Witness Name: Dr Michael Laffan
Statement No.: WITN3089003
Exhibits: WITN3089004 – WITN3089007
Dated: November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR MICHAEL LAFFAN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 28 July 2020.

I, Dr Michael Laffan, will say as follows: -

Section 1: Introduction

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

1.1. NAME: Michael Arthur LAFFAN

1.2. DATE OF BIRTH: GRO-C 1956

1.3. ADDRESS: Department of Haematology
Imperial College Academic Health Sciences Centre
Hammersmith Hospital
Ducane Road
London W12 0NN

1.4. 1978: B.A. Hons II Physiological Sciences

1.5. 1981: BM BCh

1.6. 1984: MRCP(UK)

1.7. 1991: MRCPath

1.8. 1993: DM

1.9. 1996: FRCP

1.10. 1999: 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.

2.1. August 1981- Jan 1982

2.1.1. H.S. to Mr K. Lloyd-Williams, Royal United Hospital Bath.

2.2. Feb 1982- July 1982

2.2.1. H.P to Nuffield Department of Medicine, John Radcliffe Hospital Oxford

2.3. August 1982-5

2.3.1. MEDICAL SHO ROTATION LEICESTER HOSPITALS, Training in acute medicine, clinical pharmacology, haematology, cardiology

2.4. Feb 1985-Jan 1987

2.4.1. REGISTRAR IN HAEMATOLOGY, Royal Postgraduate Medical School, Hammersmith Hospital, London

2.5. Jan 1987- Dec 1989

2.5.1. MEDICAL RESEARCH COUNCIL TRAINING FELLOW, Hon. Research Fellow, Hon. Senior Registrar, Royal Postgraduate Medical School and Hammersmith Hospital. Research position, no clinical duties.

2.6. Jan 1990 - Mar 1992

2.6.1. SENIOR REGISTRAR IN HAEMATOLOGY, Royal Free Hospital, London. Training in haematology

2.7. April 1991- Mar- 1992

2.7.1. LOCUM CONSULTANT, Katherine Dormandy Haemophilia Centre, Royal Free Hospital, Supervised responsibility for patients with disorders of coagulation.

2.8. April 1992 – date

2.8.1. SENIOR LECTURER IN HAEMATOLOGY, Later (2007)

2.8.2. PROFESSOR OF HAEMOSTASIS AND THROMBOSIS, Royal Postgraduate Medical School/ Imperial College

2.8.3. HONORARY CONSULTANT, Hammersmith Hospital, Care of patients in general medicine and in general and non-malignant haematology including coagulation disorders. Later reduced to haematology only and finally to coagulation disorders only. Director of the Hammersmith Hospital Haemophilia Centre.

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

3.1. 2010 -2017 Secretary to the UK Haemophilia Centre Doctors Organisation

3.2. 2012-date Chair of the UKHCDO Working Party on von Willebrand Disease (VWD).

3.3. I attend the Data Management Working Party as chair for VWD

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

4.1. I have not been involved in any such inquiries or litigation.

5. **The questions below primarily focus on your time as Registrar in Haematology, Consultant Haematologist and finally Director of the Hammersmith Haemophilia Centre, but insofar as your experiences at the Royal Free Hospital between January 1990 and March 1992 are relevant to the questions asked, please include reference to these too.**

<u>Section 2: Decisions and actions of those treating patients with haemophilia at the Hammersmith Hospital Haemophilia Centre</u>

6. **Please describe the facilities, organisation, roles, functions and responsibilities of the Hammersmith Hospital Haemophilia Centre ("the**

Centre") during the time that you have worked there, and how they have changed over time. Please provide an account of the Centres history, its establishment and its activities during this time.

6.1. As a registrar in haematology during 1985-1987 I did not have any knowledge of the organisation of haemophilia care beyond the immediate local arrangements. These comprised a treatment room, supplies of therapeutic products and the staff of the haematology department. Towards the end of this period there was also a part time nurse with responsibility for haemophilia. Patients attended the transfusion laboratory directly when they needed attention for bleeding problems but were also seen in scheduled outpatient appointments.

6.2. In 1992 there was more structure to the service. There was a dedicated room and a full-time clinical nurse specialist who also had responsibility for anticoagulation services. The service was provided from haematology outpatients and day care centre rather than the transfusion laboratory. There were two social workers attached (not full time) to the centre who provided services primarily to patients with HIV. The centre provided information to the national database (then in Oxford) about the amount of therapeutic products used each year and the numbers of patients attending the centre.

6.3. Key developments over the following years included:

6.3.1. Establishment of a computerised database of patients and treatment use;

6.3.2. Allocation of a registrar specifically for coagulation;

6.3.3. Increase to 2 Clinical Nurse specialists;

6.3.4. Loss of the two social workers;

6.3.5. Appointment of Dr Millar as a second consultant with responsibility for coagulation;

6.3.6. Move to dedicated space with treatment room, three consulting rooms, waiting room, kitchen and CNS office space;

6.3.7. Appointment of a data manager;

6.3.8. Appointment of a full-time social worker shared with the haemoglobinopathy service;

6.3.9. Funding obtained for dedicated physiotherapy time;

6.3.10. Formation of the North London Adult Haemophilia Network;

6.3.11. Reconfiguration of paediatric services in West London and move of paediatric haematology to the St Mary's hospital site;

6.3.12. Closure of paediatric haemophilia service at St Mary's Hospital and transfer of patients to Great Ormond Street;

6.3.13. Appointment of specialist haemophilia physiotherapist.

6.3.14. A full contemporary description is given by the report of the 'Peer Review' carried out in 2019.

Not Relevant

Not Relevant

Not Relevant (Exhibit WITN3089004)

7. **Please identify senior colleagues and their roles and responsibilities during the time that you have worked at the Centre.**

7.1. In 1985 the consultant in charge of haemophilia care was Dr J Hows

7.2. Between 1985 and 1987 there were two Senior Registrars that I recall: Dr D Swirsky and Dr S Durrant

7.3. When I took over responsibility for haemophilia care in 1982 the consultant in charge was Dr D Swirsky.

7.4. I remained the sole consultant with responsibility for haemophilia until 2008 when I was joined by Dr Carolyn Millar.

7.5. As a result of expansion and mergers of hospitals there are now 5 consultants responsible for bleeding disorders: Dr Millar, Dr Salooja, Dr Lo, Dr Shlebak and me. Dr Arachchillage works 3 sessions at the Hammersmith hospital and 7 PAs at the Royal Brompton Hospital.

7.6. I remain the director of the haemophilia centre.

7.7. In response to the request for 'senior colleagues' I have not listed the nurses working in the centre over this time or other consultant haematologists who supported the service without having direct responsibility.

8. Please describe:

a. your role and responsibilities at the Centre and how, if applicable, this changed over time;

8.1. In 1985 I began as a registrar in haematology at the Hammersmith Hospital/Royal Postgraduate Medical School (RPMS). I did not immediately have responsibility for patients with haemophilia, but during my 2 years in the post I treated many of the patients in the centre and for a period of approximately 5 months I would have been the registrar responsible for haemophilia. During this time, I was supervised by the consultant Dr Hows and the two Senior Registrars Dr Durrant and Dr Swirsky.

8.2. 1992. On taking up my honorary consultant and senior lecturer post, I took over consultant responsibility for care of inherited bleeding disorders from Dr Swirsky, who was by then a consultant. At this time, I also had responsibility for general medical and non-malignant haematology patients as well. For two periods, approximately 1992-1994, 1997-1999 the transfusion consultant post was vacant and Professor Luzzatto asked me to take this responsibility during these periods.

8.3. As director of the haemophilia centre, my responsibility has not fundamentally changed since 1992. The responsibility now includes participation in the North London Adult Haemophilia Network. I have however been joined by 4 other consultants and I have given up the transfusion, general medical and general haematology responsibilities.

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

8.4. I was primarily responsible for the haematological care of patients with bleeding disorders. Although some also had HIV infection and/or hepatitis, I did not take primary responsibility for these aspects of their care and my policy was and remains, to refer them to the relevant specialist clinics. Nonetheless we supported joint care and provided treatment via the haematology department when this was convenient for the patient. For example, prescribing AZT or providing nebulised Pentamidine.

8.5. I have not had clinical responsibility for patients with HIV or hepatitis who did not have a primary blood disorder.

9. Approximately how many patients with bleeding disorders were under the care of the Centre when you first started working there and over the years that followed? Approximately what proportion have been adults and what proportion have been children? If you are able to give exact rather than approximate figures, please do so.

9.1. I do not know the total number but in 1985 I think there were approximately 40 patients with severe haemophilia and when I returned in 1992 there were approximately 20. There are now approximately 38 patients with severe haemophilia out of a total of 200 patients with bleeding disorders.

9.2. I do not recall treating children with haemophilia when I was a registrar and at that time there was not a consultant paediatric haematologist at the Hammersmith. There were some children registered at the Hammersmith when I returned in 1992. After appointment in 1992 I continued to treat children in collaboration with a paediatric haematology consultant (first Dr I Roberts and later Dr H New) until a reorganisation of services in approximately 2012 when paediatric care for haemophilia transferred to Great Ormond Street.

10. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there. What if any involvement did you have in these decisions? (If you have any information about the approach to the selection, purchase and use of blood products at the Centre prior to you taking up your position as registrar there in 1985, please also set that out). In addressing this issue, please answer the following questions:

10.1. As a registrar at the Hammersmith between 1985 and 1987 only a small part of my time was spent looking after patients with haemophilia. As a registrar I did not have any responsibility for or play any part in the purchase of blood products.

10.2. As a consultant I had full responsibility for these decisions, whilst working within national guidelines. There are no written policies other than the national guidelines.

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

10.3. I cannot answer this with respect to 1985-1987.

10.4. When I took up the consultant post in 1992, I inherited patients with established treatment plans. I cannot recall details, but these would obviously have been plasma derived products. I remember that at this time companies were changing and working to improve the safety of their products. We adopted these as they became available.

10.5. I can recall five significant changes when specific decisions were made:

10.5.1. Ensuring dual viral inactivation after Hepatitis A transmissions;

10.5.2. Choosing concentrates to reduce risk of avoid parvovirus transmission to mothers;

10.5.3. Using monoclonal antibody purified FVIII for HIV positive patients;

10.5.4. Introducing recombinant FVIII and FIX;

10.5.5. Withdrawal of concentrates made from UK plasma and additional measures for non-concentrate products after vCJD emerged.

10.6. These reflected national rather than local policy changes.

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

10.7. As detailed in the previous question, all the major changes I can recall were made on the basis of safety. In some cases, decisions were prompted by changes in product availability. Some of the decisions required approval locally or nationally.

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

You might wish to refer to the minutes of the Hammersmith Hospital NHS Trust Blood Transfusion Committee to assist you [NHBT0086563_003 and NHBT0086562_001]

10.8. Introduction of new therapies required approval which involved an application to the New Drugs Panel. As for all new therapies, this included an estimate of any change in expenditure that would ensue.

10.9. This was no longer necessary after the introduction of the national tendering process.

10.10. As noted elsewhere I sought funding for the monoclonal antibody purified FVIII and for recombinant FVIII. The latter was rejected on grounds of cost versus benefit. However, once government funding became available recombinant FVIII was introduced. Monoclonal antibody purified FVIII was funded via the AIDS drug budget until the change to recombinant products took place.

10.11. The Hammersmith Hospital NHS Trust Blood Transfusion Committee papers [NHBT0086563_003 and NHBT0086562_001] record discussions regarding the choice of plasma to be used in the hospital. The costs of the different products and their different properties are listed but there is no record of any discussion about how price or commercial factors should influence the decision.

11. What particular products were used for treating patients at the Centre, over what period of time and for which categories of patients?

11.1. <u>Plasma derived products for haemophilia A (until 2003)</u>

11.1.1. 8Y

11.1.2. Monoclate

11.2. Recombinant products for haemophilia A (after 1998)

11.2.1. Recombinate

11.2.2. Kogenate/Helixate

11.2.3. Refacto

11.2.4. Advate

11.2.5. Novo8

11.2.6. Nuwiq

11.2.7. Elocta

11.3. Plasma derived products for haemophilia B

11.3.1. 9A

11.3.2. Alphanine

11.4. Recombinant products for haemophilia B

11.4.1. Alprolix

11.4.2. Benefix

11.5. Products for von Willebrand disease (all plasma derived)

11.5.1. HaemateP

11.5.2. Voncento

11.5.3. 8Y

11.5.4. Wilate

11.5.5. Wilfact

11.6. Products for Factor XI deficiency (all plasma derived)

11.6.1. Hemoleven

11.6.2. Factor XI (BPL)

11.7. Bypassing agents

11.7.1. Novoseven -recombinant

11.7.2. FEIBA – plasma derived.

11.8. Immuno factor VII concentrate (plasma derived)

11.9. Since becoming a consultant, I can think of only two instances where patients were given different products on the basis of some categorisation;

11.9.1. When we obtained funding to give monoclonal antibody purified concentrate to patients with HIV infection. This began in approximately 1992 and lasted until recombinant products were available;

11.9.2. During the early phase of 'recombinant for all' in which young patients were the first to receive recombinant concentrate. This period was from 1998 to 2003.

12. What was the relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre's decisions and actions?

12.1. Relationships with manufacturing companies were good. I found them to be a useful source of information on developments in manufacturing. They made no significant attempt to influence prescribing directly.

13. In the enclosed February 2003 email chain between yourself and a number of colleagues [HCDO0000109_031], the possibility of a pharmaceutical company sponsoring new guidelines on the treatment of von Willebrand's disease was discussed. Please provide some context for those discussions. Were the guidelines sponsored? Are you aware of a pharmaceutical company sponsoring any other guidelines, whether issued by UKHCDO or any other organisation? If so, what (if any) effect did the sponsorship have on the contents of the guidelines?

13.1. The guidelines were being written by a working party composed of members from the UKHCDO. I do not recall what prompted the suggestion that a company might support the publication of the guidelines. As is clear from the correspondence, this suggestion was not supported. The guidelines were written and published in a scientific journal without any financial or any other support from companies.

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

14.1. I was not aware of external guidelines in the period 1985-7. Subsequently, beginning in 1988, the UKHCDO and NHS UKHCDO published guidelines on choice of products for bleeding disorders. Until approximately 2000 I had no direct involvement in generating these guidelines.

14.2. Subsequently from 2007 the choices of concentrate were determined in

large part by the results of the national tendering process. Contracts guaranteeing use of specific amounts of particular concentrates were awarded. These amounts were then implemented pro rata in regions and individual haemophilia centres.

14.3. This contracting process was repeated in subsequent years until 2020.

14.4. The contracting was carried out by The NHS Purchasing and Supplies Agency (PASA) which later became The Central Medicines Unit (CMU) in collaboration with UKHCDO. The history and development is described in Hay, C.R.M. (2013), Purchasing factor concentrates in the 21st century through competitive tendering. Haemophilia, 19: 660-667. (Exhibit WITN3089005).

14.5. The contracting process defined the concentrates that we could use although there was provision for exceptions to this and choices for individual patients could be made within the centre.

15. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions? To what extent, if at all, were patients offered a choice as to which products to use?

15.1. The choice of products during the period 1985-1987 when a risk of disease transmission was uncertain is described in question 17.

15.2. Since 1992 specific blood derived or recombinant products were not given to specific patients on the basis of either's characteristics. The only exceptions I can recall are:

15.2.1. the use of monoclonal antibody purified FVIII for HIV-infected patients;

15.2.2. the introduction of recombinant concentrates when use was initially based on age;

15.2.3. selection to minimise risk of parvovirus transmission for pregnant women;

15.2.4. prior to the introduction of recombinant products, when beginning prophylaxis for children we used the monoclonal purified Factor VIII concentrate.

15.3. After the introduction of national tendering in 2007, the choice of products was limited to those for which a contract had been awarded. Changes in prescriptions provided to patients were sometimes required to fulfil the requirements of the national contract. This was explained to patients, but I do not recall any patient ever raising an objection to this. The contracting process was predicated on the conclusion that all the products were equally effective and equally safe.

15.4. An exception was made for patients with a history of inhibitor in which case we would avoid switching.

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

16.1. Tranexamic acid

16.2. Desmopressin

16.3. Plasma

16.4. Cryoprecipitate

16.5. Platelets

16.6. Hormonal therapy

17. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Centre make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

Agent	Advantages	Disadvantages
Tranexamic acid	Oral administration. Can be self-administered Synthetic	Limited efficacy No assay to measure effect Increased risk of seizures
Desmopressin	subcutaneous, oral or intranasal administration Synthetic Effect can be measured	Only for mild HA and VWF. Variable, limited and brief effect. Reduced effect of repeated dose within ~48 hours Hyponatraemia (especially in children) Requires fluid restriction Risk of thrombosis
Cryoprecipitate	Entails exposure to relatively small number of donors Effect can be measured	For HA and VWD only Difficult to achieve normal levels. Cumbersome to use compared to concentrate. Plasma derived.

		Donations tested for known viruses, but not virally inactivated.
Fresh frozen plasma	Entails exposure to relatively small number of donors Effect can be measured Contains all plasma coagulant and anticoagulant factors	More dilute than normal plasma which limits ability to elevate factor levels. Plasma derived Donations tested for known viruses, but not virally inactivated.

17.1. In 1985 -7 patients at the Hammersmith were treated with non-concentrate therapies whenever possible and whenever it was judged safe from a haemostatic point of view. When it was thought essential to use a concentrate in order to achieve haemostasis, then the UK concentrate was preferred.

18. What was the Centre's policy and approach as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?

18.1. In 1985 cryoprecipitate was used whenever possible for patients with VWD and haemophilia A. After 1992 we rarely used cryoprecipitate for inherited bleeding disorders.

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

18.2. Cryoprecipitate was used less after the introduction of improved donation practice and viral inactivation of concentrates. It was used rarely after I became a consultant in 1992.

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

18.3. I cannot answer this for the period 1985-7

18.4. After 1992, this was discussed frequently by UKHCDO and at local level meetings.

19. What was the Centre's policy and approach in relation to home treatment? Did the policy and approach change over time and if so how?

19.1. I do not recall a defined policy in 1985-7, however some patients did keep concentrate at home and others attended the hospital whenever they needed treatment.

19.2. As far as I recall, home treatment was available to all patients who wished to use this approach.

19.3. Home treatment became the norm for patients with severe haemophilia when prophylaxis became standard care and was the preferred approach at the Hammersmith after 1992. This was further facilitated by home delivery and the greater stability and smaller volumes of concentrates. Although clearly beneficial the principal advantage for home delivery at the time was that it avoided the VAT payable on recombinant products (as opposed to plasma derived products).

20. What was the Centre's policy and approach in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

20.1. When I took over in 1992 my recollection is that few, if any patients were on prophylaxis.

20.2. I introduced prophylaxis from the outset, including the initiation of prophylaxis prior to development of haemarthroses in children.

20.3. The only change over time has been to increase the amount and intensity of prophylaxis for all patients.

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

21.1. Apart from the period when recombinant concentrate was funded only for children, the policy for children was generally not different from adults. The introduction of recombinant for all, later encompassed the use of rFVIIa rather than FEIBA for children with inhibitors.

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

22.1. The principles were not different, except that mild bleeding disorders in general did not warrant prophylaxis. Patients with mild or moderate haemophilia A or VWD are the only groups who could use desmopressin and this was used in preference to concentrates when it could achieve the necessary haemostatic effect.

23. What, if any, viruses or infections, other than HIV, hepatitis B and hepatitis C, have been transmitted to patients at the Centre in consequence of the use of blood products during the time that you have worked there? As far as you are aware (from your current knowledge of the patients that you have treated at the Centre over the years), what (if any) viruses or infections, other than HIV, hepatitis C and hepatitis B, were transmitted to patients at the Centre in consequence of the use of blood products prior to the time you joined the Centre?

23.1. Other viruses can be transmitted by coagulation factor concentrates; notably hepatitis A and parvovirus. I have not personally had to deal with transmission of either of these at this centre. Other infections including vCJD remain hypothetical risks at present.

Section 3: Knowledge of, and response to, risk

General

24. The Inquiry understands that you began your career as a registrar in haematology at the Hammersmith Hospital in February 1985. At that time, 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?

24.1. In February 1985 I knew relatively little about transfusion transmitted infection when compared with the situation now.

24.2. I was familiar with Hepatitis B and with the risks of malarial and other parasitic transmission. I knew about CMV transmission in relation to immunosuppressed patients.

24.3. In 1984 I read an editorial in the British Medical Journal (Bruce-Chwatt LJ. Infection, immunity, and blood transfusion. Br Med J (Clin Res Ed). 1984;288(6433):1782-3. doi:10.1136/bmj.288.6433.1782). (Exhibit WITN3089006) and noted the progress and also the uncertainties relating to the acquired immunodeficiency syndrome. The article was cautious in attributing the syndrome to the newly identified retrovirus and optimistic about the scale of the problem and the ways in which it was being tackled.

24.4. I also remember seeing Dr P Duesberg (Professor of molecular and cell biology at the University of California, Berkeley) give a lecture at the RPMS between 1985-7. Although his contention that AIDS was not caused by the virus received a hostile reception, the very fact that he was invited to talk suggested that some uncertainty still remained.

24.5. Since 1990 I have worked in academic centres and been exposed to continuous discussion and with full access to the literature regarding transfusion transmitted infection. I have been fortunate to have attended

national or international meetings several times a year. In the 1990's one of the principal topics at these meetings was viral transmission and the safety of coagulation factor products. This has slowly subsided in importance following the introduction of recombinant FVIII and FIX but has not entirely gone away.

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

25.1. I cannot answer this for the period 1985-7.

25.2. From 1992 the final responsibility rested with me. Introduction of new products was discussed at hospital transfusion committee, the AIDS committee and the New Drugs Panel. However, in large part I relied on regulations imposed at European and National levels and the guidelines produced by the UKHCDO.

26. What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products, and (ii) the use of NHS blood products?

26.1. The relative risks of commercial and NHS products have changed over time.

26.2. I recall that in 1985-7 the blood products produced by the NHS (and from UK plasma) were regarded as having a **lower risk** of transmitting infection than the commercially supplied products from overseas.

26.3. By 1990 this was less of an issue and commercial products were regarded as being at **least as safe** and in some cases safer, than the NHS products.

26.4. After 1998 it was understood that commercial products should be regarded **as safer** than NHS products because UK plasma may contain vCJD. UK

plasma was no longer used for the manufacture of concentrates.

Hepatitis

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

27.1. I understood that Hepatitis B could be transmitted by blood transfusion but that blood donations were tested for this and so it was unlikely to be transmitted. Nonetheless it was recognised that transmission could still occur.

27.2. In 1985, it is my recall that little was known about NonANonB hepatitis. At the time its aetiology was uncertain, its prognosis was uncertain and no transmissible agent had been identified.

27.3. I recall the isolation of Hepatitis C virus in 1989. What I knew about this came from information via journals, colleagues in UK and overseas and meetings. Isolation was followed by the development of diagnostic testing, although for several years these tests were regarded as not entirely reliable.

27.4. Nonetheless, availability of testing revealed the extent of exposure, prevalence in the general populations in different countries, allowed investigation of modes of transmission and helped map the natural history of infection.

27.5. This understanding eventually led to development of treatment and monitoring of treatment.

27.6. All these steps were reported widely in the academic literature and at meetings.

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

28.1. I did not personally carry out any investigations into the risks of transmission of hepatitis.

29. What, if any, actions did you take to reduce the risk to patients of being infected with hepatitis (of any kind)?

29.1. In 1985-7 the principal concern was the transmission of HIV/HTLV- III. There were no additional measures taken for hepatitis. It was not established that NonANonB hepatitis was an infection.

29.2. In 1992 and subsequent years the risk of transmission of hepatitis C and B by factor concentrates was estimated to be very low and no additional measures were taken other than the use of high purity virally inactivated concentrates from tested donors and plasma pools.

29.3. In or around 1995 there were two reports of transmission of Hepatitis A by factor concentrates. It was quickly realised that being a non-enveloped virus, Hepatitis A would 'escape' solvent detergent (s/d) inactivation. Other factors taken into account were the fact that a carrier state for hepatitis A did not exist and so this was unlikely to be a frequent problem and the possibility that increased purity of concentrates had facilitated these episodes by removing anti-hepatitis A antibodies in normal human plasma. After these episodes we did not use any concentrates that relied on s/d treatment alone for viral inactivation.

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?

30.1. As a medical student from 1975-1981 we were taught that hepatitis B could be transmitted by blood and that infection could sometimes persist and cause liver damage.

30.2. It was only after the hepatitis C virus was identified in 1989 that I became aware of reliable epidemiological data on rates and routes of transmission, prevalence and contribution of the hepatitis C virus to long term liver damage.

30.3. Subsequently I have learnt about several other hepatitis viruses (D, E, F, GB) with different risks and severity.

HIV and AIDS

31. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products during your time working at the Centre? How did your knowledge and understanding develop over time?

31.1. As detailed elsewhere, by the time I started as a registrar in 1985, I was aware that the HTLV-III virus had been isolated and was the likely cause of the acquired immunodeficiency syndrome. Although this was not entirely certain, it was generally accepted by my colleagues to be true and we acted on this assumption.

31.2. Identification of the virus enabled an estimate of how many patients had become infected. This showed that many, but not all had been infected. What was much less clear was how many of the infected patients would progress to AIDS, so the overall severity of the problem was not known.

31.3. I accumulated knowledge over the following years.

31.3.1. This included:

31.3.1.1. frequency of infection;

31.3.1.2. prognosis;

31.3.1.3. factors determining prognosis;

31.3.1.4. infections associated with AIDS;

31.3.1.5. value of therapies; and

31.3.1.6. prophylaxis.

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

32.1. My first distinct recollection is when reading the BMJ editorial in 1984 (Bruce-Chwatt LJ. Infection, immunity, and blood transfusion. Br Med J (Clin Res Ed). 1984;288(6433):1782-3. doi:10.1136/bmj.288.6433.1782

33. What, if any, enquiries and/or investigations did the Centre carry out or cause to be carried out in respect of the risks of transmission of HIV or AIDS? What information was obtained as a result?

33.1. When I arrived in the Centre in 1985, I recall that most if not all patients had been tested for antibodies to HTLV III. I do not think that any studies regarding the risks of transmission were carried out.

34. What, if any, actions did the Centre take to reduce the risk to your patients of being infected with HIV?

34.1. In 1985-1987, wherever or whenever possible, exposure to blood products was avoided. When they were used, the most effective product thought to carry the least risk of HIV infection was chosen.

35. Did the Centre continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

35.1. By the time the risk of HIV infection had been identified, the majority of transmissions had already occurred. In the small number of patients who were not infected, the lowest risk approaches were used; again as detailed elsewhere, this would, when possible, involve using

35.1.1. desmopressin rather than plasma derived products,

35.1.2. cryoprecipitate rather than concentrate and

35.1.3. UK-derived concentrates rather than foreign commercial concentrates.

35.2. After 1992 the risk was extremely small, and concentrates were widely used.

Response to risk

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

36.1. I cannot recall any such steps in 1985-7.

36.2. In and after 1992 the risks were extremely small, but were discussed with patients, particularly when switching to recombinant concentrates.

37. When did the Centre begin to use heat treated factor products and for which categories of patients?

37.1. Although I am aware that heat treated products became available in 1986, I cannot recall their use before I left at the beginning of 1987. However, during this period, I was primarily working with patients with leukaemia.

37.2. In 1992 all the concentrates had undergone some form(s) of viral inactivation procedure and improved purification.

38. Do you consider that heat-treated products should have been made available earlier? If not, why?

38.1. I am not qualified to answer this question.

39. Did the Centre revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

39.1. Yes, many patients were treated with cryoprecipitate rather than concentrate in 1985-1987. This can be used only for haemophilia A and von Willebrand disease. The only reason for not using it that I can recall is when higher levels of coagulation factor were required. I do not recall any shortage of supply.

40. Do you consider that the decisions and actions of the Centre 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.

40.1. As a registrar, it was my view that the Centre was taking appropriate measures.

41. Looking back now, what decisions or actions by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

41.1. The question implies that there were 'non-infected blood products' available, but in fact there were no blood products that could definitely be

said to be uninfected until the advent of PCR testing in around 1990.

41.2. The question also implies that there is no cost to avoiding the use of blood products that have an uncertain risk of infection. At the time, for the reasons given above, this would mean avoiding all blood products. Taking this path would mean leaving bleeding episodes untreated and with consequent serious risk for patients.

41.3. Given the knowledge at that time, a pragmatic and sensible course of action was therefore to minimise exposure to plasma, particularly in those who were apparently uninfected. This is what was done.

42. 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?

42.1. Inasmuch as this question must refer to events prior to 1985, I am not able to answer.

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

43.1. I do not have sufficient knowledge of the technology available, the organisation of health care or the pharmaceutical industry in that period to be able to answer this question.

Section 4: Treatment of patients at the Centre

Provision of information to patients

44. What information did you provide or cause to be provided (or was, to you knowledge, provided by others) to patients at the Centre with a bleeding disorder about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

44.1. I cannot answer this question for the period prior to 1985.

44.2. In the period 1985-7, I do not recall specific information being provided to patients although it was frequently discussed and my impression was that patients were well aware of the risks. Most patients had been receiving concentrates for many years.

44.3. After 1992, the risks of viral transmission were discussed in clinic but no specific literature was provided.

44.4. After the concern that vCJD might be transmitted by plasma emerged, there was an extensive programme established to inform patients about the risk. The UKHCDO coordinated this programme in 2004 in which all possibly exposed patients were written to. However, this was entirely about risk from previous exposure, not current or future exposure.

45. 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.

45.1. In 1985-7 I do not recall general information being provided. However, when treatment was requested or required, I recall that the reasons for the choice of treatment were explained to the patient.

45.2. This changed in parallel with the estimated risks from the treatments available.

46. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients before they began home treatment/home therapy?

46.1. I do not recall any particular information being given specifically at the initiation of home therapy.

HIV

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

47.1. I do not remember, but I assume it must have been shortly after starting in 1985 because it was a major problem at that time and many patients knew that they were infected.

48. Please describe how and when you learned that patients under the care of the Centre had been infected with HIV.

48.1. This was already known when I began work at the Hammersmith in 1985.

49. What if any arrangements were made at the Centre for pre-test counselling?

49.1. In 1985 most patients had been tested and knew the result of the test.

49.2. In 1992, because most patients had already been tested, initiating testing was an infrequent event. However, when required, there was an extensive information sheet for HIV testing and accompanying consent form for patients and doctors to sign. Counselling was provided by the doctor in clinic although two social workers were also available and attended clinic.

49.3. There were no corresponding forms for Hepatitis, which would have been explained to the patient.

50. How and when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by phone? Were they seen individually or in groups? What if any involvement did you have in this process?

50.1. As a registrar I do not recall any occasion when I had to give this information to a patient.

50.2. After 1992, in parallel with the consent forms, there were guidelines about how the result of a test should be delivered. This included not sending the result by mail or by phone and never on Friday. On the few occasions I had to do this, it was usually a non-haemophilia patient who had thrombocytopenia or some other problem that had led to testing.

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

51.1. The significance of a positive result changed over time. At all stages patients were made aware of current knowledge of disease course, treatments available and the possible psychological and social consequences of a positive result, including transmission.

51.2. Patients would be referred to a specialist clinic where more information would be available.

51.3. To the best of my knowledge patients were never told to keep their infection secret.

52. What was the Centre's policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?

52.1. The possibility of sexual or other transmission was explained to patients. It was for the patient to inform partners or family members if they wished. It

was made clear that testing for partners and family members would be available if they requested it.

53. What, if any, information or advice was provided by the Centre to partners or family members of people who were at risk of infection with HIV or were infected with HIV?

53.1. The information and advice was the same as for the patient. The significance of a positive result changed over time. At all stages they were made aware of current knowledge of disease course, treatments available and the possible psychological and social consequences of a positive result.

54. What if any arrangements were made at the Centre for post-test counselling?

54.1. I am not aware of any post-test counselling in the time patients at Hammersmith were tested, which was prior to 1985.

54.2. After 1992, the results were given by the doctor and 2 social workers were available to help them manage their life if they were found to be HIV positive. However, I cannot recall ever making the diagnosis of HIV infection in a patient with haemophilia.

55. How many patients at the Centre were infected with HIV? Of those infected,

55.1. A total of 31 patients infected have attended the centre

55.2. 2 patients acquired infection before attending.

a. How many had severe haemophilia A?

55.3. 31

b. How many had moderate haemophilia A?

55.4. 0

c. How many had mild haemophilia A?

55.5. 0

d. How many had haemophilia B?

55.6. 0

e. How many had von Willebrand disease?

55.7. 0

f. How many were children?

55.8. 3 attended the centre and were <16 in 1985

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

56.1. The only work of which I am aware was published by Dr S Ball in 1985. (BMJ 1985 Vol 290 Page 1705) (Exhibit WITN3089007).

57. Please refer to the letters between you and Dr Hewitt, the Deputy Director of the then North London Blood Transfusion Centre dated 6 August, 14 August, 18 August, 25 August, 28 August, 29 October, 3 November and 23 November 1992 regarding donors who tested positive for HIV and whose donations were issued to the Centre [NHBT0090047, NHBT0090049, NHBT0090062, NHBT0090063, NHBT0090064, NHBT0090050, NHBT0090066, NHBT0090069]. The letters relate to the tracing and testing of possible recipients of infected donations. Please describe, generally:

a. What steps would have been taken by you/the Centre, when Dr Hewitt, or others from the North London Blood Transfusion Centre notified you of donations likely to have been infected.

57.1. Dr Hewitt requested that I identify the recipient of the blood units in question. I did this with the help of laboratory staff using the hospital blood transfusion records. Dr Hewitt also requested that the patient be counselled, informed and tested if they wished. Since I was not directly looking after these patients, I contacted the relevant doctors who arranged these steps. I then reported the results to Dr Hewitt.

57.2. There were no positive results and so no further steps were required.

b. What steps would have been taken to investigate the matter, and what was the standard process for tracing recipients of infected blood at the Centre?

57.3. The transfusion laboratory records are very clear and comprehensive. The blood unit number is directly linked to the recipient and their hospital number. By then obtaining the notes it is possible to trace the patient. The objective was to identify the patient, inform them of the risk and offer testing.

c. Whether you believe that the investigations which were carried out were sufficient, if not why not?

57.4. The investigations were sufficient.

d. What difficulties, if any, were encountered by the Centre in tracing recipients of donations known to have been infected? If you were unable to trace recipients known to have been infected, what were the next steps, if any?

57.5. The recipients of such donations were all successfully traced without difficulty.

e. Whether recipients who were traced were tested by the Centre, and if so, whether their consent was sought for such testing. If not why not?

57.6. None of the recipients were tested by the centre. The patients involved in these cases were not patients with bleeding disorders.

f. Whether counselling was offered to such patients by the Centre. If not why not?

57.7. Not applicable. These were not patients at the centre.

Hepatitis B

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

58.1. In 1985 a specific test for hepatitis B was available and as a result of blood donation testing, transmission of this infection was unusual. Moreover, since only a minority of infected patients develop chronic infection it was unusual to encounter this problem. I do not recall discussing this with patients in 1985-7.

58.2. Since 1992 I have had some patients with chronic hepatitis B infection. I think these are all overseas patients who acquired it before coming to the UK. Their hepatitis is managed by the hepatology clinic.

59. Please refer to the correspondence between you and Dr Hewitt dated 29 July 1993, 17 August and 19 September 1994 regarding a donor who tested positive for the Hepatitis B marker and whose donation was issued to the Centre [NHBT0098395; NHBT0055084_022; NHBT0055084_016]. Please describe:

a. What steps would have been taken by you/the Centre, when Dr Hewitt, or others from the National Blood Transfusion Service notified you of donations likely to have been infected.

59.1. The recipients of the units would have been identified from the transfusion laboratory records and the patient's details and notes retrieved. Patients would have been informed of the risk and offered testing.

b. What steps would have been taken to investigate the matter, and what was the standard process for tracing recipients of infected blood at the Centre?

59.2. After identifying the patient their current status would have been established and the relevant doctor informed.

c. Whether you believe that the investigations which were carried out were sufficient, if not why not?

59.3. The recipient was later identified by Dr Skacel and reported to be in terminal care. It appears that no further investigations were necessary.

d. Whether you can recall any cases where recipients of infected blood were not able to be traced? If so, why not?

59.4. I cannot recall any such cases brought to my attention by the blood transfusion service. Within the haemophilia centre I am aware of one patient who has left the country and cannot be contacted.

e. What difficulties, if any, were encountered by the Centre in tracing recipients of particular donations known to have been infected?

59.5. I cannot recall any difficulties. The transfusion records are usually complete. The above correspondence relates to the blood transfusion laboratory not to the haemophilia centre.

f. Whether recipients who were traced were tested by the Centre, and if so, whether their consent was sought for such testing. If not why not?

59.6. The above correspondence relates to the blood transfusion laboratory not to the haemophilia centre. The tracing of recipients was complete.

g. Whether all patients who were suspected of being the recipients of infected blood were notified of the risk of infection. If not why not? And

59.7. In the specific instance cited above, the recipient was receiving terminal care for lymphoma and showed no signs of infection. Dr Skacel suggested that no further action was required.

h. Whether counselling was offered to such patients by the Centre. If not why not?

59.8. Not applicable

60. How many patients at the Centre were infected with hepatitis B?

60.1. 64 patients were found to have evidence of hepatitis C infection.

60.2. Only one of these has evidence of concurrent hepatitis B infection.

NANB Hepatitis/Hepatitis C

61. Were patients 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 if any involvement did you have in this process?

61.1. In 1985-1987 I recall little attention being paid to this question. There was

no test available, no treatment available and it was unclear that it was an infectious disease or how frequently long-term effects developed.

61.2. In 1992 a test for hepatitis C was available (although early tests were not entirely reliable) and I was aware of data that described the natural history of hepatitis C. I was aware that some patients developed chronic liver disease. I discussed this with patients and most patients were tested. Treatments became available and literature was provided, often by pharma companies.

61.3. I referred patients with evidence of hepatitis C infection to the hepatology clinic for management.

62. When did the Centre begin testing patients for hepatitis C? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What if any involvement did you have in this process?

62.1. Testing for hepatitis C in the centre began before 1992.

62.2. Any cases subsequently identified were usually informed by me in clinic. It was not policy to inform patients by phone or by letter.

63. Please refer to the correspondence between Dr Hewitt and Dr Ward (which is copied to you) dated 18 February 1993, regarding a patient who was found on routine screening to have seroconverted to HCV [NHBT0055080_020]. In respect of this letter, please answer the following questions:

a. When did the routine screening of patients at the Centre commence, and what did it involve? Which category of patients were chosen for routine screening?

63.1. This letter does not relate to the haemophilia centre and the patient identified was not a patient of the haemophilia centre. I do not know what

form of 'routine screening' identified his hepatitis C. The letter is copied to me because I was also responsible for the transfusion laboratory at this time and to ask me for his transfusion record.

b. Dr Hewitt states that "*If, after checking, we ascertain that none of the* units came from a donor subsequently identified as anti-HCV positive, we shall have to consider very carefully whether there is any justification in investigating any further, since so many of the transfused units come from unscreened donations" . Do you recall any instances where further investigation by the North London Blood Transfusion Centre was not justified? If so, please provide details of such instances.

63.2. I do not recall any such cases.

c. Were patients who were found on routine screening to have seroconverted to HCV informed of their results? Did you share information uncovered during your correspondence with the National Blood Transfusion Service with the patient(s) in question? If the answer to any of these questions is no, please explain why not.

63.3. I was not the doctor responsible for these patients' care and not the doctor who requested the test for hepatitis C.

63.4. I do not know what constituted 'routine screening' in this case.

64. In the enclosed letter dated 13 September 1993 [NHBT0055088_008], Dr Hewitt refers to having checked records of all donors in respect of whose donations were given to a patient suspected of post transfusion hepatitis, and states that "*it is unlikely that we have missed an anti-HCV positive donor or that one of the donors were seroconverting at the time of the donation in question*. In your experience, do you agree that it would have been unlikely that the North London Blood Transfusion Centre would have missed any HCV positive donors? If not, why not?

64.1. I cannot answer this question. It requires knowledge of the sensitivity and specificity of the tests performed at the Transfusion Centre at that time, which I do not have. It also requires knowledge of the relative timing of different donations, frequency of subsequent donations and the fate of the

donations which I do not have.

65. In the enclosed letter dated 20 August 1993 [NHBT0055088_011], Dr Hewitt states that a case of possible post transfusion hepatitis at the Centre was required to be reported to the Department of Health. What information was being sought by the Department of Health and for what purpose? In what circumstances was information of this kind shared with the Department of Health? When information about patients was shared with the Department of Health and/or the North London Blood Transfusion Service, were patients informed that you had done so? (You may also wish to refer to your response to Dr Hewitt enclosing the patients records, [NHBT0055088_009])

65.1. The letter does not refer to a patient at the centre. I do not know what information the Department of Health requested from the Blood Transfusion Service or in what circumstances any requests were made.

65.2. In replying to Dr Hewitt's request for this information, I would not have informed the patient.

66. When a test for HCV became available, what if any steps were taken by the Centre to ensure that all patients who had received blood or blood products were traced and invited to be tested?

66.1. After arriving in 1992 I tried to ensure that all such patients were tested for hepatitis C antibodies. Later, it became possible to test for Hepatitis C virus by PCR and this was also done. However, this was not done systematically. A systematic review to ensure that all patients who received any blood products were tested was carried out in 2010 and followed up in 2017 under direction of the UKHCDO.

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

67.1. Patients attending the haematology clinics were informed about the results of their tests and given preliminary information available at the time regarding significance, prognosis, treatment options and management. They were told that we would refer to the hepatology clinic for further advice.

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

68.1. 64 patients were found to have evidence of hepatitis C infection.

Delay/public health/other information

69. 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.

69.1. When testing for HIV, it was customary to make special arrangements to inform patients of the result. For hepatitis C this was not usually done. I'm not aware of any factors causing a delay in delivery of results.

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

70.1. Informing patients about the mechanisms and risks of viral transmission were an important part of counselling in clinic.

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

71.1. Apart from Hepatitis B, Hepatitis C, HIV and vCJD, there were no other infections about which information was provided.

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

72.1. The mechanisms of transmission were discussed with patients and testing was offered to others who may have been infected.

73. What actions or decisions were taken by the Centre to trace patients who may have been infected through the use of blood or blood products?

73.1. The UKHCDO provided lists of all patients with record of exposure to blood products and these patients were traced to ensure they had been tested and if appropriate offered treatment. For some patients there were insufficient details to allow this to be completed.

Consent

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

74.1. Blood samples were taken at most clinic visits. The purpose varied between patients and over time. In some cases it was a simple check on overall health, in others it was to monitor for occult bleeding, test for inhibitor development or to monitor changes in liver tests. It was routine practice for the virology laboratory to retain samples. This practice preceded hepatitis C and HIV and was not restricted to patients receiving blood products. The purpose of testing was usually explained to patients but there was no recording of consent for performance of blood tests, except for HIV testing as described in response to Q49.

75. Were patients under your care or under the care of your colleagues at the Centre 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?

75.1. Treatment, choice of treatment and the benefits and risks of using the treatment were explained to patients at all times, including when changing treatment. Consent was not recorded.

76. 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?

76.1. Patients who had received blood products would be tested for HIV and hepatitis C. The reasons for doing so were explained to patients but consent was not usually recorded except for testing for HIV as described in response to Q49.

PUPS

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

77.1. In 1985-7 I do not recall treating any PUPs.

77.2. After 1992 we did treat PUPs. In some cases these were adults who had mild or moderate disease and required treatment for trauma or surgery. In some cases they were children requiring treatment after birth or to begin prophylaxis. Treatment entailed choosing an appropriate therapy with the patient or carer and assessing the risks and benefits of the therapy and of any procedure.

Research

78. Please list all research studies that you were involved with during your time as a consultant at the Centre. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, 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.

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.

78.1. I have not conducted any studies regarding the transmission of infection by blood products.

78.2. Other studies, not relevant to the inquiry:

78.2.1. Continuous infusion of concentrates for surgery

78.2.2. Post marketing studies for voncento and alprolix

78.2.3. Phase 1 studies for recombinant VWF, anti-TFPI

78.2.4. Use of a pharmacokinetic model aid in treating haemophilia

78.2.5. Gene therapy studies for haemophilia A

78.2.6. Genetic basis of inherited bleeding disorders.

79. The Inquiry understands that the various research studies undertaken at the Centre, or that you otherwise contributed to or were involved in or provided data for, included or may have included the following:

a. An article published in November 1997: "Mortality from liver cancer and liver disease in haemophilic men and boys in UK given blood products contaminated with hepatitis C" [HCDO0000264_150]

79.1. I was involved in this study only to the extent that all the UK haemophilia centres report the death of registered patients and the cause of death, to the national haemophilia database.

b. An article published in September 1995: "Mortality before and after HIV infection in the complete UK population of haemophiliacs" [HCDO0000016_009]

79.2. I was involved in this study only to the extent that all the UK haemophilia centres report the death of registered patients and the cause of death, to the national haemophilia database.

c. An article published in 1994: "Dendritic Cells Persistently Stimulate Antibody but not Proliferative Responses to HIV in Seropositive Individuals" [ICHT0000156] Please set out what you recall of these research studies and explain what involvement you had in them.

79.3. I was not involved in this study and nor was the patient mentioned in Dr Knight's letter.

79.4. The patient mentioned in Dr Knight's letter was curious to know why he had not developed HIV infection despite using a great deal of commercial Factor VIII concentrate. He asked me if this could be investigated. Dr Knight's laboratory agreed to test his blood and was able to provide some answers for him. He gave express consent.

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

80.1. The two articles mentioned above [HCDO0000016_009] and [HCDO0000264_150] were publications of data previously collected as part of NHS management and service provision.

80.2. Neither I nor any patients under my care took part in the study published as [ICHT0000156]

80.3. A study of samples from one patient was subsequently carried out with their express consent but was not published.

80.4. Other studies carried out (those listed under Q78) were clinical trials in which written consent was taken.

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

81.1. Data was not used in any of these ways by the centre after 1992.

81.2. I cannot answer this question for the period 1985-7

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

82.1. Patient data that was held in the hospital records was returned to the National Haemophilia Database as requested by the database. This included the diagnosis of patients with bleeding disorders and any adverse events, including disease transmission and death that occurred to them.

82.2. Details of concentrates used were returned although until recently, this was only overall totals and did not identify what specific patients received.

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

83.1. Pasi KJ , Collins PW, Keeling D, Brown S A , Cumming A, Dolan G, Hay CRM, Hill FG M, Laffan M A, and Peake IR. "Management of von Willebrand Disease: A guideline from the UK Haemophilia Centre Doctors' Organisation" Haemophilia 10 (2004) 218-231

83.2. D. Perry, E. Bentorp, C. Tait, G. Dolan, P. A. Holme, M. Laffan, R. Lassila, A. Mumford, J. Pasi, J. Wilde, A. Will, T. T. Yee. ' FEIBA prophylaxis in haemophilia patients: a clinical update and treatment recommendations Haemophilia 16 2010 80-89

83.3. Laffan MA, Lester W, O'Donnell JS, Will A, Tait RC, Goodeve A, Millar CM, Keeling DM. The diagnosis and management of von Willebrand disease: a United Kingdom Haemophilia Centre Doctors Organization guideline approved by the British Committee for Standards in Haematology. Br J Haematol 167 (2014) 453-465

83.4. Tuddenham, E.G.D. and Laffan, M.A. Purified factor VIII. British Medical Journal 311 (1995) 465-466

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

84. How was the care and treatment of patients with HIV/AIDS managed at the Centre? In particular:

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

84.1. All patients with HIV infection were referred to a dedicated HIV clinic.

84.2. All patients with Hepatitis C were referred to a dedicated Hepatology clinic or advice obtained on the need for such a referral.

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

84.3. This was managed by the HIV clinic.

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

84.4. This was managed by the HIV clinic.

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

85.1. This was managed by the HIV clinic.

86. How was the care and treatment of patients with hepatitis B managed at the Centre? In particular:

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

86.1. This was extremely rare but hepatitis B infection was detected, patients were referred to a hepatology clinic.

b. What treatment options were offered over the years?

86.2. This was managed by the hepatology clinic.

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

86.3. This was managed by the hepatology clinic.

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

87.1. This was managed by the hepatology clinic.

88. What if any involvement did you and/or colleagues at the Centre have with any clinical trials in relation to treatments for HIV and Hepatitis C? Please provide details.

88.1. We did not conduct or take part in trials for HIV or Hepatitis C although some patients did take part in these studies via the respective clinics.

89. How was the care and treatment of patients with NANB hepatitis managed at the Centre? In particular:

89.1. When I took over care in 1992 NANB hepatitis was no longer a diagnostic entity, but patients who had been exposed to blood products and/or had evidence of liver inflammation, were tested for hepatitis C infection. Patients who showed evidence of hepatitis C infection were managed as described in response to Q90.

89.2. This question therefore refers to the period prior to 1992 of which I have no knowledge.

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

89.3. N/A – for hepatitis C, please see Q90

b. What treatment options were offered over the years?

89.4. N/A – for hepatitis C, please see Q90

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

89.5. N/A – for hepatitis C, please see Q90

90. How was the care and treatment of patients with hepatitis C managed at the Centre? In particular:

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

90.1. Patients with evidence of hepatitis C infection were referred to a hepatology clinic or advice was obtained regarding suitability for such a referral.

b. What treatment options were offered over the years?

90.2. This was managed by the hepatology clinic.

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

90.3. This was managed by the hepatology clinic.

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

91.1. This was managed by the hepatology clinic.

91.2. When a liver biopsy was required, the centre provided management of coagulation.

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

92.1. The arrangements were the same as for adults.

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

93.1. In 1992 the Centre had two social workers who provided this support. At some point in the mid 1990's their funding was removed and the centre no longer had dedicated social workers. In 2000 as part of a reorganisation, funding was obtained for 0.5 whole time social worker. This post is still funded.

93.2. We have never had direct funding for psychology services. This could be accessed via our nearest comprehensive care centre at the Royal Free Hospital.

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

94.1. I am not certain of the funding sources for the two social workers in 1992. My recollection is that it was part local authority and part dedicated AIDS funding.

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

95.1. With regard to specific therapeutics, any such problems were dealt with by

the hepatology and HIV clinics.

95.2. With regard to specific blood products, I had initial difficulty in obtaining funding for the high purity Factor VIII concentrate but this was supported from the AIDS budget.

High Purity products and Recombinant Products

In answering the following questions, you might wish to refer to the paper written by you and Professor Tuddenham, "Purified Factor VIII: Theoretical advantages but at a cost" ("the BMJ paper") [HSOC0006487] and the minutes of the North East and North West Thames Regional Haemophilia Centre Directors Working Party meetings [BART0000584, BART0000582 and BART0000581]

96. Please set out your involvement in the debate about the need for and/or use of high purity products for HIV positive patients. Did you use such products for HIV positive patients at the Centre or at the Royal Free Hospital and if so which?

96.1. The evidence for the benefit of high purity concentrates in HIV patients came from a study published in October 1991. I left the Royal Free in March 1992. I cannot recall whether we started using high purity concentrates for this reason during this period.

96.2. However, I do recall applying for funding to use high purity concentrates (specifically a monoclonal antibody purified concentrate) after starting at the Hammersmith. The additional cost of this concentrate at the Hammersmith was met from the 'AIDS budget' as it was then called. This was then approved by the department of Health, as noted in BART0000584.

97. Please explain your involvement with efforts to obtain recombinant blood products for patients with haemophilia. What difficulties were encountered and why?

97.1. My efforts to obtain recombinant blood products are set out in DHSC0003540_126. The problem I faced was that a change of practice to introduce this new type of concentrate would incur an increase in cost and this required approval by the hospital New Drugs Panel.

98. Please refer to the enclosed correspondence dated 15 June 1995 between Colin T Dollery and Dr Calman regarding a request to the Department of Health to approve use of recombinant Factor VIIIfor patients with haemophilia [DHSC0003540_126]. The letter refers to you preparing a scientific case for the use of high purity Factor VIII prepared by recombinant DNA technology. Please provide the Inquiry with a copy of documents you prepared for this purpose. If you do not have a copy of this document, please explain why you believed that recombinant Factor VIII should be used for patients with haemophilia.

98.1. I do not have any relevant documents

98.2. My impression is that Professor Dollery accurately reproduced the case for using recombinant concentrates that I made at that time. These are essentially the same as those made in the BMJ paper HSOC0006487 that I wrote with Professor Tuddenham. Professor Dollery also details the reasons why the request was rejected and the commissioning problems that this issue raised.

98.3. The only point that I think Prof Dollery does not give enough emphasis to, is the possibility of unknown infections. My impression from the experience with HIV and hepatitis C was that by the time it was realised there was a problem, virtually all the patients at risk had been exposed. It was therefore important to introduce recombinant products before any such new problem emerged.

98.4. In fact, this was more or less what had already happened with vCJD and a ban on use of UK plasma for manufacture of concentrates was subsequently introduced.

99. The letter dated 15 June 1995 [DHSC0003540_126] further states that while you believed that recombinant product should be used, you agreed to look into the evidence that the immune-purified and treated material from the Blood Products Laboratory might be as good as recombinant factor VIII. Did you look at this evidence, and if so, what conclusions did you draw?

99.1. I do not have any record of this review. I think the conclusions would have been the same as set out above, in Prof Dollery's letter and in the BMJ paper.

100. Please refer to the letter dated 15 December 1997 from Dr Pickles to the Directors of Public Health (which is copied to you) [BART0002080] which discusses shifting patients from plasma based products to product from non-UK sources, or recombinant factor VIII in light of the possibility of transmission of vCJD to haemophiliacs. The letter states that both Professor Lee and Dr Colvin were of the view that there was no justification for this shift as the risk of vCJD transmission was still theoretical and remote. Please explain whether or not you shared this view, and the reasons why.

100.1. As detailed above, my view was that we should move all patients to recombinant concentrates. Not specifically for vCJD, but as a principle. We are fortunate that vCJD does not seem to have been transmitted by concentrates but in fact, as with HIV, it was already too late to prevent exposure of most patients.

101. In your view, should recombinant blood products have been made available to all patients with haemophilia earlier than they were? If so, why, and when?

101.1. My view is that they should have been made available when they were licensed.

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

102.1. Recombinant products were made available to our patients in keeping with the government approvals of 1998 for children and 2003 for adults.

Records

103. What was the Centre's policy as regards to recording information on death certificates when a patient had been infected with HIV or hepatitis?

103.1. We did not have a policy for completion of death certificates.

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

104.1. There was no policy of retention that differed from the standard hospital policy.

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

105.1. In 1985 a brief summary file for each patient was kept in the centre in addition to the patient's hospital notes. This provided key information about the patient if the notes had been taken to a different department for some reason. Treatment episodes could be recorded in these.

105.2. After 1992 the patient records were kept as far as possible in the haemophilia centre and I established a computerised database (only within the centre) so that patient details were always available and we did not need the additional file system.

106. 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 Centre? If so, why, what information and where is that information held now?

106.1. No

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

107.1. No

Section 5: UKHCDO

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

108.1. When I became centre director in 1992, I became a member of the UKHCDO and have attended its annual meetings and received correspondence from it since then.

108.2. In 2013 I became chair of the von Willebrand disease working party. I have demitted from this post this year (2020)

108.3. In 2012 I became secretary to the UKHCDO and served two terms over a total of 6 years.

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

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

109.1. Without reference to the terms of reference, my understanding was that the

UKHCDO existed to help coordinate care for patients with inherited bleeding disorders. It did this by pooling knowledge and experience, by writing guidelines, negotiating funding with the NHS and monitoring developments in care so that these could be disseminated. It helped to ensure good and uniform care by collecting data on treatment and outcomes. These functions remain largely the same today.

109.2. Since the UKHCDO is a charity and a voluntary organisation set up by its members, I am not sure it had many responsibilities other than those it defined for itself. The only external one of which I am aware is to provide an annual report on haemophilia care to the DoH.

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

109.3. The UKHCDO established working parties to deal with specific problems or needs that it identified. For example, the von Willebrand disease working party. Once these working parties had completed their task, most frequently writing or updating guidelines, then the intention was that they would be disbanded and reformed when needed. Some had continuous roles, such as the Data Management Working Party because it had a continuing obligation to provide an annual report to the Department of Health. The composition of these working parties was primarily UKHCDO members, although experts from other areas could be co-opted when needed.

109.4. There were no committees.

109.5. The whole membership met annually for an Annual General Meeting.

109.6. The directors of the comprehensive care centres met every 3-4 months in what was called the 'Advisory Board'. For most of the time after 1992 I did not attend these because the Hammersmith was not a CCC.

109.7. During my tenure as secretary, the officers i.e. Chair, vice chair, secretary

and treasurer met regularly, informally and usually by phone every week to deal with day to day business.

c. The relationships between UKHCDO and pharmaceutical companies.

109.8. My understanding is that the UKHCDO exists in two forms: Firstly, the charity, which carries out the business of the UKHCDO as described above (Q109b); Secondly there is UKHCDO Ltd which runs meetings and handles finances which the charity cannot.

109.9. As a charity UKHCDO's relationship with pharmaceutical companies was extremely limited.

109.10. The company UKHCDO Ltd, had interactions with companies. Pharmaceutical companies pay for advertising or promotional space at the AGM and this helped fund the UKHCDO and the National Database.

109.11. Companies also helped support the database directly via UKHCDO Ltd and sometimes pay for specific analyses of data.

d. How decisions were taken by UKHCDO.

109.12. Depending on the magnitude of the decision this would be made by the executive committee, the advisory board or at the AGM.

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

109.13. Sometimes this would be presented at the AGM other times by mail, historically conventional and now by email.

109.14. The advice was disseminated to its membership. The membership broadened over the years. Now a circular from the UKHCDO will reach all doctors, AHPs and data management staff.

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;

109.15. The only guidance I have been directly involved in is that set out in the guidelines for the management of von Willebrand disease.

ii. the manufacture of blood products;

109.16. None. I do not think the UKHCDO had any direct role in the manufacture of blood products.

iii. self-sufficiency;

109.17. This debate predates my involvement in UKHCDO.

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

109.18. Only as set out in the VWD guidelines.

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

109.19. I received the UKHCDO guidelines but was not involved in writing them.

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

109.20. None

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

109.21. None

viii. heat treatment;

109.22. None

ix. other measures to reduce risk;

109.23. None

x. vCJD exposure; and

109.24. I received the UKHCDO guidelines and the instructions for notification of patients but was not involved in writing them.

xi. treatments for HIV and hepatitis C.

109.25. None

Section 6: Pharmaceutical companies/medical research/clinical trials

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

110.1. I have provided advice and consultancy services to many companies. Specifically:

110.1.1. Bioproducts Laboratory (BPL)

110.1.2. Armour

110.1.3. Bayer

110.1.4. NovoNordisk

110.1.5. CSL-Behring

110.1.6. Baxter-Baxalta-Takeda

110.1.7. Sobi

110.1.8. Octapharma

110.2. The advice usually involved explaining to companies what issues I felt were important or my views on what issues patients felt were important. It sometimes involved explaining details of coagulation mechanisms, behaviour of molecules and laboratory measurements.

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

111.1. Advice is given on a continuing informal basis and mostly is unremunerated.

111.2. In some cases formal meetings (advisory boards) are arranged. These meetings would last for whole or part of a day and are usually remunerated. Time from work would be taken as leave. I have not retained records of the details of payments.

111.3. I have never been retained as a contracted consultant.

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

112.1. Please see my answer to Q111.

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

113.1. No

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

114.1. No

115. 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.

115.1. No

116. What regulations or requirements or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

116.1. In 1992 I do not recall any regulations, but it was many years before I received any such payments.

116.2. Over the last 10 years (I estimate) it has become practice for organisations such as Imperial College, NHS Trusts, BSH and UKHCDO to request an annual declaration of these involvements. I have always provided these.

116.3. Also the ABPI now request permission to publish these involvements. I have always given permission to do so.

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

117.1. I have taken part in clinical trials organised or sponsored by pharmaceutical companies:

117.1.1. Continuous infusion of concentrates for surgery;

117.1.2. Post marketing studies for voncento and alprolix;

117.1.3. Phase 1 studies for recombinant VWF, anti-TFPI;

117.1.4. Use of a pharmacokinetic model aid in treating haemophilia;

117.1.5. Gene therapy studies for haemophilia A.

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

118.1. No

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

119.1. I have received funding for research from pharmaceutical companies but only in the form of unrestricted grants ie the funding was not to perform any particular work on behalf of the company. These were always administered by my employing organisation (RPMS/Imperial College) and the source of the funding was always explicit.

Section 7: vCJD

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

120.1. I cannot recall a specific point at which this occurred.

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

a. What steps were put in place at the Centre for informing patients about possible exposure to vCJD?

b. What steps were taken to tell patients of possible exposure to vCJD?

c. What steps were taken to provide information to patients about the risks of vCJD?

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

121.1. a-d. In the 2004 exercise all patients with bleeding disorders were contacted and offered information about their risk. Letter formats were provided by the UKHCDO. If they wished to have details of their risk (or absence of risk) they were provided with this at a clinic appointment.

121.2. Advice regarding their risk was given at the consultation. There were no special arrangements for counselling.

122. In the enclosed letter dated 31 October 2005 [HCDO0000244_012], you inform Dr Hill of a patient who could not have an endoscopy due to his high risk CJD status. Please detail the problems you experienced with endoscopies, and how, if at all, they were resolved.

122.1. After the identification of patients deemed to be 'high risk' for CJD, it was not possible to perform endoscopies on this group. Arrangements were sought to fund the provision of endoscopes specifically for patients but to my knowledge these funds never materialised. Subsequently the regulations were relaxed somewhat and

some but not all procedures could be carried out. The problem has never been fully resolved.

Section 8: The financial support schemes

123. What if any involvement did you 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?

123.1. I had no direct involvement with these organisations.

124. To what extent, during your time at the Centre, did staff (including you) inform patients about the different trusts or funds?

124.1. In my experience, patients and their relatives have been well informed about these funds. When they were not, we supplied the information.

125. Did the Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

125.1. We did not have any specific guidance.

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

126.1. The information supplied was usually given in response to specific questions on an application form. Sometimes a letter of support was required. The form and any letter were always returned to the patient, not to the trust or fund. So no information was supplied directly to the trust or fund.

127. Did the 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.

127.1. We never did this.

128. Was the 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.

128.1. Decisions regarding applications were always made by patients.

129. 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?

129.1. I do not recall any major problems or having to enter into dispute with the trusts on behalf of patients.

Section 9: Current haemophilia care and treatment

130. The questions in this section are aimed at enabling the Inquiry to understand how haemophilia care is currently provided and how the provision of care and treatment and the approach to patients may have changed over the years. Please describe:

a. How the provision of care and treatment for bleeding disorders is currently organised at the Centre; and

130.1. Patients with possible bleeding disorders are referred from primary care,

from consultants in other specialties and from haematologists at other hospitals.

130.2. Patients with previously diagnosed bleeding disorders are referred from other adult centres or from paediatric centres when they reach adulthood.

130.3. Patients with newly diagnosed or previously diagnosed bleeding disorders have follow up and regular reviews arranged at the haemophilia centre. They are given a card with contact details for the staff at the centre in and out of hours. They are given a 'passport' to use at the Trust emergency departments so that their assessment and treatment is expedited.

130.4. If they consent, their details are sent to the National Haemophilia Database.

130.5. Patients with frequent bleeding or at high risk of bleeding are offered prophylactic treatment and the pros and cons of this are explained. Patients who embark on prophylaxis may need instruction in self-administration, which is provided. When they are competent and confident in self-administering treatment, there are arrangements made for regular delivery to their home or other selected address.

130.6. At present there are several different forms of treatment available for haemophilia and these are discussed before a particular one is selected by the patient.

130.7. Patients receiving prophylactic treatment are asked to keep a record of treatments using the Haemtrack system.

130.8. All patients are contacted or seen on at least annual basis. Patients with severe haemophilia are seen twice a year. At one of these reviews they are asked to complete a quality of life questionnaire and allow a joint score to be recorded.

130.9. Patients are advised to contact the centre if any problems arise or any

procedures requiring additional treatment are planned.

b. Your current roles and responsibilities at the Centre.

130.10. I am currently designated the director of the centre. I chair the monthly management meetings and attend the monthly quality meetings. I represent the centre at the North London Adult Haemophilia Network meetings. I liaise with the UKHCDO regarding management and policy implementation. I communicate relevant information to my colleagues.

130.11. I see patients with all types of bleeding disorder in a weekly clinic. I take responsibility for active management problems on a rotating basis with my consultant colleagues. Similarly, I provide on-call support out of hours on a rotating basis.

131. Please outline the treatments currently provided to patients with bleeding disorders at the Centre.

131.1. Coagulation factor concentrates:

131.1.1. Elocta, Advate, Refacto, Novo8. Nuwiq

131.1.2. Alprolix, Benefix

131.1.3. Novoseven

131.1.4. Riastap

131.1.5. Octaplex

131.1.6. Voncento

131.1.7. Wilate

131.1.8. Hemoleven

131.2. Non-concentrate

131.2.1. Desmopressin

131.2.2. Tranexamic acid

131.2.3. Platelets

131.2.4. Hormonal therapy

131.2.5. Physiotherapy

132. 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?

132.1. Typically the characteristics, risks and benefits of the available treatments are explained to patients at an outpatient review appointment. At present none of the recombinant factor concentrates or any of the plasma derived concentrates have any identified infectious risk. It is made clear that the plasma derived concentrates retain a theoretical risk that does not exist for recombinant products. However there are no circumstances at present in which we choose a plasma product rather than a recombinant equivalent. (I am aware that an exception to this is Factor XIII, but this is extremely rare and we do not have any relevant patients).

132.2. The risk of inhibitor development is explained.

132.3. When there is a lack of data, this is explained to the patient.

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

132.4. I would not regard infection transmission as a 'side effect" and this is dealt with above in the answer to Q132a. The risk of allergic or idiosyncratic reactions is explained. When using factor concentrate to treat patients with VWD, the risk of promoting thrombosis is explained.

132.5. The risk of inhibitor development is explained.

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

132.6. The risks of not treating depend on the nature and severity of the patient's bleeding disorder and the nature and severity of the injury, risk of injury or planned procedure. In general the information provided describes the risk of bleeding and the consequences of bleeding.

132.7. This may vary from lethal or disabling to a minor nuisance.

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

132.8. For patients with haemophilia and without inhibitors undergoing surgery or after trauma, the benefit of treatment is that it restores their risk of bleeding closer to that of the general population.

132.9. When considering prophylaxis for haemophilia, the benefit of treatment is that it can reduce the risk of joint damage closer to that of the general population. It can also permit the patient to undertake activities that would be excessively dangerous if undertaken without treatment.

132.10. The efficacy and risks vary between different bleeding disorders. For some disorders, such as VWD it will reduce the risk of bleeding but may not be effective to the same extent as for haemophilia.

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

133.1. Typically the points discussed and the conclusion would be documented in the patient's notes.

134. Do you routinely take blood samples from patients attending the 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?

134.1. We do not routinely take samples from patients attending the centre.

134.2. Samples are taken for specific tests for specific purposes. We do not store samples beyond the fact that not all tests are performed immediately and that it is sometimes necessary to repeat a test for various reasons.

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

135.1. The benefit and intention of testing and the tests proposed are explained to the patient. The amount of explanation varies according to the complexity of the test and how much it differs from previous tests they may have had.

135.2. Similarly, consent is only specifically recorded for unusual or rarely performed tests.

136. How many current patients at the Centre were:

a. Infected with HIV through blood products?

136.1. 3

b. Infected with hepatitis C through blood products?

136.2. 13

c. Infected with hepatitis B through blood products?

136.3. 4 possible. 3 probably overseas

d. Co-infected with HIV and hepatitis C through blood products?

136.4. 3 although all three have been treated for hepatitis C

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

137.1. Patients with HIV and/or hepatitis C continue to be seen in specialist HIV and hepatology clinics. Apart from general support, the haemophilia centre plays a relatively small role in this aspect of their care. I think that multidisciplinary clinics (i.e. joint haematology-HIV/Hep C clinics) would be feasible but would add little value.

138. What, if any, psychological services are available at the 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?

138.1. We do not have funding for a psychologist at our centre. We have access to psychological services via the Royal Free Hospital as part of the North London Adult Haemophilia Network. This is not specific for HIV or hepatitis C.

139. What, if any, other support services are available at the Centre?

139.1. Physiotherapy

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

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

140.1. Clearly the most concrete effect has been that many patients died prematurely as a result of these infections and in some cases suffered prolonged periods of illness and debilitation beforehand.

140.2. For those that survived, the effects are complex. My impression is that they include:

140.2.1. Physical problems due to drugs;

140.2.2. Psychological problems from drugs such as interferon;

140.2.3. Psychological problems from stigmatisation;

140.2.4. Psychological problems from guilt and fear of transmission;

140.2.5. Physical damage from interrupted or delayed prophylaxis;

140.2.6. Physical and mental problems from chronic liver disease;

140.2.7. Loss of income and career progression resulting from any of the above.

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

140.3. For many years HIV and hepatitis constituted a major part of care and a major portion of time, energy and resource in the haemophilia centre. Improved management of plasma donations, plasma concentrate manufacture, development of recombinant products and development of effective treatments for HIV and hepatitis C mean that this is now no longer the case. However, until the affected generation has passed on and until recombinant products are available for all replacement therapy, the impact will not be entirely gone.

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

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

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?

141.1. a, b, c, The trajectory of my professional practice has been significantly influenced by HIV and hepatitis but they now play a very small part in my current practice. There are several disorders for which we do not yet have recombinant manufactured concentrates and for these, the lessons of HIV and hepatitis remain important, not because these remain a risk but because they are reminders of how novel agents can appear without warning.

141.2. The similarity of effect on colleagues' careers and practice depends greatly on the time at which they entered the specialty.

141.3. I think that the transmission of HIV and hepatitis delayed the general introduction of prophylaxis in the UK and this is now a priority once more. We are now able to focus on the prevention of bleeding and joint damage and on removing the burden of haemophilia from patients' lives. Apart from

the delay, this is not influenced by previous infection transmission.

Section 10: Other Issues

142. 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.

142.1. A complaint under Rule 9 was made to the inquiry regarding a mother receiving information about her son's hepatitis C by letter.

142.2. I am not aware of any other complaints to any other body.

143. 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.

143.1. I do not have any other matters to raise.

Statement of Truth

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

Signed GRO-C

Dated 6 NOV 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
	Imperial Final Report	WITN3089004
	Hay, C.R.M. (2013), Purchasing factor concentrates in the 21st century through competitive tendering. Haemophilia, 19: 660-667	WITN3089005
	Bruce-Chwatt LJ. Infection, immunity, and blood transfusion. Br Med J (Clin Res Ed). 1984;288(6433):1782-3. doi:10.1136/bmj.288.6433.1782	WITN3089006
	BMJ 1985 Vol 290 Page 1705	WITN3089007