Witness Name: Debra Anne Pollard
Statement No: WITN03094
Exhibits: Nil
Dated: 07 August 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DEBRA ANNE POLLARD

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 23rd April 2020 ("**the Request**"). Where appropriate, I make reference to questions from the Request, with the question number identified in bold italics.

I, Debra Anne Pollard, will say as follows:

Section 1: Introduction & Professional History

1. I am Debra Anne Pollard of a London address known to the Inquiry. My date of birth is GRO-C 1963 and my professional qualifications are: MSc, RGN.

2. I qualified as a nurse in December 1985. From December 1985 to the summer of 1986 I was a Staff Nurse on a general medical ward at the Royal Free Hospital. From the summer of 1986 until January 1987, I was a Staff Nurse on a surgical ward, and from January 1987 until June 1990 I was employed as a Staff Nurse on a renal unit (specialising in dialysis and transplantation); both of these positions were at the Royal Free Hospital. From the autumn of 1991 until

February 1992 I was an agency nurse, posted at the Royal Free Hospital within the Haemophilia & Thrombosis Centre.

3. I am currently employed by the Royal Free London NHS Foundation Trust as a Lead Nurse Specialist within the Haemophilia & Thrombosis Centre ("**the Centre**"). I have worked for the Trust in the Centre since February 1992 – as a part-time Staff Nurse in the first instance, and then as a Clinical Nurse Specialist from 1999. I have been in my current role since May 2014. I have therefore worked at the Centre for 28 years.

4. As the Lead Nurse Specialist, my responsibilities include leading and managing a team of specialist nurses and allied health professionals. I am also responsible, together with the Centre Director, for the strategic development and management of the department.

5. I currently hold the following posts and memberships:

   a. Member of the UK Haemophilia Society's Clinical Advisory Group;
   b. Member of the European Haemophilia Consortium's Medical and Scientific Advisory Group; and
   c. Chair of the Board of Trustees for the Haemnet Charity (registered charity number: 1152241).

6. Between 2004 and 2011, I was a trustee of the UK Haemophilia Society.

7. I can confirm that I have never provided any evidence or been involved in any other inquiries, investigations, criminal or civil litigation in relation to HIV, HBV, HCV and/or vCJD in blood and/or blood products.

Section 2: The Haemophilia Centre Hospital and the Royal Free Hospital ("the Centre")

8. I have worked at the Centre for 28 years and was first employed by the Trust as a part time Staff Nurse in February 1992. Whilst Dr Peter Kernoff was officially the Centre Director until he was medically retired in 1992, when I started at the Centre, Dr Kernoff was on long term sick leave and had been since the spring of 1991. Therefore, when I started at the Centre, notable staff members included:

    a. Professor Christine Lee – Consultant Haematologist and acting Centre Director until 1992, who was later appointed permanent Centre Director until her retirement in 2005;
    b. Dr Eleanor Goldman – Clinical Assistant until 1984, and Associate Specialist until 1995;
    c. Patricia Lilley – Lead Nurse and Clinical Nurse Manager until 1995, and Lead Research Nurse until her retirement in 2010; Chris Harrington – Clinical Nurse Manager and Nurse Consultant between 1995 and 2014;
    d. Riva Miller – Social Worker and Psychotherapist; and
    e. Dr Angus McGraw – Chief Biomedical Scientist, Laboratory Manager and Departmental Service Manager.

9. Between 1990 and 1991 the Centre was supported by three locum consultant haematologists – Dr (later Professor) Mike Laffan, Dr Marian Wood and Dr Ali Taher. In 1993, the Centre appointed two Consultant Haematologists – Professor John Pasi and Dr David Perry. Riva Miller was supported by Elizabeth Boyd who provided patients at the Centre with advice on benefits and welfare rights. It remained a stable group for some time.

10. During my time at the Centre, the Centre Directors have been Professor Christine Lee, Professor Edward Tuddenham, Professor Amit Nathwani and Professor Pratima Chowdary.

11. I am currently employed as a Lead Nurse Specialist and have been in this role since May 2014. As mentioned above, my responsibilities include leading and managing a team of specialist nurses and allied health professionals. I am an autonomous nurse practitioner and I am also responsible, together with the Centre Director, for the strategic development and management of the department. I therefore work closely at present with the following individuals:

    a. Professor Pratima Chowdary – Centre Director;
    b. Dr Anja Drebes – Consultant for Thrombosis and Anticoagulation;
    c. Dr Keith Gomez – Consultant Haematologist;
    d. Dr Mary Mathias – Consultant Haematologist;
    e. Dr Thynn Yee – Associate Specialist;
    f. Paul McLaughlin – Specialist Physiotherapist;
    g. Nicola Dunn – Counsellor and Family Therapist (who retired 19 June 2020).

12. I also work closely with a wider team of multi-disciplinary healthcare professionals.

13. ***(Q6) I have been asked to explain the hierarchy and dynamics at the Centre, and to identify who was responsible for (a) decisions as to the selection and purchase of blood products, (b) decisions as to use of blood products (including factor VIII and IX concentrates) for patients' treatment and (c) decisions as to what information to provide to patients about treatment, testing and/or diagnosis.***

14. In the 1990s, contracts for the purchase of blood and blood products were made by individual hospitals and negotiated between the hospital and the supplying company. At the Royal Free, decisions about products to treat haemophilia were made by the Consultant Medical

Staff and the actual purchase of those products was managed by the Centre's Service Manager (when I started at the Centre, this post was held by Angus McGraw). This was (and remains) separate to the Trust's Blood Transfusion Department who procure blood and blood products for general use within the hospital. More recently, the purchase of clotting factor concentrates, blood products and other treatments in relation to treating haemophilia and other bleeding disorders has become centralised, and the process is overseen by the NHS Commercial Medicines Unit.

15. The choice of treatment for bleeding disorders was a consultant led decision and would be led by their own research and expertise in a particular field. For example, following his appointment in 1993, Professor Pasi decided to change the product used to treat von Willebrand Disease at the Centre; he had completed his PhD in this area, and felt that the new product would improve patient care.

16. Decisions about treatment, testing and diagnosis were also consultant led, and remain so to this day. However, these discussions are now more likely to be multi-disciplinary and patients and their families are invited to comment on the proposals during their medical reviews. In the last ten years, there is one notable exception that I am aware of. In the last national tendering process, a number of Factor VIII concentrates were taken off the market and replaced by new products. On that occasion, patients received a letter (rather than being spoken to directly) explaining that they would be switched to a similar product and were invited to contact the Centre if they had any concerns about the new product.

Section 3: Knowledge of Risk

17. ***(Q7) I have been asked about the Centre's approach and the approach of senior clinicians at the Centre, including Dr Christine***

Lee, to the use of blood products (in particular factor VIII and IX concentrates) and how this changed or developed over time.

18. When I started at the Centre in February 1992, there was already an emphasis on developing and using recombinant clotting factors and, in the early 1990s, clinical trials were carried out in relation to High Purity Factor VIII and Factor IX; "purity" in this context relates to the protein levels in the concentrates, rather than to any viral inactivation processes. Before the clinical trials in the 1990s, products were considered to have "intermediate purity" meaning that there were other plasma proteins within the blood products.

19. The products that were tested as part of the clinical trials were licensed sometime in the mid-1990s. The main products in use were Replenate (produced by BPL) and Monoclate (produced by Armour) for Haemophilia A and Replenine (produced by BPL) and Mononine (produced by Armour) for Haemophilia B. There were small amounts of other products in use, too.

20. Christine Lee had an interest in supporting clinical research and, as a result, we had a number of adult patients involved in early trials of recombinant Factor VIII. The Centre (with John Pasi acting as Principle Investigator) was also involved with studies relating to recombinant clotting factors in "previously untreated patients" ("**PUPS**"), which meant that many of the children in the Centre were among the first in the country to receive recombinant Factor VIII, FVIII SQ (later licensed as Refacto) and Factor IX (later licensed as Benefix).

21. We were the first centre in Europe to treat a child with Recombinant Factor IX (licensed as Benefix) in a PUPS study; again, John Pasi acted as the Principle Investigator for this study.

22. I remember very clearly that the Consultant medical staff (led by Professor Lee at the Royal Free in conjunction with the UKHCDO and

the Haemophilia Society on a national level) lobbied for the introduction of recombinant clotting factors from the point of UK licensing. However, the initial cost of commercially available recombinant clotting factor concentrate in comparison to the plasma-derived clotting factor concentrates at the time would have more than doubled the overall cost and individual hospitals did not have the budget to support this. This led to the "recombinant for all" campaign, and there were significant representations made to hospital boards, health care commissioners and Government by individual patients and their families via their local MPs, the Haemophilia Society and professional organisations including the UKHCDO.

23. Although funding was made available to treat children aged 16 years and under with recombinant clotting factors in 1998, there was no funding for older patients until the Government announced a "recombinant for all policy" in 2003, with the relevant funding being made available around 2004/2005.

24. ***(Q8) I have been asked about the Centre's approach and the approach of senior clinicians at the Centre, including Dr Christine Lee, to home treatment and to prophylactic treatment for patients with bleeding disorders and how this changed or developed over time.***

25. The Centre's approach to home treatment was known as The Home Treatment Programme (the "**Programme**") and had been introduced during Katharine Dormandy's tenure as Centre Director (Dr Dormandy established and ran the Centre in the 1960s and into the 1970s). The Programme is well documented in the relevant literature and I refer you to the following texts:

    a. Britten, Dormandy et al – Home Treatment for Patients with Haemophilia (The Lancet, 31 August 1975, pages 507-509); and

b. Colvin, Dormandy et al – Regional Co-ordinator for haemophilia in domiciliary practice (British Medical Journal, 1977 vol. 2, pages 814-815).

26. The Programme started with Cryoprecipitate and later extended to clotting factor concentrates which meant that patients could be treated much quicker when a bleed occurred, with a lesser need for hospital visits and admissions which, in turn, reduced disruption to family life.

27. By 1977, the Programme had expanded and required staffing, so a regional co-ordinator was appointed as highlighted in the BMJ text above. This post continued into the late 1990s with a Community Nurse Specialist dividing their time between Great Ormond Street, the Royal Free and the Royal London hospitals. In 1995, the post became hospital-specific and Patricia Lilley took over the role for the Royal Free. I took up the post in 1999.

28. By the time I started at the Centre, prophylaxis was being given to most children and was beginning to be extended to adults. This increased over time as the advantages of prophylaxis became better understood and supported with evidence obtained in studies worldwide. Now, in the Centre (as with most UK centres), more than 85% of individuals with moderate and severe haemophilia receive prophylaxis at home. Those remaining on "on demand" treatment do so by their own choice.

29. ***(Q9) I have been asked about the Centre's approach and the approach of senior clinicians at the Centre, including Dr Christine Lee, to the use of factor concentrates for children with bleeding disorders and how this changed and developed over time.***

30. Before recombinant clotting factors became available for children in 1998, children with bleeding disorders were kept on a single batch of factor concentrates to limit exposure. Many were switched to high purity products as they became available because it meant that

children (who often have veins that are more difficult to access) could be infused with a much smaller volume of product. As mentioned elsewhere, because the Centre enrolled patients in PUPS studies; patients had access to treatments before licensed products became available, and the same applied to recombinant clotting factors.

31. Similarly, the Centre has always been concerned with the prevention of bleeding with prophylaxis in severe and moderate haemophilia. Our understanding of what is required for prophylaxis to be highly effective has grown over time and now both the dosing and frequency are higher than in the early 1990s. The benefits of this can be clearly seen in some of those young men born and registered here throughout the 1990s who have a healthy musculo- skeletal system as a result.

32. Professor Christine Lee did not routinely see the children registered at the Centre. Dr Eleanor Goldman saw children & families until her retirement, and Professor John Pasi was appointed as a Paediatric Haematologist in 1993 and took over responsibility for their care until he left in 1999. Their care transferred to Dr Simon Brown and ultimately to Dr Mary Mathias who is a joint appointment with the Great Ormond Street Hospital for Children. Since 2005, children with haemophilia and other inherited bleeding disorders under five years of age are under the care of Great Ormond Street Hospital. As a result, the Centre now only cares for adolescents during their transition to adult care. As far as I am aware, the youngest patient currently at the Centre is around 15 years old.

33. ***(Q10) I have been asked whether I recall any policies or standard operating procedures (written or otherwise) relating to the use of blood products being in place and, if so, to describe what they were and whether they changed or developed over time.***

34. The departmental guidelines and policies in place at the time were based on the guidelines produced and advocated by the United Kingdom Haemophilia Centre Doctors' Organisation ("**UKHCDO**").

35. ***(Q11) I have been asked about my general understanding as to the risks of infection associated with the use of blood and blood products; the source of my understanding; whether I was provided with any information or training (whether at the Centre or elsewhere) about the risks of infection and, if I did, when this would have been. I have also been asked how my understanding developed over time and how this knowledge affected my nursing practice.***

36. I was aware of exposure to blood borne viruses when I started my training in 1982. It was standard practice for all healthcare staff to be immunised against HBV (which was already understood to be a blood borne virus) to protect against occupational risks – for example, needle-stick injuries. I cannot say when I became aware of the risks of transmission from blood and blood products, and I do not remember patients receiving blood transfusions or other blood products being given any information about the risk of transmission of hepatitis during the early years of my career, although there is now specific written patient information on this issue for those receiving a blood transfusion.

37. My own training about the risk of infection through blood and blood products took place at the Centre and at Haemophilia related meetings and education events. However, it is important to note that, by the time I started my training, the treatments we used were virally inactivated so the training focused on what had happened in the past in relation to (i) infections transmitted by blood and blood products and (ii) how processes had changed in response to developments in infection research and knowledge.

38. ***(Q12) I have been asked to explain my understanding as to the risks of the transmission of hepatitis (including Hepatitis B and Non A Non B Hepatitis/Hepatitis C) from blood and blood products, and the source of that understanding; when I first became aware that hepatitis could be transmitted by blood or blood products; whether I was provided with any information or training (at the Centre or elsewhere) about the risks of the transmission of hepatitis, and when this may have been; how my understanding developed over time; and how this knowledge affected my nursing practice.***

39. While working on the renal unit between 1987 and 1990, I was aware that a number of the chronic haemodialysis patients had "Non A Non B Hepatitis", now known as HCV. These patients were not isolated during dialysis, and I was under the impression at the time (from information I was told by other medical staff) that HCV was not considered either as infectious or as clinically significant as HBV. The impression the medics gave was that HCV was not something to worry about and that patients were likely to live a long life even with HCV. In contrast, those with HBV and HIV were dialysed in very strict isolation to avoid the risk of transmission to staff and other patients.

40. By the time I started at the Centre, there were robust blood donor screening procedures in place which had been recommended and implemented by the Blood Transfusion Service for any donations used in blood products. My understanding at the time was that the risk of transmission of hepatitis from blood and blood products had been greatly reduced by the introduction of these measures. I was broadly aware of reports and claims in the wider press that there was an issue with transmission of infections in haemophiliacs, but I did not become aware of the full extent of the issue until I started in the field in 1992 and met those affected.

41. During the 1990s, a number of studies were carried out in relation to the progression of HIV and HCV in patients who had both infections. The consensus was that co-infection would lead to poor clinical outcomes and evidence was beginning to emerge to show that HCV could lead to fibrosis, cirrhosis, liver failure and/or liver cancer in some patients. This was being seen in my own clinical practice and I recall that sadly a number of patients with hepatitis died of liver failure.

42. Mandatory and statutory training for healthcare professionals was introduced much later although I am unsure of the exact date. This tends to focus on ensuring that the correct unit is administered to the correct patient at the correct time, the risk of transfusion reaction and the steps to be taken should a patient have an adverse reaction during or after transfusion. The training is therefore to ensure the safety of the patient receiving the blood or blood product.

43. I am aware that the current patient information leaflet from NHS Blood and Transplant (which has been in circulation since 2016) mentions a small risk of blood borne viruses and vCJD in blood and blood products (https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/14661/160511-27360-will-i-need-a-blood-transfusion- final.pdf).

44. ***(Q13) I have been asked to explain my understanding as to the risks of the transmission of HIV from blood and blood products, and the source of my understanding; when I first become aware that HIV could be transmitted by blood or blood products; whether I was provided with any information or training (at the Centre or elsewhere) about the risks of the transmission of HIV and, if so, when; how my understanding developed over time; and how my knowledge affected my nursing practice.***

45. I have, throughout my career, been aware of the risks of the transmission of HIV from blood and blood products. As a student nurse in 1984 and then as a newly qualified Staff Nurse working on general

medical wards in 1985, I cared for a number of AIDS patients who were receiving end of life care. As far as I can remember, these patients had not been infected by HIV found in blood and blood products, and my understanding of those individual cases at that time was that transmission was sexual.

46. Between 1987 and 1990 I was working on a renal unit. As far as I am aware, only one patient on the ward (who was receiving chronic haemodialysis for End Stage Renal Disease) was HIV positive. He was known to have previously used intravenous drugs and this was assumed to be the source of transmission.

47. I started working at the Centre in 1991/2 and nearly all the HIV patients there knew they had HIV and that they had contracted the infection from contaminated blood and/or contaminated blood products. As mentioned elsewhere, the only exception to this were three children whose parents had been informed and had chosen not to tell them at that point in time.

48. ***(Q14) I have been asked to explain my understanding of the relative risks of infection from (a) the use of commercially supplied blood products and (b) the use of NHS blood and blood products and whether my understanding changed or developed over time.***

49. When I started at the Centre in 1992, I was (along with other staff at the Centre) required to undertake training about the blood products used to treat people with bleeding disorders; this training was led by Patricia Lilley, Professor Lee and Dr Goldman. We were taught about donor selection and donor panels, and how this process increased product safety; by the time I started at The Royal Free, all blood products in use were sourced in this way. Blood products would then undergo heat treatment and/or solvent detergent treatment to destroy any potential viral contamination. Patricia Lilley also arranged for me

and some other newly recruited colleagues to attend a training event at Bio Products Laboratories ("**BPL**") in Elstree, where we saw first hand how plasma was treated in a fractionation plant.

50. Testing for HIV, HBV and HCV was carried out at all stages during product manufacture. For example, large pools of plasma would be tested and once condensed into smaller pools, the smaller pools would be tested, too. The individual batches of factor concentrate would be created and tested prior to release to the hospitals. Nursing staff were advised to keep patients on the same batch of concentrate as long as possible and to never mix batches for an individual patient. If more than one person in a household was receiving blood products, the Centre would issue products from the same batch if possible. We tried to expose children to fewer batches and our supplier, BPL, would keep one batch aside purely to be used by infant and adolescent patients at the Centre.

51. The supply of blood and blood products was largely outside my remit as a nurse, and fell under the jurisdiction of the Services Manager – a post held by Angus McGraw during my time in the Centre in the 1990s. In 1992, most patients were receiving factor concentrates (including Factor VIII, Factor IX and Factor XI) produced by a company known as BPL. There was some clinical input in relation to the supply of blood and blood products. For example, after his appointment in 1993, Professor Pasi changed the products we used in relation to the treatment of von Willebrand Disease from BPL Factor VIII to Haemate P following his PhD research and clinical expertise in this area.

52. ***(Q15) I have been asked if any training or advice was provided (and if so, what training or advice) to clinical staff at the Centre in relation to advising patients of the risks of infection associated with the use of blood and blood products and, if this was the case, who provided this training or advice.***

53. By the time I started at the Centre in 1991, the risks associated with the use of blood and blood products had been mitigated by the steps described above. Notwithstanding this, the Centre held regular educational sessions which increased my knowledge and understanding of the potential risks posed by the products used; with increasing experience over time I became confident discussing this with patients. The remaining risk that might not be destroyed by the viral inactivation and donor screening that was in place was referred to as the "unknown unknown". It was my understanding that the "unknown unknown" inspired the drive to obtain recombinant products as soon as they became available.

54. ***(Q16) I have been asked if any steps were taken at or by the Centre to mitigate or reduce the risk of infection from the use of blood or blood products and if steps were taken, what they were and when.***

55. I am unable to comment on the steps taken at or by the Centre to mitigate or reduce the risk of infection as the infections caused by blood or blood products had taken place prior to my employment at the Centre (from 1992) which was the start of my career in haemophilia.

Section 4: Testing, treatment and care of patients

56. ***(Q17) I have been asked what information was provided to patients at the Centre about the risks of infection (generally and/or specifically in relation to hepatitis and/or HIV) associated with the use of blood and blood products, and by whom.***

57. I cannot speak about the pre-HIV and pre-Hepatitis days as, when I started in 1991, all the clotting factors were heat treated and some had second viral inactivation steps. As part of the consent process, the patient was told how the product was sourced and how it was treated to eliminate viruses. A consent form was then signed by the consultant

and the patient. However, the consent process was used in relation to new patients having their first exposure to this kind of treatment. I am unaware of what conversations had taken place regarding the risks of infection with patients who had been receiving these products before I started working at the Centre.

58. ***(Q18) I have been asked about what information was provided to patients at the Centre about alternatives to treatment with factor concentrates, and by whom.***

59. I cannot comment on the practices in place before I started at the Centre but, when I started in 1991, those with mild haemophilia and von Willebrand's Disease were treated (wherever possible and when clinically indicated) with Desmopressin.

60. Clotting factor concentrates were given to individuals who either did not mount an adequate response to Desmopressin (assessed by measuring factor levels before and after a test dose) or in whom Desmopressin is contraindicated.

61. ***(Q19) I have been asked what information was provided to patients at the Centre before they began home treatment, and by whom.***

62. By the time patients (usually children) began home treatment, they had already received numerous treatments as part of their hospital care. Patients were also expected to undertake a home treatment training programme where the patient and/or other family members were assessed in relation to their injection technique and their knowledge of how to manage the bleeding disorder; this was assessed on a competency basis. During my time at the Centre (i.e. from 1991-2), the home treatment training programme has always been led by a nurse and continues to be so.

63. ***(Q20) I have been asked to explain the Centre's approach and the approach of senior clinicians at the Centre, including Dr Christine Lee, to obtaining patient consent to treatment and to testing; what information would be provided to patients and by whom; to what extent decisions about treatment and testing were taken by the doctors rather than the patients; and whether this changed or developed over time and, if so, how.***

64. When taking blood, I assumed that the doctor had obtained consent for testing for HIV and HBV as it was my understanding at the time that patients had been told they were regularly being tested. I appreciate that this is now being challenged, but it was common practice for blood tests to be ordered by doctors and taken by nurses or by phlebotomists, and it remains so to this day in most disease areas. Although phlebotomists may take the sample and be able to explain what the test is, they would not be able to explain the implications of the result to a patient. For this reason, the results are returned to the clinician who ordered the test so that the clinician can discuss these with the patient.

65. When I started at the Centre, there was a local consent form to be provided to and signed by patients being exposed to blood and/or blood products for the first time. As part of that process, the patient was told how the product was sourced and how it was treated to eliminate viruses through heat treatment and viral inactivation steps.

66. When patients were receiving clotting factor for the first time, a blood sample was taken for HIV, HBV and HCV testing before starting treatment. As far as I am aware, the test itself and the purpose of the test was always discussed with the patient and their family beforehand; I remember having some of those conversations with patients myself.

67. ***(Q21) I have been asked if any training, advice or instruction was provided to me at the Centre in relation to obtaining patient***

consent to treatment and to testing and if such was provided, to describe the training, advice or instruction given.

68. Patient consent would almost always be obtained by a doctor. As far as I am aware, the only exception to this was when the Centre introduced the "recombinant for all" policy in 2003, which changed the way we obtained consent in relation to patients who were switching to a recombinant factor. Nurses were given a checklist setting out the information that had to be given to the patient before treatment could begin, and both the patient and the nurse would sign the checklist to confirm that the specified information had been provided and that the patient consented to treatment.

69. ***(Q22) I have been asked if I was ever told to withhold information from a patient or patients about risks, or treatment, or testing, or diagnosis, or their condition and if I had, by whom and in what circumstances.***

70. I was never told to withhold information.

71. ***(Q23) I have been asked if it was customary to take blood samples from patients when they attended the Centre and if so, for what purpose. I have also been asked about what information was given to patients about the purposes for which blood samples were taken, and by whom.***

72. It was customary to take blood from people who were attending the clinic; samples were usually ordered by the doctor and taken by the nurse, but some doctors who needed samples for research purposes would often take their own samples. The samples were used for routine blood tests – full blood count, clotting test, renal and liver function tests, and continued screening for HIV, HBV and HCV. Routine virology screening did stop at some point, but I cannot remember exactly when. Samples taken from patients who were HIV or HCV positive were sent

for additional testing so that clinicians could monitor their conditions – for example, viral load measurements and T-cell counts. These patients knew that the samples were taken for this particular purpose and would very often contact the Centre the next day for their results. In the days before HIV treatment, these counts were monitored very closely as a CD4 count below 200 was considered an "AIDS defining illness" requiring introduction of some prophylactic treatments against some opportunistic infections.

73. ***(Q24) I have been asked what information would routinely be given to patients about liver function tests and the results of such tests.***

74. The results of liver function tests would be given to and discussed with the patient in clinic with the consultant. If the test results showed changes that required repeat testing or the need for intervention, the patient would be referred to the joint Haemophilia and Hepatology clinic, also known as the Liver Clinic.

75. ***(Q25) I have been asked if patients were informed if their blood was going to be tested for HIV, HBV and/or HCV (and if so, by whom) and whether the approach to informing patients changed over time.***

76. I cannot comment on those patients who were diagnosed before I started at the Centre (i.e. before 1991-2), although I believe they were aware of ongoing testing in relation to HIV, HBV and/or HCV. During my time at the Centre (i.e. from 1991-2), new patients and/or any patient who was being exposed to clotting factors for the first time were always told they were being tested for those specific infections.

77. The clinical team at the Centre did discuss stopping routine virology screening as there had been no transmission of viral infections since the introduction of heat treatment. Notwithstanding these discussions,

routine virology screening continued until the introduction of recombinant clotting factors in 2003.

78. ***(Q26) I have been asked what the practice was at the Centre about informing patients of test results (whether positive, negative or inconclusive) for HIV, HBV and/or HCV; if the patients were informed of the test results promptly or if there were delays in test results being communicated to them; how, as a matter of usual practice, were they advised of their test results (e.g. by letter, or by telephone, or in person at a routine appointment or at a specific appointment) and by whom; and what, if any, involvement did I have in informing patients of test results.***

79. HIV testing was available from 1985 and, by the time I started at the Centre, all the HIV patients at the Centre (apart from three) knew they had HIV. The Centre also inherited a number of patients either from other hospitals (for example, many patients were transferred to the Centre from Great Ormond Street Hospital) or as a result of patients moving in and out of the local area (and therefore falling within the catchment area for healthcare provision). I therefore cannot speak for how the majority of the patients at the Centre, nor how the patients that the Centre inherited, were informed of their test results and that the test results had come back positive.

80. As referred to above, there were only three patients at the Centre who did not know they had HIV, all of which were under 16 years of age; one a young child, and the remaining two were teenagers. I remember clearly how the two teenagers were told. Whilst they were ultimately told by their parents, a lot of guidance and support had been given by Riva Miller, the Centre's psychotherapist, and Dr Goldman. They rehearsed scenarios with the parents as to how and when they may tell their boys.

81. In relation to HIV and patients who were newly at risk (for example, a sexual partner of a man with Haemophilia and HIV), there were procedures in place in relation to pre- and post-test counselling and giving out test results. Staff at the Centre would make arrangements with each patient in relation to how and when they would receive their result and we would never give results over the telephone unless it was absolutely necessary. It was also Centre policy to never give HIV results on a Friday afternoon as a patient would then have the whole weekend to dwell on the results with no one to talk to – whether that be a friend, family member, colleague or someone at the Centre. The hospital continues to have an HIV Counselling Service (which was first set up by Riva Miller in the 1980s); this service also offers support and guidance to the wider patient population at the hospital.

82. In contrast, HCV testing only became available in 1991 so procedures relating to testing and informing patients of test results were still relatively new when I started at the Centre in late 1991. I had no responsibility for having those conversations with patients and was not required to attend HCV clinic sessions. However, I understand that patients were told in clinic. There was some delay informing some patients with mild inherited bleeding disorders of HCV test results but that was because these patients would attend clinic less frequently (about once a year or even less). As with HIV test results, patients were not told of a positive result without the opportunity to discuss it with a clinician.

83. ***(Q27) I have been asked about what information or advice was provided to patients diagnosed with HIV, HBV and/or HCV regarding the management of their infection including the risks of infecting others and how this changed or developed over time.***

84. I was not regularly involved with providing this kind of advice to patients. These conversations typically took place either in the patient's consultation with the doctor, or in organised sessions with Riva Miller.

Partners, wives and girlfriends were also invited to come for counselling sessions, either with the patient, or on their own, as part of the provision of advice and information.

85. ***(Q28) I have been asked what the practice was at the Centre as regards testing and/or providing information to the partners and/or family members of people known or suspected to be infected with HIV, HBV or HCV.***

86. I cannot comment on the testing and counselling practices offered to family members at the Centre before I started there in late 1991/1992, but when I started, testing continued to be offered regularly to partners and occasionally to family members if they were considered at risk.

87. In terms of HIV, those who were HIV positive were provided with information about all of the options and services available to them. Support also extended beyond the individual patient. Couples were encouraged to attend the Centre for testing or to seek testing locally (for example, at their GP surgery) in the event that a condom failed. Ovulation kits were made available to couples that were planning to start a family in order to minimise the number of exposures, and early referral to specialist fertility services was available. Couples that were trying to conceive naturally were followed up frequently by being invited for a consultation, invited for an HIV test, or both. Irrespective of whether a couple were trying to conceive, couples were supported by clinicians in the Centre; Riva Miller, Dr Goldman and Professor Lee would hold regular consultations regarding the risk of transmission and infection.

88. One instance that I remember clearly involved a man (who knew he had HIV) who had brought his partner for testing. The result came back positive. Arrangements were made for pre- and post-testing counselling, and the couple were informed of the test results with a psychotherapist present.

89. Parents of children born to an HIV positive father were invited to be seen in a joint clinic with Dr Goldman, Riva Miller and the Consultant Paediatrician, Professor Brent-Taylor, and testing was offered and carried out when the child was still young, with an initial test in infancy and annual testing during their early years. This clinic is no longer in operation; I believe it stopped when Dr Goldman retired.

90. At the time, physicians believed the risk of sexual transmission of HCV to be minimal and this has since been confirmed by studies commissioned by the Hepatitis C Trust. Testing and providing information to partners and family members in relation to HCV was therefore not considered necessary. Notwithstanding this, some patients and family members did raise questions about HCV and the risks of transmission, and these individuals were invited to have consultations with Dr Goldman and Dr Lee so that they could discuss any concerns with the clinical team.

91. In relation to HBV, all patients were immunised against HBV upon admission to the Centre and were tested for the infection at every review to ensure they still had immunity. If their immunity in relation to HBV had decreased, a booster immunisation was given. This procedure, coupled with the fact that there were very few patients at the Centre who had been infected with HBV, meant that there was less emphasis on providing testing and information to partners and family members of those with HBV.

92. ***(Q29) I have been asked whether any form of counselling or psychological support was made available to patients infected with HIV, HBV and/or HCV or to their families and, if such support was offered, to provide details of the available support.***

93. Counselling services have always been available to all HIV, HBV and HCV patients and their families, and counsellors have been a constant

presence throughout my time at the Centre. Throughout the 1990s, most of the nurses at the Centre (including myself) were trained in relation to managing distress, uncertainty and bereavement. Whilst we were not registered counsellors, it meant that we were able to offer additional support to our patients and their families.

94. I chose to undertake some extra training (given by the charity Marie Curie) in relation to managing end of life care and bereavement as I felt that was very important in my role at the time; others sought similar training.

95. In terms of formal training, Chris Harrington was appointed in 1995 as Clinical Nurse Manager and was a trained counsellor. Similarly, Riva Miller, Dr Goldman and Nicola Dunn (who was appointed as a counsellor and family therapist when Dr Goldman retired and Riva Miller went part-time) were all trained family therapists.

96. The Centre also offered bereavement counselling to those who lost family members as a result of contracting infections from their treatments, and some took it up. A number of children grew up without a father and some families lost all of their sons. Some young women are still very aware of having lost brothers or fathers as a result of infections and those memories are huge factors when those women (who are carriers of haemophilia) consider pregnancy. There has been a huge effect on families and bereavement counselling and family therapy is still available today.

97. ***(Q30) I have been asked if any form of social work support was made available at the Centre to patients infected with HIV, HBV and/or HCV or to their families and, if so, to provide details of the available support.***

98. Riva Miller was a Medical Social Worker and offered social work support and counselling to patients and their families; various

examples of this have been referred to above. She was joined and supported by Elizabeth Boyd who advised patients on their welfare rights and any benefits they may be entitled to. They both facilitated access to the various support schemes on offer through the Haemophilia Society, the Macfarlane Trust and the Skipton Funds (which later became EIBSS).

99. ***(Q31) I have been asked to explain how the care and treatment of patients diagnosed with HIV, HBV and/or HCV was managed at the Centre; what treatment options, follow-up and/or ongoing monitoring was offered/arranged over the years to those infected; to what extent patients at the Centre were referred for specialist care elsewhere; and how any of the above changed and developed over time.***

100. All patients were very closely monitored. They were seen more frequently than those without viral infections and as Professor Christine Lee had forged such strong links with the Consultant Hepatologists and Professor Margaret Johnson (HIV Consultant), they were also seen in the joint clinics where there was access to both specialists at the same time. This meant that patients registered at the Centre had access to treatments as soon as they became available and sometimes in clinical trials or on compassionate use programmes as both of the associated services had strong research portfolios.

101. Initially of course, before treatments were available to control the virus, care revolved around treating opportunistic infections and as the disease progressed this often meant frequent admissions to hospital. Prognosis was poor in the early 1990s for those with very reduced immunity and some individuals progressed to end of life care much more quickly than others.

102. I was involved with the care of patients diagnosed with HIV, HBV and/or HCV as a result of infected blood products throughout the 1990s. It was

a difficult time and the lack of treatment for HIV meant that, sadly, a lot of patients were dying. We had to liaise closely with palliative care but unfortunately, due to the stigma attached to HIV, palliative care and some hospices would initially refuse to accept HIV patients. However, we developed strong links with some excellent services provided both locally and further afield, and where that was not possible, nurses from the Centre visited patients at home themselves. During the 1990s, it was not unusual for one of the Centre nurses to spend considerable amounts of time supporting individuals and their families at home. We were also able to get nursing care and equipment supplied by and paid for by the Macfarlane Trust to support the needs of patients in their own homes.

103. ***(Q32) I have been asked if I recall patients diagnosed as HIV, HBV and/or HCV positive being treated differently to others, and, if so in what respect(s). I have also been asked what (if any) measures were implemented to address any risks of cross-infection.***

104. Universal precautions relating to infection control have applied to all clinical staff in all hospital wards and departments (including the Centre) as part of NHS standard practice, which mean that everyone is treated the same irrespective of their diagnosis. The only exception to this is that if a patient who has been diagnosed with HIV or Hepatitis is required to have surgery, a note of their infection status is made on the operating list so that the theatre can be deep cleaned afterwards.

105. Whilst patients diagnosed with HIV, HBV and/or HCV were not treated any differently within the Centre, there were issues with prejudice against HIV patients in the wider community, for example in palliative care.

106. ***(Q33) I have been asked if, to my knowledge, clinical staff were made aware of patients' infected status in relation to HIV, HBV and/or HCV.***

107. It was clinically necessary (for reasons of infection control and management of clinical symptoms) that any staff caring for or treating patients with HIV, HBV and/or HCV were made aware of a patient's infected status. There was a clear record of this in a patient's hospital notes specifically for this purpose which would help inform clinical staff at the Centre and in the wider hospital, and GPs and other practitioners were informed by letter.

108. ***(Q34) I have been asked to describe (as fully as I am able), my involvement in the treatment and care of those who were infected with HIV, HBV and/or HCV and what I can recall about the impact of the infection(s), and/or of treatment for the infection(s), and/or of the stigma associated with the infection(s), upon them and upon their families over the years.***

109. There was very little available in the1990s in terms of treatment for HIV. This meant that we were dealing with patients who were very sick upon admission and required very intensive care throughout their time at the Centre. As a Haemophilia Nurse, I was heavily involved in that care whether that was at the Centre, at the patient's home or liaising with palliative care. Patients with significantly damaged immune systems were seen at the Centre every three months by either Professor Lee or Dr Goldman to monitor their symptoms, side effects and any deterioration in their condition.

110. Initially, treatment was largely symptomatic; opportunistic infections (for example, Candida (Thrush) or Pneumocystis Carinii Pneumonia) were common and treatment would be targeted towards that particular infection or episode. There were a number of drugs available to try and minimise the risk of infections in patients with suppressed immune systems, but some had toxic side effects and the majority of treatments were not available until much later. Some opportunistic infections were much more serious and became life threatening, for example, some

patients developed HIV or HCV associated cancers which required medical advice and treatment from the oncologists. Some patients were admitted on multiple occasions with opportunistic infections.

111. Patients could be admitted with a variety of symptoms which meant that there was an emphasis on collaborating with other medical teams at the Royal Free. Extreme weight loss was common (especially in the early days of HIV) so a dietician became part of the multi-disciplinary team caring for patients at the Centre, and clinicians had access to their advice and support. Following an HIV diagnosis and depending on the symptoms a patient displayed, a patient may have to be referred to Neurology, Haematology, Oncology and/or Thoracic Medicine. As referred to elsewhere, Professor Lee was very proactive in establishing and maintaining a network of clinicians across a variety of specialisms, and this meant that our patients were able to access other clinics for investigation and treatment of their symptoms.

112. When treatments started to become available, some were more effective than others and some had intolerable side effects. For example, early HIV treatments were very time specific, requiring administration of the drug at set times which was difficult for patients to adhere to at work. Early treatments for HCV included Interferon which had horrible side effects. Some patients reported fatigue and/or depression which meant they were unable to work or manage the normal activities of daily life. Interferon was prescribed for a period of between 6 and 12 months (depending on the genotype of HCV), so the treatment had a huge impact on the patient's daily life for a notable period of time. The combination of mood changes (as a result of Interferon therapy) along with the uncertainty of whether the treatment would work and what would happen next had terrible emotional and psychological effects on individuals. Some long term relationships did not survive this, illustrative of the strain of treatment on a patient's family and personal life.

113. As noted elsewhere, the stigma associated with the infections was enormous and affected patients and their families throughout their lives. I have heard stories of families being excluded from and even abused by their local communities, with local schools refusing entry to children from affected families or households. Some hospices would not admit patients because of their HIV status irrespective of their need for end of life or palliative care.

114. On a more personal level, individuals would and continue to go to extreme lengths to hide a haemophilia diagnosis in case associations are made with HIV. Some individuals are still yet to share their HIV status with anyone, and the role of healthcare professionals in relation to confidentiality is key to respecting their wishes.

115. There is also a huge sense of loss among those affected. For some young men, the diagnosis of HIV and/or hepatitis affected their life choices. Some patients have told me how they chose not to engage at school, or chose not to go on to tertiary education because it was assumed that they would die soon. As a result, these individuals have missed out on job and career opportunities. Many have also missed out on long-term relationships and family life as they have chosen to remain single and/or childless due to the infection risk.

Section 5: Research

116. ***(Q35) I have been asked to provide detail of any knowledge I have of any research that may have taken place at the Centre including the names of clinicians who were involved in or leading the research.***

117. During the 1990s, the Centre took part in a clinical trial in conjunction with Hepatology looking at the treatment of HCV with pegylated Interferon and Ribavirin; those who were HIV positive or those with HCV with abnormal liver function were a particular focus of the study. Dr

Sanjay Bhagani oversaw the trial in his capacity as Research Registrar, with support from Professor Margaret Johnson (an HIV Consultant); the patients were in regular contact with Sanjay (whether through face to face consultations, written correspondence or telephone conversations) throughout the trial.

118. Professor Lee regularly collaborated with those in Hepatology and HIV medicine in both joint clinics and clinical trials. As a result, patients at the Centre had early access to treatments as they emerged. Whilst not all treatments were effective, some patients really benefitted from that early access to treatment and their prognosis changed dramatically as a result. For example, one patient who was previously sleeping up to 20 hours a day as a result of advanced HIV disease and who was expected to die soon commenced on a "compassionate use" programme involving a number of emerging drugs. Eventually, this patient was able to return to work, start a family and is still alive today. This was a direct result of the collaboration between Professor Lee and Professor Johnson, who saw this patient together regularly. I remember feeling a sense of relief that things were improving, and the Centre's role in clinical trials was part of providing that improvement in treatment, medication and ultimately patient care.

119. ***(Q36) I have been asked if I knew whether patients were made aware of their involvement in research and what approach was taken with regards to obtaining their consent to such involvement.***

120. All clinical research that I was aware of during my time at the Centre was formally undertaken with written Patient Information and Consent. Every clinical trial is required to present these documents to participants for reading and signing, and these documents are then submitted to the Ethics Committee as part of the review process.

121. ***(Q37) I have been asked what the term 'PUPS', an acronym for a category of patients referred to as 'Previously Untreated Patients',***

means to me and if the term was used at the Centre (and if so, by whom and in what respects).

122. PUPS is a common term used in haemophilia treatment and continues to be used to this day by clinical professionals specialising in haemophilia. It refers to patients (most often children, but occasionally adults with mild haemophilia) who have never been exposed to treatment before. An alternative phrase to refer to these type of patients is "treatment naïve".

Section 6: vCJD

123. ***(Q38) I have been asked if I was aware of the risks of transmission of vCJD associated with the use of blood and blood products and, if I was, when and how I became aware of such risks.***

124. I cannot recall exactly when, but I probably first became aware of the risks of vCJD around 1999 or 2000. At that time it was a theoretical risk, based on mathematical modelling of the expected incidence in the general population. I believe it remains a theoretical risk to this day.

125. In 2000, there was an initial notification that a vCJD implicated donor had contributed to plasma in batches of BPL products. However, all of the implicated batches had been used by 1998. I do not remember if individuals who had received those batches as part of their treatment were informed of the risk.

126. In 2000/2001, there was an announcement that clotting factor concentrates would no longer be made from UK-sourced plasma. US-sourced plasma was to be used instead as the USA was considered a "low risk area" in relation to vCJD. New batches of BPL products were labelled with an 'N' preceding their batch number to indicate that the product had been sourced from the USA.

127. It was not until 2004 that anyone who had received British plasma products between 1980 and 2001 were considered "at risk of vCJD for public health purposes". Government and Public Health notifications soon followed.

128. ***(Q39) I have been asked what the process was at the Centre for informing patients about possible exposure to vCJD (i.e. when and how patients were told of possible exposure to vCJD).***

129. As above, in 2000 there was an initial notification that a vCJD implicated donor had contributed to plasma in batches of BPL products. A small number of patients were informed, but the implicated batches had been completely used by 1998.

130. There followed a risk assessment exercise by the vCJD Incidents Panel and the Health Protection Agency. The decision was then taken to inform any individual who had been exposed to a British blood product that there was a risk of vCJD. The procedure for informing patients about possible exposure to vCJD was set by the Health Protection Agency. The process was to involve a blanket health notification which would be sent by first class post under cover of a letter from the Health Protection Agency. Haemophilia centres across the UK were advised of the notification process on 9 September 2004, and the Centre had no input in relation to how patients would be told.

131. The letters were sent out on 20 September 2004. The letters were seven pages long and an information pack (comprising eight pages) was sent alongside the letter. There was no account taken for those with English as a second language, or for those who may have had learning difficulties.

132. Patients could opt (either in writing or in person) to be told whether they had received an implicated batch, and were invited to book an appointment with their usual Consultant to discuss any concerns they

may have, and the implications of a possible vCJD risk. They were also told that the information (i.e. either a confirmed diagnosis, or that they had possibly been exposed to vCJD) would be recorded in their hospital records and that their GP would be informed.

133. Whilst I understand the need for a blanket health notification, the notification process used was impersonal and (given that only a small number of patients were actually considered at risk) did more to scare people than reassure them. Many of those that were notified were children and I am conscious that many of them are living now with what they consider to be a "ticking time bomb" which has had detrimental effects on their mental health.

134. ***(Q40) I have been asked about what information was provided to patients about the risks of vCJD.***

135. I am not aware of any information being provided to patients about the risks of vCJD prior to the notification procedure implemented in 2004 (which is referred to and explained in more detail above).

136. ***(Q41) I have been asked about what counselling, support and/or advice was offered to patients who were informed that they might have been exposed to vCJD.***

137. As mentioned above, the Centre was informed of the vCJD notification process on 9 September 2004, and were told that letters (sent by first class mail) would be sent to affected patients on 20 September 2004. We were also acutely aware that the issue would receive national press attention.

138. Chris Harrington and I therefore set up a telephone helpline to handle any calls from Centre patients regarding vCJD; any calls were handled by Chris and I personally. We expected there to be a large volume of calls from patients requiring urgent assistance so Chris and I stayed late

into the evening for three consecutive evenings. We also audited the calls so that we had a record of the number of calls and the concerns patients had.

139. Whilst letters were sent to 711 people, the audit records show that there were very few calls – 26 on day 1, 16 on day 2 and only 6 on day 3. The same records show that the main concerns related to the blood products patients had received and whether these were considered 'at risk'; the 'real risk' of a patient contracting vCJD; the symptoms of vCJD and when to seek further medical help; and the circumstances in which to inform other people (for example, their dentist or school) that the individual was at risk.

140. Patients who contacted the helpline were offered a variety of counselling and support ranging from counselling sessions with us on the telephone, or more formal counselling sessions with Riva Miller or Nicola Dunn (who had joined the Centre by this time as a therapist). Follow up calls with the Psychotherapy team were also offered. Alternatively, patients could raise concerns directly with their consultant or the team of specialist nurses.

Section 7: Effect on clinical staff

141. ***(Q42) I have been asked how the Centre's practices changed over time to reflect the risk that HIV, HBV, HCV and vCJD infections posed to clinical staff.***

142. Universal precautions relating to infection control have applied to all clinical staff in all hospital wards and departments (including the Centre) throughout my career, and these deal specifically with the risks posed by HIV and Hepatitis infections. There has never been a risk of transmission of vCJD to clinical staff in the Centre because this is an outpatient service where no high risk procedures are performed.

143. ***(Q43) I have been asked about the Centre's protocol for reporting concerns or complaints about staff and/or patient safety. I have also been asked whether I ever reported any such concerns or complaints and, if I did, who I reported these to.***

144. The Trust offers a "needlestick" helpline to deal with concerns or complaints about staff and/or patient safety. During normal working hours, the helpline is staffed by Occupational Health, and out of working hours, the helpline is staffed by members of the Accident and Emergency team. The helpline is intended to offer advice and support in relation to occupational exposure (for example a needlestick injury) or other exposure to blood and/or bodily fluids that causes any member of staff concern. If considered appropriate, the helpline can direct the caller to the clinical team where they will be started on a short course of anti-retroviral therapy and closely monitored.

145. Nursing staff at the Centre also have regular supervisions with a member of the counselling team where they can discuss any concerns or particular cases.

146. In any event, I have never had any concerns or complaints relating to staff safety, and I have always felt well supported by the Centre and the Trust.

147. At the time of the vCJD risk notification in 2004, the Trust set up a steering group to develop Trust policy in relation to patient safety. The steering group was led by the Director of Nursing, the Lead Nurse for Infection Control, the Clinical Lead for Infection Control and Prevention, the Clinical Lead for Endoscopy and the Operating Department Lead in conjunction with the Trust Equipment Decontamination Lead, Professor Christine Lee and myself. The group had a clear objective; that no patient should have their care affected as a result of the infection risk. This objective was, on the whole, achieved. There were some instances

where this objective was unachievable. For example, a lack of disposable equipment meant that some procedures had to be delayed until the right equipment was sourced, and there was a brief delay in endoscopic procedures whilst policies were established for decontaminating equipment. The Trust received no additional funding following the vCJD notification and there would be a huge impact on many other services (including urgent cancer diagnostic pathways) if a piece of equipment such as an endoscope needed to be quarantined. However, the Trust learnt quickly from these events and developed a number of communication pathways to prevent reoccurrence of similar delays.

148. ***(Q44) I have been asked about the impact treating haemophilia patients who subsequently contracted infections from their treatment has had on me both personally and professionally.***

149. The relationship fostered between clinicians and patients at the Centre was very different to other disease areas. I became very close to patients and their families because of the intensity and length of their treatment, and that this disease area often leads to very emotionally charged situations and discussions. I would see some patients every day whilst they were in-patients, and then two or three times a week (either at the Centre or at their home) as part of their out-patient care which could last a very long time.

150. I learnt a lot from the patients and their families about what had happened during their treatment and how they had come to learn that they had contracted infections. Unsurprisingly, there was a lot of anger, hurt and sadness and many questioned how this could have happened to them.

151. We were also dealing with patients who were very sick which had an enormous effect on patients' families and friends, as well as the wider team. We offered bereavement counselling where appropriate, and a

representative from the Centre attended nearly every funeral which is testament to the close relationship between clinicians and the patients at the Centre. I remember those years being at times very difficult and very sad.

152. Some families have stayed in touch far beyond their time at the Centre to exchange Christmas cards, or to share photographs of subsequent children being born or children growing up.

Section 8: The Haemophilia Society ("the Society")

153. ***(Q45) I have been asked to provide details of my role as Trustee within the Society, including the dates that I held this position and my responsibilities.***

154. I was elected as Trustee in approximately 2003/2004 and served for two terms before stepping down in 2011.

155. As Trustee, my role was to ensure that the Trustees and the Board managed the affairs of the Society in the best interests of the members. During my time as Trustee, the overwhelming focus of the Board was in relation to managing the Society's financial resources. When I first took up the role, the Society was receiving a Government grant to the value of £100,000 a year but this source of funding was later removed, resulting in a significant shortfall in the Society's budget. As a result, I was involved with staff restructuring (including consultations and redundancies) and renegotiating the lease for the central London office; these tasks were very time consuming.

156. ***(Q46) I have been asked to provide details of any other Society committees or panels that I have been involved with, including the name of the committee or panel, the position that I held and the dates I held the position, and my responsibilities.***

157. The Society appointed its first 'Women's Board' around 2000/2001, and I was invited onto the panel by the Chief Executive at the time, Karin Pappenheim. The Women's Board determined and oversaw the strategy for the first campaign raising awareness for women with bleeding disorders which involved the organisation of a number of educational events for members and healthcare professionals, and the publication of an information booklet on the issue for women and girls.

158. In or around 2003/2004 (around the same time I was elected as Trustee), I became a member of the Society's Medical Advisory Board. This group, along with key members and the Chief Executive, met twice a year to discuss the treatment and management of haemophilia, and whether any changes needed to be recommended or implemented. Members were invited (via the London office) to submit questions to the group, and the group would then advise on any specific issues. As far as I am aware, the group has not been invited to meet for many years, and the number of questions and requests for information has also dropped.

159. ***(Q47) I have been asked to explain the hierarchy and dynamics at the Haemophilia Society, identifying in particular who was responsible for (a) decisions as to the publication of information and advice relating to the use and safety of blood and blood products and (b) decisions as to what information to provide members of the Society about treatment, testing and/or diagnosis.***

160. Decisions as to the publication and provision of information and advice ultimately lay with the Chief Executive, irrespective of subject matter. If there was any uncertainty about content, these concerns could be raised with the Medical Advisory Board (if further research or clinical guidance was needed) or with the Trustees Board.

161. ***(Q48) I have been asked to identify who was responsible for framing the Society's policy on particular issues such as the use of***

blood and blood products, the use of recombinants, treatment, testing and diagnosis.

162. By the time I became Trustee in 2003/2004, there was a UK-wide 'recombinant for all' policy already in place.

163. ***(Q49) I have been asked how the Society was advised as to the safety and use of blood and blood products and (i) if the Society was advised by an individual, to detail which individuals provided this advice and (ii) if the Society relied on publications for advice, to detail which publications were used.***

164. As detailed elsewhere and insofar as the treatment and management of haemophilia is concerned, the Society was advised by the recommendations of the Society's Medical Advisory Board and key staff members.

165. For blood products still in use, I believe the Society follows the guidance of the World Federation of Haemophilia which provides evidence-based guidelines and advice on the safety, supply and distribution of blood and blood products.

166. ***(Q50) I have been asked how the Society ensured, to the best of its ability, that the information disseminated to its members was accurate.***

167. As detailed above, the Society's Medical Advisory Board was instrumental in ensuring that the information disseminated to its members was accurate. Their work was also supported by other individuals and entities (for example, key staff members) who were involved in researching, reading and editing the information.

168. ***(Q51) I have been asked to explain the relationship (financial or otherwise) that the Society had with:***

i. ***Pharmaceutical companies manufacturing and/or supplying blood products;***

ii. ***Haemophilia centres;***

iii. ***Government; and***

iv. ***The trusts and schemes;***

and what impact (if any) these relationships had on the Society's actions and decisions.

169. The Society received sponsorship from the pharmaceutical industry which helped fund the educational events put on for members and specific research and project work. It should be noted that, during my time as Trustee, the pharmaceutical industry had no influence on the strategic direction of the Society or the information the Society produced for its members.

170. The Society has over time reduced its contact with haemophilia centres in the UK; this was the case during my time as Trustee and continues to be so. The Society occasionally sends out information about an event or small pack of information booklets if the Society thinks the subject matter may be of interest to the centres. The Society sometimes sends a representative to certain events. For example, I invited a member of the Society to several events held by the North London Haemophilia Network when it established its Patient Partnership Network. However, broadly speaking, the Society remains very distant from the national and regional haemophilia centres.

171. I cannot remember any direct contact with Government during my time as Trustee apart from two occasions. The first relates to funding support which I have explained above. Secondly, the Board was approached by Lord Morris in 2007 in relation to pledging Society support for a public inquiry into contaminated blood, which we did; this later became known as the Archer Inquiry, but was not publicly funded.

As there were no other funds available, the Board agreed to fund members' expenses to enable them to attend the Archer Inquiry. The Board continued to support the Chief Executive and the members to campaign for a full public inquiry.

172. The Society was very involved with the Macfarlane Trust ("MFT"), and appointed both a board trustee (during my time as a Trustee, this was Philip Dolan) and user trustees to the board of MFT. The Society became increasingly aware that MFT members were finding it difficult to apply and access funding, and that the way MFT was run was being changed to the detriment of its members. The Society therefore invited the Chief Executive of MFT to come and explain the changes to us. As far as I am aware, not all of the Board's concerns were considered before the changes were implemented, and I know that those changes have been the cause of great concern amongst MFT registrants and their families.

Section 9: Other Issues

173. ***(Q52) I have been asked if I was aware of any of the trusts or funds that were set up to provide financial assistance to people who had been infected (such as the Macfarlane Trust, the Eileen Trust, the Skipton Fund and the Caxton Foundation).***

174. I was very aware of the trusts and funds that were set up to provide such assistance, and would often refer my patients to them for further information. During my time as a Trustee of the Society, I was acutely aware of the Macfarlane Trust and the Society tried to remain very involved with it. However (and as described in more detail above), the Macfarlane Trust appeared to be distancing itself from the other organisations involved with haemophilia care.

175. ***(Q53) I have been asked if patients at the Centre were provided with any information about these organisations or given any assistance***

to obtain financial support from them and, if so, what information and/or assistance was provided.

176. When I started at the Centre, those with HIV were already registered with the Macfarlane Trust. It was my understanding at the time that the Macfarlane Trust contacted all of their members directly to provide updates and assistance, especially in relation to support payments.

177. When the Skipton Fund was established in 2004, all patients who were Hepatitis C positive were written to and encouraged to register with the fund in order to receive support payments. I believe that (where necessary) medical support for these applications was provided by Professor Christine Lee and Dr Thynn Yee.

178. Elizabeth Boyd (Welfare & Benefits Advisor at the Centre) was responsible for helping patients with their applications for financial support from these organisations, as well as for wider benefits. As well as the organisations named, Elizabeth Boyd also submitted applications to the Haemophilia Society Tanner Fund and the Roald Dahl Children's Charity for funds to support individuals, if they were deemed to meet the criteria.

179. I would sometimes provide letters of support when patients were making applications for grants to cover the cost of specific items (for example, a special mattress to be used at home).

180. ***(Q54) I have been asked to detail any involvement or dealings that I had with any of these organisations.***

181. Initially, I had very little contact with these organisations (particularly the Macfarlane Trust ("MFT") and the Skipton Fund) as Elizabeth Boyd would take the lead with applying and arranging funding. As mentioned above, I would occasionally write a letter of support, or help with the preparation of clinical evidence, but these instances were rare.

182. When Elizabeth Boyd retired, nurses and medical staff became more involved with preparing and responding to requests for clinical support but these often came to Chris Harrington in the first instance, owing to her links with the MFT as she had previously been a Trustee of the organisation.

183. The links between haemophilia centres and MFT and/or the Skipton Fund have deteriorated over time. In the 1990s, we would often seek emergency funds to facilitate end of life care at home which would include purchasing essential equipment to paying for agency nurses so that an individual's wish to be at home could be achieved. The team at MFT were well regarded and were willing to answer questions and provide advice over the phone.

184. However, more and more registrants are now encountering problems when applying for funds and find the systems difficult to navigate. I sometimes call the organisation on a family's behalf but the organisation often refuses to speak to me, requesting that they speak to the patient and that the patient complete an application form. This is often unachievable given the urgent nature of the request.

185. My contact with the Skipton Fund to date has been completing forms on behalf of families so that widows can access much needed funds. This has been another difficult time for families as they often have to request evidence of cause of death and review medical records which is very painful and upsetting. On one occasion, I was asked to confirm in writing that a widow had been married to the deceased at the time of this death, despite the fact that the Skipton Fund had already been provided with the marriage certificate. Many of those families suffered enormous financial hardship for many years as they were not entitled to any support.

186. The EIBSS scheme has similar problems, with patients telling me that operators appear to have been poorly prepared and trained, with many fundamentally not understanding how the patient acquired the infection.

187. ***(Q55) I have been asked about the retention policies of the Centre in regards to medical records during the time that I worked there.***

188. Until the Trust moved to electronic records in or around 2014/2015, all patient medical records were retained by the Centre. Our records were not stored in the Central Medical Records as the Centre was a separate and distinct department and the first place of treatment for our patients.

189. In 2014, Trust policy in relation to historic medical records changed. Old records must now be scanned in and added to the electronic record as a "legacy note", to ensure that a patient's notes (whether historic or current) are all in the same place. This exercise has been carried out by the Trust's Medical Records team.

190. Notes of deceased patients were also kept in the department up until 2014 when the decision was taken to scan these records in, and hold them in a separate, secure electronic filing system. These notes can be requested as with any medical record. I understand that many have been obtained by individuals or by their next of kin for the Inquiry.

191. ***(Q56) I have been asked if the Centre, or any clinicians at the Centre, kept any separate records or files or information about patients who had been treated with factor concentrates and/or patients who had been infected with HIV, HBV and/or HCV.***

192. The Centre has always kept separate treatment records for all patients, and continues to do so today. Whilst the paper copies never leave the Centre, the records are entered electronically onto the Haemophilia Information System, which are then uploaded to the National Haemophilia Database. When I first started at the Centre, this system

formed part of what was then known as the Oxford Returns – a manual reporting system which has become more electronic over time. The treatment record forms part of a patient's medical record and is therefore obtainable by a patient or their next of kin as part of a standard record request.

193. The Centre also keeps stock records which detail a patient's name and the time and date when a treatment is administered. This information is duplicated in the treatment record described above.

194. ***(Q57) I have been asked if I have had, at any time, any discussions or conversations or interactions with senior clinicians at the Centre, including Dr Christine Lee, about any of the matters set out above and to provide (to the extent that I am able to) details of those discussions or conversations or interactions.***

195. In 2019, I attended a meeting of the Haemophilia Nurses Association where the Inquiry was discussed in the context of personal recollections of the contaminated blood issue and the events of the 1990s and 2000s. The session was led by Chris Harrington and Maureen Fearns and members of the Inquiry were also present. Whilst I believe both Chris and Maureen have been asked to give evidence to the Inquiry, I have not discussed any of the matters referred to above with them.

196. I remain in regular contact with Chris Harrington as not only was she my mentor and colleague for over 15 years, but she remains a close friend. We have discussed the events of the 1990s and 2000s on occasion and we share the same memories.

197. I met with Professor Christine Lee last year at an event to celebrate a colleague's promotion. Again, we discussed the Inquiry in general terms but did not discuss any of the matters set out in this document in any detail.

198. ***(Q58) I have been asked to provide, in as much detail as I am able, information about any other issues associated with my work at the Centre that may be relevant to the Inquiry's investigation. I have been informed that I can find the Inquiry's Terms of Reference and List of Issues on the Inquiry's website www.infectedbloodinquiry.org.uk and that if I am in doubt as to whether or not to include something, I should contact the Inquiry Team.***

199. I am not aware of any other information that may be relevant to the Inquiry's investigation.

200. ***(Q59) I have also been asked to identify any documents which I have that may be relevant to the Inquiry's Terms of Reference.***

201. I do not hold any documents that might be relevant to the Inquiry's Terms of Reference in my personal capacity, and it is in my personal capacity that I am required to make this statement to the Inquiry.

Statement of Truth

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

Signed GRO-C

Dated 07-08-2020