Witness Name: **Dr Gerard Dolan**
Statement No.: **WITN4031003**
Exhibits: **WITN4031004-WITN4031006**
Dated: 9TH Nov 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR GERARD DOLAN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 29 July 2020.

I, Dr Gerard Dolan, will say as follows: -

Section 1: Introduction

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

   My name is Gerard Dolan. My date of birth is GRO-C 1959. My address is GRO-C

   My professional qualifications are : MB ChB 1982 Glasgow University Medical School; FRCP (Edin); FRCP (London); FRCPath.

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. Please include an account of your work at the Trent Regional Transfusion Centre from November 1988 to May 1989.*

   My employment history is as follows:

   August 1982 to February 1983:

Junior House Officer, General Surgery, Southern General Hospital, Glasgow – care of surgical inpatients including emergency surgery cases.

February 1983 to August 1983:

Junior House Officer, General Medicine, Glasgow Royal Infirmary – care of general medical inpatients including emergency medical cases.

August 1983 to February 1984:

Senior House Officer, General Medicine, Royal Infirmary, Edinburgh – mainly ward based care of medical inpatients, limited outpatient work.

February 1984 to February 1985:

Senior House Officer, Haematology, Glasgow Royal Infirmary – most of this year was spent training in various aspects of haematology. I had no involvement in the care of patients with bleeding disorders during this year.

February 1985 to August 1987:

Registrar in Haematology, Glasgow Royal Infirmary. Most of this period was spent as a member of the team looking after patients with haematological malignancy. For a short period of time (I cannot remember exactly how long), I did a small number of supervised haemophilia clinics and provided very limited out of hours emergency care for haemophilia. I was not involved in the choice of therapy for haemophilia patients, this had been decided by the Haemophilia Directors and the Blood Bank issued factor concentrates.

August 1987 to September 1991:

Senior Registrar in Haematology to the Sheffield Hospitals. This was a training post and I rotated through the Haematology Units at the Royal Hallamshire Hospital, Sheffield Childrens' Hospital, Northern General Hospital and the Trent Regional Transfusion Service. My main duties at the Royal Hallamshire Hospital were the review of all diagnostic haematology work including blood films, bone marrow samples, coagulation investigations, acute blood transfusion issues. I worked with a team of junior doctors under the

supervision of the Haematology Consultants to provide clinical inpatient care to haematology patients, most of whom had haematological malignancy; I worked in outpatient clinics in general haematology, malignant haematology, haemophilia and bleeding disorders. I was a member of the team providing emergency care for all patients with haematological conditions including haemophilia.

Duties at the Children's hospital was very similar to the range of conditions at the Royal Hallamshire Hospital but for paediatric patients. This included children with haemophilia. Duties at the Northern General Hospital included the provision of diagnostic haematology, general haematology and malignant haematology services.

As part of the Senior Registrar Training Rotation, I spent approximately 6 months at the regional transfusion centre. My primary activity at this centre was learning about the various aspects of blood transfusion and preparing for the MRCPath examination. At the time, there was a great focus on blood donor selection and there was discussion on the changing exclusion criteria for blood donors with respect to the risk of HIV infection. I was part of the team providing transfusion advice to the hospitals in Trent region.

September 1991 to September 2015:

Consultant Haematologist, Queen's Medical Centre, Nottingham (later Nottingham University Hospitals). Queen's Medical Centre is a large teaching hospital but in 1991, the haematology service was not well developed. Adult Physicians and Paediatricians were responsible for supervising in-patient care of haematology patients, there were only two Consultant Haematologists and few junior doctors. I became jointly responsible, with one other Consultant who had worked there for more than 20 years for laboratory haematology including blood transfusion, malignant haematology, red cell disorders including sickle cell disease, the haemophilia service, the thrombosis and anticoagulation service, support for the paediatric haematology service. I was joint Haemophilia Centre Director for Nottingham from 1991 and became sole Centre Director from around 1993.

September 2015 until present:

Haemophilia Centre Director and Consultant Haematologist Guy's and St Thomas' NHS Trust, London. I am the lead Consultant for Haemophilia and am administrative lead for the South London Haemophilia Network. My clinical and administrative activities are mainly in providing care for individuals with bleeding disorders and thrombosis.

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.*

As Joint Haemophilia Centre Director for Nottingham, I became a member of the United Kingdom Haemophilia Centre Directors Organisation in 1991. Nottingham was recognised as a Comprehensive Care Centre after publication of HSG (93) 30 in 1994; I was the representative for Nottingham on the UKHCDO Advisory Committee.

I was elected to the Executive of UKHCDO, as Treasurer in 1997.

I was elected to the post of Secretary of UKHCDO in 2003

I was elected to the role of Vice-Chairman of UKHCDO in 2005.

I was elected to the role of Chairman of UKHCDO in 2011 and retained this role

until 2015.

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

I confirm, I have not given any evidence to any inquiries related to transfusion-transmitted infection, nor have I been involved in any criminal or civil litigation in relation to HIV, viral hepatitis or vCJD.

5. *The questions below focus, as appropriate, on your time as a Registrar in Haematology at Glasgow Royal Infirmary ("Glasgow") between 1985 and 1987, as Senior Registrar in Haematology at Sheffield University Hospitals ("Sheffield") between 1987 and 1991 and as Director of the Nottingham Haemophilia Centre ("the Nottingham Centre") from 1991 to 2015 and as Director of the Guy's and St Thomas' Haemophilia Centre ("the Guy's Centre") from 2015 onwards. Some questions focus on Glasgow and/or Sheffield, but if you have information concerning Nottingham relevant to the period or issue to which the question relates, please include that in your response.*

-

Section 2: Decisions and actions of the Centres at Glasgow, Sheffield and Nottingham and your decisions and actions

6. *In relation to your work in Glasgow as Registrar in Haematology please:*

a. describe your role and responsibilities and how they changed over time;

b. 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 blood or blood products;

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

As a Senior House Officer and Registrar at Glasgow Royal Infirmary (GRI), my duties included in-patient care of haematology patients, most of whom had

haematological malignancy; reviewing blood films; performing bone marrow diagnostic tests; managing anticoagulated patients; obstetric haematological issues; general haematology outpatient clinics. The haemophilia service at Glasgow Royal Infirmary had traditionally been provided by the University Department of Medicine and the haematology team were not involved in the care of these patients until around 1986.

I was briefly associated with the haemophilia unit around 1986. My involvement was mainly attending routine haemophilia clinics. I also provided some out of hours cover for emergency clinical issues. I was not involved in the testing and treatment of those patients with HIV infection or in the management or assessment of liver disease. I was not involved in choosing which factor concentrate to prescribe for patients. The treatment was stocked by and issued from the Blood bank at GRI after being prescribed by the clinician managing the situation.

The Haemophilia Service was led by Professor Charles Forbes (deceased) and Professor Gordon Lowe. They were the Haemophilia Directors and oversaw all aspects of the service.

7. *In relation to your work at Sheffield please:*

a. describe your role and responsibilities and how they changed over time;

b. 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 blood or blood products;

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

As a Senior Registrar to the Sheffield Hospitals, I rotated through the Royal Hallamshire Hospital, Sheffield Children's Hospital, Northern General Hospital and Trent Regional Transfusion Service.

Royal Hallamshire Hospital: I and one other senior registrar and two registrars were primarily involved in managing the inpatient haematology patients, most of whom had haematological malignancy but included other patients such as those with sickle cell disease and a small number of patients with bleeding disorders. I attended a number of out-patient clinics including haematological malignancy, myeloproliferative disorders, haemophilia, bleeding disorders and red cell disorders. We provided a consultative service to the other clinical services at the hospital and we were involved in reviewing blood films, performing bone marrow diagnostic tests, managing anticoagulated patients, and obstetric haematological issues.

Sheffield Children's Hospital: There was a small haematology clinical team. Duties related primarily to the inpatient and outpatient care of children with haematological disorders, mostly acute leukaemia. The hospital did look after children with haemophilia and there was a regular haemophilia clinic in which I was involved.

Northern General Hospital: I was one of a small team delivering care to patients with a wide range of haematological disorders but did not include the care of individuals with bleeding disorders.

Trent Regional Blood Transfusion Service: All Senior registrars in Trent region spent a period of their training at the regional transfusion service to gain experience in blood transfusion. My time there consisted mainly of receiving lectures and laboratory experience on the different aspects of blood transfusion. I was one of two senior registrars taking calls from blood donors, blood donor units and clinicians across the region. These queries were almost always discussed with the relevant Consultant for Blood Transfusion.

In Sheffield, as Senior registrar, I attended haemophilia clinics and was involved in assessing and treating acute clinical issues as well as managing inpatient care such as those patients undergoing surgery. The Haemophilia

service at the Royal Hallamshire hospitals had a longstanding research interest in non-A, non-B hepatitis (NANBH) in individuals with haemophilia and subsequently in HCV. I am unaware of any specific policy for managing these individuals but the testing and investigation of patients with potential liver disease was largely led by the research group including hepatologists and pathologists. Those patients infected by HIV had already been tested and identified by the time I arrived in Sheffield in 1987. The care of these individuals was primarily by the clinical haematology team with input from the relevant specialist including genitourinary specialists.

At Sheffield Children's Hospital there was a small haemophilia service and, as senior registrar, I attended most of these. I cannot recall what arrangements there were for managing children with or suspected as having HIV and HCV.

The director for the adult haemophilia service at the Royal Hallamshire Hospital was Professor Eric Preston and he was responsible for all key decisions about choice of treatment, testing and counselling of patients. He led a number of research initiatives on haemophilia and HIV/HCV but I was not involved in these.

Professor John Lilleyman was the lead for the paediatric haemophilia service and he was responsible for all key decisions about choice of treatment, testing and counselling of patients with haemophilia.

8. *In relation to your work at the Nottingham Centre please:*

a. describe the facilities, organisation, roles, functions and responsibilities of the Nottingham Centre during the time that you worked there and how they changed over time, and provide (if you can) an account of the history of the Nottingham Centre, its establishment and its activities during this time;

b. describe your role and responsibilities and how they changed over time;

c. 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 blood or blood products;

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

I took up my role as Consultant Haematologist in Nottingham in September 1991. I was one of two Consultant Haematologists. We were jointly responsible for leading the diagnostic haematology service, the adult haematological malignancy service, the general haematology service, the haemophilia service, consulting haematology service for the other clinical services in the hospital and support service for paediatric haematology. In 1991, the haemophilia centre was not a Comprehensive Care Centre and Nottingham, Leicester and Derby were linked to the Trent Regional Haemophilia Service in Sheffield.

There were meetings of the haemophilia centre directors in Sheffield where UKHCDO discussions were presented and there was discussion about treatment policies but I cannot recall details.

There had been little development of haemophilia services in Nottingham. There was a small and inadequate haemophilia centre. There was no haemophilia nurse, no physiotherapy service, no data manager, no psychologist, no social worker and no paediatric haematologist.

As Nottingham was not a regional haemophilia centre, I did not attend UKHCDO advisory meetings but I did attend the annual general meetings.

The concept of Comprehensive Care for Haemophilia was developed by UKHCDO and ratified by the department of Health in 1993 (HSG (93) (30); I used this document to argue for better services. In the years from 1991, I was able to appoint a Haemophilia Nurse Specialist, a data manager, a molecular biology scientist a social worker, clinical psychologist and a paediatric

haematologist. I also established joint clinics with orthopaedics and hepatology. Around 1994, Nottingham was recognised as a Comprehensive Care Centre for Haemophilia. The service improved further by establishing three nurse specialists, a further two paediatric haematologists, and two further colleagues specialising in bleeding and thrombotic disorders.

My colleagues and predecessor had developed a focus on malignant and red cell haematology and had no special interest in haemophilia. When I was appointed, I had very little time allocated in my job plan for haemophilia. It was clear to me that this was the part of our service that needed most attention and I was able, over time, to devote more time and recruit more colleagues to provide a better service.

When I arrived in Nottingham in 1991, only virucidally treated factor concentrates were prescribed. All of the patients had been previously tested for HIV and those that had tested positive were referred to the HIV service run by the genitourinary clinical service based at Nottingham City Hospital. Those patients attended outpatient clinics there and there was good dialogue between the haemophilia service and GU service. The GU team directed all treatment for HIV. The patients registered at the Nottingham Centre had been tested for hepatitis B and all eligible patients had been vaccinated. A major deficiency in the clinical services in Nottingham was that there was no dedicated hepatologist. There was a general physician who had some interest in gastroenterology and in some aspects of liver disease but there had been no real involvement in the assessment of individuals with haemophilia or other recipients of blood products. A senior lecturer in Virology, Professor Will Irving, had been recently appointed and had a special interest in Hepatitis C. The hepatitis antibody test had become available and Professor Irving had developed PCR testing for HCV viraemia. We were able to offer testing of the registered patients with bleeding disorders. The confirmation that a significant number of individuals with bleeding disorders and other groups of patients had been infected with HCV increased the momentum to establish a specialist hepatologist. Dr Stephen Ryder was appointed around 1993 and we established joint clinics for hepatitis and haemophilia. With the development of

the hepatitis team and new treatments for HCV, the patients were subsequently managed directly by the hepatology service

Dr Alec French (deceased) was my immediate predecessor in Nottingham. He had worked there for around 30 years and had taken the lead for the testing for HIV. Dr Chris Bignell was a Consultant in GU medicine who managed the patients with HIV. Dr Peter Toghill was a physician with an interest in some aspects of liver disease and who assessed some of the patients with HCV. Dr Stephen Ryder is Consultant Hepatologist who managed (and still manages) all the HCV infected patients.

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

I cannot remember the exact number of patients with bleeding disorders who were managed by the Glasgow and Sheffield service. In Nottingham, there were approximately 669 individuals with bleeding disorders of whom approximately 51 had severe haemophilia A or B.

10. *To the best of your knowledge, what policies were formulated at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? What if any involvement did you have in the formulation and application of these policies?*

I cannot remember what policies were formulated in Glasgow and Sheffield. I had no involvement in any policies. Regarding Nottingham: I cannot remember full details of what policies there were for factor concentrate purchase. There was a Trent Region NHS body responsible for setting prices and choice of products but I have no recollection of which policies they operated or how long this continued for. I was involved in selecting products from the approved list, as were the managers of the Pathology directorate and hospital finance department.

11. *Who had responsibility at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre for the selection and purchase of blood products, and what decisions were taken at each as to which products to purchase and use? In addressing this issue, please answer the following questions:*

a. How, and on what basis, were decisions made about the selection and purchase of blood products and how did those decisions change over time?

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

c. Where were the products sourced? From whom were they purchased?

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

e. What involvement did you have?

I do not have the knowledge, and/or did not have the necessary involvement, to be able to answer this question in respect of Glasgow and Sheffield.

Regarding Nottingham: There was a Trent Region NHS Body which arranged tenders and set prices for factor concentrates. There was very little choice and the prevailing principle was to use UK sourced plasma products where possible. Subsequently, the Department of Health, Deloitte and UKHCDO set up the UK National Tender and this was then administered by the Commercial Medicines Unit.

The principle had been to use the therapeutic products with the highest levels of safety. This changed with emerging evidence.

The products used in Nottingham were largely UK sourced from BPL. I cannot recall exact details.

From memory the key consideration was safety, rather than any commercial and/or financial consideration.

I was involved in choosing therapeutic products from the approved list, as was the manager from the pathology directorate and the hospital finance director. This was subsequently replaced by the UK national tender where allocations were assigned to each centre by the department of health and implemented by the East Midlands regional haemophilia committee.

12. *What products were used for treating patients at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre, over what period of time and for which categories of patients? How were decisions taken, at Glasgow, Sheffield and Nottingham, as to which products to use for individual patients? What involvement did you have in such decisions? To what extent were patients given a choice and/or involved in decisions as to which products to use?*

I am unable to answer this question in respect of Glasgow and Sheffield; I do not know which products were used or how decisions were made. I had no involvement in any decisions about choice of product and I do not know what choice patients had.

Regarding Nottingham: I cannot recall the details of how the use of factor concentrates evolved over time. In 1991, the predominant product for haemophilia A was 8Y made by BPL and for haemophilia B was 9A, also made by BPL. I remember a gradual change from intermediate purity plasma products to highly purified plasma products and subsequently to recombinant products under the national contract. I was involved in deciding which products. The limited choice of product was discussed with patients and followed the pattern described above.

13. *What was the relationship between (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre, and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?*

I have no knowledge of any relationship between the Glasgow, Sheffield and Nottingham centres and the pharmaceutical companies.

After 1991, I am not aware of any direct relationship. With the advent of recombinant factor concentrates and an expansion in the number of pharmaceutical companies, there were educational events for nurses and doctors sponsored by pharma. I do not believe that there was any influence on decisions as to which products to use.

14. *If the responsibility for the selection and purchase of blood products at Glasgow, Sheffield or the Nottingham Centre lay with an external organisation, please specify which organisation and provide as much information as you can about its decision-making.*

In relation to Glasgow and Sheffield, I have no knowledge of selection and purchase of factor concentrates.

Regarding Nottingham, my recollection is limited. I have little recollection of the processes involved in the selection and purchase of products before the advent of the national Contract. The Trent Region NHS body was involved in tenders and contracting. The hospital finance team was closely involved as was the Pathology directorate which managed the haemophilia service. I cannot remember specific details. Subsequently, the East Midlands Haemophilia Committee was involved and one major role of this committee was to ensure local delivery of the national Contract.

15. *What alternative treatments to factor concentrates were available for people with bleeding disorders?*

The main alternative to factor concentrates available to individuals with bleeding disorders is desmopressin but this is only effective for those with mild haemophilia A and some types of Von Willebrand disease (VWD).

For some individuals, cryoprecipitate was a potential alternative for haemophilia A and VWD, but this is not as effective and was not easily amenable to virucidal treatment. I always had access to prescription of virucidally inactivated therapy and cannot recall instances where cryoprecipitate was chosen over factor concentrate.

16. *What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at Glasgow and Sheffield? 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?*

Desmopressin has the advantage that it is not a blood product and it may be effective at boosting endogenous levels of FVIII and Von Willebrand Factor. It may cause unpleasant side effects in some patients and should only be used with great caution in individuals with hypertension and cardiovascular disease.

Cryoprecipitate is a weak concentrate of FVIII and Von Willebrand Factor. It has the advantage that it is prepared from much smaller pools of plasma than lyophilised concentrate. The disadvantage is that it cannot be used for home treatment; it must be thawed before use and this causes a delay in treatment, it is very difficult to achieve the higher levels of FVIII and VWF than can be achieved with concentrates and was initially and for a long time not suitable for virucidal treatment.

I cannot remember what the policy was for use of cryoprecipitate in Glasgow.

When I started work in Sheffield, all factor concentrates were virucidally treated. I do not know what the policy was for the use of cryoprecipitate before 1987. I cannot recall whether patients were treated with cryoprecipitate in Sheffield. DDAVP was used for the treatment of mild haemophilia A and VWD.

17. *What was the policy and approach at Glasgow and Sheffield as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?*

a. Did that policy and approach change over time and if so how?

b. How, if at all, was the policy and approach informed by discussions with external parties?

I do not know what the policy was for the use of cryoprecipitate in Glasgow. I do not know what the policy was for the use of cryoprecipitate in Sheffield before 1987 and cannot recall if there was an official policy after that date.

18. *What was the policy and approach at Glasgow and Sheffield in relation to home treatment? Did the policy and approach change over time and if so how?*

I do not know what the policy was for home treatment in Glasgow. I cannot remember what the policy was for home treatment in Sheffield before 1987. I cannot remember what the policy was between 1987 and 1991.

19. *What was the policy and approach at Glasgow and Sheffield in relation to prophylactic treatment? Did the policy and approach change over time and if so how?*

I do not know what the policy was for prophylaxis in Glasgow or Sheffield.

20. *What was the policy and approach at Glasgow and Sheffield in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?*

The haemophilia service in Glasgow did not manage children with haemophilia. The haemophilia centre based at Sheffield Children's hospital was responsible for all children with haemophilia. I do not know what the policy was with respect to factor concentrates before 1987. The same factor concentrates used by the adult service were used in the children's hospital and, from 1987, were virucidally treated.

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

I cannot remember what treatment was given to patients with mild and moderate bleeding disorders in Glasgow.

Desmopressin (DDAVP) was used for treatment of patients with mild haemophilia A and some types of VWD in Sheffield.

Desmopressin was used, where appropriate and possible for the management of adults and children with mild haemophilia A and VWD.

22. *What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre in consequence of the use of blood products?*

I do not know any detail of which infectious agents were transmitted to patients in Glasgow.

Apart from HIV, HBV and HCV, I do not know whether any patient in Sheffield was infected by any other transfusion transmitted infection.

When variant CJD emerged in the UK, and BPL and NBTS informed hospitals of potentially contaminated blood products, the team in Nottingham identified potential recipients of such products but there was no evidence of actual infection. I am unaware of any other infections apart from HIV, HBV and HCV.

Section 3: Knowledge of, and response to, risk

23. *When you began work as a Registrar in Haematology at Glasgow, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?*

Until I began my career in Haematology, I had only fairly basic education in transfusion transmitted infection. As part of the training in blood transfusion, I was aware of screening of blood and blood donors for potential infection. In the 1980s there was a great deal of discussion on emerging evidence of what was to become known as HIV – departmental discussion / hospital grand ward rounds. This was the main source of information as well as publications. I cannot recall what specific discussion there was around the risk of HIV for haemophilia patients. I estimate I spent about three months with some limited attachment to the haemophilia unit. I was aware of the policy for vaccinating patients against hepatitis B. I cannot recall discussion about NANBH and the hepatitis C virus had only just been identified at that time.

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

I cannot remember what advisory and decision making structures were in places during my time in Glasgow or Sheffield.

25. *What was your understanding of the relative risks of infection from the use of commercially supplied blood products and the use of NHS blood products?*

I estimate that I became aware of a potential increased risk of HIV infection with commercially sourced concentrates compared to BTS derived concentrates during my training in Sheffield. There was a great deal of discussion about the emerging impact of HIV in haemophilia during attachments to the haemophilia service on my Senior Registrar rotation. This discussion concerned the historical situation since, by 1987, only virucidally treated products were used.

26. *When you began work as a Registrar in Haematology at Glasgow, what was your knowledge and understanding of the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis) from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?*

Through the beginning of my training in haematology, I was aware of the risk of hepatitis B through blood products. I cannot remember when I first became aware on NANBH and cannot recall any discussion with the haemophilia service on this subject. My attachment to the haemophilia service was quite limited.

27. *What, if any, further enquiries and/or investigations did you carry out or cause to be carried out or was, to your knowledge, carried out in the Centres in which you worked in respect of the risks of the transmission of hepatitis? What information was obtained as a result?*

As a junior and relatively minor contributor to the haemophilia service in Glasgow, I was not involved in decisions about which therapeutic products should be used in haemophilia and any decisions about whether patients required treatment were discussed with senior colleagues. I was not involved in testing for or assessing hepatitis.

In Sheffield, there was a very active interest in NANBH and HCV. Patients were reviewed by a Consultant Hepatologist and there was a pathologist with an interest in NANBH. When HCV was identified, patients were investigated. This was largely the responsibility of the academic team within haematology. Sheffield made a major contribution to the understanding of HCV in Haemophilia.

28. *What, if any, actions did you, or the Centres at which you worked, take to reduce the risk to patients of being infected with hepatitis (of any kind)?*

In all the Centres I was involved in, there was a consistent policy for reducing the risk HBV through vaccination of individuals with the risk of requiring pooled plasma products or those individuals likely to require multiple units of blood over time (e.g. in thalassaemia). In Nottingham, when reports of HAV transmission through factor concentrates were published, all patients still being treated with blood products were vaccinated against HAV.

In Sheffield and Nottingham, where appropriate and safe, individuals with mild haemophilia A and VWD were treated with DDAVP rather than plasma derived factor concentrates.

In Sheffield and Nottingham, all patients were prescribed plasma derived concentrates that had undergone virucidal treatment.

In Nottingham, dual inactivated therapeutic products were prescribed when they became licensed and when recombinant products were approved for use; all patients were offered these.

29. *What liver function tests and/or other forms of monitoring were undertaken at Glasgow, at Sheffield and at the Nottingham Centre and how did that change over time? What was the purpose of such testing and monitoring?*

I cannot remember what the practice of LFT testing was in Glasgow. In Sheffield and Nottingham, LFT testing was part of the routine assessment of all patients and was part of the specific assessment for progress of liver disease in patients with hepatitis.

30. *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?*

I understood that HBV was common in patients with haemophilia who had received plasma derived factor concentrates. I was aware that the majority of patients cleared infection but that a small percentage developed chronic infection that could result in serious liver disease and liver cancer.

I understood that more than 90% of patients receiving plasma derived concentrate became infected with HCV and that this was responsible for the vast majority of cases of NANBH. I understood that NANBH had been thought to be a relatively benign condition, that this had been wrong, and that HCV was responsible for serious liver disease in haemophilia including cirrhosis and hepatocellular carcinoma.

31. *Did you take steps to ensure that patients were informed and educated about the risks of hepatitis? If so, what steps?*

I do not know what information was given to patients concerning the risks of hepatitis. By the time I moved to Sheffield and subsequently Nottingham and London, all therapeutic products that were used for haemophilia and other major bleeding disorders had been greatly improved through donor testing, donor exclusion and virucidal treatment. I do not know what information was given to patients concerning the risks of hepatitis before 1987 in Sheffield and before 1991 in Nottingham.

Patients continued to be vaccinated against HBV and HAV until the adoption of recombinant factor concentrates for haemophilia A and B. The reasons for continued vaccination were explained in clinic.

For the Glasgow patients, my involvement in the service was largely as an educational experience and I was not involved in decisions on which therapeutic products or on counselling or testing of patients for hepatitis.

32. *Do you consider that your decisions and actions, and the steps taken at Glasgow and/or Sheffield, 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.*

In Glasgow, I had a very limited role.

In Sheffield, by the time I started work, all patients were treated with products that had been shown to be safe from the risk of hepatitis.

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

In Glasgow, I had a very limited role.

In Sheffield, by the time I started work, all patients were treated with products that had the benefit of improved donor plasma safety and virucidal treatment including solvent detergent heat treatment.

34. *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?*

It is very difficult to answer this question since I was not involved in any discussion regarding the options available to clinicians before 1987.

Section 4: Treatment of patients

35. *What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre 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.*

Glasgow: As far as I can remember, I did not initiate new treatment for patients with haemophilia during my limited attachment to the haemophilia service in Glasgow.

Sheffield: To my knowledge, only factor concentrates that had been subject to virucidal treatment were used for patients with haemophilia. I cannot remember what written information was given to patients with regard to potential risk with these products.

Nottingham: In the early 1990s in Nottingham, the only plasma-derived therapeutic products that were prescribed were heat treated, solvent detergent. As far as I can remember there was a discussion with patients about the characteristics of any new therapeutic agent and the reasons for any change in treatment. Initiation of therapy for newly diagnosed children with haemophilia was managed through the paediatric haemophilia clinic led by a paediatric haematologist and paediatrician. I cannot remember what written information was given to patients.

36. *What information, if any, did you provide to your patients about the risks of chronic and/or serious liver disease?*

Glasgow: I do not know what information was given to patients about the risk of liver disease.

Sheffield: As far as I am aware, only products that had been shown to eliminate any risk of HCV were prescribed during this time.

Nottingham: There was evidence by this time that the plasma derived products prescribed in Nottingham were safe from the risk on lipid-enveloped viral infection.

Patients with HBV and HCV infection were counselled about the steps that could be taken to reduce the risk of serious liver disease such as modifying alcohol intake. Detailed counselling was taken over by Dr Stephen Ryder, Consultant Hepatologist, from around 1994.

37. *What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients about alternatives to treatment with factor concentrates? Please detail whether, and if so, how this changed over time.*

Glasgow: I am unaware of what discussions took place.

Sheffield: For patients with mild haemophilia A and Von Willebrand disease, DDAVP was discussed as an alternative to factor concentrate. I cannot remember if any options were discussed with patients with severe disease, but, as discussed above, by 1987, only virucidally treated products were prescribed.

Nottingham: Only virucidally treated products and subsequently recombinant factor concentrates were prescribed for severe patients. DDAVP was prescribed where appropriate.

38. *Were you involved in the process of arranging for patients at Glasgow to be tested for HIV and/or in the process of informing them of their diagnosis? If so please provide full details.*

I was not involved in testing patients for HIV in Glasgow.

39. *Were patients at Glasgow and at Sheffield who were infected with NANB hepatitis informed of their infection and if so, how and by whom? What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management? What involvement did you have in this process?*

I do not know what the process was for informing and assessing patients for NANBH in Glasgow.

In Sheffield there was a very active interest in NANBH and this was primarily led by Professor Eric Preston and Dr David Triger. Through their research interest in NANBH, I believe Professor Charles Hay and Professor Mike Makris were involved in this process too. I did not have any role in this.

40. *When did you begin testing patients for HCV? How, when and by whom were patients informed of their diagnosis of HCV? Were they told in person, by letter or by phone? What involvement did you have in this process?*

When I arrived in Nottingham in 1991, I noted that some patients had been tested for antibodies against HCV. I cannot recall when they had been tested or how many had been tested. I repeated testing; I and the Haemophilia team began testing HCV antibody positive patients for evidence of HCV viraemia in 1992. The reasons for the testing were explained verbally and consent noted in the case records. Results were explained in person by myself or the haemophilia registrar who had a special interest in HCV. Subsequently, further testing for HCV was explained by a Consultant Hepatologist.

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

Glasgow: I do not know what information was given to patients.

Sheffield: I cannot recall what specific information was given to patients.

Nottingham: PCR testing for HCV Ab positive patients started around 1992 in Nottingham. Hepatology services were not well established in Nottingham. Patients were counselled and consented for testing for HCV viraemia and results discussed. The patients were counselled about possible synergism with alcohol. The possibility of response to interferon was discussed. HIV positive patients were already under the care of the GU service in Nottingham and they undertook assessment and discussion about HCV. Some patients were referred to one of the general physicians who had some interest in

hepatology for assessment. Patients had regular liver function testing, ultrasound and clinical examination and were all managed by Dr Stephen Ryder and his team when the hepatology service was established around 1994. Under his supervision, patients were offered eradication therapy as it evolved.

42. *How many patients at the Nottingham Centre were infected with HCV?*

I estimate there were about 30 patients with bleeding disorders who had been infected by HCV in Nottingham.

43. *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.*

Glasgow: I was not involved in this process.

Sheffield: I was not involved in testing and informing patients in Sheffield.

Nottingham: By the time I arrived in Nottingham, all patients had been screened for HIV and were under the care of the HIV service run by the paediatricians for children and the GU service for adults. I do not know what the testing process was or if there were any delays in informing patients. Treatment options were discussed by paediatrics and the GU team.

By the time I arrived in Nottingham, some patients had been tested for HCV and I and my colleagues completed this process. We had the ability fairly early on to undertake PCR testing for viraemia. I am unaware of delay in presenting patients with results of testing.

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

The testing and assessment for HIV, HBV, NANBH and HCV was undertaken by a number of different health care teams in Nottingham. This included

paediatricians, GU physicians, general physicians and haematologists. I do not know for certain what specific discussion took place with regard to public health implications in all cases at the time of testing and discussion of results. At haemophilia clinics, it was standard practice to discuss safe sex and the avoidance of other potential risks such as piercings and tattoos.

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

In Sheffield and Nottingham, it was part of the discussion at clinic visits to discuss the value of vaccination against HBV and hepatitis A.

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

Through the GU clinic visits, the hepatology clinic visits and the haemophilia clinic visits, there was regular discussion about the potential risk to others through unprotected sex, procedures such as tattoos and piercings, and sharing of needles.

47. What actions or decisions were taken at any of the hospitals at which you worked to trace patients who may have been infected through the use of blood or blood products?

I do not know what the process was at Glasgow or Sheffield.

Nottingham: There was regular review of our local register and all patients were reviewed in clinic. There had been a review of all potential patients at risk of having received contaminated products at the time HIV testing was introduced – this was done in conjunction between my predecessors and UKHCDO. I was not involved in this process.

For HCV we reviewed our register annually and we tried to track any patients who had been lost to follow up - through letters to the patients, their primary care team, and through checking with UKHCDO regarding any possible re-registration with other centres.

48. *How often were blood samples taken from patients attending (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre and for what purposes? What*

information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so how and where?

I cannot remember how often blood samples were taken from patients in Glasgow or Sheffield.

In Nottingham, adults with severe haemophilia were seen for routine clinic assessment 2-3 times a year. As far as I recall, blood was taken twice a year. A general health check included bloods for full count, renal function and liver function tests. A trough FVIII or FIX was taken at least annually as were post vaccination antibody titres for HBV and HAV. HCV PCR testing and HBV viraemia levels were taken for those patients undergoing treatment. CD4 counts and HIV viraemia levels were assessed as directed by the GU team.

When I met patients for the first time, I would confirm the results of HIV testing, HCV testing, HBV testing and vaccination status where appropriate. Initially consent for HIV tests was recorded in the case notes as was consent for HCV PCR testing.

I believe it was our practice to discuss which blood tests were being requested.

Results were shared in subsequent clinic visits by the haemophilia, hepatology or HIV teams.

As far as I can recall, the only samples stored were those used for genetic testing and for which the patients did give written consent; or samples were stored for verification of coagulation parameters and for which patients did not usually give formal, written consent.

A special form was used for genetic samples. They were not formally consented for other blood tests though they were given an explanation as to the purpose of testing.

This remains the case today for haemophilic and non-haemophilic patients.

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

For patients already established on treatment with factor concentrates, it was not standard practice to consent patients for each treatment with factor concentrates. For PUPs there was an explanation as to why factor concentrates were needed and the nature of the therapeutic agent. Implied consent was assumed. The patients came to the hospital either as an emergency or for a scheduled appointment for treatment; the preparation of the factor was demonstrated so that they could subsequently reconstitute the treatment in their own home and very often, the patient or their parents administered the treatment themselves under supervision. Obtaining formal written consent was not a standard policy and, as for many hospital-based treatments, is still not a standard of care.

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

I was not directly involved in testing patients for HIV and HCV in Glasgow.

By the time I arrived in Sheffield, all patients had been tested for HIV and were being tested for HCV through the research programme for liver disease in haemophilia. I was not involved in this.

By the time I arrived in Nottingham, All patients had already been tested for HIV, HBV and HCV. Any further testing was usually confirmatory or for new patients moving into the area. Consent was recorded in the case notes.

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

I cannot remember looking after PUPs in Glasgow. Children were not treated at GRI.

I am likely to have been involved in the care of PUPs in Sheffield: either infants at the Children's Hospital or adults with milder bleeding disorders. The first use of any factor concentrate was always discussed and agreed with the Consultants. Only virally inactivated products were used where possible and there was a principle of trying to avoid exposure if possible – either through considering DDAVP if appropriate or even avoiding unnecessary surgery (e.g. routine circumcision).

In Nottingham, only virally inactivated products were used to treat PUPs. All PUPs were vaccinated against HAV and HBV. I started prescribing recombinant factor concentrates for PUPs soon after they were available for use (around 1996) and before formal approval was granted nationally.

52. *How was the care and treatment of patients with HIV/AIDS managed at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre? In particular:*

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

b. What treatment options were offered over the years 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?

I cannot remember what the arrangements were for managing patients with HIV/AIDS in Glasgow or Sheffield.

In Nottingham, by 1991, all HIV positive patients were managed by the GU physicians or paediatricians. All patients in Nottingham were under the care of specialist teams by 1991 and remained so.

HIV care was directed by the specialist teams. The specialist teams managed all aspects of antiretroviral therapy. All monitoring and follow up was directed by the specialist teams.

53. *How was the care and treatment of patients with HBV managed at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre? In particular:*

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

b. What treatment options were offered over the years?

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

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

I cannot remember what the arrangements were for managing HBV in Glasgow or Sheffield.

All haemophilia patients with viral hepatitis were managed by the hepatology and haemophilia teams.

There were a small number of patients in Nottingham with chronic HBV infection. Initially these patients were referred to the infectious disease team or gastroenterology teams. By 1994, all were managed directly by the newly established hepatology team. The hepatology team directed assessment, treatment and monitoring of HBV positive patients.

54. *How was the care and treatment of patients with NANB hepatitis managed at (a) Glasgow and (b) Sheffield? 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 NANB hepatitis?

I cannot remember what the arrangements were for managing NANBH in Glasgow.

All haemophilia patients with viral hepatitis were managed by the hepatology and haemophilia teams. I cannot remember details of which treatments were offered in Sheffield.

By 1991, all patients had been tested for HCV and were managed as viral hepatitis rather than NANBH.

55. *How was the care and treatment of patients with HCV managed at the Nottingham Centre? In particular:*

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

b. What treatment options were offered over the years? When did you begin to treat patients with interferon?

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 HCV?

The lack of formal hepatology input to patients with NANBH and subsequently shown to have HCV liver disease was one of the most pressing issues I encountered in Nottingham in 1991. I and the team began systematic assessment through clinical examination, ultrasound and liver function testing. Any patients causing concern were referred to gastroenterology or infectious disease specialists. Coinfected patients were initially managed by the GU

team. I lobbied within the hospital and at district level about this lack of specialist hepatology service and this accelerated the appointment of a Consultant Hepatologist who took over the management of all patients from 1994.

Patients were offered interferon when it was the standard of care for HCV in the hope that it may eradicate infection or slow down the progression of liver disease.

Subsequently patients were offered interferon and ribavirin – this was directed by the hepatology team as were all other treatments.

The patients all had detailed discussion regarding the potential benefits and risks of each treatment.

Follow up was arranged initially through the haemophilia team and subsequently by the hepatology team.

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

I did not manage children with haemophilia in Glasgow. There was a separate Children's Haemophilia Service based at the Royal Hospital for Sick Children.

In Sheffield, children with HIV and HCV were referred to the paediatric physicians and were managed by them.

In Nottingham, the children with HIV and HCV were managed by the paediatric physicians with whom there was close liaison with the haematology service.

The clinical teams managing children were different for those managing adults.

57. *What if any involvement did you and/or colleagues at the Centres at which you worked have with any clinical trials in relation to treatments for HIV and HCV?*

I do not know if there were any clinical trials of treatment for HIV in Glasgow.

I cannot remember if there were clinical trials of therapy for HIV in Sheffield. There was a major research interest in NANBH and HCV in Sheffield led by Professor Eric Preston.

I was not involved in HIV trials in Nottingham. I and Professor Will Irving were interested in patterns of viraemia in patients with haemophilia. I was not directly involved in clinical trials of therapy for HIV and for HCV.

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

In 1991 there was very little resource for patients infected through blood products. There was access to counselling through the district HIV service and this provided some support to those infected by HIV and this arrangement had been established around the time of testing patients and before I arrived in Nottingham. I was able to establish a post of Clinical Nurse Specialist for Haemophilia by 1992 and she was a major boost to the service and for the support of patients and their families. Through the district AIDS budget we were successful in appointing a clinical psychologist who worked with patients and their families and we also established a specific social worker for all patients with haemophilia.

59. *Did any of the centres at which you worked receive funding from the Department of Health and Social Security or from any other source to help with the counselling of patients infected with HIV?*

I cannot remember where the funding came from for the HIV counselling service.

The psychologist was appointed from Nottingham District Health Authority and from Haemophilia department charitable funds.

The social worker and nurse specialist were funded by the district health authority.

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

I cannot remember any major difficulty in obtaining funding for treating patients with HIV and HCV.

61. *Please provide (to the extent that you are able to from your own knowledge) a chronological account of the introduction of recombinant products in the UK. You may be assisted by consideration of the various UKHCDO minutes enclosed with this letter.*

Recombinant FVIII was first licensed in the United Kingdom around 1993. There was no reimbursement process for funding the use of recombinant FVIII in England until 2003. I and my colleagues in Nottingham anticipated that approval would eventually be given for the use of recombinant FVIII and started prescribing it for PUPs from around 1995. The use was initially confined to infants who had not previously received any factor concentrate and those with mild haemophilia A who had not been exposed. Recombinant FIX concentrates were licensed later in 1997.

The use of recombinant factor concentrates for all individuals with haemophilia A or B was eventually agreed in 2003, and in Nottingham there was a progressive switch from plasma derived factor concentrates to recombinant.

62. *Please explain your involvement, and that of UKHCDO, with efforts to obtain recombinant blood products for patients with haemophilia. What difficulties were encountered and why? You may wish to consider the enclosed LOTH0000089_026 letter from Dr Waugh to colleagues dated 24 February 1998 [LOTH0000089_026] and email from Professor Hill to Richard Gutowski dated 4 August 2003 [HCDO0000244_087].*

Recombinant FVIII was licensed in the UK around 1993 and the development of recombinant factor concentrates was a triumph in technology driven by the need to provide safe factor concentrates for individuals with haemophilia. In 1996, in its review of therapeutic products available for treating haemophilia,

UKHCDO clearly noted that recombinant factor concentrates were safer than plasma derived with respect to transfusion transmitted infection, and raised concern about future emerging infections. This was published around 1996 from work done by a UKHCDO task force of which I was a member. Under chairmanship of Professor Christopher Ludlam, negotiations between UKHCDO and the departments of health in the UK sought authorisation to offer recombinant products to persons with haemophilia. I cannot remember when negotiations actually started but from the minutes sent by the Inquiry, there were meetings from 1998, and this topic of the request (to be able to prescribe recombinant factor concentrates) remained on the table for advisory committee meetings and meetings with the departments of health. A major issue was that recombinant factor concentrates were considerably more expensive than plasma derived concentrates. The departments of health in Scotland and Wales accepted the case for recombinant concentrates from 1998 but English approval did not come until 2003. The final decision to fund recombinant products came in the light of the information that UK haemophilic individuals may have been exposed to vCJD through the use of blood products.

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

In my view recombinant factor concentrates should have been made available from the publication of UKHCDO guidelines on therapeutic products in 1996.

64. *When were recombinant products available to patients (and which categories of patients) treated at the Nottingham Centre?*

Recombinant factor concentrates were introduced in Nottingham around 1995, initially for PUPs, and when the agreement for reimbursement was agreed in 2003, all patients were switched in line with the roll out programme devised by the department of health.

65. *Please list all research studies that you were involved with during your time at Glasgow, Sheffield and Nottingham that could be relevant to the Inquiry's Terms of Reference, and please:*

a. Describe the purpose of the research.

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

c. Explain what your involvement was.

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

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

f. State the number of patients involved.

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

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

I was not involved in any research in the area of haemophilia or blood transfusion in Glasgow or Sheffield.

Nottingham and subsequently:-

Interaction of hepatitis B and hepatitis C infection in haemophilia

Hanley JP, Dolan G, Day S, Skidmore SJ, Irving WL. Br J Haematol. 1993 Nov;85(3):611-2.

This study examined the potential of hepatitis B and C viruses to interfere with each other's replication in co-infected patients with haemophilia. Consent was given by participants for testing and study. I was involved in the design, review of results and writing. No other body was involved. The study was funded by a grant from Queens Medical Centre. This study involved 60 patients. The study was discussed with patients in clinic and consent obtained.

Hepatitis C virus infection in multi-transfused children with haematological malignancy

Myers B, Irving W, Hollingsworth R, Readett D, Lilleyman JS, Dolan G, Br J Haematol. 1995 Oct;91(2):480-2

The study examined potential exposure to HCV in children with haematological malignancy and who required multiple exposure to blood and blood products. I cannot remember the exact details of how consent was obtained but the study was presented to the research and ethics committees of both Queens Medical Centre Nottingham and Sheffield Childrens Hospital. Both bodies required informed consent. I was involved in the design, review of results and writing. No other body was involved. The study was funded by a grant from Queens Medical Centre. This study involved 98 patients. I cannot remember for certain how patients were consented for this study.

European study on orthopaedic status of haemophilia patients with inhibitors

Morfini M, Haya S, Tagariello G, Pollmann H, Quintana M, Siegmund B, Stieltjes N, Dolan G, Tusell J. Haemophilia. 2007 Sep;13(5):606-12

This was a collaborative international study assessing the burden of joint disease in patients with haemophilia A and B with and without inhibitors. This was a formal international study and necessitated informed consent from study participants. I was involved in the review of the results and writing. The study sponsor was Novonordisk. The study was funded by Novonordisk. This study involved 79 patients. The study was discussed with patients in clinic and consent obtained.

The risk of variant Creutzfeldt-Jakob disease among UK patients with bleeding disorders, known to have received potentially contaminated plasma products

Zaman SM, Hill FG, Palmer B, Millar CM, Bone A, Molesworth AM, Connor N, Lee CA, Dolan G, Wilde JT, Gill ON, Makris M. Haemophilia. 2011 Nov;17(6):931-7

This study examined the data on potential exposure to vCJD through blood products. This study examined data from the National Haemophilia Database

annual returns and was covered by the agreement for collection and use of anonymised patient data. I was involved in review of the data and writing. This was a collaborative study between UKHCDO and Department of Health. The study was funded by the Katherine Dormandy Trust, Department of Health and UKHCDO. This study involved 787 patients. Consent was obtained through the registration process for the National Haemophilia Database.

Risk reduction strategies for variant Creutzfeldt-Jakob disease transmission by UK plasma products and their impact on patients with inherited bleeding disorders

Millar CM, Connor N, Dolan G, Lee CA, Makris M, Wilde J, Winter M, Ironside JW, Gill N, Hill FG. Haemophilia. 2010 Mar;16(2):305-15

This study examined the impact on patients as a result of measures introduced for reducing the risk of vCJD. This study examined data from the National Haemophilia Database annual returns and was covered by the agreement for collection and use of anonymised patient data. I was involved in review of the data and writing. This was a collaborative study between UKHCDO and Department of Health. The study was funded by the Katherine Dormandy Trust, Department of Health and UKHCDO. This study involved 787 patients. Consent was obtained through the registration process for the National Haemophilia Database.

Acquired haemophilia A in the United Kingdom: a 2-year national surveillance study by the United Kingdom Haemophilia Centre Doctors' Organisation

Collins PW, Hirsch S, Baglin TP, Dolan G, Hanley J, Makris M, Keeling DM, Liesner R, Brown SA, Hay CR; UK Haemophilia Centre Doctors' Organisation. Blood. 2007 Mar 1;109(5):1870-7

This was an observational study examining the outcomes of patients with acquired haemophilia in the UK. This study examined data from the National Haemophilia Database annual returns and was covered by the agreement for collection and use of anonymised patient data. I was involved in review of the

data and writing. No other body was involved. The study was funded by UKHCDO. This study involved 172 patients. Consent was obtained through the registration process for the National Haemophilia Database.

Use of the UKHCDO Database for a post marketing surveillance study of different doses of recombinant factor VIIa in haemophilia

Hay CRM, Sharpe T, Dolan G; UKHCDO. Haemophilia. 2017 May;23(3):376-382

This study examined the outcomes of different doses of recombinant factor VIII on bleeding patterns in patients with acquired haemophilia and haemophilia A and inhibitors. This study examined data from the National Haemophilia Database annual returns and was covered by the agreement for collection and use of anonymised patient data. I was involved in design review of data and writing. This was a pharmacovigilance study and Novonordisk was involved in the design of the study. The study was funded by Novonordisk. This study involved 98 patients. Consent was obtained through the registration process for the National Haemophilia Database.

European retrospective study of real-life haemophilia treatment

Berntorp E, Dolan G, Hay C, Linari S, Santagostino E, Tosetto A, Castaman G, Álvarez-Román MT, Parra Lopez R, Oldenburg J, Albert T, Scholz U, Holmström M, Schved JF, Trossaërt M, Hermans C, Boban A, Ludlam C, Lethagen S. Haemophilia. 2017 Jan;23(1):105-114

An international collaborative study using register data looking at treatment patterns for haemophilia across Europe. This study examined data from the National Haemophilia Database annual returns and was covered by the agreement for collection and use of anonymised patient data. I was involved in the design, review of results and writing of this study. The study involved anonymised data from centres across Europe. The study was funded by SOBI. This study involved 2058 patients. Consent was obtained through the registration process for the National Haemophilia Database.

66. *Please provide the same details in relation to any epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.*

See reply to 65.

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

The details of consent are given in the answer to 65. For studies involving the National Haemophilia Database, registered patients gave consent for collection of data for NHS commissioning and they had written information about how anonymised data could be used for research purposes. There were posters in the haemophilia centres and updated information was provided by leaflet produced by the National Haemophilia Database. Patients were able to opt of the use of their data for research purposes but if they did not use this opt out, their data could be used under the conditions of the Data Protection Act. For other studies, not involving NHD, informed consent was obtained for each individual study.

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

See above.

69. *Was patient data (anonymised, de-identified or otherwise) shared with third parties (and if so, who) without their express and informed consent? If so how, and why did this occur, and what information was provided to whom?*

Anonymised, aggregated patient data for pharmacovigilance studies were shared with the sponsoring pharmaceutical agency. Consent was implied through the registration process by which data collection was explained and consent for ongoing research obtained. For specific clinical trials, there was a rigorous informed consent process overseen by individual Research and Ethics Committees.

70. The questions above have focused on the care and treatment of patients with bleeding disorders. In your witness statement WITN4031001 dated 22 April 2020, you stated that when you were a Consultant Haematologist in Nottingham you were responsible for blood transfusion and malignant haematology.

a. Over what period of time were you the hospital haematologist responsible for the blood transfusion and/or responsible for patients with haematological malignancy? Please provide details of your role and responsibilities in this capacity.

b. How frequently (approximately) did you speak to patients about the risks of blood transfusion and/or the risks of blood products (other than products used in the treatment of patients with bleeding disorders) and in what kinds of circumstances?

c. What (if any) information did you typically provide to patients about the risks of infection from transfusion?

d. What (if any) information did you typically provide to patients about the risks of infection from blood products (other than products used in the treatment of patients with bleeding disorders)?

e. What discussions did you have with colleagues about the risks of transfusion?

f. Who was responsible for providing information to patients about the risks of infection from transfusion – the treating clinicians, you as haematologist responsible for blood transfusion or some other person?

Responsibility for the blood bank was part of my role as Consultant Haematologist from 1991 until around 1994 when we appointed a Consultant Haematologist with a special interest in Blood Transfusion. My role was to work with the Biomedical Scientists to supervise the function of the blood bank, to ensure management of blood stocks, to screen requests for blood products, to manage incidents related to blood transfusion and to liaise with

clinicians throughout the hospital regarding safe transfusion. This role was subsequently taken over by the Hospital Transfusion Committee.

I jointly managed patients with malignant haematological conditions from 1991 until around 2000. In this role, I was involved in the diagnosis and treatment of patients with a range of malignant haematological conditions.

For patients with haematological problems and who required transfusion of blood or blood components, I or a member of the team explained the reasons why transfusion was recommended. I cannot remember when the viral safety of blood was specifically discussed.

I cannot remember what information was given to patients about the risk of infection from transfusion at that time.

By 1991, blood components were only released from the blood bank after discussion with the relevant clinical team regarding the benefits versus risks. Large pool concentrates were rarely used in patients who did not have congenital bleeding disorders and was usually in the form of prothrombin complex concentrates for emergency reversal of warfarin therapy.

I cannot remember exact details I had with colleagues regarding risks of transfusion. The person responsible for providing information directly to patients regarding the risks of transfusion was the prescribing physician.

71. *What was the policy at (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre as regards to recording information on death certificates when a patient had been infected with HIV or hepatitis?*

Glasgow: I do not know what the policy was.

Sheffield: I cannot remember what the policy was.

Nottingham: I cannot remember if there was a specific policy.

72. *What were the retention policies of (a) Glasgow, (b) Sheffield and (c) the Nottingham Centre in relation to medical records during the time you were practising there?*

Glasgow: I do not know what the policy was.

Sheffield: I do not know what the policy was.

Nottingham: I cannot remember what the exact policy was; this policy did change over time.

73. *In your statement of WITN4031001, you stated in paragraph 10 that you remembered that there had been "a significant issue with case records" when you first started in Nottingham. Please explain what the issue was, how it arose and what steps, if any, you and/or others at the Nottingham centre, took to address the issue.*

When I arrived in Nottingham in 1991, the responsibility for the local register had been delegated to the biomedical scientists in the coagulation laboratory. The case records were part of the general hospital records though there appeared to be some paper records in the laboratory. After appointment of the clinical nurse specialist I was able to secure funding for a haemophilia service secretary and administrator, and over the next few years, working with UKHCDO, was able to organise the register, case records and documentation properly.

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

In Nottingham, there were separate case records for the patients with bleeding disorders. The files were located in the haemophilia office at Nottingham University Hospital.

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

I did not keep any information about patients at home or anywhere else.

Section 5: UKHCDO

76. *Please describe your involvement with UKHCDO (including any of its working parties, committees or groups), including your periods as Treasurer, Secretary and Chair.*

As Joint Haemophilia Centre Director for Nottingham, I became a member of the United Kingdom Haemophilia Centre Directors Organisation in 1991.

After Nottingham was recognised as a Comprehensive Care Centre after publication of HSG (93) 30 in 1994, I was the representative for Nottingham on the UKHCDO Advisory Committee.

I was elected to the Executive of UKHCDO, as Treasurer in 1997.

I took over the post of Secretary of UKHCDO in 2003.

I was elected to the role of Vice-Chairman of UKHCDO in 2005.

I was elected to the role of Chairman of UKHCDO in 2011 and retained this role until 2015.

The roles of these posts are described in the UKHCDO constitution (**Exhibit WITN4031004**).

The Treasurer's main responsibility was to manage subscriptions from the membership of the organisation, to manage the funds for the organisation – this involved paying expenses of the working parties and the organisation, managing the financial aspects of the annual general meeting, preparing the accounts with our appointed accountants and liaising with the charity commission. In this post, I was also a member of the executive of UKHCDO and so was involved in planning of the advisory committee meetings and annual general meeting.

The Secretary's main responsibility was the organisation of the meetings of the advisory committee, planning the agendas with the chairman, planning the AGM with the chairman and taking minutes of the meetings of the organisation.

Vice Chairman: This role was largely as a supportive role for the chairman, to deputise where appropriate and to chair the data management working party. This was the body that oversaw the work of the database and included all chairs of the working parties, national haemophilia database staff, patient representatives and commissioners.

Chairman: The principal role of this post was to lead discussion with the haemophilia community in the UK on key issues related to haemophilia care, to organise discussion with the advisory committee and action agreed decisions. The chair of the working parties appointed individuals to the working parties.

I have been a member of other working parties/task forces of the organisation:

In 1996, I was a member of the Therapeutics Task Force that recommended the use of recombinant factor concentrates in the treatment of haemophilia.

I was a member of the Genetics Working Party from 2000-2009 and, again, briefly in 2016.

I was a member of the Rare Disorders Working Party from 2002-2005.

I was a member and Chair of the Data Management Working Party from 2004-2015.

I was a member of the Transfusion Transmitted Infection Working Party from 2006-2009.

I was a member of the Morbidity and Mortality Working Party in 2010.

I was a member of the Clinical Outcomes Group 2010.

I was a member of the Triennial Audit Committee 2011-2015.

I was a member of the Haemtrack Group 2014-2016.

I was a member of the Musculoskeltal Working party in 2015.

The activities and the annual report for each of these committees is summarised in the annual reports of UKHCDO and are attached (**Exhibit WITN4031005**)

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

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

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

c. The relationships between UKHCDO and pharmaceutical companies (You may be assisted by considering the following documents: Email chain re. UKHCDO Meeting 2005 dated 7 March 2005 [HCDO0000242_031]; Email from you to Amanda Kiely dated 7 March 2005 [HCDO0000242_034]; Letter from Frank Hill dated 8 March 2005 [HCDO0000242_023])

d. How UKHCDO was funded.

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

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

i. the importation, purchase and selection of blood products;

ii. the manufacture of blood products;

iii. self-sufficiency;

iv. alternative treatments to factor products for patients with bleeding disorders;

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

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

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

viii. heat treatment;

ix. other measures to reduce risk;

x. vCJD exposure; and

xi. treatments for HIV and hepatitis C.

The Inquiry may be assisted by the constitution document at **Exhibit WITN4031004**, which deals with the function of UKHCDO.

UKHCDO is a body of healthcare professionals who have a special interest in Haemophilia. It exists to promote the highest standards of care for patients with Haemophilia and other Inherited Bleeding Disorders. Key functions and purposes include:-

i) to preserve, protect and relieve persons suffering from haemophilia and other inherited bleeding disorders;

ii) to advance the education of the medical profession, the nursing profession, professions allied to medicine and the general public in the knowledge of haemophilia and other inherited bleeding disorders and their treatment;

iii) to promote or assist in the promotion of audit and research into the causes, prevention, alleviation and management of haemophilia and other inherited bleeding disorders and to disseminate the useful results of such research.

The executive committee of UKHCDO consisted of the Chairman, Vice Chairman, Secretary and Treasurer. These individuals led the discussions with the advisory committee and key stakeholders on key aspects of haemophilia care in the UK.

The Working Parties were charged with focussing on a particular area of haemophilia care (e.g. Genetics or Von Willebrand). Some Working parties (e.g. the data management working party) functioned in continuity while others were constituted in light of perceived need. Suggestions for working parties could come from any source but most usually form the membership of UKHCDO, the suggestion would be discussed by the advisory committee and, if agreed, requests for nominations of chairs of the working party would be invited and would be selected by the chairman of UKHCDO. The chair of the working party would then select membership from the list of volunteers.

UKHCDO was first established in the late 1960s to establish key information about haemophilia. As a rare disease whose treatment was viewed as very expensive, the department of health wished to understand where the patients lived and where they were treated so that resources could be focussed appropriately. As a result of the realisation that many patients had been infected with HIV and HCV, UKHCDO became a major body in monitoring the impact of transfusion transmitted infection. The data produced by UKHCDO was important in helping guide treatment decisions and resources, monitoring the safety of virucidally treated factor concentrates, and subsequently all new treatments for haemophilia. Through this activity, close dialogue developed between UKHCDO and the pharmaceutical industry. Exchange of information was and remains very important though always with careful governance and in recent years, UKHCDO and the national haemophilia database have successfully undertaken major pharmacovigilance projects in collaboration with the pharmaceutical industry and regulators, yielding data that would otherwise be very difficult to establish.

The funding of UKHCDO has come from various sources. A significant part of the funding comes from donations made by pharmaceutical companies to exhibit at the annual general meeting. This is in common with many national and international bodies including the World Federation of Haemophilia, International Society for Thrombosis and Haemostasis, British Society for Haematology and others. The pharmaceutical companies could attend the UKHCDO AGM open session but could not attend most of the meeting which

was closed to them. In addition, UKHCDO received ad hoc donations which were unrestricted in the sense that no information or special favour was accorded to the donating body, and that any sum would be acknowledged in the accounts and annual report of the organisation. Such funds were used to massively scale up the activity of the database when it moved from Oxford to Manchester around 2001. The increased sophistication and capacity of the database was of great direct benefit to the NHS and commissioners – for example, the national contract for therapeutic products could not have been delivered without the capability of the database and this ensures that price for therapeutic products in the UK are the lowest in the world. This was eventually recognised by the commissioners and they too now make a significant contribution to the database.

UKHCDO also receives direct funding from pharmaceutical companies for defined pharmacovigilance studies.

Information from UKHCDO was distributed to haemophilia centres and members via the UKHCDO secretariat based at the National Haemophilia Database in Manchester. The information was distributed via mail and email. Information was also posted on UKHCDO website.

I was involved in the discussions regarding the contracting for factor concentrates from the time that Nottingham was recognised as a Comprehensive Care Centre and I was invited to attend the UKHCDO advisory committees. This advanced to the stage when the National Contract for haemophilia therapeutic products was established during my tenure on the UKHCDO executive committee. The national contact was initially led by a collaboration between UKHCDO, the Departments of Health and Deloitte. It was later managed by CMU for NHSE.

I had no involvement in the discussions on the manufacture of factor concentrates.

I had no involvement in the discussion on self-sufficiency.

I did not have any direct involvement on the discussions on alternatives to blood products in the 1970s and 80s.

I was a member of the UKHCDO task force in 1996 that recommended that recombinant factor concentrates were safer than plasma derived product with regard to the risk of infection. I was also a member of the advisory committee and executive of UKHCDO during the period where the potential risk of exposure to vCJD was recognised and was involved in the discussions and recommendations on the mitigation of this risk. This ultimately led to the national agreement to offer recombinant FVIII and FIX to patients with haemophilia.

As a member of the UKHCDO advisory committee and executive of UKHCDO, I was involved in the discussions on what information regarding the risk of vCJD should be given to patients and their families. These discussions involved consultation with experts in vCJD and public health.

I was not involved in the earlier discussions on obtaining consent for the storage of blood samples for surveillance for viral infection. I was involved in discussions regarding consent for post mortem sampling for individuals who may have been exposed to vCJD.

I was not involved in discussions about heat treatment.

I was not involved in the earlier discussions on alternative treatments to factor concentrates during the period of risk of viral transmission.

I was not involved in discussion regarding treatment for HIV. I was a member of the UKHCDO working party on the management of HCV. Guidance was published in 2011.

78. *Please describe the establishment and operation of the National Haemophilia Database, its purpose and objectives, your involvement in it, the range and kind of data recorded in the Database and how data is collected and organised.*

See reply to 76 and 77 above.

79. *Please explain how the work of the National Haemophilia Database has been funded over the years; how it is currently funded; and what if any financial contributions have been offered or made by (a) pharmaceutical companies and (b) the Department of Health. (Amongst the documents enclosed with this letter, you may wish to consider: Letter to Dr Ludlam dated 22 September 20*

1997 [HCDO0000133_147]; Letter from Eddie Owens dated 9 July 2002 [HCDO0000264_010]; Minutes of UKHCDO meeting on 5 September 2002 [HCDO0000109_064]; Email from Dr Hill dated 24 April 2003 [HCDO0000111_074])

See reply to 76 and 77 above.

80. *Please explain how the question of patient consent in relation to the National Haemophilia Database has been approached over the years. (You may wish to consider the email chain regarding the Genetic Working Party meeting on 10 September 2007 [HCDO0000004_045]) Please address in your response the extent to which there have been differences of opinion and approach amongst haemophilia centre directors in relation to this issue.*

I do not know when patients were first asked to give consent for data to be collected by UKHCDO and the National Haemophilia Database. The mechanism for obtaining consent from patients evolved over time as it did for medicine in general. The current system which has been reviewed by ethics committees and the Caldicott guardian is that patients are asked for consent at the time of registration with a centre and it is the responsibility of the registering centre to explain the nature of the consent and data collected. Anonymised data are then used for the various projects undertaken by NHD/UKHCDO (e.g. commissioning, audit, research). Information as to the nature of data gathered by NHD is provided in written and electronic form by NHD and the website updates any major changes. Patients may opt out of data collection.

Section 6: Pharmaceutical companies/medical research/clinical trials.

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

I have provided advice and consultancy services to several pharmaceutical companies. I have not kept systematic records on historical activity but include (below) my current disclosures which I present if giving any talk on the subject of haemophilia, or if I am involved in any publication or meeting to discuss treatment options for haemophilia. This year, I have been involved in 'virtual' presentations on the potential impact of COVID 19 on haemophilia services and more recently on how haemophilia services may prepare for the advent of gene therapy.

Shareholder	No relevant conflicts of interest to declare.
Grant / Research Support	Pfizer, Novonordisk
Consultant/Advisor	Pfizer, Bayer, Takeda, Novo Nordisk, CSL Behring,Octapharma, Biomarin, Roche, Sobi.
Employee	No relevant conflicts of interest to declare.
Paid Instructor	No relevant conflicts of interest to declare.
Speaker bureau	Pfizer, Bayer, Shire, Novo Nordisk, Takeda, Biomarin, Spark Therapeutics,

	Roche, CSL
Other	No relevant conflicts of interest to declare.

82. *Have you ever received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products? If so, please provide details.*

I have received honoraria for speaking engagements (please see 81 above). Such honoraria are strictly governed by the Association of British Pharmaceutical Industry (ABPI).

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

I have participated in advisory boards for the pharmaceutical companies referred to above. My involvement has mainly been in international advisory boards and more recently have been on the subject of gene therapy and the effects of the COVID 19 pandemic on haemophilia services. I have received honoraria for participation in such advisory boards; payments are strictly governed by the ABPI code and any participation in advisory boards are declared through UKHCDO, NHSE England, CMU and in any publication or presentation. I have not retained all relevant records. The Medicines and Healthcare Products Regulatory Agency has decreed that UK healthcare professionals should no longer participate in international advisory boards.

84. *Have you ever received any financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.*

I have not received incentives to prescribe blood products or recombinant factor concentrates.

85. *Have you ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.*

I have not received non-financial incentives to prescribe blood products or recombinant factor concentrates.

86. *Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.*

I have not received funding to prescribe, supply, administer, recommend, buy or sell any blood product or recombinant product from a pharmaceutical company.

87. *What regulations or requirements or guidelines were in place (at any time relevant to your answers above) 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?*

A large part of the declaratory process is governed by the ABPI and I fully adhere to this. Before any lecture/talk, a clear description of disclosure is made; for any publication, a declaration of interests is made. UKHCDO requires that an annual declaration of interest is made. The Commercial Medicines Unit (CMU) requires a declaration of interest before any meeting related to discussion on therapeutic products as does NHSE. I adhere to all these requirements.

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

I have been involved in a small number of clinical trials or observational studies:

European retrospective study of real-life haemophilia treatment.

Berntorp E, Dolan G, Hay C, Linari S, Santagostino E, Tosetto A, Castaman G, Álvarez-Román MT, Parra Lopez R, Oldenburg J, Albert T, Scholz U, Holmström M, Schved JF, Trossaërt M, Hermans C, Boban A, Ludlam C, Lethagen S.

Haemophilia. 2017 Jan;23(1):105-114. doi: 10.1111/hae.13111. Epub 2016 Oct 20. PMID: 27761962 Clinical Trial.

Use of the UKHCDO Database for a post marketing surveillance study of different doses of recombinant factor VIIa in haemophilia.

Hay CRM, Sharpe T, Dolan G; UKHCDO. Haemophilia. 2017 May;23(3):376-382. doi: 10.1111/hae.13139. Epub 2016 Dec 27. PMID: 28026073

Vigam-S, a solvent/detergent-treated intravenous immunoglobulin, in idiopathic thrombocytopenic purpura.

Newland AC, Burton I, Cavenagh JD, Copplestone A, Dolan G, Houghton J, Reilly T. Transfus Med. 2001 Feb;11(1):37-44. doi: 10.1046/j.1365-3148.2001.00281.x. PMID: 11328570 Clinical Trial.

European study on orthopaedic status of haemophilia patients with inhibitors.

Morfini M, Haya S, Tagariello G, Pollmann H, Quintana M, Siegmund B, Stieltjes N, Dolan G, Tusell J. Haemophilia. 2007 Sep;13(5):606-12. doi: 10.1111/j.1365-2516.2007.01518.x. PMID: 17880451 Clinical Trial.

Clinical experience with a highly purified factor IX concentrate in patients undergoing surgical operations.

Thomas DP, Lee CA, Colvin BT, Dasani H, Dolan G, Giangrande PL, Jones

P, Lucas G, Cantwell O, Harman CT. Haemophilia. 1995 Jan;1(1):17-23. doi: 10.1111/j.1365-2516.1995.tb00035.x. PMID: 27214217

In addition, at Guy's and St Thomas' hospital, I was lead investigator for the Haven 1 study on the role of emicizumab in prophylaxis in persons with haemophilia and inhibitors.

I was lead investigator for the Pathfinder clinical trial of prophylaxis with pegylated recombinant factor VIII.

I am co-lead investigator for the Biomarin Gene therapy trial.

89. *Have you ever provided a pharmaceutical company with results from research*
studies that you have undertaken? If so, please provide details.

The conduct of clinical trials is strictly governed by Good Clinical Practice and the conditions set by each Research and Ethics Committee. The criteria for handling data confidentially are clearly described and do not permit giving data to trial sponsors. I have not given information directly to pharmaceutical organisations.

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

I have not received funding for these clinical trials.

Section 7: vCJD

91. *When and in what circumstances did you first become aware of the risks of transmission of vCJD associated with the use of blood and blood products? How did your knowledge develop over time? Please include in your answers reference to your research and publications in relation to vCJD.*

I first became aware of vCJD through the medical press and news agencies around 1996. This information began to emerge not long after the UKHCDO

taskforce publication which recommended recombinant factor concentrates as the safest with respect to transfusion transmitted infection, and in this document the possibility of some future emerging infection was raised. The emergence of vCJD in the general population raised the potential concern for the safety of individuals with haemophilia, the majority of whom were at that time treated with plasma products prepared from UK donors. The first blood donor reported to have vCJD was reported in 1997 and further cases emerged over the following years. The concern that vCJD could be a transfusion transmissible disease increased when in 2003 the first report emerged of a blood donor who had been diagnosed with vCJD; by 2004, 9 blood donors had been diagnosed with vCJD. It was subsequently demonstrated that these donors had made 23 donations from which 24 batches of FVIII and FIX were prepared and it had been found that 792 patients had received these products. It was acknowledged that this was likely to be an underestimate as 47% of the potentially affected units had not been accounted.

92. *Please describe your involvement in decisions as to what information to provide to patients about vCJD, both in your capacity as a member of the Executive Committee of UKHCDO and in your capacity as Director of the Manchester Centre. Please address in your answer the 2004 notification process, the 2006 notification process and the 2009 notification process. (Amongst the documents enclosed with this letter, you may wish to consider: Minutes of the UKHCDO on 15 January 2001 [BART0000938], Minutes of the UKHCDO Advisory Committee on 29 November 2004 [BART0000926], Note of meeting of Transfusion Transmitted Infection Working Party on 30 November 2007 [HCDO0000899] and email chain from Prof Hill dated 9 April 2009 [HCDO0000880])*

The emergence of vCJD as a possible transmissible disease was the subject of a great many conversations within UKHCDO and within haemophilia centres. I cannot remember exact timelines but many discussions centred on what information should be given to patients and how this information should be given. A source of real concern was the potential anxiety and distress to

patients on being informed they may have been exposed to a potentially fatal disease though blood products, and that we had no means of confirming or ruling out infection as there were no tests available.

There was close collaboration between the Health Protection Agency and the variant CJD incidents panel. The HPA in particular had a major influence in what information was given to patients. As a member of the UKHCDO advisory committee, member of the Transfusion Transmitted Infection Working party, Vice Chairman and then Chairman of UKHCDO, I took part in many discussions and decision making processes. I was never the director of the Manchester centre.

During this period of emerging concern about vCJD, there were many discussions at the UKHCDO advisory committee with the relevant experts. There was clear consensus about how patients should be approached and templates were agreed to harmonise the process across the UK. In Nottingham, we used all the agreed templates in written and face to face communications with patients and endeavoured to keep patients informed of any news, developments or recommendations

93. *Please also answer the following questions:*

a. What discussions took place (a) within UKHCDO, (b) with other organisations (including the CJD Incidents Panel and UK Health Departments) and (c) within the Centre?

b. What steps were Centres/Centre Directors asked to take?

c. What procedures were put in place for informing patients about possible exposure to vCJD?

d. What steps were taken, and when, to tell patients of possible exposure to vCJD?

e. What information was provided, and when, to patients about vCJD?

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

g. What precautions were recommended, and why, in relation to patients notified to be at risk?

There were many discussions within UKHCDO, within centres and between different stakeholders.

Within UKHCDO there was regular review of the facts in light of new information. There was much discussion on what information should be given to patients and how this should be presented.

Between agencies, there was also discussion on what information should be given to patients as well as what further surveillance of patients should be considered, and what measures may be required to protect against human to human transmission.

Within centres, including the Nottingham centre, there was multidisciplinary discussion on how patients should be approached and how to manage their concerns as well as steps to protect them from stigmatisation.

Centre directors were asked to send out information prepared jointly by HPA and UKHCDO, informing patients of potential exposure and asking what further information they wished to receive regarding possible exposure and whether they wished to receive this by mail or in person. Centre directors were also asked to take public health measures to reduce the risk of human to human transmission, such as identification of patients considered at risk, and to ensure that they did not undergo non-urgent high risk procedures such as ENT, neuro or spinal surgery and endoscopy; where such procedures were considered necessary, to liaise regarding safe measures such as disposal of any instrument used.

The multidisciplinary team in Nottingham was aware of the potential distress to patients and was available for all patients who wished to have face to face

discussion and counselling. The nursing staff in particular had a major role in counselling patients.

As above, the key precautions we were asked to take was to reduce the risk of human to human transmission through surgery or endoscopic procedure by avoiding non-urgent surgery or arranging for disposal of any surgical instruments.

94. *In 2013, you wrote to Haemophilia Centre Directors about the re-assessment of vCJD risk and de-notification of certain recipients of plasma products [CVHB0000011_024].*

a. What discussions took place (a) within UKHCDO, (b) with other organisations (including the CJD Incidents Panel and UK Health Departments) and (c) within the Centre?
b. What steps were Centres/Centre Directors asked to take?
c. What procedures were put in place for informing patients about the re-assessment?
d. What information was provided, and when, to patients about the re-assessment?
e. What procedures were put in place for removing the need for precautions for patients who had previously been notified that they were at risk, and for recording the change to their status in their medical records?

There was a continuous reassessment of the risk of having acquired vCJD through blood products and the risk posed to others.

The letter I sent out in 2013 was from the HPA in which there had been a re-evaluation of the potential periods of exposure to vCJD and thus many patients thought to have been considered at risk were to be denotified.

In my letter, I requested that NHD undertake a review of the data on patients' potential exposure before any formal communication was made with patients.

Centre directors were asked to review their patients in light of verified data from UKHCDO and amend the status of those individuals.

I cannot remember exact details of how patients were re-approached in Nottingham. There was regular discussion with patients with respect to vCJD risk at clinics and on request from patients.

There was liaison with UKHCDO to verify the changed status of patients and amendments to the register and case records.

Section 8: The Financial support schemes

95. *What if any involvement did you have (and in the case of EIBSS continue to have) 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? Please provide as much detail as you can.*

I did not have any role within any of these bodies. I supported several patients registered in Nottingham in their application for support, principally with the MacFarlane Trust and Skipton Fund. In Nottingham we were fortunate to have an excellent social worker who steered all patients through the application process.

96. *At the AGM of the UKHCDO on 13 October 2005 (attended by you as incoming Vice Chairman) one of the attendees "pointed out the problem that arose if patient's notes had been lost, and therefore could not provide evidence of chronic hepatitis" [BART0000904]. The suggestion at the meeting was that such patients should appeal "saying that there is no information available due to destroyed notes". Was this a widespread problem? As far as you are aware, to what extent, if at all, did the suggested route of appeal, with the patient pointing out that notes had been destroyed,*

succeed? Were there patients under the care of the Nottingham Centre who experienced this difficulty and, if so, what happened to their applications to the Skipton Fund?

I am not aware of patients in Nottingham having problems in applying for support as a result of destroyed notes. I do not know how widespread this issue was across haemophilia centres.

97. *To what extent, during your time at (a) Sheffield and (b) the Nottingham Centre, did staff (including you) inform patients about the different trusts or funds?*

I cannot remember how often patients in Nottingham were informed about the different Trusts. A dedicated social worker for haemophilia attended the adult and paediatric haemophilia clinics and reviewed each patient in detail. There was discussion with patients in the clinical haemophilia clinics regarding their eligibility for support. There was liaison with the HIV and hepatology teams. The Consultant Hepatologist took over supervising applications .

98. *Did Sheffield and/or the Nottingham Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support? If so please provide details.*

I do not know what the process was for Sheffield. In Nottingham we did not, as far as I can remember, have an official policy in this regard.

99. *What kind of information did Sheffield and/or the Nottingham Centre provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?*

I do not know what the policy was in Sheffield for informing patients about the Trusts and Funds. In Nottingham, we appointed a social worker who reviewed all patients and discussed in detail how patients could apply to various Trusts and Funds. She provided written information and gave assistance to those

who struggled to apply. She attended all clinics for regular updates and consulted with me if patients required direct support.

100. *What kind of support or assistance was provided by you and/or Sheffield and/or the Nottingham Centre to patients making applications for financial assistance?*

There was a multidisciplinary approach to providing support. The social worker, clinical nurse specialist, haemophilia director and hepatologist were all closely involved. There was regular discussion between the team on progress of patients' applications.

101. *Did Sheffield and/or the Nottingham Centre, or any of their staff, 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.*

Different patients required different levels of support in applying to the Trusts and Funds. Some patients required a lot of support because they lacked confidence, motivation or the literacy skills to apply. As far as I can remember, all patients were encouraged to apply and the criteria were carefully explained.

102. *Was either Centre or any of its staff involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.*

As above, many patients required a lot of support in making applications but as far as I am aware, members of staff did not determine applications.

103. *Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of your 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?

In my experience, many patients received support from the Trusts/Funds but for several patients the burden of proving eligibility was daunting, sometimes difficult and a cause of distress. The process could be cumbersome and in my view those administering the Trusts/funds could have adopted a more sympathetic and pragmatic approach to applicants.

104. *What if any dealings have you had with EIBSS? Have there been difficulties or shortcomings in the way in which it operates or takes decisions or in its dealings with applicants for assistance?*

I have personally had relatively few direct dealings with EIBSS. The hepatology service took over the support of patients applying for support in Nottingham from the mid-1990s. At Guys and St Thomas' we have a dedicated joint hepatology clinic and one of my colleagues led on support for patients for the last few decades. I have managed some appeals and difficult cases in the last few years, most of which were successful.

Section 9: Recent haemophilia care at the Nottingham Centre

105. *Did you routinely take blood samples from patients attending the Nottingham 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 was that recorded?*

Most patients had regular blood tests at clinic visits in Nottingham. For severe and moderate patients they attended 2-3 times each year and for the mild bleeding disorders they attended annually. They had routine health screens annually, full blood count, liver function tests, renal function. Annually, they

had a trough factor level where appropriate and an inhibitor screen. The patients were informed of the purpose of the tests and results were explained at clinic visits. No formal written consent was obtained. This was not a standard of care and is still not a standard of care. Each patient with a bleeding disorder had a formal test for identification of their underlying genetic mutation causing the bleeding disorder. Formal written consent was obtained for this including the request to store the sample of DNA for later confirmation of the mutation. Patients attending the HIV clinics had a full profile of immune status including HIV viraemia levels and CD4 counts. These bloods were sometimes taken at the HIV clinic visit, or the patient would request that they be taken at the haemophilia clinic to avoid unnecessary duplication of venepuncture. There was a similar process for the patients with HCV. For those undergoing treatment, the HCV clinic team directed their blood testing and after treatment, liver function tests continued to be taken at the haemophilia clinic. No formal consent was obtained for these blood test which were part of routine clinical care. There was no long term storage of blood samples except for the genetic tests for which consent was obtained.

106. *Please describe how you typically (a) obtained and (b) recorded your patients' consent to testing (of any kind).*

For first test of HIV, HCV and HBV, the reasons for the testing were explained. For any first HIV test, written consent was recorded in the case notes. In Nottingham, when we began viraemia testing for HCV, written consent was obtained but formal consent was not obtained for subsequent testing. Outside haemophilia, testing for viral hepatitis was not associated with formal consent processes either in Nottingham or London. For routine bloods, formal written consent was not obtained nor is it for any other clinical service. For genetic testing, written formal consent was and is obtained. The current situation at GSTT is that all patients admitted for any reasons are asked if they consent to HIV testing, this is not formally recorded. Testing for hepatitis viruses is a core investigation for any individual with suspected liver disease. Tests are explained to patients but no formal consent is obtained. For radiological investigations patients give verbal consent. For genetic tests,

written consent is obtained and for any surgery or biopsy, consent is obtained. My own practice is that I always explain the reasons why I recommend investigations, the nature of these and, as directed by our Trust policy, whether written consent is required.

107. *At the time you left the Nottingham Centre in 2015, how many patients at that time (a) were infected with HIV through blood products; (b) were infected with HCV through blood products; (c) were infected with HBV through blood products; (d) were co-infected with HIV and HCV through blood products?*

In 2015, there were a) 4 individuals who had been infected by HIV through blood products, b) 31 infected by HCV through blood products, and c) 1 patient who had chronic HBV as a result of receiving contaminated blood products. D) The 4 individuals infected by HIV had also been infected by HCV.

108. *What if any involvement did you have/the Nottingham Centre have in the treatment of the Centre's patients for HIV and/or HCV and/or HBV? Were there multidisciplinary clinics (e.g. haematology and hepatology), and if not would such arrangements have been feasible and beneficial?*

By the time I arrived in Nottingham, all HIV positive patients had been referred to and were managed by either the adult HIV service or the paediatric medical services. There was good liaison between these services and the haemophilia services. The treatment of HIV was managed directly by those services. There were a relatively small number of HIV infected patients in Nottingham and it was not considered feasible by the HIV services to run joint clinics. The Haemophilia service arranged social work and psychological support for these patients. In 1991 there was no dedicated liver service in Nottingham. Through necessity, I initially jointly managed patients with liaison and joint consultation with a gastroenterologist who had an interest in liver disease and with the infectious diseases team. Some patients were treated with interferon based on consensus. In 1993, a Hepatologist was appointed and a joint

hepatology/haemophilia clinic was established. Dr Ryder reviewed and then directed all treatment for patients. The HCV infected children were managed by the paediatric gastroenterology service.

109. *What if any psychological services were available at the Nottingham 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?*

When I arrived in Nottingham, the HIV infected patients were under the care of the HIV service. They had access to psychological support through this. The support was not focussed of haemophilia and I applied for a new post specifically for haemophilia. She was appointed around 1992 and saw both children, families and adult patients. This was a highly valued service. She saw some HCV infected patients. As the hepatology/hepatitis service developed in Nottingham, the psychological support for HCV and HBV infected patients also grew. The lead haemophilia nurses also maintained a very important role in the support of the Nottingham patients.

110. *What if any other support services were available at the Nottingham Centre?*

Nottingham University Hospitals is one of the larger Trusts in the UK and has the full range of clinical services. We were able to offer the full range of clinical services locally (e.g. neonatology, paediatrics, orthopaedic surgery, neurosurgery, dental etc.).

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

a. upon patients at the Nottingham Centre (without identifying any individual patient);

b. the ways in which decisions about treatment and care were taken, and treatment and care were provided, at the Nottingham Centre?

The impact of HIV on patients with haemophilia in Nottingham was devastating and I was very disappointed when I took up my post in 1991 at how little support and care they had received. I recall in particular two children who had been infected by HCV and HIV and whose families were really struggling to deal with the situation. Both families required a great deal of psychological and clinical support, particularly with respect to school and social life and transitioning through to adulthood. There was still a great deal of stigma regarding HIV and hepatitis in the 1990s and 2000s and these families and indeed all patients really struggled. Indeed, some of this stigmatisation came from other healthcare professionals and I was shocked at how callous some medical and nursing staff could be to our patients. I recall having to intervene many times to ensure patients had access to proper medical care (e.g. surgery) and to reprimand junior members of our clinical team for their attitude to our patients. Before the advent of effective treatment for HIV, it was harrowing to care for highly distressed patients and their families as they progressed to AIDS. At one point the psychologist had established a social and support group for patients infected by HIV but, after a few patients died there was enormous distress among the members of the group and it became too painful for them to continue to meet. HIV greatly complicated the lives of other patients who had other major issues such as opiate addiction, self-harm, chronic pain, depression, anxiety, alcohol abuse, and it was very challenging to help patients manage these other situations. Many patients experienced real difficulty in their personal lives and relationships.

The patients with hepatitis C and B experienced many of the difficulties described above and this was also complicated by the fact that so little was known about the potential impact of HCV, the significance of blood tests and proper risk assessment. The lack of effective eradication therapy for the majority of patients or, in the case of interferon, treatment associated with potentially awful side effects was very difficult for many patients.

The devastation caused by transmitted infection was for many patients long lasting and in some cases this resulted in difficulty in the relationship with the

medical profession, including the haemophilia team. For many others it was truly humbling to see how they and their families dealt with these major challenges and established successful personal and professional lives in the face of sometimes overwhelming odds.

On treatment: For HIV, treatment decisions were made by the HIV clinical service.

For HCV , in the early 1990s there was a major challenge due to the lack of a dedicated hepatitis clinical service. For patients with evidence of chronic liver disease, there was consultation with the HIV service, infectious disease service and gastroenterology service and some patients were offered treatment such as interferon to attempt to eradicate the virus or slow down progression of liver disease. The service available to patients was considerably enhanced with the arrival of the dedicated hepatology service with a specific interest in HCV. Thereafter, all major treatment decisions were made by this expert team.

112. *In an email dated 12 July 2004, you said an individual who had written "clearly did not know the background to this or the dismay of the haemophilia treater community who are f*****g sick of being the first route of attack for many*

patients who have been warped by their experiences" [HCDO0000254_558]. You go on to suggest that the "evolution of testing/consent etc" might be put "in perspective" by way of introductory paragraphs of the document that is being discussed. Why did you write in these terms? What did you mean about the haemophilia treater community being "the first route of attack"? What did you mean by patients being "warped by their experiences"?

I am surprised and disappointed at reading this quote. In truth, I cannot remember this at all and I cannot remember the context. I cannot think of what prompted me to write in these terms and it is certainly not typical of any other correspondence or of my attitude in general. I cannot recall any circumstance where I have used this language or terms in any debate, open discussion or

document and I deeply regret any distress or concern that may arise to any persons from any interpretation of this statement.

Section 10: Current haemophilia care

113. *Please describe:*

a. how the provision of care and treatment for bleeding disorders is currently organised at the Guy's Centre; and

b. your current roles and responsibilities at the Guy's Centre.

The haemophilia service at Guy's and St Thomas' is one of the largest Comprehensive Care Centres in the UK. The full service is described in great detail in the recent external review process (December 2019) – **Exhibit WITN4031006**.

I am the clinical lead for Haemophilia services and lead the multidisciplinary team.

114. *Please outline the treatments currently provided to patients with bleeding*
disorders at the Guy's Centre.

The patients at GSTT are treated with a range of therapies. All of these treatments are guided by the national contract for therapeutic agents. For any major changes in treatment, proposals are discussed at our weekly multidisciplinary meetings and formal agreement reached. All changes are carefully discussed with patients and written information is given in advance of any change; verbal consent is taken for any change.

For any surgical procedure, formal written consent is obtained by the surgical teams.

For HIV therapy, all changes in treatment are supervised by an HIV physician in the joint HIV clinic. Verbal consent is taken before any change.

For HCV therapy, all changes in treatment are supervised by a Consultant Hepatologist and verbal consent is obtained.

For any clinical trial, a rigorous consent process exists consistent with Good Clinical Practice.

115. *Please describe how you typically obtain your patients' consent to treatment. In particular:*

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

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

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

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

For all patients with haemophilia A and B, recombinant therapeutic products are prescribed. The nature of these products and in particular their record of safety with respect to TTI are explained to patients. The potential risk of inhibitors is explained to patients and families of PUPs. For those patients where recombinant products are not available e.g. rare bleeding disorders, the nature of the therapeutic product is explained, the potential for risk of infection from plasma products is explained and all patients are vaccinated against hepatitis A and B.

For newer therapeutic products such as emicizumab the clinical trial data are explained as well as real world experience. The patients are given written information on the nature, potential benefits and risks.

It is our policy to only use recombinant products where available. The remaining major risk for patients who are PUPs or who have mild haemophilia A is the possibility of developing an inhibitor. For those patients who do not wish to receive plasma or blood products, a small number in my experience and may include individuals who are Jehovah's Witnesses, the virucidal safety measures are explained, an alternative such as DDAVP or recombinant VIIa is explored. For patients who decline blood products, we explain that there is risk of haemorrhage which may cause serious morbidity or even death.

Patients are only offered treatment if it is thought necessary to prevent haemorrhage. The clear benefit of accepting treatment is that haemorrhage is prevented and best outcome of (for example) surgery is facilitated.

116. *Please describe how you typically record your patients' consent to treatment.*

Treatment decisions are recorded in the case notes and in clinic letters. Patients receive copies of the clinic letters. For surgical procedures, including intended treatment, a formal plan is agreed with the MDT, and patients have copies. Verbal consent is obtained.

117. *Do you routinely take blood samples from patients attending the Guy's Centre? If so, what information do you provide to patients about the purposes for which the samples are being taken? Do you obtain patients' consent to the storage and use of the samples and if so how and is that recorded?*

Written consent is not obtained for routine blood tests that are part of a patient's clinical care. Written consent is obtained for the processing and storage of genetic tests.

Blood samples are not stored unless this is a part of a clinical trial for which written consent is obtained.

118. *Please describe how you typically (a) obtain and (b) record your patients' consent to testing (of any kind).*

See above.

119. *How many current patients at the Guy's Centre (a) were infected with HIV through blood products; (b) were infected with HCV through blood products; (c) were infected with HBV through blood products; (d) were co-infected with HIV and HCV through blood products?*

a) There were 51 registered patients who had been infected by HIV; b) there were 176 registered patients who had been infected by HCV; c) there were no patients with chronic HBV; d) all 51 HIV infected patients were infected by HCV.

120. *What if any involvement do you have/does the Guy's Centre have in the treatment of the Centre's patients for HIV and/or HCV and/or HBV? Are there multidisciplinary clinics (e.g. haematology and hepatology), and if not would such arrangements be feasible and beneficial?*

At GSTT, there is a dedicated, joint HIV/Haemophilia service led by an HIV physician specialist. The HIV team direct all treatment and management of complications. There is a joint haemophilia/HIV clinic held monthly but the HIV team are available 24/7 for any urgent issues. At GSTT there is a joint hepatology/haemophilia clinic for managing patients with hepatitis. This clinic is also linked with King's Hospital MDM clinic.

121. *What if any psychological services are available at the Guy's Centre? Do you have a psychologist as part of the staff team? Is there psychological*

support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

We do have a clinical psychologist for the support of individuals with bleeding disorders who have been infected through blood products.

122. *What if any other support services are available at the Guy's Centre?*

At GSTT we have a large clinical multidisciplinary team and administrative team to support patients. The Trust has a full range of services available for all other clinical needs.

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

a. upon patients at the Guy's Centre (without identifying any individual patient);

b. the ways in which decisions about treatment and care are taken, and treatment and care are provided, at the Guy's Centre?

I was appointed to GSTT 5 years ago and so do not have first-hand knowledge of the impact of the emerging knowledge of HIV and hepatitis on the patients. It is clear that, as for Nottingham, many patients and their families were devastated and many patients died of AIDs or liver disease. It is also clear that the care of patients improved dramatically with the establishment of dedicated joint hepatology and HIV services. There is a similar experience to the patients in Nottingham as described above, except that there was a much better infrastructure at GSTT at the time that HIV and HCV emerged.

As for the experience in Nottingham, I and my team are in awe of the many patients who have dealt with huge challenges to their personal and professional lives though transfusion transmitted infection. The establishment

of the Inquiry has generated further discussion with patients and I and my team are reminded of the terrible physical and emotional distress that many patients have had to deal with, and are still dealing with.

The establishment of dedicated hepatology and HIV services for haemophilia, as well as the range of expert tertiary services explains the wide geographical spread of patients registered at GSTT.

124. *Has the infection of patients with HIV and/or HBV and/or HCV through blood products:*

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

b. changed or influenced the practice and approach of your colleagues and if so how?

c. changed or influenced the way in which haemophilia care is now provided and if so how?

The terrible impact of transfusion transmitted infection has undoubtedly influenced my clinical practice. I started prescribing recombinant factor concentrates for children before formal agreement was reached with the commissioning bodies. I have been a strong advocate of recombinant factor concentrates and, on discovering a significant number of patients at GSTT still treated with plasma products, I initiated specific efforts to inform them of the risks and successfully switched all eligible patients.

Although I had no first-hand experience of how the emerging risk of HIV and hepatitis was managed by the haemophilia community in the 1980s, it is clear to me that the experience of having to manage an unknown risk of infection clearly influenced those clinicians who had experienced this. In my opinion, this explained the UKHCDO early stance on the recommendation for the use of recombinant factor concentrates and resulted in the UK being one of the

first countries to switch all patients to recombinant products. It was also clear to me that many senior colleagues had been seriously distressed by their experiences of transfusion transmitted infection in their patients.

The experience of TTI drove the need to improve standards of care for haemophilia including the establishment of multidisciplinary working, the establishment of Comprehensive Care Centres and the policy of using the safest products available for haemophilia care.

Section 11: Other issues

125. *Please provide details of any advice sought by, or provided to, the Department of Health by you on matters relevant to the Inquiry's Terms of Reference. In your answer, please include a description of your meeting with Dr McGovern in January 1998 ([HCDO0000464] and [HCDO0000133_134]).*

I remember my participation (as a member of the executive of UKHCDO) in several meetings with the department of health. I remember that my role was supporting the chairman in such meetings. I remember that there were several discussions about advances in treatment including UKHCDO therapeutic guidelines but cannot the details of these meetings.

One of the issues I had been unprepared for as a 32 year old newly appointed Consultant was just how difficult it was to navigate the financial aspects of haemophilia care. I remember real hostility from hospital managers over the budget for therapeutic products. Sometimes hospital 'overspends' were blamed on the haemophilia service. It made it very difficult to introduce best therapy such as highly purified factor concentrates when there was evidence for potential benefit for HIV positive patients, and frustration at not being able to prescribe recombinant products at an earlier stage. This situation improved considerably when central funding of therapy was established but some centres continued to face real challenges in their efforts to improve standards.

126. *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.*

I am not aware of any complaints made against me. I have made one previous statement to the Inquiry.

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

I have nothing further to add.

Statement of Truth

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

Signed GRO-C

Dated 9th NOVEMBER 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
15 November 2013	UKHCDO Constitution	**Exhibit WITN4031004**
Various (see below)	UKHCDO Annual Reports	**Exhibit WITN4031005**
March 2020	GSTT Peer Review Report	**Exhibit WITN4031006**

Exhibit WITN4031005:

Title	Page
Annual Report for 2004 and Annual Returns for 2002	1-62
Annual Report for 2005 and Annual Returns for 2003	63-133
Annual Report for 2006 and Annual Returns for 2004/05	134-232
Annual Report for 2007 and Annual Returns for 2006	233-310
Annual Report for 2008 and Bleeding Disorder Statistics for 2007	311-404
Annual Report for 2010 and Bleeding Disorder Statistics for 2009/10	405-507
Annual Report for 2011 and Bleeding Disorder Statistics for 2010/11	508-643
Annual Report for 2013 and Bleeding Disorder Statistics for 2012/13	644-772
Annual Report for 2015 and Bleeding Disorder Statistics for 2014/15	773-893
Annual Report for 2016 and Bleeding Disorder Statistics for 2015/16	894-1007