Witness Name: Dr David Perry
Statement No: WITN3173004
Exhibits: WITN3173005-10
Dated: 6 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR DAVID PERRY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 15 July 2020.

I, David James Perry will say as follows: -

Section 1: Introduction

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

1.1. Name: David James Perry

1.2. DOB: GRO-C 1954

1.3. Address: GRO-C

1.4. Professional Qualifications:

1.4.1. 1975 BSc University of Edinburgh

1.4.2. 1978 MB ChB University of Edinburgh

1.4.3. 1980 MRCP (UK) The Royal College of Physicians

1.4.4. 1985 MRCPath The Royal College of Pathologists

1.4.5. 1992 MD University of Edinburgh

1.4.6. 1993 PhD University of Cambridge

1.4.7. 1995 FRCPath The Royal College of Pathologists

1.4.8. 1997 FRCPEdin The Royal College of Physicians of Edinburgh

1.4.9. 2008 FRCPLond The Royal College of Physicians of London

1.4.10. 2014 FAcadMEd Fellow of the Academy of Medical Educators

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

2.1. August 1978 – July 1979, Surgical/Medical House Officer, Edinburgh, Management of in-patients with medical and surgical problems requiring admission to hospital.

2.2. August 1979 – July 1980, Senior House Officer, Cardiology/General Medicine, Western General Hospital, Edinburgh, Management of in-patients in the Coronary Care Unit and Medical Wards under the consultant supervision of Dr M Matthews and Dr A Kitchin.

2.3. August 1980 – January 1981, Senior House Officer, Nephrology/General Medicine, Western General Hospital, Edinburgh, Management of in-patients/out-patients in the Renal unit at the Western General Hospital. The management of general medical patients under the consultant supervision of Dr J Anderton.

2.4. February 1981 – July 1981, Registrar, Nephrology/General Medicine, Western General Hospital, Edinburgh, Management of in-patients/out-patients in the Renal unit at the Western General Hospital and the

management of general medical patients under the consultant supervision of the Dr J Anderton.

2.5. July 1981 – June 1983, Registrar Haematology, Western General Hospital/Bangour General Hospital, Edinburgh, A trainee post in general and malignant haematology under the consultant supervision Dr N Allan and Dr G Stockdill [Western General Hospital] and Dr M Cook [Bangour General Hospital]. This post did not involve the management of patients with inherited bleeding disorders. These patients and their families were managed at The Royal Infirmary of Edinburgh and The Royal Hospital for Sick Children.

2.6. July 1983 - November 1987, Senior Registrar, Haematology, West Midlands Rotational Training Scheme in Haematology

2.7. July 1983 - October 1984, Coventry/Warwickshire & Walsgrave Hospitals. This was a training post involving the management of in-patients and out-patients with haematological disorders. The post did not involve the management of patients with inherited bleeding disorders.

2.8. October 1984 - March 1985, Regional Blood Transfusion Centre, Birmingham. This was a 6-month attachment in the Blood Transfusion Service but involved no clinical responsibilities.

2.9. April 1985 - November 1987, Birmingham Children's Hospital. This was a training post in paediatric haematology under the consultant supervision of Dr FG Hill and latterly Dr P Darbyshire. The post involved the management of in-patients and out-patients with haematological disorders including inherited bleeding disorders. My only prior experience in paediatrics was as a medical student in Edinburgh graduating in 1978 and my practice was, therefore, carefully supervised both by the consultant staff and the senior nursing staff.

2.10. December 1987 – November 1993, Wellcome Trust Lecturer in Molecular Haematology, Department of Haematology, University of Cambridge.

Under the supervision of Professor RW Carrell. This was a research post with no clinical commitments.

2.11. July 1994 – July 2004 Senior Lecturer in Haemophilia and Haemostasis/Honorary Consultant Haematologist, Royal Free & University College Medical SchoolKatharine Dormandy Haemophilia and Thrombosis Centre. This was primarily a research/teaching post but included the management of in-patients and out-patients with thrombotic disorders. The provision of the service for patients and their families with inherited and acquired bleeding disorders was provided by Professor CA Lee, Dr [Prof] KJ Pasi and latterly Dr S Brown.

2.12. October 2004 – July 2017, Consultant Haematologist, Haemostasis, Thrombosis, General Haematology, Obstetric Haematology. My role together with my colleague Dr TP Baglin and latterly Dr M Besser was to manage in-patient and out-patients with general haematological disorders. I was, together with Dr Baglin and my nursing/laboratory colleagues, responsible for the management of in-patients, out-patients and their families with inherited and acquired bleeding disorders. The Paediatric Service was led by Dr M Gattens [appointed July 2004], Dr M Bradbury [now erased from the GMC register] and latterly Dr A Kelly. I led the development of the Obstetric Haematology Service. I was actively involved in student teaching. I was not involved in the Transfusion service or in the management of patients with malignant haematological disorders.

2.13. July 2017. I retired formally from the NHS and clinical practice in July 2017. I returned as a part-time locum consultant Haematologist until August 2017.

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

3.1. United Kingdom Haemophilia Centre Doctors' Organisation [UKHCDO]: I was a member of the UKHCDO. I cannot recall precisely when I joined the UKHCDO, but it was prior to 2004 as I was a member of the UKHCDO Rare

Coagulation Disorders working party. I left the UKHCDO I recall in 2017. My roles in the UKHCDO were:

3.1.1. Membership of the Rare Inherited Diseases Working Party [Chair: Dr P Bolton-Maggs].

3.1.2. Publications:

3.1.2.1. The rare coagulation disorders--review with guidelines for management from the United Kingdom Haemophilia Centre Doctors' Organisation. Haemophilia 2004 Sep;10(5):593-628.

3.1.2.2. A review of inherited platelet disorders with guidelines for their management on behalf of the UKHCDO. Br J Haematol 2006 Dec;135(5):603-33.

3.1.3. Membership of the Genetics Working Party [Chair: Prof CA Ludlam].

3.1.4. Publications:

3.1.4.1. A framework for genetic service provision for haemophilia and other inherited bleeding disorders. Haemophilia 2005 Mar;11(2):145-63.

3.1.5. Audit Lead UKHCDO Triennial Audit Programme. I took on the lead of the UKHCDO audit programme from Dr J Wilde in 2012 and in close collaboration with the Haemophilia Society, I coordinated the triennial audit of Haemophilia Comprehensive Care Centres [CCCs] in the UK in 2013. I resigned from this post in 2015.

3.2. UK NEQAS Blood Coagulation. I was a member of the steering committee for UK NEQAS Blood Coagulation [2003] and subsequently chair [2011] of the steering committee. My role was to review the National External Quality Assessment Service Scheme for Blood Coagulation and to review the results for each scheme. I am no longer a member of NEQAS.

3.3. British Society of Haematology [BSH]: I was a past member of the BSH and participated in a number of its meetings. I am no longer a member.

3.4. BCSH: British Committee for Standards in Haematology [Haemostasis and Thrombosis.] I was a member of the BCSH and latterly secretary [2015] and chair [2015-2016]. I was involved in developing guidelines for the BCSH in Haemostasis and Thrombosis.

3.5. International Society of Thrombosis and Haemostasis [ISTH]: I was a member of the ISTH and participated in a number of meetings. I am no longer a member.

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

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

Section 2: Decisions and actions of those treating patients with bleeding disorders at the hospitals, haemophilia centres or other medical facilities at which you have worked

5. **Please identify those hospitals, haemophilia centres and other medical facilities at which you carried out or assisted in the treatment or management of patients with bleeding disorders, or in the care or treatment of patients infected with HIV, HCV or HBV in consequence of infected blood or infected blood products, regardless of your own level of seniority at the time.**

5.1. I have worked at the following centres that have provided care for patients with bleeding disorders. I have not been involved directly in the management of patients infected with HIV and/or HCV and/or HBV.

5.1.1. Birmingham Children's Hospital - Ladywood Middleway: April 1985 - November 1987. This was prior to its move to its current site at Steelhouse Lane.

5.1.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

5.1.3. Cambridge University Hospitals NHS Foundation Trust [Addenbrooke's Hospital]: October 2004 – July 2017

6. It is understood that you spent time as a registrar training under Dr Frank Hill at Birmingham Children's Hospital Haemophilia Unit ("the Centre"). Please confirm:

a. Whether that is correct;

b. If so, across what time period you worked under Dr Hill at the Centre; and

c. Whether you worked under other senior colleagues while at the Centre and, if so, who they were;

6.1. Birmingham Children's Hospital - Ladywood Middleway: April 1985 - November 1987

6.1.1. I was a trainee in Haematology attached to the Birmingham Children's Hospital from April 1985 - November 1987. This was a training post in paediatric haematology under the consultant supervision of Dr FG Hill and latterly Dr P Darbyshire.

d. Whether you also worked underneath Dr Hill in any capacity at the Queen Elizabeth Hospital, Birmingham.

6.2. I did not work at the Queen Elizabeth Hospital in Birmingham under Dr FG Hill.

7. It is also understood that, subsequent to your time at the Centre, you worked at the Royal Free Hospital ("the Royal Free"). Please confirm:

a. **Whether that is correct;**

b. **If so, across what time period you worked there;**

c. **Under which (if any) senior colleagues you worked.**

7.1. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

7.1.1. I worked at the Royal Free London NHS Foundation Trust from July 1994 - July 2004.

7.1.2. I was a Senior Lecturer in Haemophilia and Haemostasis and an honorary Consultant Haematologist in the Katharine Dormandy Haemophilia and Thrombosis Centre, part of the Department of Haematology.

7.1.3. Dr [Professor] CA Lee and Dr [Professor] KJ Pasi were responsible for the delivery of the Haemophilia Service and for the management of, in close collaboration with Professor Margaret Johnson [Thoracic/General medicine, consultant in HIV/AIDS medicine] and the Hepatology service, patients with bleeding disorders and with HIV and/or HCV and/or HBV. The head of the Haematology Department was Prof AV Hoffbrand and subsequently Prof G Prentice.

8. **In relation to each of those hospitals, haemophilia centres and other medical facilities which you identify in response to question 5 above, and in any event including the Centre and the Royal Free:**

a. **Please describe your role and responsibilities and how, if applicable, this changed over time;**

b. **Please describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products;**

c. **Please identify senior colleagues:**

i. **Under whom you trained as a haematologist; and/or**

ii. **Who were involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products, and their roles and responsibilities during the time that you worked there.**

8.1. Birmingham Children's Hospital - Ladywood Middleway: April 1985 - November 1987

8.1.1. I was a trainee in Haematology under the close supervision of consultants Dr FG Hill and latterly Dr P Darbyshire. As a trainee I was involved in the management of in-patients and out-patients with haematological disorders. My only prior experience in paediatrics was as a medical student in Edinburgh [graduating in 1978] and my practice was, therefore, carefully supervised both by the consultant staff and the senior nursing staff. I was involved in the care of children with inherited bleeding disorders but as this was a training post I sought advice on their management from my senior consultant colleagues and from the senior Haemophilia nursing staff. I had no prior experience of managing adults or children with inherited bleeding disorders.

8.1.2. I was not involved in any studies that involved screening patients for HIV and/or HCV and/or HBV. I am not a co-author on any of the publications from the Birmingham Children's Hospital that involved these studies. My main objective during this attachment was to expand my knowledge of paediatric haematology and to sit the MRCPath examination in Haematology which I did in 1985.

8.2. Royal Free London NHS Foundation Trust: July 1994 - July 2004

8.2.1. I worked at the Royal Free London NHS Foundation Trust from July 1994 - July 2004.

8.2.2. I was a Senior Lecturer in Haemophilia and Haemostasis and an honorary Consultant Haematologist in the Katharine Dormandy Haemophilia and Thrombosis Centre, part of the Department of Haematology. My role was to develop/continue the research interests of the department and the management of patients and their families with thrombotic disorders. I was not involved in the day-to-day management of individuals with Haemophilia. My research focused on the molecular basis for the inherited bleeding and thrombotic disorders.

8.2.3. As a consequence of my research interests in the rare inherited bleeding disorders, I was involved in the management of a small number of such patients.

8.2.4. I was not involved in the management of patients with a bleeding disorder that were also co-infected with HIV and/or HCV and/or HBV. This was undertaken by my colleagues – Prof CA Lee, Dr [Prof] KJ Pasi and latterly following the departure of Dr [Prof] Pasi, Dr Simon Brown, and the senior nursing staff, in close collaboration with Professor M Johnson [Thoracic/General medicine, consultant in HIV/AIDS medicine] and the Hepatology team. I was not involved in any studies that involved screening for or treating patients with HIV and/or HCV and/or HBV. I am not a co-author on any of the publications from the Katharine Dormandy Haemophilia and Thrombosis Centre that involved these studies.

8.2.5. I was not involved in the care of children with inherited bleeding disorders as children were managed in the Haemophilia Centre at the Great Ormond Street Hospital for Children.

8.3. Cambridge University Hospitals NHS Foundation Trust [Addenbrooke's Hospital] October 2004 – July 2017

8.3.1. I was appointed as a consultant haematologist in Cambridge in 2004 and became co-director of the Haemophilia Centre with Dr TP Baglin. Dr TP Baglin had been appointed as a consultant Haematologist in

September 1990 on the retirement of Dr Muriel Seaman and managed the Haemophilia Centre and patients with inherited and acquired bleeding disorders.

8.3.2. I was, together with Dr Baglin and my nursing/laboratory colleagues, responsible for the management of in-patients and out-patients with inherited and acquired bleeding disorders. Patients with inherited bleeding disorders who were also co-infected with HIV and/or HCV and/or HBV were managed by the Hepatology and/or Infectious Diseases consultants.

8.3.3. I was not actively involved in the management of children with inherited bleeding disorders. The Paediatric Service was led by Dr M Gattens [appointed July 2004], Dr M Bradbury [now erased from the GMC register] and latterly Dr A Kelly.

9. With respect to each of the hospitals, haemophilia centres and other medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free:

a. Approximately how many patients with bleeding disorders were under the care of each hospital, haemophilia centre and medical facility when you first started working there and over the years that followed?

b. In each case, approximately what proportion were adults and what proportion were children? (where you are able to give exact rather than approximate figures, please do so).

9.1. I do not recall how many patients were registered with and attending each of the three Centres in which I have worked:

9.1.1. Birmingham Children's Hospital: April 1985 - November 1987

9.1.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

9.1.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

9.2. I am unable to comment on how the numbers of patients changed during my time in these Hospitals. Please contact the relevant Trusts for this information.

9.3. In the Birmingham Children's Hospital all of the patients were children.

9.4. At the Royal Free London NHS Foundation Trust [Katharine Dormandy Haemophilia and Thrombosis Centre] there were no children registered with inherited bleeding disorders as they were managed in the Haemophilia Centre at the Great Ormond Street Hospital for Children.

9.5. In the Cambridge University Hospitals NHS Foundation Trust, I do not recall how many of the patients registered in the Centre were adults or children and how these numbers changed during my time there. Please contact the CUHFT.

10. To the best of your knowledge and recollection, what decisions and actions were taken, and what policies were formulated, whether by you or by your colleagues, at each of the hospitals, haemophilia centres and other medical facilities you identify in your response to question 5 above (in any event including the Centre and the Royal Free), regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In particular, please address, in relation to any hospital, haemophilia centre or other medical facility at which you worked during the 1980s, the following questions:

a. Who was responsible for the selection and purchase of blood products (in particular factor concentrates) for use there?

b. What particular products were used for treating patients there, over what period of time and for which categories of patients? In addressing this issue, please answer the following questions:

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

ii. What decisions were taken as to which products to purchase and use?

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

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

v. What, if any, involvement did you have?

c. What was the relationship, respectively, between each hospital, haemophilia centre and medical facility and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?

d. If, in any particular case, the responsibility for the selection and purchase of blood products lay with an organisation other than the relevant hospital, haemophilia centre or medical facility, please specify which organisation and provide as much information as you can about its decision-making.

e. How were decisions taken as to which products to use for particular patients? What role did you have in such decisions? Were patients given any choice, or involved in any discussions, as to which products to receive?

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

g. **What was the policy and approach as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and, if so, how? How, if at all, was the policy and approach informed by discussions with external parties?**

h. **What was the policy and approach in relation to home treatment? When was home treatment introduced? Did the policy and approach towards home treatment change over time and if so how?**

i. **What was the policy and approach in relation to prophylactic treatment? Did that policy and approach change over time and if so how?**

j. **What was the policy and approach in relation to the use of factor concentrates for children? Did that policy and approach change over time and, if so, how?**

k. **To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates?**

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

m. **Please provide, insofar as you have not already done so above, a full account of Dr Hill's policies, decisions and actions during the time that you worked with him, as regards the use of factor concentrates, the risks of infection, the treatment of patients and the provision of information to patients.**

10.1. a-m: Birmingham Children's Hospital - Ladywood Middleway April 1985 - November 1987

10.1.1. I was a trainee in Haematology during this period and I was not involved in any discussions relating to the selection of/or purchase of clotting factor concentrates, policy decisions, interactions with the

pharmaceutical industry or the generation of information that was provided to the children or the families of children with inherited bleeding disorders.

10.1.2. I was not involved in decisions relating to which product a specific patient received, the risks of infection, how or if this changed over time and I am unable to comment on whether this was discussed with the patient and his/her parents. These decisions were made by Dr FG Hill, consultant in Paediatric Haematology.

10.1.3. There were a limited number of treatments available for the treatment of patients with inherited bleeding disorders. In cases of severe Haemophilia A or B and a bleeding problem, replacement of the missing clotting factor was necessary. This could be achieved by the use of a clotting factor concentrate, Cryoprecipitate or Fresh Frozen Plasma. Desmopressin is not suitable for use in Haemophilia B or in severe Haemophilia A or in children under the age of 2 years.

10.1.4. During my attachment to the Birmingham Children's Hospital - Ladywood Middleway, I cannot recall all of the products that were in use, but I recall the use of plasma-derived Factor VIII concentrates.

10.1.5. I am unaware of any discussion between Dr Hill and Armour Pharmaceuticals [29th September 1986] in relation to previous heat-treated products.

10.2. a-l: Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

10.2.1. I worked at the Royal Free London NHS Foundation Trust from July 1994 - July 2004.

10.2.2. I was a Senior Lecturer in Haemophilia and Haemostasis and an honorary Consultant Haematologist in the Katharine Dormandy Haemophilia and Thrombosis Centre. I was not involved in the management of individuals with Haemophilia A, B or von Willebrand's

Disease and unable, therefore, to comment on decisions that related to the choice of products, interactions with the pharmaceutical industry or the generation of information that was provided to individuals with a bleeding disorder. This would have been undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi and latterly Dr S Brown.

10.2.3. I was involved in the management of a small number of patients with rare inherited bleeding disorders. In these patients, there were very limited treatment options available and their treatment depended upon their clotting factor deficiency and in particular whether surgery was planned. Commercial and financial considerations did not come into any of the discussions relating to the use of these products. I was not involved in any discussions with the pharmaceutical industry relating to the supply of specific blood products or clotting factor concentrates.

10.2.4. It has been my usual practice as a consultant for patients under my care to be copied into their correspondence so that they had a summary of their consultation, the discussions, investigations and planned treatment(s).

10.2.5. For the rare inherited bleeding disorders the therapeutic options for treatment were limited. The possibilities were:

10.2.5.1. No Treatment

10.2.5.2. Tranexamic acid

10.2.5.3. Desmopressin

10.2.5.4. Fresh Frozen Plasma

10.2.5.5. Clotting factor replacement if a product was available.

10.2.5.6. Recombinant FVIIa [NovoSeven]

10.2.6. The use of specific treatments depended upon the nature of a patient's problem. If surgery was planned then the therapeutic options were limited and commonly employed the use of either Fresh Frozen

Plasma, or a clotting factor concentrate to elevate the clotting factor to a level that was considered safe [derived from published data] for surgery to proceed.

10.2.7. Cryoprecipitate was a source of Fibrinogen and was used to treat patients with inherited disorders of Fibrinogen.

10.2.8. I was not involved in discussions at the Katharine Dormandy Haemophilia and Thrombosis Centre relating to prophylaxis or home treatment. To the best of my recollection patients with rare bleeding disorders would rarely, if at all, have been on prophylaxis or home treatment due to the rarity of their disorder and would, therefore, have been seen in the Haemophilia Centre.

10.2.9. I was not involved with the care of children at the Katharine Dormandy Haemophilia and Thrombosis Centre as they were seen in the Haemophilia Centre at the Great Ormond Street Hospital for Children.

10.2.10. In the case of patients with mild or moderate rare inherited bleeding disorders, their treatment would have depended upon the nature of the problem, in particular whether surgery was planned and the duration of the planned treatment.

10.2.11. I am aware that Parvovirus B19, Hepatitis D possibly Hepatitis G and Hepatitis A, have been transmitted, at least by some, plasma-derived clotting factor concentrates.

10.2.12. It has been my practice as a consultant for my patients to be copied into correspondence following visits to see me so that they had a summary of the consultation and discussion, a plan of management including planned treatments and to forward on a copy of their investigations as they became available. If patients wished to discuss any aspect of their treatment then they could do so either by telephone and/or I would arrange a further appointment for them.

10.3. a-l: Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

10.3.1. The national tender process for clotting factor concentrate procurement came into operation in 2004 and the Cambridge Centre had to commit to using certain volumes of specific products. Patients with inherited bleeding disorders would have been treated wherever possible with recombinant clotting factor concentrates. Patients who were not on a recombinant product would have been treated with virally inactivated plasma-derived clotting factor concentrates or solvent-detergent treated Fresh Frozen Plasma. This would have been either because no recombinant product was available, or they had a history of Factor VIII inhibitors and having been successfully tolerised there were concerns that switching them to a new product would result in a return of their Factor VIII inhibitor, or that they had a rare bleeding disorder.

10.3.2. Decisions to switch patients to a different recombinant clotting factor concentrate would have been made in consultation with the patient and the reasons for considering the change would have been discussed. If patients did not wish to switch they would have remained on their original treatment. The national contract stated what products were available and I was not involved in discussions with pharmaceutical companies regarding the use of specific concentrates.

10.3.3. Patients with mild-moderate Haemophilia A and some cases of von Willebrand's disease would have been treated with Desmopressin and Tranexamic Acid but this would have been dependent upon the nature of their problem and a documented previously established response to treatment. Patients requiring major surgery or prolonged periods of treatment were not suitable for treatment with Desmopressin and in these cases these patients would have been treated with a clotting factor concentrate with careful monitoring.

10.3.4. Cryoprecipitate was used rarely if at all for patients with inherited bleeding disorders.

10.3.5. All patients wherever possible were on home treatment. Home treatment was in place when I joined the centre in 2004. This policy did not change over time. Prophylactic administration of clotting factor concentrates was discussed with all patients with a severe bleeding phenotype to minimise their bleeding risk and maintain joint function.

10.3.6. I cannot comment on clotting factor concentrate usage in children as this was managed by the paediatric Haematologists – Dr M Gattens, Dr M Bradbury [now erased from the medical register] and latterly Dr A Kelly.

10.3.7. It was my usual practice for my patients to be copied into their correspondence following visits to see me so that they had a summary of the consultation and discussion, a plan of management including planned treatment(s) and I would forward on a copy of their investigations as they became available. If patients wished to discuss any aspect of their treatment then they could do so either by telephone and/or I would arrange a further appointment for them.

Section 3: Knowledge of, and response to, risk

General

11. When you first began to work with patients with bleeding disorders (and please specify when that was):

a. What did you know and understand about the risks of infection associated with blood and/or blood products?

b. What were the sources of your knowledge?

c. How did your knowledge and understanding develop over time?

11.1. Birmingham Children's Hospital: April 1985 - November 1987

11.1.1. a-c. My attachment as a trainee to the Birmingham Children's Hospital - Ladywood Middleway was from April 1985 - November 1987. This was my first involvement in the management and the care of patients with a bleeding disorder.

11.1.2. I cannot recall precisely when I became aware of risks of infection associated with blood and/or blood products, but I believe it was during the time I was attached to the Birmingham Children's Hospital. My sources of information were likely to have been from the medical literature and from meetings that I attended. My knowledge of these events continued as I attended further meetings and from further publications.

d. With respect to the Centre, did you ever discuss the above matters with Dr Hill? If so, please provide details of what was discussed and when.

11.1.3. d. I do not recall discussions with Dr FG Hill relating to the safety of clotting factor products.

e. What was your understanding of the relative risks of infection from:

i. the use of commercially supplied blood products and

ii. the use of NHS blood products?

11.1.4. e. I do not recall, at the time that I was a trainee in Haematology, of being aware of the relative risks of commercial clotting factor concentrates compared to NHS blood products.

f. With respect to the Centre, did you ever discuss such matters with Dr Hill? If so, please provide details of what was discussed and when.

11.1.5. f. I do not recall discussions with Dr FG Hill relating to the relative risks of commercial clotting factor concentrates compared to NHS blood products.

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

12.1. Birmingham Children's Hospital: April 1985 - November 1987

12.2. I was a trainee in Haematology at the Birmingham Children's Hospital - Ladywood Middleway from April 1985 - November 1987. I have no recollection of what advisory and decision-making instructions were in place, or were put in place, in the Haemophilia Centre, to consider and/or assess the risks of infection associated with the use of blood and/or blood products. I was involved in the care of children with inherited bleeding disorders but as this was a training post I sought advice on their management from my senior consultant colleagues and from the senior Haemophilia nursing staff.

13. What decisions and actions were taken at any relevant hospital or centre or facility at which you worked to minimise or reduce exposure to infection?

13.1. Foundation Trust: July 1994 - July 2004

13.1.1. I was a Senior Lecturer in Haemophilia and Haemostasis and an honorary Consultant Haematologist in the Katharine Dormandy Haemophilia and Thrombosis Centre at the Royal Free London NHS Foundation Trust from July 1994 - July 2004. The care of patients with inherited bleeding disorders was undertaken by my colleagues Prof CA Lee, Dr [Prof] KJ Pasi and latterly Dr S Brown.

13.1.2. For patients with rare bleeding disorders and whose management I was involved in, there were only a limited number of treatment options available due to the rarity of these disorders. To minimise the risk of infection the duration of treatment was limited to that which was

essential to cover any invasive procedure including surgery and the selection of clotting factors and/or blood products was limited.

13.2. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

13.2.1. I was appointed as a consultant haematologist in Cambridge in 2004 and became co-director of the Haemophilia Centre with Dr TP Baglin. I retired from clinical practice in July 2017.

13.2.2. All patients attending the Cambridge Haemophilia Centre and requiring treatment would have received recombinant clotting factor concentrates unless such a product did not exist to treat their specific disorder. In these cases, a plasma-derived virally inactivated concentrate, or virally-inactivated Fresh Frozen Plasma would have been used.

13.2.3. Patients with mild-moderate Haemophilia A and some types of von Willebrand's disease would have received treatment with Desmopressin frequently combined with Tranexamic Acid unless this was contra-indicated because of the underlying problem that required treatment. The national tender process for clotting factor concentrate procurement came into operation in 2004 and would have been adhered to in identifying products to treat patients.

13.2.4. Treatment guidelines from the UKCHDO and BCSH would have been adhered to and guided practice.

13.2.5. Weekly meetings between the Haemophilia Staff [Administrative/Medical/Nursing] and the Laboratory staff were held to discuss all issues relating to the Haemophilia Centre and its practice.

13.2.6. My general recollection is that the risks and benefits of treatment would have been discussed with patients. Patients also had time to discuss treatment options or alternatives. My practice was that patients who I managed would be sent copies of their clinic letters that

summarised their consultation, planned treatment(s), follow-up plans and the results of any investigations. Patients would have been aware that they could contact us at any time to discuss any concerns or questions that they might have.

Hepatitis

14. When you first began working with patients with bleeding disorders:

a. What was your knowledge and understanding of the risks of the transmission of hepatitis, including hepatitis B and NANB hepatitis (hepatitis C), from blood and/or blood products? What were the sources of your knowledge?

b. How did that knowledge and understanding develop subsequently over time, while working there?

c. With respect to the Centre, did you ever discuss such matters with Dr Hill? If so, please provide details of what was discussed and when.

14.1. My recollection is that I became aware of the possible transmission of hepatitis including NANB hepatitis [Hepatitis C] through blood products whilst working at the Birmingham Children's Hospital. My sources of information were likely to have been from the medical literature and from meetings that I attended as a trainee in paediatric haematology. I cannot recall how my knowledge and understanding changed during that period.

14.2. I do not recall discussions with Dr FG Hill relating to the risk of hepatitis including NANB hepatitis [Hepatitis C] during my attachment as a trainee to the paediatric haematology unit.

15. What, if any, enquiries and/or investigations were carried out at any hospital, haemophilia centre or other medical facility at which you worked at any relevant time in respect of the risks of transmission of hepatitis? What information was obtained as a result?

15.1. Birmingham Children's Hospital: April 1985 - November 1987

15.1.1. I cannot recall what enquiries/investigations were performed whilst I was a trainee at the Birmingham Children's Hospital, in respect of the risks of transmission of Hepatitis. I was not involved in these studies and I am not a co-author on any of the published data in relation to this.

15.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

15.2.1. During my period at the Royal Free London NHS Foundation Trust, the management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee, Dr [Prof] KJ Pasi and latterly Dr S Brown. Individuals with Hepatitis were closely managed in collaboration with the Hepatology unit. My understanding is that the transmission of Hepatitis by blood and blood products had been established by 1991. I cannot recall what enquiries/additional investigations were undertaken during this period by my colleagues.

15.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

15.3.1. The transmission of hepatitis by blood and blood products had been established by the time I joined the staff of Addenbrooke's Hospital in Cambridge in October 2004. Patients that I managed who were infected with Hepatitis were managed in close collaboration with the Hepatology unit. I am unaware of what, if any, additional enquiries/investigations were performed by the Hepatology Unit.

16. What if any actions were taken at any hospital, haemophilia centre or other medical facility at which you worked at any relevant time to reduce the risk to patients of being infected with hepatitis (of any kind)?

16.1. Birmingham Children's Hospital: April 1985 - November 1987

16.1.1. I am unaware what actions were taken whilst I was a trainee at the Birmingham Children's Hospital, in respect of reducing the risks of infection with Hepatitis. Please discuss with Dr FG Hill.

16.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

16.2.1. During my period at the Royal Free London NHS Foundation Trust, the management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee, Dr [Prof] KJ Pasi and latterly Dr S Brown.

16.2.2. Patients that I managed would have received virally inactivated products or blood products from the NHS Blood and Transplant Service that I understood to be safe. I cannot recall precisely when a vaccine for Hepatitis A and B became available, but this would have been advised for all patients with a bleeding disorder.

16.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

16.3.1. The transmission of hepatitis by blood and blood products was established by the time I joined the staff of Addenbrooke's Hospital in Cambridge. Patients that I supervised the care of, would have received only recombinant clotting factor concentrates, or virally inactivated plasma-derived clotting factor concentrates, or virally inactivated Fresh Frozen Plasma or blood products from the NHS Blood and Transplant Service and which I understood to be safe.

16.3.2. Patients would have been advised to be immunised for Hepatitis A and B through their General Practitioners and their viral serology checked to confirm immunity. Patients that I saw would have been aware of the investigations that were being performed and were sent a copy of their results.

17. What liver function tests and/or other monitoring were undertaken at any hospital, haemophilia centre or other medical facility at which you worked with patients with bleeding disorders, and how did such practices change over time?

17.1. Birmingham Children's Hospital: April 1985 - November 1987

17.1.1. I cannot recall what liver function tests and/or other monitoring tests were undertaken whilst I was a trainee in paediatric haematology at the Birmingham Children's Hospital.

17.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

17.2.1. During my period at the Royal Free London NHS Foundation Trust, the management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee, Dr [Prof] KJ Pasi and latterly Dr S Brown. Patients that I reviewed would have had their liver function tests performed as part of their follow-up. Patients that I saw would have been aware of the investigations that were being performed. If the Liver Function tests were abnormal, this would have been discussed with the patient, with investigations then undertaken to establish a cause and depending upon the results, may have led to a referral to the Hepatologists. I do not recall this practice changing during my employment at the Royal Free London NHS Foundation Trust.

17.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

17.3.1. During my period at Addenbrooke's Hospital, patients attending my clinics would have had their Liver Function Tests checked. If these were abnormal this would have been investigated to identify a cause. All new patients or patients transferring from another Centre would have been screened for Hepatitis as part of the initial consultation

which would include Liver Function Tests and in addition a hepatitis viral serology screen.

18. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time? With respect to the Centre, did you ever discuss such matters with Dr Hill? If so, please provide details of what was discussed and when.

18.1. Birmingham Children's Hospital: April 1985 - November 1987

18.1.1. I was aware as a trainee in Haematology that there were a number of viruses that could cause Hepatitis and that the mode of transmission was dependent upon the virus. My understanding of the viruses that could cause Hepatitis increased with time from publications in the medical literature and from attending various meetings.

18.1.2. I do not recall discussing the nature and severity of the different forms of blood borne viral hepatitis with Dr FG Hill whilst I was a trainee in Paediatric Haematology at the Birmingham Children's Hospital.

HIV and AIDS

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

19.1. Birmingham Children's Hospital: April 1985 - November 1987

19.1.1. I recall I became aware of an association between the risk of developing the Acquired Immune Deficiency Syndrome [AIDS] through the use of blood products whilst a trainee in paediatric haematology at the Birmingham Children's Hospital. I cannot recall how I became aware of this association, but it is likely to have been from the medical literature and/or from meetings that I attended as a trainee in paediatric haematology.

20. When you first began working with patients with bleeding disorders, what was your knowledge and understanding of HIV (HTLV-III) and AIDS and in

particular of the risks of transmission from blood and blood products? How did your knowledge and understanding develop over time? With respect to the Centre, did you ever discuss such matters with Dr Hill? If so, please provide details of what was discussed and when.

20.1. Birmingham Children's Hospital: April 1985 - November 1987

20.1.1. As a trainee in paediatric haematology at the Birmingham Children's Hospital, when I joined the department I cannot recall any knowledge of HTLV-III/HIV and AIDS in relation to the use of blood products. I cannot recall how I became aware of this association, but it is likely to have been through meetings that I attended and/or the medical literature and publications.

20.1.2. I cannot recall discussions with Dr FG Hill on this association. Advice and guidance on the management of specific patients, as I was a trainee, would have been after discussion with Dr FG Hill and latterly with Dr P Darbyshire – consultant paediatric haematologists.

21. **What, if any, enquiries and/or investigations were carried out at (insofar as relevant in each case) the Centre, the Royal Free and any other hospital, centre or medical facility at which you worked, in respect of the risks of transmission of HIV or AIDS? What was your involvement? What information was obtained as a result?**

21.1. Birmingham Children's Hospital: April 1985 - November 1987

21.1.1. I am not aware of what enquiries or investigations were carried out whilst I was a trainee at the Birmingham Children's Hospital in respect of the risks of transmission of HTLV-III/HIV or AIDS. I was not involved in any of these enquiries/investigations and I am not a co-author on any of the publications relating to this from the centre.

21.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

21.2.1. When I joined the staff at the Katharine Dormandy Haemophilia and Thrombosis Centre, the management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi. I am not aware of the enquiries or investigations carried out whilst I was at the Centre. I am not a co-author on any publications from this Centre in relation to HTLV-III/HIV or AIDS.

21.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

21.3.1. When I joined the staff at Addenbrooke's Hospital, the risks of transmission of HIV by blood products was established. I am not aware of any additional investigations performed during this period. Patients with an inherited or acquired bleeding disorder and co-infected with HIV and/or HCV and/or HBV would have been managed in collaboration with the Infectious Diseases and Hepatology teams respectively.

22. What, if any, actions were taken at (insofar as relevant in each case) the Centre, the Royal Free and any other hospital, centre or medical facility at which you worked, to reduce the risk to your patients of being infected with HIV?

22.1. Birmingham Children's Hospital: April 1985 - November 1987

22.1.1. I am unable to comment on what actions were taken to reduce the risk of patients being infected with HIV as I was a trainee in paediatric haematology during this period and not involved in these decisions.

22.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

22.2.1. When I joined the staff at the Katharine Dormandy Haemophilia and Thrombosis Centre, viral inactivation of clotting factor concentrates was in place and I understood these products to be safe. In cases of

a mild-moderate bleeding disorder, Desmopressin frequently combined with Tranexamic Acid, would have been used unless there were reasons that these products could not be used – the underlying problem and the duration of treatment.

22.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

22.3.1. When I joined the staff at Addenbrooke's Hospital, patients that I supervised the care of, would receive only recombinant clotting factor concentrates, or virally inactivated plasma-derived clotting factor concentrates, or virally inactivated Fresh Frozen Plasma or blood products from the NHS Blood and Transplant Service. I understood these products to be safe with no risk of transmission of HIV and/or HCV/HBV.

22.3.2. In cases of a mild-moderate bleeding disorder, Desmopressin frequently combined with Tranexamic Acid would have been used unless there were reasons that these products could not be used – the underlying problem and the duration of treatment.

23. Did you and your colleagues at (insofar as relevant) the Centre, the Royal Free or any other hospital, centre or medical facility at which you worked, continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why, and which products did you use?

23.1. Birmingham Children's Hospital: April 1985 - November 1987

23.1.1. I am unable to comment on the continuing use of clotting factor concentrates in relation to the possible transmission of HIV.

23.1.2. I was a trainee in paediatric haematology during this period and not involved in these decisions. Which product to use to treat a specific patient was not a decision I made but was made by my senior colleagues – Dr FG Hill and Dr P Darbyshire.

23.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

23.2.1. When I joined the staff at the Royal Free London NHS Foundation Trust, the management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi and latterly Dr S Brown. The risk of transmission of HIV by blood products was established and I am not aware that my colleagues continued to use products that carried any risk of transmitting HIV.

23.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

23.3.1. When I joined the staff at Addenbrooke's Hospital, patients that I supervised the care of, would receive only recombinant clotting factor concentrates, or virally inactivated plasma-derived clotting factor concentrates, or virally inactivated Fresh Frozen Plasma or blood products from the NHS Blood and Transplant Service. I believed these products to be safe with no risk of transmission of HIV and/or HCV/HBV.

24. Did you ever discuss with Dr Hill whether to continue to use factor concentrates after becoming aware of the possible risks of infection of HIV? If so, please provide details of what was discussed and when.

24.1. I am not aware of and do not recall, discussions with Dr FG Hill regarding continuation of factor concentrate usage. I was a trainee in paediatric haematology and not involved in these decisions. Which product to use to treat a specific patient was not a decision I made but was made by my senior colleagues – Dr FG Hill and Dr P Darbyshire.

Response to risk

25. In relation to your time working at each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and

in any event including the Centre and the Royal Free, insofar as relevant to your time there:

a. **Did you or your colleagues take any steps to ensure that patients and/or the public were informed and educated about the risks of hepatitis and HIV, as those risks became known or suspected? If so, what steps? With respect to your time at the Centre, did you ever discuss with Dr Hill what steps should be taken, and, if so, when was this and what was discussed?**

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

c. **Did you or your colleagues, or the hospital, haemophilia centre or other medical facility generally revert to treatment with cryoprecipitate for some or all of your patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not?**

d. **Do you consider that your decisions and actions, those of your colleagues and those of the relevant hospital(s), haemophilia centre(s) or other medical facility(ies) generally, in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.**

e. **Looking back now, what decisions or actions by you, your colleagues and/or the relevant hospital(s), haemophilia centre(s) or other medical facility(ies) generally could and/or should have avoided, or brought to an end earlier, the use of infected blood products?**

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

25.1. Birmingham Children's Hospital: April 1985 - November 1987

25.1.1. a. I was a trainee in paediatric haematology during this period and decisions relating to information on the potential risks associated with blood products and how this was or would be communicated or discussed with the parents of children with inherited bleeding disorders, was not an area that I was involved with. I do not recall discussions with Dr FG Hill in relation to this.

25.1.2. b. I recall that heat-treated clotting factor concentrates were introduced when I was a trainee at the Birmingham Children's Hospital.

25.1.3. c. I cannot recall if any decisions were made whilst I was a trainee at the Birmingham Children's Hospital to revert to cryoprecipitate in response to the risk of infection.

25.1.4. d-f. As a trainee at this time I cannot answer this question as I was unaware of the discussions at a senior/national level.

25.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

25.2.1. a. When I joined the staff at the Royal Free London NHS Foundation Trust, the management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi. My understanding is that my colleagues would have communicated the risk of Hepatitis and HIV to their patients. I cannot comment on how and when these risks would have been communicated to their patients as this pre-dated my joining the department.

25.2.2. b. The use of heat-treated products pre-dated my joining the department in July 1994.

25.2.3. c. I am not aware of the use of cryoprecipitate for patients with Haemophilia A who required treatment whilst I was employed at the Royal Free London NHS Foundation Trust.

25.2.4. d-f. I cannot answer this as the decisions and policies in relation to the management of adults with inherited bleeding disorders, were made prior to my joining the department.

25.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

25.3.1. a-c. I joined the CUHFT in October 2004. My colleagues [Dr TP Bagin and prior to this Dr M Seaman] had been involved in the management of patients and their families with inherited and acquired bleeding disorders and would have been involved, I understand, in communicating this information to their patients.

25.3.2. The introduction of heat-treated products pre-dated my arrival in the CUHFT. I cannot be more specific as to when heat-treated products were introduced.

25.3.3. I am not aware of the use of cryoprecipitate for patients with Haemophilia A who required treatment. I understood that the products that were being used – virally-inactivated clotting factor concentrates, or recombinant clotting factor concentrates to be safe and effective if appropriately managed.

25.3.4. d-f. I cannot answer this as the decisions and policies in relation to the management of adults with inherited bleeding disorders, were made prior to my joining the Cambridge Haemophilia Centre.

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

26.1. I was a trainee in Haematology from April 1985 - November 1987 and I was only aware of the emerging risks associated with the use of blood products from meetings that I subsequently attended and from papers in medical journals. I am unable to answer this question as I did not have the information at this time and I was unaware of decisions and discussions at a senior/national level.

Section 4: Treatment of patients

Provision of information to patients

27. During the course of your time working at each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free:

a. **What information did you or (insofar as within your knowledge) your colleagues or the relevant hospital(s), haemophilia centre(s) or other medical facility(ies) generally, provide or cause to be provided to patients with a bleeding disorder about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates), prior to such treatment commencing? Please detail whether and if so how this changed over time.**

b. **What information did you or (insofar as within your knowledge) your colleagues, or the relevant hospital(s), haemophilia centre(s) or other medical facility(ies) generally, provide or cause to be provided to patients about alternatives to treatment with factor concentrates? Please detail whether and if so how this changed over time.**

27.1. Birmingham Children's Hospital: April 1985 - November 1987

27.1.1. a. I was a trainee in paediatric haematology during this period and decisions relating to information on the potential risks associated with blood products and in particular clotting factor concentrates and how this was or would be communicated or discussed with the parents of

children with inherited blood disorders, was not an area that I was involved with.

27.1.2. b. I was a trainee in paediatric haematology during this period and I am unaware of what information/discussions took place or were provided to the families and to individuals with inherited bleeding disorders. This information would have been provided by my consultant colleagues and possibly by the senior haemophilia nursing staff.

27.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

27.2.1. a. I joined the staff at the Royal Free London NHS Foundation Trust in July 1994. The management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi. I do not know what information was provided to patients in relation to the risks associated with blood products and clotting factor concentrates prior to my joining the staff at the Centre. Please discuss with Prof CA Lee and/or Prof KJ Pasi.

27.2.2. It was my usual practice to discuss with patients and their families, whose care I was involved with and who required treatment with a clotting factor concentrate, that the products were being used – virally-inactivated clotting factor concentrates, or recombinant clotting factor concentrates, I understood to be safe and effective if managed appropriately. This did not change in the time I was at the Royal Free London NHS Foundation Trust.

27.2.3. b. It was my usual practice to discuss with patients and their families, whose care I was involved with, the possible treatment options. The treatment options depended upon their specific disorder and the reasons for treatment. This did not change in the time I was at the Royal Free London NHS Foundation Trust.

27.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

27.3.1. a. I joined the staff at the Cambridge University Hospitals NHS Foundation Trust - Addenbrooke's Hospital in October 2004. Prior to this, my colleagues [Dr TP Baglin and Dr M Seaman] would have provided information on blood products and clotting factor concentrates to the patients/families, under their care. It was my usual practice with patients whose care I was involved with, that they would be provided with information on their planned treatment and therefore, would have been aware that although these were in some cases plasma-derived clotting factor concentrates, we believed these to be safe. Patients would have been advised that they could contact us at any time to discuss their planned treatments or any concerns or questions that they or their families might have. It was my usual practice that patients were to be copied into their correspondence so that they were aware of and had a record of their consultations, discussions, planned treatment(s) and what this treatment involved.

27.3.2. b. It was my usual practice to discuss with patients whose care I was involved with, the possible treatment options and that we would use non-blood products if this was possible. In cases of a mild-moderate bleeding disorder, Desmopressin usually combined with Tranexamic Acid would be used unless there were reasons that these products could not be used – the specific bleeding disorder, the underlying problem and the duration of treatment.

HIV

28. At which hospital, haemophilia centre or other medical facility were you working when you first discussed AIDS or HIV (HTLV-III) with patients? What was your role and what were your responsibilities at the time? What did you tell those patients?

28.1. Birmingham Children's Hospital: April 1985 - November 1987

28.1.1. I do not recall discussions relating to HIV [HTLV-III] or AIDS whilst a trainee at the Birmingham Children's Hospital [April 1985 - November 1987].

28.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

28.2.1. As a senior lecturer, honorary consultant haematologist at the Royal Free London NHS Foundation Trust, my appointment in July 1994 was at a time when the transmission of HIV [HTLV-III] or AIDS was, I believe, understood. I was involved primarily in research and teaching. The care of patients and their families with inherited and acquired bleeding disorders and who were in addition co-infected with HIV [HTLV-III] or who developed AIDS, would have been undertaken by my colleagues Prof CA Lee and Dr [KJ] Pasi in collaboration with, I believe, Professor Margaret Johnson [Thoracic/General medicine, consultant in HIV/AIDS medicine].

28.2.2. Discussions in relation to HIV [HTLV-III] or AIDS, pre-test and post-test counselling would have been undertaken by Prof CA Lee, Dr [Prof] KJ Pasi and possibly the senior nursing staff. I believe that during the period I was employed at the Royal Free London NHS Foundation Trust, counselling services were provided by Ms Riva Miller and latterly Ms Nicola Dunn.

28.2.3. I do not recall discussions in relation to HIV [HTLV-III] or the development of AIDS with the patients whose care I was involved with.

28.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

28.3.1. I joined the staff of Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital in October 2004 and prior to this my colleague Dr TP Baglin and prior to 1990 Dr M Seaman, had managed individuals and their families with inherited and acquired bleeding disorders. The care of patients who were co-infected with HIV [HTLV-

III] or who developed AIDS was managed by the Infectious Diseases Team. Discussions in relation to HIV [HTLV-III] or AIDS would have been undertaken by Dr M Seaman and subsequently Dr TP Baglin.

28.3.2. Patients whose care I was involved with and who were co-infected with HIV [HTLV-III] would have been informed that they could contact me at any time to discuss any problems or concerns that they might have. New patients referred to the Cambridge Centre or who were transferring their care from other Centres would have been screened for HIV [in addition to Hepatitis.] Patients and their families would have been aware of this and the reasons for the screening tests. My usual practice was that patients who I saw were to be copied into all of their correspondence and their results. I do not recall any new patients that I saw in Cambridge and who were screened for HIV as being positive. Patients in whom the viral Hepatitis serology was positive, would have been contacted by telephone and informed of the results and then seen in clinic to discuss the results. These individuals would then have been referred to the Hepatology team for further investigation and management.

28.3.3. Patients transferring to us from another Centre and who were HIV positive were referred to the Infectious Diseases team for management.

29. Please describe how and when you learned that patients to whom you were providing care had been infected with HIV. What was your role and what were your responsibilities at that time? What tests were undertaken, where and over what period of time?

29.1. In the Centres in which I have worked – Birmingham Children's Hospital ; Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust; Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital – I do not recall being involved in the care of patients or their families with whom I have had to discuss a new diagnosis of HIV. I took over the care of patients in whom the diagnosis

had already been made. These patients would already be being managed through collaboration with the appropriate team. In Cambridge, patients transferring from another Centre and who were HIV positive, would be referred to the Infectious Diseases team for management of their HIV.

29.2. I do not recall what tests were performed for HIV screening at the Royal Free London NHS Foundation Trust. I recall that in Cambridge this would have been an HIV antibody test and if positive the HIV viral load would be checked. I do not know how these tests changed, if at all, over the period I was employed at the Cambridge University Hospitals NHS Foundation Trust.

30. During the course of your time working at each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free, insofar as relevant in each case:

a. **What arrangements were made for pre-test counselling?**

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

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

d. **What if any arrangements were made for post-test counselling?**

e. **Were you aware of any discussions among clinicians about whether they should or should not tell their patients of their HIV status? If you were aware of such discussions, when and where did they happen, and what reasons were considered and discussed for informing or not informing people that they had HIV?**

f. **What was your policy, and/or that of each relevant haemophilia centre hospital or other medical facility, in relation to testing partners/family**

members of people known or suspected to be infected with HIV? Under what circumstances were tests carried out?

g. **What if any information or advice did each relevant haemophilia centre, hospital or other medical facility provide to partners or family members of people who were at risk of infection with HIV or were infected with HIV?**

30.1. a-g: Birmingham Children's Hospital: April 1985 - November 1987

30.1.1. I was a trainee in paediatric haematology during this period and I was not involved in any discussions with patients and their parents/families in relation to infections with HIV [HTLV-II].

30.2. a-g: Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

30.2.1. The care of patients and their families with inherited and acquired bleeding disorders and who were in addition co-infected with HIV [HTLV-III] or who developed AIDS, was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi in collaboration with, I believe, Professor Margaret Johnson [consultant in Thoracic/General medicine, consultant in HIV/AIDS medicine]. Discussions in relation to HIV [HTLV-III] or AIDS, pre-test and post-test counselling would have been undertaken by Prof CA Lee, Dr [Prof] KJ Pasi and possibly the senior nursing staff. During the period I was employed at the Royal Free London NHS Foundation Trust, counselling services would have been provided by Ms Riva Miller and latterly Ms Nicola Dunn.

30.2.2. I am not aware of any discussions amongst clinicians or senior nursing staff, about whether or not they should inform their patients of their HIV status.

30.2.3. I am unable to comment on the additional questions. Please contact Prof CA Lee and/or Prof KJ Pasi for information.

30.3. a-g:Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital: October 2004 – July 2017

30.3.1. Patients whose care I was involved with and who were co-infected with HIV [HTLV-III] would have been informed that they could contact me at any time to discuss any problems or concerns that they might have. New patients referred to the Cambridge Centre or who were transferring their care from other Centres, would have been screened for HIV [in addition to Hepatitis.]

30.3.2. There would have been discussions with patients and their families about the reasons for these screening tests. My usual practice was that patients that I saw were to be copied into all of their correspondence and the results of their tests.

30.3.3. I do not recall any new patients that I saw in Cambridge and who, as a new patient were screened for HIV and were positive. If the HIV test had been positive, the patient would have contacted and advised of the result and then seen in clinic as soon as possible to discuss the results. A formal referral to the Infectious Diseases team would have been made for further investigation, counselling and management. I understood that screening of partners/family members would be undertaken by the Infectious Diseases Team should it be required.

30.3.4. Patients in whom the viral Hepatitis serology was positive, would be contacted and informed of the results and then seen in clinic to discuss the results. They would then be referred to the Hepatology team for further investigation and management.

30.3.5. Patients transferring to us from another Centre and who were HIV positive would be referred to the Infectious Diseases team for management.

30.3.6. I am not aware of any discussions amongst clinicians or senior nursing staff, about whether or not they should tell their patients of their HIV status.

30.3.7. As a consultant at the Cambridge University Hospitals NHS Foundation Trust I believed the treatments we were using to treat

patients with inherited bleeding disorders, were safe and effective if appropriately managed. I did not believe they carried a risk of transmission of HIV. The transmission of HIV within families, would have been discussed, I understood, by the Infectious Diseases team.

31. In relation to each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free, insofar as relevant in each case:

a. How many patients were infected with HIV?

31.1. a. I do not have this information. Please contact Birmingham Children's Hospital, the Royal Free London NHS Foundation Trust and Cambridge University Hospitals NHS Foundation Trust who will be able to provide this.

b. Of those infected with HIV:

i. How many had severe haemophilia A?

ii. How many had moderate haemophilia A?

iii. How many had mild haemophilia A?

iv. How many had haemophilia B?

v. How many had von Willebrand's disease?

vi. How many were children?

31.2. b i-vi. I do not have this information. Please contact Birmingham Children's Hospital, the Royal Free London NHS Foundation Trust and Cambridge University Hospitals NHS Foundation Trust who will be able to provide this.

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

Please provide the highest degree of specificity you can in responding, even if that means providing highly approximate or indicative figures.

31.3. c. I am unaware of what studies were undertaken to establish the time period during which patients seroconverted. As a trainee at the Birmingham Children's Hospital I was not involved in these studies and I am not a co-author on any of the published studies in relation to this.

31.4. At the Royal Free London NHS Foundation Trust and Cambridge University Hospitals NHS Foundation Trust, I do not recall what studies were undertaken but any studies would have pre-dated my employment in these centres.

32. With respect to your time at the Centre, please comment on the memo of 29 September 1986 [ARMO0000585] which suggested that two children who were patients at the Centre had tested positive for antibodies following receipt of heat treated Factorate. Insofar as is within your knowledge, please explain the circumstances of this, what enquiries and investigations were carried out as a result, and whether the findings of this episode were published or brought to the attention of the haematology/haemophilia community.

32.1. I am unaware of the discussion between Dr FG Hill and Armour Pharmaceuticals [29th September 1986] outlined in the memo of 29 September 1986 [ARMO0000585] in relation to previous heat-treated products and I am, therefore, unable to comment further on this question.

Hepatitis B

33. In relation to each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free, insofar as relevant in each case:

a. Were patients infected with hepatitis B informed of their infection and if so how?

b. What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and management?

c. How many patients were infected with hepatitis B?

Please provide the highest degree of specificity you can in responding, even if that means providing highly approximate or indicative figures.

33.1. Birmingham Children's Hospital: April 1985 - November 1987

33.1.1. a-c. I am not aware of how many patients were infected with Hepatitis B whilst I was a trainee at the Birmingham Children's Hospital or how information relating to Hepatitis B, was provided to the patients and families attending the Centre. I am, therefore, unable to answer these questions. Please contact Dr FG Hill or the Birmingham Children's Hospital.

33.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

33.2.1. a-c. The care of patients and their families with inherited and acquired bleeding disorders, was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi. I am not aware of how many patients were diagnosed with Hepatitis B or how information relating to Hepatitis B, was provided to the patients and their families attending whilst I was working at the Royal Free London NHS Foundation Trust or prior to my joining the Centre. I am, therefore, unable to answer this question. Please contact Prof CA Lee, Prof KJ Pasi or the Royal Free London NHS Foundation Trust for this information.

33.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

33.3.1. a-c. I am unaware of how many patients with Hepatitis B were diagnosed before I joined the Cambridge University Hospitals NHS

Foundation Trust: Addenbrooke's Hospital, in October 2004. Please contact the CUHFT.

33.3.2. Patients with viral hepatitis would have been managed in close collaboration with the Hepatology team and individuals with a bleeding disorder and Hepatitis B would have been referred to the Hepatologists for further investigation, management and counselling.

NANB Hepatitis/Hepatitis C

34. In relation to each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free, insofar as relevant in each case:

a. Were patients infected with NANB hepatitis informed of their infection and if so how?

b. What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management?

c. When did testing of patients for hepatitis C begin? Over what period of time was testing for hepatitis C carried out after a test became available? How and when were patients told of their diagnosis of hepatitis C? Were they told in person, by letter or by phone?

d. What information was provided to patients infected with hepatitis C about the infection, its significance, prognosis, treatment options and management?

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

34.1. Birmingham Children's Hospital: April 1985 - November 1987

34.1.1. a-c. I am not aware of how many patients were infected with NANB Hepatitis/Hepatitis C whilst I was a trainee at the Birmingham Children's Hospital. I do not know when testing for NANB

Hepatitis/Hepatitis C was instituted and what information was provided to the patients, parents and family of patients found to have NANB Hepatitis/Hepatitis C. I am, therefore, unable to answer this question. Please contact Dr FG Hill or the Birmingham Children's Hospital.

34.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

34.2.1. a-c. The care of patients and their families with inherited and acquired bleeding disorders, was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi. I am unaware of when testing for NANB Hepatitis/Hepatitis C began and how many patients were infected with NANB Hepatitis/Hepatitis C prior to my joining the Royal Free London NHS Foundation Trust. Please contact Prof CA Lee, Prof KJ Pasi or the Royal Free London NHS Foundation Trust for this information.

34.2.2. 2 I do not recall any patients whose care I supervised, developing NANB Hepatitis/Hepatitis C whilst I was employed at the Royal Free London NHS Foundation Trust.

34.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

34.3.1. a-c. I do not know when testing for NANB Hepatitis/Hepatitis C began and how many patients with NANB Hepatitis/Hepatitis C were diagnosed before I joined the Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital, in October 2004 or when I retired from the Trust in July 2017. Please contact the CUHFT.

34.3.2. Patients with viral hepatitis would have been managed in collaboration with the Hepatology team, and individuals with a bleeding disorder and NANB Hepatitis/Hepatitis C would have been referred to the Hepatologists for further investigation, management and counselling. The Hepatologists would discuss the significance, prognosis, treatment options and management of Hepatitis C.

34.3.3. I am aware of one patient who moved to the Cambridge Centre from abroad and who was diagnosed as having Hepatitis C at his first consultation. My recollection is that he was contacted and seen promptly in clinic to discuss the results with both himself and his partner and then referred to the Hepatologists for further investigation, counselling and management. He would have been copied him into all his correspondence and laboratory results so that he had a record of the discussions and of his blood tests. He and his partner would have been informed that they could contact the team at any time to discuss problems or concerns that they might have.

Delay/public health/other information

35. In relation to each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free, insofar as relevant in each case:

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

b. **To what extent, if at all, did you and/or your colleagues and/or the hospital, haemophilia centre or other medical facility take into account the public health implications of HIV, AIDS, hepatitis B and NANB hepatitis/hepatitis C, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?**

c. **What information was provided to patients about the risks of other infections?**

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

35.1. Birmingham Children's Hospital: April 1985 - November 1987

35.1.1. a-d: I was a trainee at the Birmingham Children's Hospital from April 1985-November 1987. I am unaware of how patients, parents and their families were notified of the results of HIV or Hepatitis testing.

35.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

35.2.1. a-d. I joined the staff at the Royal Free London NHS Foundation Trust in July 1994. The management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi. Testing for HIV and Hepatitis was in place in July 1994, but I am unable to comment on how the results of tests were notified to patients and if there were delays in doing so. I am unable to comment on the public health implications of a positive test for HIV, Hepatitis B, NANB Hepatitis/Hepatitis C or the development of AIDS in a patient, as these decisions pre-dated my joining the Centre. Please discuss with Prof CA Lee and/or Prof KJ Pasi.

35.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

35.3.1. a-d. I joined the staff of Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital in October 2004. Testing for HIV and Hepatitis was in place at that time and had been established by my colleague Dr TP Baglin and prior to 1990, Dr M Seaman.

35.3.2. I am unable to comment on how and when patients were informed of their results and whether my colleagues had taken into account the public health implications of the infections when discussing this with their patients, as this pre-dated my joining the Centre.

35.3.3. Patients with HIV would have been referred to the Infectious Diseases team and all patients with Hepatitis would have been referred to the Hepatologists, for further investigation, counselling and management.

This would, I understood, include a discussion relating to the potential risk of infecting others.

35.3.4. I am unable to comment on what information was provided to patients about the risks of additional infections prior to my joining the Cambridge Centre. The information I would have provided to patients with inherited bleeding disorders, would indicate that it was believed that the treatments being discussed were safe and effective if managed appropriately.

Consent

36. In relation to each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free, insofar as relevant in each case:

a. **How often were blood samples taken from patients? For what purposes were samples taken? What information was given to patients about the purposes for which blood samples were taken? Were patients able to give informed consent for the storage and use of those samples?**

b. **Were patients treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent to treatment? If it is your position that patients did give express and informed consent to treatment with factor concentrates, please explain the basis for that position and set out the information that was provided to patients.**

c. **Were patients tested for HIV or for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing?**

36.1. Birmingham Children's Hospital: April 1985 - November 1987

36.1.1. a-c: I was a trainee at the Birmingham Children's Hospital from April 1985 - November 1987. Although it is now over 30 years ago, blood samples would be taken for laboratory tests to aid with the diagnosis

of a bleeding disorder or its management if a patient was on treatment. The reasons for blood tests would have been discussed with the parents and with the patient. I cannot recall if parents gave consent for the storage and subsequent use of blood samples. In the patients that I saw, the collection of blood samples from children for tests would usually be undertaken by the phlebotomy staff or the senior haemophilia nursing staff.

36.1.2. At the Birmingham Children's Hospital, I do not know if parents of a child with an inherited bleeding disorder gave consent for their child to receive a specific clotting factor concentrate or blood product. I was not involved in these decisions or discussions. This was performed by my senior consultant colleagues, Dr FG Hill and latterly Dr P Darbyshire.

36.1.3. I am unable to comment on whether patients were tested for HIV or for hepatitis or for any other purpose without the consent of their parents. I would request blood tests to help with the diagnosis of a bleeding disorder or its management if a patient was on treatment, the collection of which was performed by the phlebotomy staff or the senior haemophilia nursing staff.

36.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

36.2.1. a-c. I joined the staff at the Royal Free London NHS Foundation Trust in July 1994. The management of patients with inherited and acquired bleeding disorders was undertaken by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi.

36.2.2. Patients that I managed would have had blood tests performed to assist with their diagnosis and to monitor their treatment if they were on treatment. Patients would have been informed about what blood tests were being performed, the reasons for these tests and it was my practice that patients be sent copies of their letters and results. Patients who were having genetic tests performed would have given

consent for the processing of their samples. I cannot recall if the consent would also have included the storage of samples.

36.2.3. Patients that I managed would not have been treated with factor concentrates or blood products without their consent and this would be discussed with the patient at their clinic visit. I believed the treatments we were using to be safe and effective if managed appropriately.

36.2.4. I am not aware that any of the patients whose care I was involved in, were tested for HIV or for hepatitis or for any other purpose without their consent and this would be outlined in the patient's case notes.

36.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

36.3.1. a-c. I joined the staff of Cambridge University Hospitals NHS Foundation Trust in October 2004. Patients would have blood tests performed at their clinic visit, or on the ward if they were an in-patient, to aid with diagnosis and to monitor treatment if they were on treatment. I would have discussed with patients what blood tests were being performed and why. All patients that I saw in the clinic would have been sent a copy of their clinic letter and their results. Patients should have been aware that they could contact me at any time to discuss the results of their tests and any concerns or questions that they might have.

36.3.2. Patients gave consent for the use of clotting factor concentrates. I and my senior nursing colleagues would discuss the indication for the treatment and how it would be managed. The usual practice was that verbal consent was recorded in their case notes.

36.3.3. I did not screen patients for HIV, or Hepatitis or for any other purpose without their knowledge and consent. Verbal consent was recorded in their case notes.

PUPS

37. Did you use the term PUP or PUPs when speaking about or referring to any of your patients? If so:

a. **Where were you working, and in what role(s) were you working, at the time?**

b. **What did you mean by the use of the term?**

c. **To whom did you use such a term and what meaning did you consider that they ascribed to the term?**

37.1. a-c: I do not recall using the term PUP or PUPS to describe a Previously Untreated Patient or Previously Untreated Patients.

37.2. The term, however, continues to be used in the medical literature.

38. Were you aware of any colleagues, including senior colleagues, using the term PUP or PUPs? If so:

a. **At which hospital, haemophilia centre or other medical facility did this occur?**

b. **Who used the term?**

c. **What did you understand them to mean by the term?**

38.1. I do not recall my senior colleagues at the Birmingham Children's Hospital or my colleagues at the Royal Free London NHS Foundation Trust using the term PUP or PUPS to describe a Previously Untreated Patient or Previously Untreated Patients.

39. Detail all decisions and actions taken by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS – see para. 6(b) of the Terms of Reference and para. 153 of the List of Issues).

39.1. Birmingham Children's Hospital: April 1985 - November 1987

39.1.1. As a trainee in Paediatric Haematology I was not involved in decisions or discussions with parents and families in relation to the treatment of Previously Untreated Patients. This would have been undertaken by my senior colleagues.

39.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

39.2.1. Children with inherited bleeding disorders were managed in the Haemophilia Centre at the Great Ormond Street Hospital for Children. I was not involved in the management of the majority of adult patients with a bleeding disorder. This was undertaken by my colleagues – Prof CA Lee, Dr [Prof] KJ Pasi and latterly following the departure of Dr [Prof] KJ Pasi, Dr Simon Brown.

39.2.2. I do not recall managing individuals who had not been previously treated with a blood product or clotting factor concentrate.

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

40. How was the care and treatment of patients with HIV/AIDS managed at each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free? In particular:

a. **What steps were taken to arrange for, or refer patients for, specialist care?**

b. **What treatment options were offered over the years to those infected with HIV?**

c. **What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

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

40.1. Birmingham Children's Hospital: April 1985 - November 1987

40.1.1. a-d: As a trainee in Paediatric Haematology I, was not involved in the management of children with HIV [HTLV-III] or who developed AIDS. Please contact Dr FG Hill or the Birmingham Children's Hospital for information.

40.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

40.2.1. a-d: I was not involved in the management of patients with HIV and/or who developed AIDS. This was coordinated by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi in conjunction with Professor Margaret Johnson [Thoracic/General medicine, consultant in HIV/AIDS medicine].

40.2.2. I am not a co-author on any of the publications relating to the diagnosis or management of HIV from the Royal Free London NHS Foundation Trust.

40.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

40.3.1. a-d: I joined the staff of the Cambridge University Hospitals NHS Foundation Trust in October 2004. I was not involved in management of patients with HIV. Patients with HIV would have been managed by the Infectious Diseases Team. These arrangements pre-dated my joining the staff of the Cambridge University Hospitals NHS Foundation Trust.

40.3.2. Please contact Dr TP Baglin, Dr M Seaman, the Infectious Diseases Team or the CUHFT for further information.

40.3.3. Patients with an inherited bleeding disorder and HIV, who transferred their care to the Cambridge Centre from another Centre and who were under my care for the management of their bleeding disorder, would

have been referred to Infectious Diseases Team for the management/treatment/follow-up of their HIV.

41. **How was the care and treatment of patients with hepatitis B managed at each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free? In particular:**

a. **What steps were taken to arrange for, or refer patients for, specialist care?**

b. **What treatment options were offered over the years?**

c. **What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

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

41.1. Birmingham Children's Hospital: April 1985 - November 1987

41.1.1. a-d: As a trainee in Paediatric Haematology I, was not involved in the management of children with Hepatitis B. Please contact Dr FG Hill or the Birmingham Children's Hospital for information.

41.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

41.2.1. a-d: I was not involved in the management of patients with Hepatitis B. This would have been coordinated by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi in conjunction with the Hepatology unit. Please contact Prof CA Lee and Dr [Prof] KJ Pasi or the Hepatology unit for information.

41.2.2. I am not a co-author on any of the publications relating to the diagnosis or management of Hepatitis B from the Royal Free London NHS Foundation Trust.

41.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

41.3.1. a-d: I joined the staff of the Cambridge University Hospitals NHS Foundation Trust in October 2004. I was not involved in management of patients with Hepatitis B. Patients with Hepatitis B would have been managed by the Hepatology team.

41.3.2. These arrangements pre-dated my joining the staff of the Cambridge University Hospitals NHS Foundation Trust. Please contact Dr TP Baglin, Dr M Seaman or the CUHFT for further information.

41.3.3. Patients referred to the Cambridge Centre from another Centre with an inherited bleeding disorder and in addition Hepatitis B would have been referred to the Hepatology team for management of their Hepatitis B.

42. How was the care and treatment of patients with NANB hepatitis managed at each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, and in any event including the Centre and the Royal Free? In particular:

a. **What steps were taken to arrange for, or refer patients for, specialist care?**

b. **What treatment options were offered over the years?**

c. **What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

d. **What follow-up and/or on-going monitoring was arranged in respect of patients who were infected with NANB hepatitis?**

42.1. Birmingham Children's Hospital: April 1985 - November 1987

42.1.1. a-d: As a trainee in Paediatric Haematology I, was not involved in the management of children with NANB Hepatitis. Please contact Dr FG Hill or the Birmingham Children's Hospital for information.

42.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

42.2.1. a-d: I was not involved in the management of patients with NANB Hepatitis. This would have been coordinated by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi in conjunction with the Hepatology unit.

42.2.2. I am not a co-author on any of the publications relating to the diagnosis or management of NANB Hepatitis from the Royal Free London NHS Foundation Trust.

42.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

42.3.1. a-d: I joined the staff of the Cambridge University Hospitals NHS Foundation Trust in October 2004. I was not involved in management of patients with NANB Hepatitis. Patients with NANB Hepatitis would have been managed by the Hepatology team.

42.3.2. These arrangements pre-dated my joining the staff of the Cambridge University Hospitals NHS Foundation Trust. Please contact Dr TP Baglin, Dr M Seaman or the CUHFT for further information.

43. How was the care and treatment of patients with hepatitis C managed at each of the hospitals, haemophilia centres and medical facilities you identify in your response to question 5 above, insofar as relevant in each case In particular:

a. **What steps were taken to arrange for, or refer patients for, specialist care?**

b. **What treatment options were offered over the years?**

c. **What information was provided to patients about the risks and benefits of specific treatments and about side effects?**

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

43.1. Birmingham Children's Hospital: April 1985 - November 1987

43.1.1. a-d: As a trainee in Paediatric Haematology I, was not involved in the management of children with Hepatitis C. Please contact Dr FG Hill or the Birmingham Children's Hospital for information.

43.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

43.2.1. a-d: I was not involved in the management of patients with Hepatitis C. This would have been coordinated by my colleagues Prof CA Lee and Dr [Prof] KJ Pasi in conjunction with the Hepatology unit.

43.2.2. I am not a co-author on any of the publications relating to the diagnosis or management of Hepatitis C from the Royal Free London NHS Foundation Trust.

43.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

43.3.1. a-d: I joined the staff of the Cambridge University Hospitals NHS Foundation Trust in October 2004. I was not involved in management of patients with Hepatitis C. Patients with Hepatitis C would have been managed by the Hepatology team.

43.3.2. These arrangements pre-dated my joining the staff of the Cambridge University Hospitals NHS Foundation Trust. Please contact Dr TP Baglin, Dr M Seaman or the CUHFT for further information.

43.3.3. Patients referred to the Cambridge Centre from another Centre with an inherited bleeding disorder and in addition Hepatitis C would have been referred to the Hepatology team for management/treatment and follow-up.

44. With respect to each of the hospitals, haemophilia centres or other medical facilities you identify in your response to question 5 above, and in any including the Centre and the Royal Free, each case:

a. **What, if any, involvement did you and/or colleagues and/or the hospital, haemophilia centre or other medical facility generally have with any clinical trials in relation to treatments for HIV and Hepatitis C? Please provide details.**

44.1. a. I was not involved in any trials in relation to the treatment of HIV and/or Hepatitis C whilst a trainee at the Birmingham Children's Hospital [April 1985 - November 1987] or whilst I was employed at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004] or the Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital [October 2004 – July 2017].

44.2. I am not a co-author on any publications from these Centres in relation to the treatment of HIV and/or Hepatitis C.

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

44.3. b. As a trainee in Paediatric Haematology at the Birmingham Children's Hospital [April 1985 - November 1987], I was not involved in the care or treatment of children with HIV and/or Hepatitis.

44.4. Whilst I was employed at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004], children were managed in the Haemophilia Centre at the Great Ormond Street Hospital for Children. I was not involved in the management of children or adults with HIV and/or Hepatitis.

44.5. Whilst I was employed at the Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital [October 2004 – July 2017], children with an inherited bleeding disorder and HIV and/or Hepatitis would have been managed by the Paediatric Haematologists and Paediatricians. Adults with an inherited bleeding disorder and HIV would have been managed by the Infectious Diseases team. Adults with an inherited bleeding

disorder and Hepatitis would have been managed by the Hepatology team. I was not involved in the management of adults with an inherited bleeding disorder and HIV and/or Hepatitis.

44.6. Please contact the Paediatric Team at CUHFT, the Hepatology Team and the Infectious Diseases Team for information.

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

44.7. c. As a trainee in Paediatric Haematology at the Birmingham Children's Hospital [April 1985 - November 1987], I cannot recall what arrangements were in place to provide support to patients [and their parents/family] infected through blood products. Please contact Dr FG Hill or the Birmingham Children's Hospital.

44.8. Whilst I was employed at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004] support for patients and their families would have been provided by Ms Riva Miller and latterly Ms Nicola Dunn. In addition there would have been a social worker to provide social work support.

44.9. In Cambridge, patients infected through blood products were managed in close collaboration with the Infectious Diseases and/or Hepatology teams. I understood these teams would provide counselling if needed. When I joined the staff at the Cambridge Haemophilia Centre in October 2004, patients with psychological problems would have been referred to the psychiatry team. I established a formal referral link with Dr Cathy Walsh, Consultant Liaison Psychiatrist and to whom I referred patients.

44.10. There was no social worker attached to the Haemophilia Centre, but this service could be accessed through the CUFHT.

d. **What, if any, difficulties did you, colleagues and/or the hospital, haemophilia centre or other medical facility encounter in obtaining**

sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

44.11. d. I have not been involved in the management of adults or children with an inherited bleeding disorder and who were/are co-infected with HIV and/or Hepatitis C. I am unable to comment on any difficulties encountered in obtaining funding for treatment.

Recombinants

45. Please explain any involvement you had with efforts to obtain recombinant blood products for patients with haemophilia. What if any difficulties were encountered and why?

45.1. When I was a trainee at the Birmingham Children's Hospital [April 1985 - November 1987], recombinant clotting factor concentrates were not available.

45.2. When I joined the staff at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004] recombinant clotting factor concentrates were available, but I was not involved in discussions relating to obtaining these products. Please contact Prof CA Lee of Prof KJ Pasi.

45.3. When I joined the staff at Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital [October 2004 – July 2017] the national tender process for clotting factor concentrate procurement was in operation [2004]. Patients with inherited bleeding disorders would have been treated wherever possible with recombinant clotting factor concentrates.

46. In your view, should recombinant blood products have been made available to all haemophiliacs earlier than they were? If so, when?

46.1. My view is that recombinant clotting factor concentrates should be used whenever possible, but this is dependent upon clinical trials demonstrating efficacy and safety.

47. In relation to those hospitals, haemophilia centres and other medical facilities at which you worked where recombinant products were made available to patients being treated there, when were they made available?

47.1. When I joined the staff at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004] recombinant clotting factor concentrates were available, but I was not involved in discussions relating to obtaining or using these products. Please contact Prof CA Lee, Dr [Prof] KJ Pasi and the Royal Free London NHS Foundation Trust.

47.2. When I joined the staff at Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital [October 2004 – July 2017] the national tender process for clotting factor concentrate procurement was in operation [2004]. Patients with inherited bleeding disorders would have been treated, wherever possible, with recombinant clotting factor concentrates

Research

48. Please list any research studies that you have been involved with insofar as relevant to the Inquiry's Terms of Reference, and please:

a. **describe the purpose of the research;**

b. **explain the steps that were taken to obtain approval for the research;**

c. **explain what your involvement was;**

d. **identify what other organisations or bodies were involved in the research;**

e. **state how the research was funded and from whom the funds came;**

f. **state the number of patients involved;**

g. **provide details of the steps taken to inform patients of their involvement and seek their informed consent; and**

h. **provide details of any publications relating to the research.**

48.1. a. I have been involved in a number of areas of research:

48.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004]

48.2.1. My research when a senior lecturer/honorary consultant haematologist at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust involved identifying and characterising the molecular defect(s) in individuals with rare inherited bleeding disorders.

48.3. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital [October 2004 – July 2017]

48.3.1. My research when employed the Cambridge University Hospitals NHS Foundation Trust - Addenbrooke's Hospital, related to studies involving:

48.3.2. A. Extended half-life studies of clotting factor concentrates

48.3.2.1. Principal Investigator B-Long Study – a novel long-acting recombinant Factor IX concentrate for use in Haemophilia B

48.3.2.2. Principal Investigator A-Long Study - a novel long-acting recombinant Factor VIII concentrate for use in Haemophilia A

48.3.2.3. Principal Investigator BYOND Study – the extension study for the B-Long Study

48.3.2.4. Principal Investigator ASPIRE Study – the extension study for the A-Long Study

48.3.2.5. Sub-Principal Investigator A-LONG and B-LONG Paediatric studies

48.3.3. The extended half-life studies involved the use of recombinant Fc-fusion FVIII or Fc-fusion FIX clotting factor concentrates to evaluate their safety, pharmacokinetic profile and efficacy for prophylaxis, the

treatment of acute bleeding and perioperative haemostatic control, in previously treated patients with severe Haemophilia A or B.

48.3.4. These studies were supported by Biogen Idec. I was the Principal Investigator [PI] for the adult studies and sub-Principal Investigator [sub-PI] for the paediatric studies. The Principal Investigator for the paediatric studies was one of the Paediatric Haematologists - I cannot recall who.

48.3.5. Patients who completed the A-LONG or B-LONG studies had the option to continue their treatment into the extension studies for these products – the ASPIRE and BYOND Studies respectively.

48.3.6. Approval for the research to be undertaken, was obtained from CUHFT Research and Development department. The proposed studies were forwarded to the CUHFT R&D team and agreement for the study was in place before we began enrolling patients into the studies. Please contact the CUHFT R&D Team for further information.

48.3.7. As Principal Investigator on these studies, I was responsible, together with my senior nursing staff and the data manager, for co-ordinating the study, discussing it with patients who fulfilled the inclusion criteria, obtaining their informed consent, reviewing the patients as outlined in the study protocol, identifying and reporting Adverse Events and Serious Adverse Events and subsequently reviewing all of their investigations in-line with the study protocols.

48.3.8. All patients whom we approached in terms of participating in the studies were provided with documentation that outlined the study, their follow-up and which we discussed with the patient and answered any questions that they might have. Informed consent was obtained from all patients and patients were provided with a copy of the consent document.

48.3.9. Funding for these studies was from Biogen Idec, the pharmaceutical company that had developed the products. Funds from the studies

were transferred to a research account. I did not access this at any point.

48.3.10. I cannot recall how many patients we enrolled into these studies. Please contact CUHFT.

48.3.11. Publications [on which I am a co-author]:

48.3.11.1. Long-term safety and efficacy of recombinant factor VIII Fc fusion protein (rFVIIIFc) in subjects with haemophilia A. Nolan B, Mahlangu J, Perry D, Young G, Liesner R, Konkle B, Rangarajan S, Brown S, Hanabusa H, Pasi KJ, Pabinger I, Jackson S, Cristiano LM, Li X, Pierce GF, Allen G. Haemophilia. 2016 Jan;22(1):72-80.

48.3.11.2. Phase 3 study of recombinant factor VIII Fc fusion protein in severe hemophilia A. Mahlangu J, Powell JS, Ragni MV, Chowdary P, Josephson NC, Pabinger I, Hanabusa H, Gupta N, Kulkarni R, Fogarty P, Perry D, Shapiro A, Pasi KJ, Apte S, Nestorov I, Jiang H, Li S, Neelakantan S, Cristiano LM, Goyal J, Sommer JM, Dumont JA, Dodd N, Nugent K, Vigliani G, Luk A, Brennan A, Pierce GF; A-LONG Investigators. Blood. 2014 Jan 16;123(3):317-25.

48.3.11.3. Treatment of bleeding episodes with recombinant factor VIII Fc fusion protein in A-LONG study subjects with severe haemophilia A. Shapiro AD, Mahlangu JN, Perry D, Pasi J, Quon DV, Chowdary P, Tsao E, Li S, Innes A, Pierce GF, Allen GA. Haemophilia. 2017 May;23(3):392-399.

48.3.11.4. Phase 3 study of recombinant factor IX Fc fusion protein in hemophilia B.

48.3.11.5. Powell JS, Pasi KJ, Ragni MV, Ozelo MC, Valentino LA, Mahlangu JN, Josephson NC, Perry D, Manco-Johnson MJ, Apte S, Baker RI, Chan GC, Novitzky N, Wong RS, Krassova S, Allen

G, Jiang H, Innes A, Li S, Cristiano LM, Goyal J, Sommer JM, Dumont JA, Nugent K, Vigliani G, Brennan A, Luk A, Pierce GF; B-LONG Investigators. N Engl J Med. 2013 Dec 12;369(24):2313-23.

48.3.11.6. Long-term safety and efficacy of extended-interval prophylaxis with recombinant factor IX Fc fusion protein (rFIXFc) in subjects with haemophilia B.

48.3.11.7. Pasi KJ, Fischer K, Ragni M, Nolan B, Perry DJ, Kulkarni R, Ozelo M, Mahlangu J, Shapiro AD, Baker RI, Bennett CM, Barnes C, Oldenburg J, Matsushita T, Yuan H, Ramirez-Santiago A, Pierce GF, Allen G, Mei B. Thromb Haemost. 2017 Feb 28;117(3):508-518.

48.3.11.8. Long-acting recombinant factor IX Fc fusion protein (rFIXFc) for perioperative management of subjects with haemophilia B in the phase 3 B-LONG study. Powell JS, Apte S, Chambost H, Hermans C, Jackson S, Josephson NC, Mahlangu JN, Ozelo MC, Peerlinck K, Pasi J, Perry D, Ragni MV, Wang X, Jiang H, Li S, Cristiano LM, Innes A, Nugent K, Brennan A, Luk A, Allen G, Pierce GF, Robinson B. Br J Haematol. 2015 Jan;168(1):124-34.

48.3.12. Observational Studies

48.3.12.1. AHEAD Study - Non-interventional Haemophilia A Outcome Study

48.3.12.1.1. The AHEAD (Advate in HaEmophilia A outcome Database) study was initiated by Baxter and was a multicentre, prospective, non-interventional observational study of Haemophilia A patients with residual FVIII activity of 5% who were on treatment with ADVATE. Study endpoints were long-term joint health outcomes, annualized (joint) bleeding rates, factor consumption, quality of life and safety data.

48.3.12.1.2. My role in this study, together with my senior nursing colleagues and data manager, was to identify patients who fulfilled the criteria for entry into the study, to discuss the study with potential patients, to answer any questions, to obtain informed consent from those patients who wished to enter the study and to ensure that we adhered to the study protocol.

48.3.12.1.3. I recall that we enrolled a single patient who subsequently withdrew from the study.

48.3.13. Publications: I am not a co-author on any publications arising from this study.

48.3.13.1. Sub-PI GENA-05 Study – Human Cell Line rFVIII study

48.3.13.1.1. This was a prospective study of the immunogenicity, efficacy and safety of treatment with a human cell line-derived recombinant FVIII [human-cl-rhFVIII] in previously untreated patients with severe Haemophilia A

48.3.13.1.2. I have not been involved in the recruitment for this study.

48.3.13.1.3. I am not a co-author on any publications arising from this study.

48.3.13.1.4. The Principal Investigator for this study was one of the Paediatric Haematologists - I cannot recall who.

48.3.13.2. Sub-PI TEN02 Study – Factor X

48.3.13.2.1. This was a study involving a high-purity, high-potency, human plasma-derived Factor X concentrate [Coagadex] produced by the Bio Products Laboratory [BPL] for the treatment of perioperative bleeding and on-demand treatment in patients with Factor X deficiency.

48.3.13.2.2. I have not been involved in the recruitment for this study.

48.3.13.2.3. I am not a co-author on any publications arising from this study.

48.3.13.3. The FEIBA PASS study

48.3.13.3.1. This was a prospective, Post-Authorization Safety Surveillance (PASS) study in patients with Haemophilia A or B and inhibitors treated with FEIBA for 1 year to collect real-world data on the safety and effectiveness of FEIBA.

48.3.13.3.2. We did not recruit any patients for this study.

48.3.13.3.3. I am not a co-author on any publications arising from this study.

48.3.13.4. B. Gene Therapy for Haemophilia A

48.3.13.4.1. I was Principal Investigator [Cambridge] for the BioMarin Gene Therapy trial for Haemophilia A.

48.3.13.4.2. I was responsible, together with my senior nursing staff and data manager, for co-ordinating the study, discussing it with patients who fulfilled the inclusion criteria, obtaining their informed consent, reviewing the patients as outlined in the study protocol, identifying and reporting Adverse Events and Serious Adverse Events and subsequently reviewing all of their investigations in-line with the study protocol.

48.3.13.4.3. All patients whom we approached in terms of participating in the study were provided with documentation that outlined the study, their follow-up and samples that needed to be collected. Patients were seen a second time to discuss the study and to answer any questions. Informed consent was obtained from all patients and patients were provided with a copy of the consent document.

48.3.13.4.4. Funding for this study was from BioMarin Pharmaceutical Inc, the pharmaceutical company that had developed the AAV5-hFVIII-SQ vector that would be used in the study. Funds from the studies were transferred to a research account. I did not access this at any point.

48.3.13.4.5. I cannot recall how many patients were enrolled into these studies. Please contact CUHFT.

48.3.14. Publications [on which I am a co-author]:

48.3.14.1.AAV5-Factor VIII Gene Transfer in Severe Hemophilia A.

48.3.14.2.Rangarajan S, Walsh L, Lester W, Perry D, Madan B, Laffan M, Yu H, Vettermann C, Pierce GF, Wong WY, Pasi KJ.

48.3.14.3.N Engl J Med. 2017 Dec 28;377(26):2519-2530.

49. Please provide the same details in relation to any epidemiological or similar studies which you undertook or in which you were involved (insofar as they are relevant to the Terms of Reference).

49.1. I have not been involved in any epidemiological studies.

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

50.1. Research depends upon the integrity, honesty and professionalism of all those involved and must conform to the guidance and requirements of National and International regulatory bodies.

50.2. A clear outline of the research planned is required. Honesty, transparency and minimising the risk of harm from the research is also required. Research that involves people should adhere to the principles of Good Clinical Practice and informed consent must be obtained from all participants. Anonymity and confidentiality is necessary. Individuals must have the right to withdraw from research. How the results of the research

will be made available should be discussed at the beginning of the project. Peer review is necessary as is avoiding conflicts of interest and declaring any potential conflicts of interest.

50.3. I believe that the studies which I have listed earlier [Statement 48], adhered to these principles. Any publications arising from these studies have disclosure statements indicating companies with which I, or the co-authors on a paper, have been involved with.

51. With respect to each of the studies you identify in your response to question 48 above:

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

51.1. a. All patients involved in the research studies and in which I was Principal Investigator, gave consent.

b. **Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express consent? If so, what data was used and how and why did this occur?**

51.2. b. The results from studies in which I have been Principal Investigator have been published. Patient data in these studies has been anonymised to allow publication. This was undertaken by the relevant companies with whom we were involved for the study.

51.3. All patients that I have managed would have been sent a copy of all their correspondence from myself and copies of their results. This would have included data from clinical trials.

c. **Was patient data (anonymised, de-identified or otherwise) shared with third parties (e.g. to UKHCDO)? If so how and why did this occur and what information was provided and to whom?**

51.4. c. Anonymised data, has not, I understand, been shared with third parties.

51.5. In line with the UKHCDO and the Department of Health, my understanding is that data on the diagnosis, management and complications of patients with bleeding disorders is recorded on the National Haemophilia Database and patients are aware of this.

51.6. d. I retired from the NHS in 2017 and I have no data or patient information on any patient that I have managed during my professional career.

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

52.1. The following letter, on which I am a co-author, was published in 1987. I cannot recall how the data outlined in the letter was collected. Please contact Prof KJ Pasi or Dr FG Hill.

52.1.1. Pasi KJ, Hamon MK, Perry DJ, Hill FGH. Factor VIII and IX Inhibitors After Exposure to Heat-Treated Concentrates. Lancet 1987:i;689

52.2. The following paper on which I am a co-author was published in 2009. The study was designed and initiated by the UK Haemophilia Centre Doctors' Organisation Inhibitor Working Party. The members of the working party were: P. Collins, R. Liesner, E. Chalmers, C. Hay, R. Maclean, S. Rajaragan and M. Williams.

52.3. The paper outlines how the data was collected from Comprehensive Care Centres [CCCs] in the UK.

52.3.1. Collins PW, Mathias M, Hanley J, Keeling D, Keenan R, Laffan M, Perry D, Liesner R; UK Haemophilia Centre Doctors' Organisation. Rituximab and immune tolerance in severe hemophilia A: a consecutive national cohort. J Thromb Haemost. 2009 May;7(5):787-794.

Records

53. With respect to each of the hospitals, haemophilia centres and other medical facilities you identify in response to question 5 above:

a. **What was the policy as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?**

53.1. **a.** Birmingham Children's Hospital: April 1985 - November 1987

53.1.1. I was not involved in providing death certificates whilst a trainee in paediatric haematology at the Birmingham Children's Hospital. I do not know what the policy was. Please contact Dr FG Hill or the Birmingham Children's Hospital

53.2. a. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

53.2.1. I do not recall what the policy was for recording information on death certificates when a patient died that had been infected with HIV or hepatitis. Please contact Prof CA Lee, Prof KJ Pasi or the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust.

53.3. a. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

53.3.1. I was not involved in providing death certificates when a patient died and has been infected with HIV and/or Hepatitis. Death certificates, I believe would have been issued by the Infectious Diseases Team, the Hepatology Team or the patient's General Practitioner.

b. **What were the retention policies with regards to medical records?**

53.4. b. Birmingham Children's Hospital: April 1985 - November 1987

53.4.1. As a trainee in paediatric haematology at the Birmingham Children's Hospital from 1985-1987. I do not know what the policy was with regards to the retention of medical records. Please contact the Birmingham Children's Hospital.

53.5. b. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

53.5.1. I do not know what the policy was with regards to the retention of medical records whilst I was at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust. Please contact the Royal Free London NHS Foundation Trust.

53.6. b. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

53.6.1. My understanding is that all medical records have been transferred to an electronic format and are kept indefinitely. Please contact CUHFT for additional information.

c. **Did you, colleagues, or the hospital, haemophilia centre or other medical facility in each case, maintain separate files for some or all patients? If so, why; where were those files located; and (insofar as it is within your knowledge) where are those files now?**

53.7. c. Birmingham Children's Hospital: April 1985 - November 1987

53.7.1. As a trainee in paediatric haematology at the Birmingham Children's Hospital from 1985-1987, I cannot re-call if there were separate files for patients with an inherited bleeding disorder. Please contact the Birmingham Children's Hospital for information.

53.8. c. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

53.8.1. I do not recall whether there were separate notes for patients registered with the Katharine Dormandy Haemophilia and Thrombosis Centre.

53.9. c. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

53.9.1. My understanding is that all case notes have now been collated into a single electronic file for each patient and separate files do not exist.

d. **Did you or colleagues keep records or information (e.g. information being used for the purpose of research) about any of your patients at home or anywhere other than the relevant hospital, haemophilia centre or other medical facility? If so, why, what information and (insofar as it is within your knowledge) where is that information held now?**

53.10. d. Birmingham Children's Hospital: April 1985 - November 1987

53.10.1. I am not aware that any patient data was kept at home or anywhere other than the hospital or Haemophilia centre.

53.11. d. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

53.11.1. I am not aware that any patient data was kept at home or anywhere other than the hospital or Haemophilia centre.

53.12. d. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

53.12.1. I am not aware that any patient data was kept at home or anywhere other than the hospital or Haemophilia centre.

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

53.13. e. Birmingham Children's Hospital: April 1985 - November 1987

53.14. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

53.15. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

53.15.1. I retired from the NHS in July 2017. I do not hold records or information about any of the patients whose care I have been involved with.

Section 5: Pharmaceutical companies/medical research/clinical trials

54. Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details (including dates) of the advisory or consultancy services that you provided.

55. Have you ever received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details, including when this was and from which company(ies) you received pecuniary gain.

56. Have you ever sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details of your involvement (including dates) and of any financial or other remuneration you received.

56.1. Response to questions 54-56:

56.1.1. I have provided consultancy services to a number of pharmaceutical companies. I have summarised these below and the Honoraria, where I have this information, below. I have no records for consultancy services prior to October 2004 when I joined the Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital.

56.1.1.1. 2004 - Laboratory Services for Haemophilia Care . Baxter BioScience UK .Travel costs + Honorarium. I cannot recall further details of this meeting

56.1.1.2. 2005 - Advisory Board, Sanofi Adventis. Travel costs + Honorarium: £400. I cannot recall further details of this meeting

56.1.1.3. 2006 - Baxter Health Care Ltd. Travel costs + Honorarium: £250. I cannot recall further details of this meeting

56.1.1.4. 2008 - FEIBA Advisory Board Meeting. Baxter BioScience UK. Travel costs + Honorarium: £700

56.1.1.5. 2009 - Advisory Board, Baxter BioScience UK. Travel costs + Honorarium: £784. I cannot recall further details of this meeting

56.1.1.6. 2010 - FEIBA Slide Development Meeting, Baxter Healthcare Corporation. Travel costs + Honorarium: £1529.76. I cannot recall further details of this meeting

56.1.1.7. 2010 - Advisory Board. Baxter BioScience UK, Travel costs + Honorarium: £734. I cannot recall further details of this meeting

56.1.1.8. 2012 - Expert Panel – Review of Factor Assays, NovoNordisk. Travel costs + Honorarium. I cannot recall further details of this meeting

56.1.1.9. 2012 - Principal Investigators A-LONG/B-Long Study -Publishers Meeting, Biogen idec. Honorarium: £1400

56.1.1.10. 2012 - Principal Investigators Meeting A-LONG/B-Long Study, Biogen idec. Honorarium: £1400

56.1.1.11. 2013 - Expert Panel Meeting – Assays, NovoNordisk. Travel costs + Honorarium: £1500

56.1.1.12. 2014 - Roundtable meeting on FVIII & FIX Assays, SOBI Advisory Board. Travel costs + Honorarium £1000

56.1.1.13. 2016 - Roundtable meeting on rFIXFc Dosing and Monitoring, SOBI Advisory Board. Travel costs + Honorarium: £1125

56.1.1.14. 2018 - Gene Therapy Meeting, BioMarin Europe Ltd. £2,109.63. This appears on the APBI website but I have not received this.

57. Have you, or insofar as you are aware, any colleagues, ever received any financial incentives from pharmaceutical companies to use certain blood

products? If so, please provide details, including when this was and from which company(ies) the incentives were received.

57.1. I have not received financial incentives from the pharmaceutical industry to prescribe specific blood products. I do not know if any of my colleagues have received financial incentives from the pharmaceutical industry.

58. Have you, or insofar as you are aware, any colleagues, ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details, including when this was and from which company(ies) the incentives were received.

58.1. I have not received non-financial incentives from the pharmaceutical industry to prescribe specific blood products. I do not know if any of my colleagues have received non-financial incentives from the pharmaceutical industry.

59. Have you, or insofar as you are aware, any colleagues, ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details, including when this was and from which company(ies) the funding was received.

59.1. I have not received funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company. I do not know if any of my colleagues have received funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company.

60. With respect to the matters you describe in response to questions 47 to 52 above, in each case what regulations or requirements or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take to comply with them?

60.1. Birmingham Children's Hospital: April 1985 - November 198

60.2. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

60.2.1. I cannot recall what regulations, requirements or guidelines were in place concerning declaratory procedures for involvement with a pharmaceutical company when I was a trainee at the Birmingham Children's Hospital [April 1985 - November 1987.]

60.2.2. I cannot recall what regulations, requirements or guidelines were in place concerning declaratory procedures for involvement with a pharmaceutical company when I was employed at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004.]

60.3. **Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October [2004 – July 2017.]**

60.3.1. I recall a Hospitality Register was available to record involvements with pharmaceutical companies. I kept a record of meetings that I had attended for which I received an honorarium and which was available for discussion if required. This was deleted and relevant files shredded when I retired from the NHS in July 2017.

60.3.2. Publications relating to clinical trials and that I have been a co-author on, have stated under Disclosures, any involvement with the pharmaceutical industry.

61. Have you ever undertaken medical research for, or on behalf of, or in association with, a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

61.1. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October [2004 – July 2017.]

61.1.1. I have been involved in a number of studies of clotting factor concentrates - see Statement 48 – in association with a pharmaceutical company. The CUHFT were aware of these. The funding went to a research fund that I did not access.

62. Have you or, insofar as you are aware, senior colleagues ever provided a pharmaceutical company with results from medical research studies that you have undertaken? If so, please provide details including when this was, to which company(ies) the results were provided and what those results concerned.

62.1. I am unaware if senior colleagues have ever provided a pharmaceutical company with results from medical research studies that I have undertaken.

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

63.1. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

63.1.1. The only funding I have received from pharmaceutical companies for research, was as a Principal Investigator on clinical trials – see Statement 48. CUHFT was aware of this. The funding went to a research fund that I did not access.

Section 6: UKHCDO

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

a. **When that involvement began, and what role you had at that time;**

64.1. a. I was a member of the UKHCDO. I cannot recall when I joined the UKHCDO, but it was prior to 2004 as I was a member of the UKHCDO Rare Coagulation Disorders working party.

b. **What other roles you held over time;**

64.2. b. My roles in the UKHCDO were:

64.3. i. Membership of the Rare Inherited Diseases Working Party [Chair: Dr P Bolton-Maggs]

64.3.1. Publications:

64.3.1.1. a. The rare coagulation disorders--review with guidelines for management from the United Kingdom Haemophilia Centre Doctors' Organisation. Haemophilia 2004 Sep;10(5):593-628.b.

64.3.1.2. A review of inherited platelet disorders with guidelines for their management on behalf of the UKHCDO. Br J Haematol 2006 Dec;135(5):603-33.

64.4. ii. Membership of the Genetics Working Party [Chair: Prof CA Ludlam].

64.4.1. Publications:

64.4.1.1. a. Gene therapy trials in the UK: is haemophilia a suitable model? Clinical Medicine 2004;4(1):54-56

64.4.1.2. b. A framework for genetic service provision for haemophilia and other inherited bleeding disorders. Haemophilia 2005 Mar;11(2):145-63.

64.5. iii. Audit Lead UKHCDO Triennial Audit Programme.

64.5.1. I took on the lead of the UKHCDO audit programme from Dr J Wilde in 2012 and in close collaboration with The Haemophilia Society, I coordinated the triennial audit of Haemophilia Comprehensive Care Centres [CCCs] in the UK in 2013. I resigned from this post in 2015.

c. **If it has not ended, what your involvement with UKHCDO is now;**

d. **If your involvement with the UKHCDO has ended, when it ended.**

64.6. c-d. I have no involvement with the UKHCDO having retired from clinical practice in July 2017.

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

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

65.1. a. The UKHCDO's role as I understood it was:

65.1.1. i. To bring together medical practitioners in the UK working in the field of Haemostasis and particularly individuals and their families, with inherited and acquired bleeding disorders.

65.1.2. ii. To improve the care of individuals and their families with inherited bleeding disorders.

65.1.3. iii. To improve the education of all health care professions involved in the management of inherited bleeding disorders. This was achieved through the creation of a number of working parties that generated freely-available, evidence-based guidelines to aid with the investigation and management of individuals and their families with inherited bleeding disorders.

65.1.4. iv. The development of educational materials for patients.

65.1.5. v. The development and maintenance of the National Haemophilia Database as required by the Department of Health to collect data on the diagnosis, management and complications of bleeding disorders.

65.1.6. vi. An audit programme of Comprehensive Care Centres [CCCs] with close involvement of Patients-Parents-Carers to ensure uniformity of care individuals with Haemophilia and other bleeding disorders across the UK and to highlight best practice and areas that required improvement.

65.1.7. vi. A forum for the discussion of areas of concern in Haemophilia Care.

65.1.8. vii. An Annual General Meeting that provided a summary of the work of the UKHCDO in the previous 12 months and a summary of the 'Bleeding Disorder Statistics' for the previous 12 months.

b. the structure, composition and role of its various committees or working groups;

65.2. b. The committees and working parties of the UKHCDO were formed to generate evidence-based guidelines for the management of individuals and their families with inherited bleeding disorders. Members of a working group had a collective/specialist interest in the area[s] of the group and could nominate themselves to be members of the group. The chair of the working party was appointed by the chair and executive of the UKHCDO. Working parties could be for either a fixed 3-year term or roll-over.

c. the relationships between UKHCDO and pharmaceutical companies;

65.3. c. I am not aware of what interactions there were between the UKHCDO and the pharmaceutical industry.

d. how decisions were taken by UKHCDO;

65.4. d. My understanding is that decisions taken by the UKHCDO were taken by the chair after discussion with the UKHCDO executive committee.

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

65.5. Information, guidance and advice from the UKHCDO was circulated from the individual working parties. The UKHCDO meetings and the AGM provided a forum for the discussion of many areas in haemophilia care.

f. any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to:

i. the risks of infection associated with the use of blood products;

ii. **the sharing of information about such risks with patients and/or their families;**

iii. **obtaining consent from patients for the testing and storage of their blood, for treatment and for research;**

iv. **vCJD exposure; and**

v. **treatments for HIV and hepatitis C.**

65.6. f. I have not been involved with the UKHCDO in any policies, guidance, actions or decisions which relate to:

65.6.1. i. The risks of infection associated with the use of blood products

65.6.2. ii. The sharing of information about such risks with patients and/or their families

65.6.3. iii. Obtaining consent from patients for the testing and storage of their blood, for treatment and for research. The Genetics working party [chaired by Prof C Ludlam] published a framework for the provision of genetic services for Haemophilia and other Inherited Bleeding Disorders in 2004. This included sections on obtaining informed consent from patients, data collection, retrieval, storage and disclosure.

65.6.4. iv. vCJD exposure

65.6.5. v. Treatments for HIV and hepatitis C.

Section 7: Treloar's

66. **Please describe (with reference to your time at each of the hospitals, haemophilia centres and other medical facilities specified in your response to question 5) any involvement you or the centre at which you worked had with Lord Mayor Treloar College/Treloar's ("Treloar's") and/or with the care and treatment of boys attending Treloar's.**

66.1. I have had no involvement with the Lord Mayor Treloar College and I do not recollect looking after any boys attending Lord Mayor Treloar College at any of the Haemophilia Centres/Medical Facilities at which I have worked.

67. Did you, or Dr Hill, or any other colleagues (and if so who) recommend that patients attend Treloar's and/or refer them to Treloar's? If so:

a. **At which hospitals, haemophilia centres or other medical facilities were you working when that occurred?**

b. **In each case, how many patients were the subject of such recommendations or referrals to Treloar's, and over what period of time?**

c. **What prompted the recommendations or referrals?**

d. **What involvement did you have in the arrangements for them to attend Treloar's?**

e. **What involvement did you have in the ongoing care and treatment of boys attending Treloar's?**

67.1. I have not recommended that any patient attend the Lord Mayor Treloar College. I do not know if Dr FG Hill or any of the colleagues with whom I have worked have recommended or referred patients to the Lord Mayor Treloar College.

68. Please describe any research and/or trials and/or experimental treatment that you are aware of involving pupils at Treloar's, including any involvement that you or senior colleagues (and in the latter case, whom) had in such research/trials/treatment.

68.1. I have no knowledge of any research and/or trials and/or experimental treatment involving pupils at the Lord Mayor Treloar College.

69. As far as you are aware, were the pupils at Treloar's treated differently to other people with bleeding disorders? If so, in what respects and why?

69.1. I have no knowledge of the Lord Mayor Treloar College treatment policies and unable to answer this.

Section 8: vCJD

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

70.1. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004].

70.1.1. I cannot recall precisely when or how I became aware of the potential risk of vCJD associated with the use of blood and blood products, but it was whilst working at the Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust.

71. At relevant hospitals, haemophilia centres and other medical facilities you identify in response to question 5 above:

a. **What was the process for informing patients about possible exposure to vCJD at the relevant hospitals, haemophilia centres or other medical facilities you identify in response to question 5 above?**

b. **How, when and by whom were patients told of possible exposure to vCJD?**

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

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

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

71.1. Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust [July 1994 - July 2004].

71.1.1. a-e: I cannot recall how the potential risks of vCJD associated with the use of blood and blood products was addressed at the Katharine Dormandy Haemophilia and Thrombosis Centre. Please contact Prof CA Lee or Dr [Prof] KJ Pasi or the Katharine Dormandy Haemophilia and Thrombosis Centre.

71.2. Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital [October 2004 – July 2017]. My recollection of events is:

71.2.1. a. In September 2004, we received a letter from the UKHCDO in relation to Variant Creutzfeldt-Jakob Disease and Plasma Products' and we were asked to identify all recipients of UK-sourced plasma products between 1980 and 2001, to inform their general practitioners of their 'at-risk' status, to offer counselling to all patients and the option of knowing whether they were 'at-risk' and whether they had received any of the FVIII or FIX batches known to be implicated.

71.2.2. We were, I recall provided with Information leaflets [Variant Creutzfeldt-Jakob Disease and Plasma Products – Information for Patients] for patients.

71.2.3. b. My recollection is that all recipients of UK-sourced plasma products between 1980 and 2001 registered with the Cambridge Centre would have been contacted using a template letter provided by the UKHCDO.

71.2.4. c. We were, I recall, provided with Information leaflets [Variant Creutzfeldt-Jakob Disease and Plasma Products – Information for Patients] for patients and which provided information on the risks of vCJD. This would have been sent to patients or provided to them in clinic.

71.2.5. d. Patients would have been aware that they could contact us at any time to discuss concerns or questions relating to their risk of vCJD.

71.2.6. e. A record would have been made in the case notes and in the electronic medical records of 'at-risk' patients, that they were 'at risk of vCJD for public health purposes.' The Infection Control Team within the CUHFT was closely involved with this. We would have advised all clinicians to contact the Infection Control Team for advice regarding the management of any patient requiring an invasive procedure and who had been identified as 'at risk' for vCJD for public health purposes.'

71.3. In 2009, patients who had received UK sourced plasma and who were believed to be at risk of vCJD would have been contacted by letter using a template provided by the UKHCDO because, I recall a patient with Haemophilia had died and investigations had shown that he was infected with the abnormal prion protein that causes vCJD although this was not the cause of death.

Section 9: Involvement with the financial support schemes

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

72.1. I have had no involvement that I can recall, with the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust or the Caxton Foundation and limited involvement with the Skipton Fund.

72.2. The England Infected Blood Support Scheme [EIBSS] was, I understand, established in November 2017. I retired from the NHS and clinical practice in July 2017.

73. With respect to your time at each of the hospitals, haemophilia centres or medical facilities you identify in response to question 5 above, to the extent that you had any involvement with the trusts or funds or with the applications made by patients for assistance, please answer the following questions:

a. **To what extent did (in each case) the hospital, haemophilia centre or other medical facility and its staff (including you) inform patients about these different trusts or funds?**

b. **Was there a policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?**

c. **What kind of information (whether through you or otherwise) was provided to the trusts and funds about or on behalf of patients who were seeking assistance from the trusts and funds?**

d. **In each case, did the hospital, haemophilia centre or other medical facility, or any of its staff (including you), act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.**

e. **In each case, was the hospital, haemophilia centre or other medical facility, or any of its staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.**

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

73.1. a-f: Birmingham Children's Hospital: April 1985 - November 1987

73.1.1. I was a trainee in paediatric haematology during this period. I do not believe these financial support schemes had been established at this time.

73.2. a-f: Katharine Dormandy Haemophilia and Thrombosis Centre - Royal Free London NHS Foundation Trust: July 1994 - July 2004

73.2.1. I have had no involvement that I can recall, with the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust or the Caxton Foundation whilst working in the Katharine Dormandy Haemophilia and Thrombosis at the Royal Free London NHS Foundation Trust.

73.2.2. Prof CA Lee and Prof KJ Pasi were responsible for the delivery of the Haemophilia Service and for the management of, in close collaboration with Professor Margaret Johnson [Thoracic/General medicine, consultant in HIV/AIDS medicine] and the Hepatology service, patients with bleeding disorders and with HIV and/or HCV and/or HBV and will be able to provide information on their involvement with these funds.

73.3. a-f: Cambridge University Hospitals NHS Foundation Trust: Addenbrooke's Hospital. October 2004 – July 2017

73.3.1. I have had no involvement that I can recall with the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust or the Caxton Foundation.

73.3.2. The England Infected Blood Support Scheme [EIBSS] was, I understand, established in November 2017. I retired from the NHS and clinical practice in July 2017.

73.3.3. I recall that I have supported applications to the Skipton Fund, but I cannot be more specific.

73.3.4. I recall that information on these funds was available in the Haemophilia Centre, there were leaflets with information on the funds in the Patient Waiting Room and in addition, I believe, were available through the Infectious Diseases and Hepatology teams.

73.3.5. I do not recall that I acted as a 'gateway' at any point to establish the eligibility criteria for receipt of assistance from any of the trusts. I recall that I supported applications to the Skipton fund, but I cannot be more specific.

73.3.6. I had no or limited interactions with the trusts and funds listed and I am, therefore, unable to comment on how well these trusts and funds were run and whether they achieved their purposes.

74. We refer to the minutes of the Combined 37th Advisory Committee and 11th Annual General Meeting of the UK Haemophilia Centre Doctors' Organisation held on 12 November 2010 [HCDO0000509]. During this meeting it is discussed that you would be involved in haemophilia centre auditing. During these audit processes were the policies or procedures of haemophilia centres in relation to the support given to patients and the referral of patients to trusts/schemes reviewed?

74.1. I coordinated the Haemophilia Comprehensive Care Centre [CCC] triennial audit in 2013 [– see Exhibits WITN3173006-10.] The audit working party comprised nursing, medical, laboratory staff and members from the Haemophilia Society all of whom were involved in the design of the audit proforma. Members of The Haemophilia Society [in addition to attending two 1-day mock audits in Cambridge], were included in all of the Comprehensive Care Centre audit teams.

74.2. A Patient-Parent Survey was designed in close collaboration with the Haemophilia Society. The survey was designed to be used at times other than the triennial audit to generate information from patients about the quality of the service offered by individual Comprehensive Care Centres [CCCs.]

74.3. The audit included the availability of comprehensive care services including access to HIV physicians and Hepatologists. A separate audit document for the Patient-Parent-Carer auditor was undertaken when a case note review was in progress by the nursing-medical auditors. This provided an opportunity for the Patient-Parent-Carers to review aspects of the service. The audit did not specifically review the policies or procedures of Comprehensive Care Centres [CCCs] in relation to the support given to patients and the referral of patients to trusts/schemes.

Section 10: Current haemophilia care and treatment

The Inquiry understands that you were until relatively recently the Director of the Cambridge Haemophilia Centre ("the Cambridge Centre"). The questions in this section are aimed at enabling the Inquiry to understand how haemophilia care is currently provided and how the provision of care and treatment and the approach to patients may have changed over the years.

75. Please describe how the provision of care and treatment for bleeding disorders is (or was by the time you ceased to be Director) organised at the Cambridge Centre.

75.1. I retired from the NHS in July 2017. I was responsible together with my nursing and laboratory colleagues, for the provision of adult services for individuals with inherited and acquired bleeding disorders. Services for children with inherited and acquired bleeding disorders would have been provided by the paediatric haematologists – Dr M Gattens, Dr M Bradbury [now erased from the Medical Register] and latterly Dr A Kelly. Children were seen in the Haemophilia Centre. If the parent of a child with a bleeding disorder also had a bleeding disorder, their review would have been scheduled to coincide with their child's review.

75.2. Exhibit WITN3173005 – Cambridge Comprehensive Care Centre Audit 2013

75.2.1. The Cambridge Haemophilia & Thrombophilia Centre moved from its previous location adjacent to the main Haematology Labs to a newly refurbished Centre on the ground floor of the hospital, at the beginning of 2013. The Centre had easy access from the main hospital entrance and there were disabled parking spaces located near to the main reception of the hospital. The Centre comprised a reception area with a separate play area for children. There was a television and a selection of reading material, including patient information.

75.2.2. There were 3 consultation rooms, with resuscitation equipment oxygen and suction in one room. There were emergency call bells

throughout the centre. There were two toilets, one of which had disabled access.

75.2.3. Patients attending the Centre would have been seen by a consultant haematologist or haematology SpR and a member of the specialised haemophilia nursing team. Patients with a severe clinical phenotype would have been seen at least every 6 months and if there were problems, more frequently. Patients or the parents of children, could contact the Haemophilia centre at any time to ask for advice and/or review. Health care professionals could contact the Haemophilia Centre at any time for advice or to refer a patient.

75.2.4. Patients with a severe clinical phenotype would have been, wherever possible, on prophylaxis and home delivery of their clotting factor concentrates. Patients would be asked to record their use of clotting factor concentrates using Haemtrack or paper records and to highlight any bleeding problems. This would be reviewed when they attended their clinic review appointment.

75.2.5. In line with the UKHCDO and the Department of Health, data on the diagnosis, management and complications of patients with bleeding disorders was recorded on the National Haemophilia Database and patients were aware of this.

75.2.6. Pharmacokinetic studies for patients on prophylaxis with a clotting factor concentrate were undertaken so that we could optimise treatment for an individual patient and minimise their risk of bleeding.

75.2.7. Patients with a severe bleeding disorder or a mild-moderate disorder and joint problems would be reviewed by the physiotherapist, who was a member of the Haemophilia Centre team.

75.2.8. Weekly meetings between the Haemophilia Staff [Administrative/Medical/Nursing] and the Laboratory staff were held to discuss all issues relating to the Haemophilia Centre, its practice and audit projects.

75.2.9. It has been my practice for patients to be copied into all of their correspondence so that they had a record of their consultation, the areas that were discussed, any planned changes in their management, referrals and details of follow-up. Patients would also be sent copies of their test results and an explanation of these, if necessary. Patients would also have been aware they could contact us/myself at any time to discuss their results or any questions that they might have.

75.2.10. Patients with HIV and/or HCV and/or HBV would have been seen independently of the Haemophilia Centre team by the Infectious Diseases and/or Hepatology teams. Appointments in the Haemophilia Centre would be scheduled to coincide with their other Hospital appointments.

75.2.11. There was close collaboration with other units within the CUHFT including the Emergency Department, Obstetrics and Gynaecology, General Surgery and Orthopaedic Surgery.

75.2.12. As a forum for discussing complex patients, I arranged for the Cambridge Comprehensive Care Centre to join the Pan Thames Haemophilia consortium for the discussion of these cases.

75.2.13. In 2005 and again in 2010-2012, I undertook an audit of the regional Haemophilia Centres in East Anglia. This was, in 2005, the first audit of Haemophilia Centres in the UK. This led to:

75.2.13.1. Regional laboratory and clinical meetings to discuss difficult clinical cases and to assist in laboratory standardisation - Well defined referral and shared care policies that ensured that comprehensive care review was offered to all severe phenotype patients in the region

75.2.13.2. Complex surgery in individuals with an inherited bleeding disorder was performed at the Addenbrooke's hospital site or at Papworth

Hospital to enable direct supervision of these patients by the Cambridge Haemophilia team

75.2.14. Treatment protocols/guidelines were available in the Haemophilia Centre and updated regularly.

75.2.15. I wrote, together with a member of Haemophilia nursing team and two previous Haematology SpRs, a 'Brief Guide to Haemophilia A, B and von Willebrand's Disease' to aid Haematology trainees who were joining the Centre as part of their training programme.

76. Please outline the treatments currently provided (or provided at the time you ceased to be the Director) to patients with bleeding disorders at the Cambridge Centre.

76.1. At the time I retired from the NHS in July 2017, the following treatments were, to the best of my knowledge, available for patients registered with the Cambridge Centre:

76.1.1. Recombinant Products:

76.1.1.1. Advate

76.1.1.2. Kogenate Bayer

76.1.1.3. Refacto A

76.1.1.4. Helixate NexGen

76.1.1.5. NovoSeven

76.1.1.6. BeneFIX

76.1.2. Plasma Derived Products

76.1.2.1. Wilate

76.1.2.2. Alphanate

76.1.2.3. FEIBA

76.1.2.4. Wilfactin

76.1.2.5. BPL FXI concentrate

76.1.2.6. BPL 8Y

76.1.2.7. Beriplex

76.1.2.8. Riastap

76.1.3. Other

76.1.3.1. Octaplas

76.1.3.2. DDAVP

76.1.3.3. Tranexamic Acid

76.1.4. Clinical Trial concentrates

76.1.4.1. rFVIIIFc [Eloctate]

76.1.4.2. rFIXFc [Alprolix]

76.1.4.3. Factor X [Coagadex]

77. Please describe how, in recent years, you typically obtained your patients' consent to treatment at the Cambridge Centre. In particular:

a. **What information did you give patients about the risks of the treatment?**

b. **What information did you give patients about the side-effects of the treatment?**

c. **What information did you give patients about the risks of not having the treatment?**

d. **What information did you give patients about the benefits of having the treatment?**

77.1. Response to a-d:

77.2. The majority of patients attending the Cambridge Comprehensive Care Centre were adults and if they had transitioned from the Paediatric service and had a severe phenotype, they would have been on prophylaxis. Consent for treatment in such cases would have been obtained from the parents. Adults moving from other centres to Cambridge or newly diagnosed adults requiring treatment would be reviewed in clinic, the potential treatment options discussed and any potential risks associated with the treatment discussed. Patients would be provided with details of The Haemophilia Society and in the waiting room prior to their consultation, there were patient information leaflets. These included information on bleeding disorders, The Caxton Fund, The Skipton Fund and The Haemophilia Society.

77.3. Patients would have time to discuss treatment options or alternatives and for any questions that they might have, to be answered. Patients were aware that they could contact us at any time to discuss concerns or any questions that they might have.

77.4. The risks of not having treatment would have been discussed and an individual's specific risk depended upon the nature of their underlying problem and if invasive treatment including surgery, would have been planned.

77.5. The benefits of treatment, the treatment options available and how these would be managed would have been discussed and this depended upon the nature of their underlying disorder. All patients would have received a copy of their clinic letter summarising the consultation, planned treatment, possible referrals and follow-up plans.

78. Please describe how, in recent years, you typically recorded your patients' consent to treatment at the Cambridge Centre.

78.1. Informed consent for treatment would have been obtained from patients and would have been recorded in the case notes. Consent would have been obtained following a consultation with a member of the Haemophilia team

and after an opportunity to discuss any questions or concerns that they might have.

79. Did you, in recent years, routinely take blood samples from patients attending the Cambridge Centre? If so, what information did you provide to patients about the purposes for which the samples are being taken? Did you obtain patients' consent to the storage and use of the samples and if so how and is that recorded? Please describe any significant differences with current practice at the Centre.

79.1. Patients that I saw would have been aware of the investigations that were being performed and would have been sent a copy of the results. Patients and their families would have been seen with a member of the senior Haemophilia nursing staff. I did not routinely take blood samples from patients that I saw. This would have been performed by a member of the Haemophilia Nursing team. Informed consent would have been obtained for all genetic tests. A copy of this would be stored with the genetic results and pedigree data. Samples would not be taken for storage unless the patient was enrolled in a specific study to which they had given informed consent.

80. Please describe how in recent years you typically (a) obtained and (b) recorded your patients' consent to testing (of any kind).

80.1. a-b. Informed consent would have been obtained for all patients enrolled in studies within the Cambridge Centre.

80.2. For clinical trials, the study would have been discussed with eligible patients. There were strict inclusion and exclusion criteria for the clinical trials that I was involved in. Patients were invited to take part and if interested were provided with written information outlining the study, the follow-up period, what samples would be collected and when. Patients would have read this at home and were then seen again to discuss any questions or concerns that they might have. If they were still interested in participating in the study then they would sign a consent form and would have been provided with a copy of their consent form. They would have

been provided with copies of their results from the clinical trial that they were enrolled in.

80.3. For genetic testing, patients would have been provided with an information document outlining the tests that were to be performed. The consent for genetic tests would be filed in the patient's case notes. This was stored with the family pedigree data. All patients would be provided with a copy of the genetic results when they became available.

80.4. For other tests including HIV and Hepatitis screening, the specific tests would have been discussed with the patients and the reasons for the test. Consent was verbal in these cases. Patients would be sent a copy of their results when these became available.

81. How many current patients at the Centre (at the time you ceased to be Director) (a) were infected with HIV through blood products; (b) were infected with hepatitis C through blood products; (c) were infected with hepatitis B through blood products; (d) were co-infected with HIV and hepatitis C through blood products?

81.1. I do not have this information. Please contact the CUHFT.

82. What if any involvement did you and/or the Cambridge Centre have in the treatment of the Centre's patients for HIV and/or hepatitis C and/or hepatitis B? Are there multidisciplinary clinics (e.g. haematology and hepatology), and if not would such arrangements be feasible and beneficial?

82.1. Patients with Hepatitis would be managed by the Hepatology team. Patients with HIV would be managed by the Infectious Diseases team. The Cambridge Centre was not involved in the treatment of HIV, Hepatitis B or Hepatitis C. There were no multi-disciplinary clinics. The system in place appeared to work and I was not aware of any criticisms or concerns from patients attending these clinics. Wherever possible follow-up appointments in the Haemophilia Centre would be scheduled to coincide with a patient's appointment in the Hepatology or Infectious Diseases clinic.

83. What if any psychological services are (or were at the time you ceased to be Director) available at the Cambridge Centre? Did you have a psychologist as part of the staff team? Was there psychological support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

83.1. When I joined the staff at the Cambridge Haemophilia Centre, patients with psychological problems would be referred to the psychiatry team. I established a formal referral link with Dr Cathy Walsh, Consultant Liaison Psychiatrist and to whom I referred patients.

83.2. A psychologist was not a member of the Cambridge Centre but the relationship we had with Dr Walsh was good. I do not recall specific psychological support for patients infected with HIV and/or Hepatitis, but these patients would have been seen by Dr Walsh or a member of her team.

84. What if any other support services were available at the Cambridge Centre?

84.1. As part of the Cambridge Centre, we had good relationships with specialised services throughout the CUHFT which allowed us to provide a high level of care for our patients. A part-time physiotherapist and a member of the Cambridge Haemophilia Centre team, would run clinics for patients to coincide with their Haemophilia follow-up appointments.

85. What has been the impact of the infection of patients with HIV and/or hepatitis through blood products:

a. **upon patients at the Cambridge Centre (without identifying any individual patient); and**

85.1. a. This is a very difficult question to answer. The impact of infection with HIV and/or Hepatitis has been overwhelming for patients, their families and for the staff who have been involved in their care. As a Haemophilia Centre, we strived to provide the best care we could for patients and families with whom we were involved.

b. **the ways in which decisions about treatment and care are taken, and treatment and care are provided, at the Cambridge Centre?**

85.2. b. My role as a consultant was to ensure we provided the best care we could for our patients. Patients under my care would be copied into their correspondence so that they had a record of their consultation with myself, were aware of planned treatment(s) and the results of any tests that had been performed. Patients could contact us at any time to discuss any questions or concerns that they might have. These frequently arose from discussions with other family members, from talking to other patients/friends with inherited bleeding disorders, via social media or via the internet. Patients were involved in the provision of their care.

86. Has the infection of patients with HIV and/or hepatitis B and/or hepatitis C through blood products:

a. **Changed or influenced your professional practice and approach and if so how?**

86.1. a. I always tried to provide the best level of care that I could for the patients and their families that I looked after. I was cautious about prescribing any products for the treatment of inherited and acquired bleeding disorders and their safety profile was important as to whether I would prescribe a specific product or not.

86.2. The patients and families that I have managed were aware that they could contact me at any time to discuss any problems or concerns that they might have. Consultant Haematologists in the region were also aware that they could contact us at any time for advice or to refer patients.

b. **Changed or influenced the practice and approach of your colleagues and if so how?**

86.3. b. I cannot comment.

c. **Changed or influenced the way in which haemophilia care is now provided and if so how?**

86.4. c. I retired from the NHS in 2017 and unable to answer this question.

Section 11: Other issues

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

87.1. I am not aware of any complaints made about myself to my employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

88. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry.

88.1. I have made a number of references to decisions relating to general and specific patient care that would have been made by others and in particular more senior colleagues, especially when I was a junior doctor/trainee. It is in some cases over 30 years since that time and was at a time when the hierarchy in clinical teams was strict and based on a more traditional approach to the practice of clinical medicine in a hospital setting. Senior colleagues were responsible for the major decision-making related to a patient's treatment.

88.2. I would hope that my responses can, therefore, be seen in the context of practice during that era and not judged by the style of practice that occurs today.

Statement of Truth

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

Signed GRO-C

Dated 6/11/20

Table of Exhibits:

Date	Notes/ Description	Exhibit number
20/6/2013	Cambridge Comprehensive Care Centre [CCC] Audit 2013	WITN3173005
20/11/2012	'The UKHCDO Audit Programme – A Guide for the Patient-Parent-Carer Auditor'	WITN3173006
20/11/2012	UK Haemophilia Centre Doctors Organisation [UKHCDO] Triennial Comprehensive Care Centre [CCC] Audit Programme 2012	WITN3173007
20/11/2012	Patient Satisfaction Survey Flyer	WITN3173008
18/10/2012	Patient Satisfaction Survey	WITN3173009
20/11/2012	UK Haemophilia Comprehensive Care Centre [CCC] Audit Proforma [Updated 20th November 2012]	WITN3173010

PAS