 meeting of the WHSCC Inherited Bleeding Disorders Group **[CVHB000007_034]**. This meeting took place in September 2012, after the Ministerial Task and Finish Group had reported. I was advocating for the findings of the Task and Finish Group to be implemented. I have described the issues relating to access to specialist hepatology services and the resolution of the same above. The issue relating to access to new drugs to eradicate hepatitis C was addressed through the Cardiff Blood Borne Virus clinic under the leadership of Dr Healey.

218. I have now been shown July 2014 documents **[CVHB0000006_066 and CVHB0000006_067]** which describe an interim decision to fund Sofosbuvir for a limited group of patients pending a full technical appraisal by NICE. At this time, patients with hepatitis C who attended the Haemophilia Centre were being managed in the Blood Borne Virus clinic for viral eradication treatment. The implementation of Sofosbuvir was through the Blood Borne Virus clinic and I was not involved.

219. I have insufficient expertise in the management of hepatitis C to comment on how these decisions affected the Centre's patients.

220. And with reference to a 15 October 2015 meeting of the WHSCC Inherited Bleeding Disorders Advisory Group **[CVHB0000006_073]**: I am not able to remember for certain which drug for the eradication of hepatitis C was being referred here to but it is likely to be Sofosbuvir. These drugs were prescribed through the Blood Borne Virus clinic and I was not involved in addressing funding issues. I am aware that the funding issues were resolved but do not know when or how this happened. Further, I cannot comment on the effects these issues had on the Centre's patients because I was not directly involved in the management of their hepatitis C eradication at that time and have insufficient clinical expertise.

Records

221. During the time that I worked at in Cardiff there has not been a Centre policy for what information should be recorded on death certificates. Clinicians completing death certificates were expected to follow standard practice which was to record the cause of death as accurately as possible.

222. There has been a policy of retaining the notes of all people who were infected with HIV after they have died.

223. I have not maintained separate medical files for any patients.

224. And I have not kept any records or information about any of the Centre's patients at my home. Not all medical records have been kept in the Centre, some have been stored at other sites within the NHS. I am not aware of any records being kept outside of the NHS.

225. The practice of not filing HIV results in the patients' notes was from a period of time before I started working at the Centre. I do not know why this was done but it may have been related to concerns about preserving patient confidentiality.

226. To the best of my knowledge, the practice of filing HIV results separately had stopped before I started working in Cardiff. I also do not know when this practice stopped or why.

227. During my time in Cardiff, HIV results have been filed in the patients' notes or maintained in their electronic medical record.

228. I am not aware of any adverse effects on patient care related to the practice of filing HIV results separate from the patients' notes.

229. I have been referred to a 10 September 1999 letter which I sent to the health records manager at University Hospital Wales **[CVHB0000002_095]**, raising concerns about a circular dated 18 August 1999. I supply the relevant circular at **[WITN4029028]**.

230. So far as I am aware, no medical records were destroyed either before or after I sent the letter.

231. The medical records department accepted my position that the medical records that were being held in the Centre should be retained for life. It was also agreed that the notes of people who had died of HIV or hepatitis C that were being held by the Centre should be retained.

232. When I started in Cardiff, the medical notes of a large number of people who had died of HIV/AIDS had been retained. I assumed the policy was to retain all the notes of people with HIV. I do not know when this policy was introduced but it appears to have been in place since the 1980s when the first person died of AIDS in Cardiff. Over the years, this policy has been complied with.

Section 5: UKHCDO

233. I became a member of UKHCDO in 1996 when I started to work at the Centre. I have been a member of the UKHCDO Advisory Committee since that date. I have also been a member of the following UKHCDO working parties: Inhibitor working party (1997-2020 and chair between 2006-2014), Von Willebrand disease working party (1999-2008), Genetics working party (2000-2009), Paediatrics working party (about 2005-2016), Rare disorders working party (2002-2008), Data management Working Party (about 2000-date) and chair 2016-2020), Executive committee (vice chair) 2016-2020 (term of vice chair ends Nov 2020), Data Analysis Group (co-chair 2017 to date), and Director of the Board of UKHCDO Limited (2016-date).

234. During my time as a member of UKHCDO:

a. My understanding of the purpose, function and responsibilities of UKHCDO is as follows:

UKHCDO is a charity whose members are medical practitioners who work in UK haemophilia centres. The overarching purpose of UKHCDO is to improve the quality of care and alleviate suffering of people with inherited bleeding disorders within the UK.

The organisation strives to achieve this purpose by advocating on behalf of people with bleeding disorders within the NHS and with UK governments, developing treatment guidelines, educating members and other groups to foster an improved understanding of bleeding disorders and responding to safety issues.

A key aspect of UKHCDO work is to maintain a registry (i.e. the NHD) of information about people with inherited bleeding disorders within the UK. The purpose of the registry is to support local Haemophilia Centres with direct patient care, guide health care planning, and support research and audit to better understand and treat inherited bleeding disorders.

b. The UKHCDO charity was established in 1991. Members of UKHCDO elect an executive committee comprised of a chair, vice chair, secretary and treasurer. The executive committee members act as the trustees for the charity. The officers serve three-year terms and can be re-appointed for a second three years. The executive committee runs UKHCDO on a day-to-day basis.

The Advisory Committee is made up of the executive committee and a representative from each comprehensive care centre and a representative of the haemophilia centres. UKHCDO decisions are taken after consultation through the Advisory Committee.

An annual general meeting ("AGM") is held each year which is open to all members of UKHCDO and other invited members.

The executive committee, after consultation with the Advisory Committee, can set up working parties or task forces which have specific remits and lifespans.

The UKHCDO charity owns UKHCDO Limited. This is a registered company that is used to run the NHD. For example, members of staff of the NHD may be employed through UKHCDO Limited. The directors of UKHCDO Limited include the UKHCDO charity executive committee members and the director of the NHD.

The NHD is owned by UKHCDO and administered, in part, through UKHCDO Limited. The NHD hosts the UKHCDO charity secretariat in Manchester.

The NHD is overseen by the Data Management Working Party which is chaired by the UKHCDO vice chair and meets twice a year. The Data Management Working Party includes patient representatives and representatives of NHS commissioners.

Requests for any analyses of data held on the NHD are referred to a subgroup of the Data Management Working Party called the Data Analysis Group. The Data Analysis Group has patient representatives and meets once month to responds to these requests.

c. Pharmaceutical companies pay UKHCDO to be present at the AGM and to display promotional stands at the meeting. They do not attend the AGM but can attend the educational sessions.

   UKHCDO runs post-marketing surveillance studies, supported by funding from pharmaceutical companies, for example, reporting the rate of inhibitor formation associated with a specific product or the efficacy of the product in preventing or treating bleeding episodes.

   Pharmaceutical companies request information about their own product from UKHCDO and pay for NHD time required to generate these requests.

   UKHCDO informs pharmaceutical companies of adverse events associated with their products.

   Pharmaceutical companies inform UKHCDO about important issues, such as safety concerns or product shortages.

d. During my time as a member of UKHCDO, all significant issues are discussed by the Advisory Committee and decisions are based on the consensus view of that committee. Day-to-day decisions are taken by the executive committee. Decisions that involved the NHD include the database director.

e. During my time as a member of UKHCDO, information or advice has been disseminated to Advisory Committee members or the whole membership through letter or email from the UKHCDO chair or the secretariat. Information is also disseminated at the AGM and in reports in the Annual Report.

f. During my time as a member of UKHCDO:

i. I was not a member of UKHCDO during the time that plasma-derived blood products were causing transmission of viral infections and played no role in the policies, guidance or actions at that time. I was involved in supporting the introduction of recombinant coagulation factor concentrates.

ii. I was not involved in any policies, guidance or actions relating to the sharing information about the risk associated with plasma-derived blood products with patients and their families.

iii. I was involved in developing the patient information leaflet and consent form about the testing and storing of blood for the purposes of genetic testing in local Haemophilia Centres.

iv. I was not involved in any other policies, guidance or actions relating to consent for storage or testing of blood for any reason other than genetic testing as above.

v. I was present at Advisory Committee meetings where policies, guidance or actions relating to vCJD were discussed and implemented the consensus decisions in Cardiff.

vi. I was not involved in any policies, guidance or actions relating to the treatment of HIV or hepatitis C.

235. I was elected to the role of vice chair of UKHCDO in October 2016. My term was due to end in November 2019, but I agreed to serve for an additional year. My term of office as vice chair ends in November 2020.

236. In the last 3 years my role has been mainly to support the UKHCDO chair in the organisation's response to the Inquiry. In this capacity I have been involved in responding to requests for information from the Inquiry and have met with members of the Inquiry team to

offer support in achieving the aims of the Inquiry. I have worked with other members of UKHCDO to respond to a Rule 9 request for statistical analyses of the NHD.

237. The vice chair of UKHCDO acts as the chair of the Data Management Working Party. In this role, I have supported the process of establishing the NHD Research Registry and gaining ethical approval for the Research Registry. The establishment of the Research Registry led to the need to set up a process for seeking written consent for data held on the NHD to be used for research purposes. I was involving in setting up, piloting, and initiating this this process across all UK haemophilia centres.

238. I have established a subcommittee of the Data Management Working Party to review applications for analyses of the NHD.

239. I have co-ordinated a look-back exercise with the aim of supporting Haemophilia Centres ensure they have offered hepatitis C testing, and if appropriate, hepatitis C eradication therapy to all patients who have received factor concentrates or blood products that were at risk of transmitting hepatitis C, as reported to the NHD.

Section 6: Pharmaceutical companies/medical research/clinical trials

240. I have provided advice and consultancies to pharmaceutical companies that manufacture products to treated bleeding disorders. This has included companies that manufacture and sell blood products. Most of the consultative advice that I have provided has been to companies that manufacture and sell recombinant coagulation factor concentrates.

241. I am unable to give accurate dates of these advisory/consultative activities. They have occurred between 1997 and 2019.

242. The list of companies that I have provided consultancy advice to is as follows: Bayer, Baxter (Baxalter, Shire, Takeda), Novo Nordisk, CSL Behring, Sobi, Roche, and Pfizer.

243. I have been paid for providing consultancy advice to Bayer, Baxter (Baxalter, Shire, Takeda), Novo Nordisk, CSL Behring, Sobi, Roche. I am not able to give full and accurate details of these gains. However, in the last seven years, where I have records available, the total amount has been between £3,100 and £5,945.14.

244. I have previously been involved in the ADAPT group although this was not an advisory board. The ADAPT group is a collaboration between employees of Baxter Healthcare (later the company was called Baxalta, Shire, Takeda) and an international group of academic

clinicians which aimed to improve the understanding of the treatment of haemophilia through analysis or data collected during Baxter sponsored clinical trials.

245. The collaboration started in about 2007 and continued until 2020. I have not received any payment for undertaking this work but travel expenses to attend meetings were reimbursed.

246. The focus of the group has been on gaining a better understanding of how factor VIII pharmacokinetics and knowledge of factor VIII levels can be used to improve patient care by optimising prophylactic treatment. The results of the collaboration have been influential in the field of haemophilia treatment and instrumental in establishing population pharmacokinetics as a tool to improve haemophilia care.

247. My involvement was to devise questions that could be addressed, give advice on analyses, interpret data and write papers.

248. The following publications have resulted from this collaboration:

a. *Break-through bleeding in relation to predicted factor VIII levels in patients receiving prophylactic treatment for severe hemophilia* A. Collins PW, Blanchette VS, Fischer K, Björkman S, Oh M, Fritsch S, Schroth P, Spotts G, Astermark J, Ewenstein B; rAHF-PFM Study Group. J Thromb Haemost. 2009; 7:413-20.

b. *Factor VIII requirement to maintain a target plasma level in the prophylactic treatment of severe hemophilia A: influences of variance in pharmacokinetics and treatment regimens.* Collins PW, Björkman S, Fischer K, Blanchette V, Oh M, Schroth P, Fritsch S, Casey K, Spotts G, Ewenstein BM. J Thromb Haemost. 2010; 8:269-75.

c. *Trends in bleeding patterns during prophylaxis for severe haemophilia: observations from a series of prospective clinical trials.* Fischer K, Collins P, Björkman S, Blanchette V, Oh M, Fritsch S, Schroth P, Spotts G, Ewenstein B. Haemophilia. 2011; 17:433-8.

d. *Population pharmacokinetics of recombinant factor VIII: the relationships of pharmacokinetics to age and body weight.* Björkman S, Oh M, Spotts G, Schroth P, Fritsch S, Ewenstein BM, Casey K, Fischer K, Blanchette VS, Collins PW. Blood 2012; 119:612-8.

e. *Association of peak factor VIII levels and area under the curve with bleeding in patients with haemophilia A on every third day pharmacokinetic-guided prophylaxis.*

Valentino LA, Pipe SW, Collins PW, Blanchette VS, Berntorp E, Fischer K, Ewenstein BM, Oh M, Spotts G. Haemophilia. 2016; 22:514-20.

f. *Modeling to Predict Factor VIII Levels Associated with Zero Bleeds in Patients with Severe Hemophilia A Initiated on Tertiary Prophylaxis*. Chowdary P, Fischer K, Collins PW, Cotterill A, Konkle BA, Blanchette V, Pipe SW, Berntorp E, Wolfsegger M, Engl W, Spotts G. Thromb Haemost. 2020; 120:728-736.

249. Apart from the ADAPT group, I have acted as a paid consultant to Baxter as mentioned above. I cannot remember the exact details of when this activity took place but was in the period from about 1998 to 2015.

250. I have also sat on committees that have advised pharmaceutical companies on the design of clinical trials. This work has been for Baxter, Pfizer, Roche and Bayer. I am not able to remember details of when these meetings took place.

251. In addition, I have attended investigator meetings related to clinical studies. These meetings cover trial protocols, conduct or trials and trial results. This work has not been paid. I cannot remember the exact dates of these meetings.

252. I am currently a member of a trial steering committee with Roche working on a study to investigate the safety and efficacy of Emicizumab for treatment of children less than 12 months old. I do not receive payment for this work.

253. I have never received any financial incentive from a pharmaceutical company to use a specific blood product or coagulation factor concentrate.

254. I have never received any non-financial incentives from a pharmaceutical company to use a specific blood product.

255. I have never received any funding to prescribe, supply, administer, recommend, or buy or sell any blood product from a pharmaceutical company.

256. I make a declaration every 6 months to the NHS about any conflicts of interest related to my involvement in the UK national tenders for treatments of haemophilia. I declare all interests that might be conceived to a conflict on each paper I have published and when I give lectures. Each year, I declare conflicts of interest to UKHCDO. To the best of my knowledge I have declared conflicts of interest appropriately.

257. During my time working in Cardiff, the Centre has conducted numerous studies of treatments for inherited bleeding disorders which have been sponsored by pharmaceutical companies. These studies have almost all been investigating recombinant coagulation concentrates rather than blood products. All studies have received ethical approval and all patients recruited in Cardiff have given informed written consent. To the best of my memory a list of products studied, and the sponsoring company is given below:

a. Pharmacokinetics of Recombinate (Baxter)

b. Pivotal, continuation and surgery studies of Advate (Baxter)

c. Replenine compared to filtered Replinine (BPL)

d. Mononine for immune tolerance of a factor IX inhibitor (CSL)

e. Refacto AF (Wyeth)

f. Pharmacokinetic tailored prophhylaxis with Advate (Baxalta)

g. Adult prophylaxis with Kogenate FS (Bayer)

h. Kogenate FS study in previously untreated patients (Bayer)

i. Novoseven by continuous infusion to cover surgery (Novo Nordisk)

j. Fc fusion factor VIII and factor IX in previously untreated patients (Sobi)

k. Bax855 (Adynovate) for prophylaxis in adults (Baxalta)

l. N8GP (Esperoct) prophylaxis and surgery (Novo Nordisk)

m. N9GP (Refixia) for prophylaxis (Novo Nordisk)

n. Emicizumab for inhibitor and non-inhibitor patients (Roche)

o. Bay 1093884 anti-TFPI prophylaxis study (Bayer)

258. I have never provided a pharmaceutical company with results from medical research except where the company sponsored the research as described above.

259. The clinical trials of investigational products that I have performed with pharmaceutical companies have been set up through my employers, Cardiff and Vale University Health

Board and Cardiff University. Funding for my time to undertake these trials and funding for the research nurse time is paid directly to my employer.

260. I have received grant funding for investigator-led medical research from the following companies:

a. Baxter Healthcare to undertake a study investigating the pattern of bruising in young children with inherited bleeding disorders and comparing these with children who did not have a bleeding disorder and those who have suffered physical abuse.

b. CSL Behring to undertake a multicentre study investigating the role of fibrinogen concentrate in the management of bleeding after childbirth.

c. Baxter Healthcare to investigate the effect of factor VIII infusions on thrombin generation in people with severe haemophilia A.

d. Haemonetics to investigate the coagulopathy associated with severe bleeding after childbirth and how this can be assessed using thromboelastometry.

261. In all cases the funding has been paid directly to either Cardiff University or Cardiff and Vale University Health Board. It has been used to fund the research and I have not received any personal payment.

Section 7: vCJD

262. I cannot remember exactly when or how I first became aware about the risk of transmission of vCJD by blood products, but it would have been between late November and early December 1997. An UKHCDO meeting was held on 20 November 1997 to discuss vCJD and the risk to people with haemophilia. However, according to the minutes of that meeting I was not present **[WITN4029012]**. A letter was sent to Haemophilia Centres by Professor Ludlam dated 25 November 1997 **[WITN4029031]** outlining the information discussed at the meeting on the 20 November. It is most likely that I became aware of the risk of vCJD to people with inherited bleeding disorders when that letter arrived.

263. I wrote a letter to other haematologists in Wales about this issue on 15 December 1997 and so I would certainly have known about vCJD at that time **[WITN4029013]**.

264. In November 1997, UKHCDO advised that patients who had received a batch of factor VIII or factor IX that had been donated by a person who subsequently developed vCJD

should be informed about this event. The decision was taken at the UKHCDO meeting on 20 November 1997. As mentioned above, I was not present at that meeting and so cannot describe how that decision was taken. My recollection from Cardiff at this time is that no patients had received one of the implicated batches.

265. In January 2001, at an UKHCDO Advisory meeting **[BART0000938]** it was unanimously decided that patients who had received batches that had been donated to by a person who subsequently developed vCJD should be told this information. According to the minutes of that meeting, the decision to inform patients was contrary to the advice of the NHS Executive.

266. In Cardiff, in 2001, the decision to tell our affected patients and offer counselling was taken by me, Dr Dasani and other members of the Centre staff in line with the UKHCDO advice. I informed Welsh Blood Service of this decision in a letter dated 17 January 2001 **[HSSG0000143_004]**. The letter states that 17 patients in Cardiff had been treated with one of the implicated batches. The letter was sent on to Mr J Morgan, Director Health Services Division, NHS Directorate National Assembly for Wales so that they were aware of the action which was divergent from the central view.

267. In 2004, national decisions about the information to be given to patients about the risk of vCJD associated with blood products and the fact that they were being designated as 'at risk' for public health purposes of vCJD were taken by the Health Protection Agency, the Department of Health and the Welsh Government. I do not know how or by whom these national decisions were taken. I am aware that the contents of the information sheet were shown to UKHCDO in advance and some suggestions were made. I am not aware of any details about this. In Cardiff we thought that the information sheet supplied was complicated and decided to write a covering letter to give a simplified precise of the information **[WITN4029014]**. In that letter we specifically informed individuals whether they were in the 'at risk' group for vCJD for public health purposes in order to help clarify the situation. The decision to send the covering letter was taken by me in consultation with Sister Loran and Dr Dasani.

268. In 2004, the steps that should be taken in relation to patient care were decided by the Health Protection Agency, the Department of Health and the Welsh Government. I do not know how, or by whom, these decisions were taken. In Cardiff, these national directives

were followed. Local protocols were developed between the Centre, the lead for infection control, Dr Ian Hosein, and the lead for endoscopy services, Dr Hawthorne.

269. In February and June 2009, the decision to inform patients about an individual who had been found to have prions in the spleen at the time of post-mortem was taken by The Health Protection Agency at a national level. I do not know how, or by whom, these decisions were taken. In Cardiff, the decision to comply with that decision, and to send a simplified covering letter, was taken by me in consultation with other members of the Centre staff.

270. In 2013, the decision to inform some people that they were no longer in the 'at risk' group for vCJD for public health purposes was taken at a national level. My understanding is that the decision was taken by the Health Protection Agency. I do not know how, or by whom, this decision was taken. In Cardiff, the decision to inform patients and to send a simplified covering letter was taken by me in consultation with other members of the Centre staff.

271. The process for informing patients about vCJD in Cardiff was as follows:

a. In 1997, I do not remember any patients in Cardiff being treated with an implicated batch and so no one was informed.

b. In 2001, the 17 patients who had received an implicated batch were informed face-to-face by Dr Dasani or me when they attended the Centre.

c. In 2004, the Centre followed the process for informing patients about the risk of vCJD that was dictated by the Health Protection Agency, the Department of Health and Welsh Government. All patients were sent the letter that had been written centrally on the same day (20 September 2004) informing them about the potential risk associated with UK pooled-blood products. The Centre added a covering letter to give a more simplified explanation about the centrally written letter and to make clear to each individual whether or not they were in the 'at risk' group for public health purposes. The covering letter gave telephone numbers for people to ring if they wished to discuss the information further.

   On the day the letters were sent I invited members of the local patient group to a meeting at the Centre to inform them about the letters, explain what information was included in the letters and answer any questions. I thought that it was inevitable that the local haemophilia group would be contacted by concerned patients and relatives

and so felt that it was important that they should be forewarned that the letters were being sent.

d. In February 2009, patients were informed about an individual who had been found to have prions in the spleen at post-mortem. This information was sent by a letter that had been written centrally by the Health Protection Agency. Haemophilia Centres were asked to send this information in a letter dated 16 February 2009 by UKHCDO.

e. In June 2009 the Health Protection Agency sent updated information about the February 2009 notification to Haemophilia Centres and a letter was provided to send to patients. In Cardiff, a covering letter was also sent because we thought that the information in the Health Protection Agency letter needed to be simplified **[WITN4029015]** (please note the date of this document is not correct and has been populated with the date it was downloaded). The covering letter from Cardiff offered the option of not being informed of future notifications because we had received feedback from some patients that they would prefer not to be informed.

f. In 2013 the at risk period of was changed from 1980 to 2001 to 1990 to 2001 and Haemophilia Centres were told that people who had only received UK plasma products between 1980 and 1989 were no longer in the at risk group for public health purposes and should be de-notified. A central letter was supplied to send to patients and a simplified covering letter was provided by the Centre **[WITN4029016]**.

272. The Centre offered face-to-face and telephone contacts for people who were informed that they might have been exposed to vCJD. Support and counselling was provided by the senior nurses, the medical staff and the haemophilia centre social worker. At the time, the Centre did not have access to a dedicated psychology service.

273. The Centre followed the central advice on public health measures.

274. Dr Ian Hosein, a consultant in infection control, set up and chaired a working group in Cardiff to co-ordinate the response. I am not sure exactly when this group was established but it was definitely in place by March 2001.

275. In 2002, a protocol was developed to cover invasive procedures such as surgery and endoscopy for people with bleeding disorders (described below) **[WITN4029017]**. Dr Hosein advised surgical teams about whether instruments should be quarantined and, if this was not

clear, he liaised with the CJD unit in Edinburgh for advice. Instruments and endoscopes were used and quarantined in line with the national policy.

276. I had no role in devising public health measures in response to vCJD in Wales or the UK.

277. I have been shown the minutes of the UKHCDO advisory meeting dated 15 January 2001 **[BART0000938]**. I do not remember the discussion. Based on the minutes, I expressed the opinion that people should be given the choice of whether they wanted to know whether they had been treated with a batch that had been donated to by a person who subsequently was found to have vCJD. The minutes record that this view was the adopted position.

278. When I returned to Cardiff, I discussed this issue with Dr Dasani. We agreed that we would inform patients who had received an implicated batch when they next attended the Centre. We informed patients that they had received an implicated batch but that vCJD was not thought to be transmitted by blood products at that time and so any risk was theoretical **[WITN4029029] [WITN4029030]**.

279. I have been shown a letter dated 24 August 2004 from BPL **[HCDO0000134_084]** which lists batches of Replenate received by the Centre. The Inquiry has asked me whether I can supply a notification letter referred to therein: I have not been able to find a notification letter and cannot recall its contents. I have though located a different letter dated 7 September 2004 that appears to be about this or a similar issue, which is supplied at **[WITN4029018]**. I expect the 24 August 2004 letter relates to vCJD even though it does not say so expressly. The Centre established which patients had been exposed to these batches and informed those patients if they had requested to be informed.

280. I have now been shown a 20 September 2004 letter **[WITN2360002]**. This letter was about people who had been exposed to UK sourced plasma derived concentrates during the 'at risk' time needing to be considered as at risk for vCJD for public health purposes. The policy of sending the letter and patient information sheet about vCJD to all patients on the same day was agreed by the Department of Health, the Health Protection Agency and the Welsh Assembly. All UK Haemophilia Centres were asked to send the letter out on the same day. My understanding was that UKHCDO had had the opportunity to comment on the letter and patient information sheet.

281. The main problems with the letter and information sheet – it seemed to us in Cardiff - were that they were too complicated and it was not explicitly clear to the person receiving the information whether they were now in the at risk group for public health purposes. In the covering letter from Cardiff we attempted to simplify the main points in the letter and made explicitly clear to each individual whether or not they were in the 'at risk' group for public health purposes.

282. The effect of receiving this information was very varied between individuals. Some people were very worried about the contents of the letter whilst other were less so.

283. I was not involved in drafting the letter to GPs about vCJD **[CVHB0000011_011]**. The letters were sent to GPs in September 2004. I agreed with the content of the letter. The letters to the GPs were not discussed with patients before they were sent to the GP.

284. I shared concerns that patients in the 'at risk' group for public health purposes might have treatment compromised because of the need to quarantine or destroy instruments. I was also concerned that patients might be stigmatised.

285. I am not aware that the treatment of any patients in Cardiff was compromised due to them being in the 'at risk' group for vCJD for public health purposes.

286. I have been shown minutes of the 13 October 2005 UKHCDO meeting **[BART0000904]**. The procedures outlined by Professor Jeffries were implemented in Cardiff. I am not aware of any differences between the approach outlined by Dr Jeffries and that implemented in Cardiff.

287. I do not know for certain when the first protocol for the surgical management of people who had been potentially exposed to vCJD was written. The earliest protocol I can find is dated 5 November 2002 **[WITN4029017]** which is the one referred to in the email to Dr Al Ismail. Later versions were produced in May 2005 **[AMBU000062]** and January 2010 **[WITN4029019]**. The current version is dated 2 December 2016 **[WITN4029032]**.

288. I was involved in preparing the 2002, 2005 and 2010 versions. I also commented on the current version. These versions were prepared jointly with Dr Ian Hosein and Dr Eleri Davies who were consultants in infection control.

289. I consider that the protocols worked effectively from the point of view of people with bleeding disorders.

290. I have been shown Dr Dasani's emails to Dr Frank Hill dated 16 September 2004 and 15 December 2005 **[CVHB0000091]**. In his September 2004 email Dr Dasani stated that he did not agree with patients being informed that they had been potentially exposed to vCJD. I did not agree with Dr Dasani on this issue and thought that people should be told about all issues related to vCJD as openly as possible.

291. The email of 15 December 2005 describes two cases where Dr Dasani thought that clinical care had been compromised. I can remember the first case. The gentleman was successfully treated for high grade lymphoma and remains in complete remission. Dr Dasani describes a delay in obtaining a definitive diagnosis of lymphoma, but I do not think this patient's overall care and outcome were compromised.

292. I do not know which endoscopy case from December 2005 that Dr Dasani is referring to. Dr Dasani's email states that the woman presented on the 9 December and the endoscopy was performed on the 13 December. 10 and 11 December 2005 were a Saturday and Sunday and, in the context of routine NHS care in Cardiff, the time from presentation to endoscopy is not unusual. Dr Dasani's email does not state that the patient came to any harm. He says that "if she was to present with variceal bleeding her care will be compromised". This is an opinion expressed by Dr Dasani about what might happen in a specific situation rather than the description of an actual event. In this instance I did not agree with Dr Dasani's view because banding and injecting varices was not affected by the public health measures and so would have proceeded normal.

293. I am not aware that the treatment of any patients in Cardiff was compromised due to being in the 'at risk' group for vCJD for public health purposes although arranging treatment was much more time consuming for Centre staff because of the need to discuss cases in more detail with other clinicians and to liaise with Dr Hosein.

294. I have been referred to a 15 June 2009 letter **[WITN2554015]** which the Centre sent to a patient. I cannot remember whether any patients contacted the Centre about this letter. I remember that a few patients wanted to discuss the issue when they attended for a routine clinic appointment. I am not aware of what effect this letter had on patients because no one expressed their views to me.

295. The letters about people no longer being in the 'at risk' group for vCJD for public health purposes were sent in February 2013 **[CVHB0000011_028]**. I do not remember any reaction from the patients who received this letter.

Section 8: Involvement with the financial support schemes

296. I have a connection with the Macfarlane Trust. My involvement has been to support applications by writing letters, often in collaboration with the Centre social worker. In respect to The Skipton Trust, I helped to identify and inform individuals who were eligible for the scheme. I collated information to support individual applications and completed application forms on behalf of individuals and families. I was involved with appeals if initial applications were unsuccessful.

297. During the time I have worked in Cardiff:

a. All people who were eligible for the Macfarlane Trust were informed by the Centre. This was done mainly by the Centre's social workers. People or families who were eligible for the Skipton Fund were identified through the Centre records and contacted by the Centre staff. This work was co-ordinated and done mainly by sister Christine Loran working with Dr Dasani.

b. There was no written policy or guidance for staff regarding referral to these schemes. All members of staff knew about the schemes which were regularly discussed within the weekly multi-disciplinary meetings to help identify whether people could apply. Members of staff actively worked to encourage people to apply and supported patients and families in any applications.

c. I supplied information in support of individual applications. The information for the Macfarlane Trust was tailored depending on the application. The contents of the supporting letters were discussed with the applicant by the Centre social workers who were experienced in making these applications and I followed their advice on what was the best way to support the applications.

d. As for the Skipton Fund, the information required was dictated by the application form. I supplied the information required by the form.

e. Centre staff did not act as a gateway to applications and encouraged people to make applications.

f. I am not aware of any member of staff at the Centre acting as a gateway to the Macfarlane Trust.

g. When there were applications to the Skipton Fund which were unlikely to succeed - for example, if a person or family member did not fulfil the eligibility criteria - I or Dr Dasani met with the individual to explain the situation and to discuss how best to make an application. I always explained that I would complete the form and submit it despite the likelihood of success was low.

h. I was not involved in determining applications made by patients to any funds. To the best of my knowledge, no members of the Centre staff were involved in determining applications made by Cardiff patients or their relatives.

i. Mr Timothy Hunt, the Centre social worker, had a role in the Macfarlane Trust. I am not sure what the role entailed.

j. Based on my own limited dealings with the funds, I do not feel I am able to say whether or not they were well run. I do not know whether they achieved their purposes. I was aware that some beneficiaries and applicants had difficulties when applying to the funds but do not know about these in detail. The Centre social workers will have more knowledge about these issues.

298. I have been referred to an email I sent in January 2011 to Dr Stephanie Barnhouse regarding the Skipton Fund **[ABMU0000016]**. The concerns I raised in that email were addressed and the settlement and eligibility criteria in Wales were the same as in England. I cannot remember having any further involvement around the decisions for the implementation of these changes.

299. I have also been referred to a letter dated 28 March 2011 from the Minister for Health and Social Services **[CVHB0000007_065]**. After the announcement by the Welsh Assembly Government, the Centre identified people and families who were potentially eligible for the scheme and contacted these people directly. This work was co-ordinated by Sister Loran, Dr Dasani and me. The potential claimants were contacted through the Centre. I do not remember any involvement of the Welsh Assembly Government in contacting potential claimants directly.

300. I confirm that I provided supporting letters for applications to the Macfarlane Trust. I am unable to remember details of individual letters and these would have depended on an individual's situation. Generally, I made cases for specific payments based on an individual's circumstances. I was assisted by the Centre social workers when writing these letters.

301. The information that I provided to the Skipton Fund was dictated by the application form. If an application was not supported by the Skipton Fund, I wrote letters in support of appeals. These letters described why specific evidence could not be submitted and explained why I thought the applicant fulfilled the criteria despite not being able to supply documentary evidence.

302. I have also provided supporting letters to the Welsh Infected Blood Support Scheme since that scheme has been established.

303. I have been referred to emails dated 23 January 2017 where I responded to a query from Jan Barlow of the Macfarlane Trust regarding evidence needed to approve one-off payments to the spouses and partners of individuals who died as a result of HIV and AIDs. I cannot remember having any further contact with Ms Barlow, or any other people, regarding the evidence needed to approve these applications.

304. I also do not remember being consulted about the creation, implementation, and forms for the Welsh Infected Blood Support Scheme. I have provided information to the Welsh Infected Blood Support Scheme when requested but cannot remember details about specific cases. The Centre social workers have supported applicants in making claims.

305. I am afraid that I have insufficient knowledge to comment on whether the Welsh Infected Blood Support Scheme is well run or achieves its purposes. No patient attending the Centre has provided me with any specific feedback about the scheme. I am aware though that there are concerns about discrepancies between the English and Welsh schemes.

Section 9: Current haemophilia care and treatment

306. Care for people with inherited bleeding disorders in South and West Wales is managed as a clinical network. There is a network lead consultant, a lead nurse and manager:

a. The Centre co-ordinates the care of patients with bleeding disorders in South and West Wales and some patients from the south west of England. It provides support to the Haemophilia Centres in Swansea and Abergavenny and other hospitals in South and West Wales.

   Patients are diagnosed with bleeding disorders either through out-patient clinics or as a result of family studies. Once a diagnosis is confirmed the patient is followed up through one of the Haemophilia Centres in the network.

Patients have open access to the service and can be seen 24 hours a day, either through the Haemophilia Centres or in the out of hours services. Patients are given ambulance letters to ensure they are brought to the correct hospital.

The Centre runs two routine bleeding disorder clinics a week. Some of these clinics are designated for young children, adolescents or families. Patients can telephone the Centre at any time and can be seen the same day as required.

The Centre has adult trained and paediatric trained nurse specialists. The nurses see patients in the Haemophilia Centres and on home visits and undertake school visits. They co-ordinate monitoring of treatment, prophylaxis and venous access. The paediatric nurses are supported by a play specialist. The Swansea Haemophilia Centre has two specialist nurses.

Patients have access to physiotherapists who specialise in the management of bleeding disorders. There are 3 physiotherapists based in Cardiff and one in Swansea. Physiotherapists can see patients in their own homes if this is more convenient. They also liaise with orthopaedic consultants and attend orthopaedic clinics.

A joint haemophilia liver clinic is run every 6 months with Dr Srivastava. A hepatology nurse attends the clinic to perform fibroscans.

People access care for HIV and hepatitis through the Blood Borne Virus clinics in Cardiff or Swansea.

The Centre has an embedded research group staffed by three nurses, who specialise in bleeding disorders clinical trials, and a trial coordinator.

The Centre provides outreach clinics to Swansea once a month and Abergavenny once every two months. A medical consultant from Cardiff goes to the Swansea Haemophilia Centre for one day a week to support the service and provides telephone support on a daily basis.

The Centre provides haemostatic support for surgery with written surgery plans. The Centre nurses administer treatment and perform clotting factor levels for monitoring. Consultants see patients post-operatively to assess for any evidence of abnormal

bleeding. Some patients who attend the Swansea Centre need to have operations in Cardiff so that adequate haemostatic cover can be given.

The Centres offer genetic testing and education.

A psychology service is embedded in the Cardiff and Swansea Haemophilia Centres and social workers provide services throughout the network.

The service is supported by data managers in Cardiff and Swansea.

b. My current role in the Centre is to act as a Consultant Haematologist and provide clinical care for people with inherited and acquired bleeding disorders. I lead on the management of children with bleeding disorders and for areas such as prophylaxis and inhibitors.

I attend the Swansea Haemophilia Centre to perform clinics and to provide clinical cover and the Abergavenny Centre to perform clinics.

Out-of-hours, I provide an on-call service on a one-in-five basis.

I am employed for 50% of my time with the NHS and 50% of time with Cardiff University.

c. Patients with haemophilia are offered treatment with desmopressin, recombinant factor VIII or recombinant factor IX concentrates, as appropriate. Patients have access to enhanced half-life factor VIII and IX, if they wish to use these products.

Patients with factor VIII inhibitors or with severe haemophilia A have access to Emicizumab. Break through bleeds in patients with an inhibitor are treated with Novoseven or FEIBA.

Patients with acquired haemophilia A are treated with Novoseven, FEIBA or recombinant porcine factor VIII.

Patients with von Willebrand disease are offered treatment with desmopressin or Voncento (von Willebrand factor concentrate).

Patients with platelet function disorders are offered treatment with HLA matched platelets or desmopressin.

Patients with fibrinogen deficiency are offered treatment with Riastap (fibrinogen concentrate).

Patients with factor XI deficiency are offered treatment with factor XI concentrate or virally inactive fresh frozen plasma.

Patients with factor VII deficiency are offered treatment with Novoseven.

307. Consent for treatment is sought by a combination of medical and nursing staff:

a. Patients being treated with recombinant factor VIII or IX are informed about the risks of factor VIII inhibitor formation and the need for regular surveillance blood tests. The risk of allergic reactions, especially with recombinant factor IX, is discussed. My practice is to describe the past history of infectious diseases but explain that the risk has been removed with the introduction of recombinant blood products. The difficulties associated with venous access, especially in young children, are discussed.

   For patients who are offered treatment with plasma derived concentrates, platelets or virally inactivated fresh frozen plasma I discuss the risk of transmission of an unknown infectious agent and the potential for allergic reactions.

   For patients who are offered treatment with Novoseven of FEIBA I discuss the risk of thrombotic side effects and, in the case of FEIBA, I explain that this is a plasma derived product.

   For patients who are offered treatment with Emicizumab I discuss the risk of microvascular thrombosis, venous and arterial thrombosis, skin reactions and headaches.

b. I explain that typical pattern of bleeding associated with the specific bleeding disorder and in particular highlight the importance of being aware of the risk of head injury. I explain that uncontrolled bleeding can lead to joint damage and musculoskeletal disability.

c. I explain that treatment will be helpful for preventing and treating bleeds, supporting daily activities and allow as normal a lifestyle as possible. I describe how prophylaxis can prevent joint and muscle damage.

308. The discussions about consent to treatment are recorded in the patient's notes.

309. Blood samples are taken if clinically indicated. Patients are told why blood tests are taken, for example, to look for anaemia or iron deficiency or to test for an inhibitor. Patients who are offered genetic testing are given an information leaflet.

310. At present, the Centre only stores blood in the context of genetic testing. Written consent is sought to store this blood and patients sign a localised version of the UKHCDO genetic test consent form and a local genetic testing form.

311. Consent to routine testing is sought verbally at the time of the blood test. The Centre does not have a system for recording consent for routine blood tests. Consent for genetic tests is recorded on a written consent form. It is exceptionally unusual to test for HIV or hepatitis C nowadays but if these tests are offered consent is recorded in the clinical notes.

312. The number of current patients attending the Centre is as follows:

a. The number of current patients who were infected with HIV through blood products is 13.

b. The number of current patients who were infected with hepatitis C through blood products is 66.

c. I do not have accurate figures for the number of current patients who were infected with hepatitis B through blood products. The number of people who are under follow up for active hepatitis B is 4.

d. The number of current patients who were co-infected with HIV and hepatitis C through blood products is 13.

313. The Centre is not involved in the treatment of HIV. Patients have HIV monitoring blood tests performed in the Centre. Patients are seen in the Centre for follow up of their bleeding disorder on the same day they attend the Blood Borne Virus clinic.

314. The Centre is also not involved in hepatitis C eradication treatment. This treatment is offered through the Blood Borne Virus clinic.

315. The Centre runs multi-disciplinary clinics for hepatitis B and C with Dr Srivastava. These clinics monitor progression of liver disease. The Centre performs screening blood tests for patients with hepatitis B and C.

316. I describe the psychological services at the Centre in paragraphs 197-198 and 205 above. There are two psychologists working as part of the staff team in Cardiff and one in Swansea. The psychology team provides services to all patients who attend the Haemophilia Centres including those infected with HIV and hepatitis as a consequence of infected blood products.

317. The Centre has a whole time equivalent social worker. At the present, time this post is filled by two people in a job share.

318. The impact of HIV and hepatitis infection on patients and their families has been extremely variable and in many cases devastating for the people concerned. Many patients have died, and others are living with the consequences of serious disease. The statements of the Cardiff patients and their families give eloquent insights into the consequences for this group of people and I do not think that I can expand on these statements.

319. The Centre has adopted a cautious approach to decisions about treatment. Decisions about individual treatment and care are discussed within the multi-disciplinary team. A holistic approach to patient care is the main aim of the Centre.

320. The transmission of HIV and hepatitis to patients with bleeding disorders has dominated my consultant practice and the way I approach the management of people with bleeding disorders. It is very hard to say how these events have changed or influenced my practice because they took place before I qualified in medicine and have always been part of my haematology training and consultant role. I cannot say how the practice and approach of my colleagues might have changed.

321. It is very hard to say how the infection of patients with HIV and/or hepatitis B and/or C through blood products has changed or influenced the way in which haemophilia care is now provided (and how). So much has changed in medicine since the 1970s/80s. Undoubtedly, the transmission of HIV and hepatitis through infected blood products has had an enormous effect on the way haemophilia care has been delivered but to specify what would have been the standard of care if infections had not occurred is not possible.

Section 10: Other issues

322. I am not aware of any complaints made about me that are relevant to the Inquiry's Terms of Reference.

323. I am aware that Cardiff and Vale University Health Board holds legal reports, produced by Professor Bloom, describing the circumstances about how individual patients becoming infected with HIV. These reports give much better insights into the clinical practice of Professor Bloom than I am able to do and may help the Inquiry resolve some of questions posed above relating to treatment practices in Cardiff in the early 1980s. I have been told that these reports have been made available to the Inquiry.

324. I have no other comments to make.

Statement of Truth

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

Signed GRO-C

Dated 2nd September 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
May 1983	Haemophilia Treatment Policy Guidelines	WITN4029002
October 1985	Coagulation Factors and Concentrates – Treatment Materials	WITN4029003
12 February 1985	Letter from Professor AL Bloom to Sister Jones Re: Feiba and HTLV III	WITN4029004
12 April 1985	Letter from Professor AL Bloom to Acting Chief Pharmacist	WITN4029005
21 August 1985	Letter from Professor AL Bloom to [blank]	WITN4029006
19 March 1985	Letter from BPL to Regional Transfusion Directors & Haemophilia Reference Centre Directors	WITN4029007
1998	Brown SA, Desani H & Collins PW. *Long-term follow up of patients treated with intermediate FVIII concentrate BPL 8Y*	WITN4029008

	Haemophilia 4:89-93, 1998	
13 May 2002	Letter to Dr D Salter, Senior Medical Officer, The Welsh Assembly Government	WITN4029009
2011	Ministerial Task and Finish Group on Haemophilia Services: terms of reference	WITN4029010
June 2011	Ministerial Task and Finish Group: Report and recommendation arising from Review of services for people with inherited bleeding disorders	WITN4029011
20 November 1997	UKHCDO Meeting Minutes	WITN4029012
15 December 1997	Letter to Haematology Department	WITN4029013
20 September 2004	Letter to Patients re vCJD	WITN4029014
June 2009	Letter to Patients re vCJD	WITN4029015
February 2013	Letter to Patients re vCJD	WITN4029016
5 November 2002	Protocol – CJD, invasive procedures	WITN4029017
7 September 2004	Letter from BPL	WITN4029018
16 January 2010	Updated CJD protocol – invasive procedures	WITN4029019
9 January 1985 (published)	*A study of cell mediated and humoral immunity in haemophilia and related disorders* Moffat EH, Bloom AL, Jones J, Matthews N, Newcombe RJ. Br J Haematol. 1985 61:157-67	WITN4029020
20 April 1985	*HTLVIII antibody status and immunological abnormalities in haemophilia and related disorders* Moffat EH, Bloom AL and Mortimer PP Lancet 325: 8434,p 835	WITN4029021
23 August 1999	Wilde JT, Lee CA, Collins P, Giangrande PLF, Winter M and Shiach C. *Increased bleeding associated with protease inhibitor therapy in HIV-positive patients with bleeding disorders.* Br J Haematol 107:556-559, 1999	WITN4029022
13 January 2009	Ethical Approval CHAVI 14, REC reference	WITN4029023

	08/H0606/85	
1 May 1997	*Aggressive treatment of HIV-associated microangiopathic haemolytic anaemia is associated with good outcome*. Am J Nephrol 18:260, 1998	WITN4029024
2001	NHD patient leaflet	WITN4029025
2007	NHD patient leaflet	WITN4029026
2019	NHD patient leaflet (website version)	WITN4029027
18 August 1999	Circular re records	WITN4029028
15 December 2000	Letter from BPL	WITN4029029
19 December 2000	Letter from Welsh Blood Service to Consultants	WITN4029030
25 November 1997	Letter from Professor Ludlam to Haemophilia Centres	WITN4029031
2 December 2016	Updated CJD procedure	WITN4029032