Witness Name: Dr Paula Bolton-Maggs
Statement No.: WITN4160001
Exhibits: WITN4160002 - WITN4160010
Dated: 17 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PAULA BOLTON-MAGGS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 24 August 2020

I, Paula Bolton-Maggs, will say as follows: -

Section 1: Introduction

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

1.1. I am Paula Helen Blundell Bolton-Maggs. My address and date of birth are known to the Inquiry.

1.2. Qualifications:

1.2.1.	BA Cambridge University (Class I)		1971
1.2.2.	BM BCh Oxford University		1974
1.2.3.	MRCP (UK) 1977,	FRCP	1997
1.2.4.	MRCPath 1988,	FRCPath	1997

1.2.5. FRCPCH 1997

1.2.6. DM, MA. (Oxford) 2008

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 1974-January 1975: House Physician at the Radcliffe Infirmary, Oxford.

2.2. February 1975-July 1975: House Surgeon, Princess Margaret Hospital, Swindon.

2.3. October 1975-July 1976 Senior House Officer in Haematology, Addenbrooke's Hospital, Cambridge

2.4. August 1976-July 1977 Senior House Officer in General Medicine and Cardiology. Norfolk and Norwich Hospital, Norwich

2.5. August 1977-January 1978 Senior House Officer in Neurology, Norfolk and Norwich Hospital, Norwich

2.6. February 1979-January 1980 Registrar in Haematology, Swansea Hospitals (Part-time)

2.7. July 1980-March 1986 Part-time Registrar in Haematology, University College Hospital, London. Dr. J.D.M.Richards, Dr. A.H.Goldstone

2.8. April 1986-December 1986 Part-Time Senior Registrar in Haematology, University College Hospital, London. Dr. J.D.M.Richards, Dr.A.H. Goldstone, 4 months spent training at North East Thames Regional Blood Transfusion Centre, Brentwood, Essex.

2.9. January 1986-December 1986, Honorary Senior Clinical Research Fellow, The Royal Free Hospital, London. (In order to carry out a research project in Factor XI deficiency at the Haemophilia centre there)

2.10. February 1987-October 1991- Part-time Senior Registrar in Haematology, a rotation based on the Royal Liverpool University Hospital which included the following:

2.10.1. 1987 4 months at Walton Hospital, Liverpool. Dr. J. Martindale, Dr. P. Stevenson

2.10.2. 1987 3 months at Mersey Regional Blood Transfusion Centre,

2.10.3. 1987-1988 12 months at the Royal Liverpool Children's Hospital, Alder Hey

2.10.4. 1988-1991 Royal Liverpool University Hospital. Professor J.C.Cawley, Dr. J.Davies, Dr. C.R.M.Hay, Dr. R.E.Clark.

2.11. November 1991- November 30, 1992 Locum consultant haematologist Alder Hey Children's Hospital

2.12. December 1992 – May 2003 Haemophilia Centre Director and Consultant Paediatric Haematologist, Alder Hey Children's Hospital, Liverpool, UK.

2.13. June 2003 to August 2011 - Consultant Haematologist (haemostasis and thrombosis) at Manchester Royal Infirmary, Manchester UK.

2.14. October 2011 to August 2018 Medical Director of the UK national haemovigilance scheme, Serious Hazards of Transfusion based in Manchester. 2012 and current: Honorary senior lecturer in the Faculty of Biology, Medicine and Health, University of Manchester.

2.15. Retired 31 August 2018

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. Member of the UK Haemophilia Society 1988-2018.

3.1.1. Member of the medical advisory panel in 1995

3.1.2. Health Resource Committee in 1998 (resigned March 2001)

3.1.3. Advisor for the production of written material for young people with hepatitis C

3.1.4. Advisor for the production of written material for women with bleeding disorders.

3.1.5. I spoke at and supported many local and national meetings.

3.2. British Society for Haematology – member since 1988

3.2.1. Paediatric Haematology Forum (a national subgroup of the BSH)

3.2.1.1. Elected onto the committee of the Paediatric Haematology Forum (PHF) of the BSH 1995

3.2.1.2. Elected to be Scientific Secretary of the PHF April 1996.

3.2.1.3. Elected Chairman of the PHF April 1998-April 2001 - ex officio member of the following national committees –

3.2.1.3.1. British Society for Haematology committee

3.2.1.3.2. Royal College of Paediatrics and Child Health (RCPCH) College Specialty Advisory Committee (Oncology)

3.2.1.3.3. UK Children's Cancer Study Group - Education and Training Committee

3.2.1.3.4. Member of the Conference of Committees, RCPCH

3.2.1.4. In addition I was asked for advice directly from the College Council on issues affecting paediatric haematology, e.g. discussion about the NHS Executive letter 'Better Blood Transfusion' led to a working group and production of a College Policy Document on blood transfusion which was circulated early in 2000.

3.2.2. I was an elected BSH committee member (2003-2006).

3.2.3. Currently I am a member of the External Affairs Committee.

3.3. UK NEQAS Coagulation: I was a member of the steering committee 2008-2014

3.4. UK Haemophilia Doctors' Organisation: Member as haemophilia centre director at Alder Hey between 1991-2003. I chaired the writing group for rare bleeding disorders (guidelines published 2004) and the writing group for platelet disorders (guidelines published 2006).

3.4.1. I represented Mersey Region on the UK Haemophilia Centre Directors committee while I was consultant at Alder Hey

3.4.1.1. I chaired of the Rare Disorders Working Party

3.4.1.2. I was a member of the Paediatric working party.

3.4.1.3. I was a member of the Genetics Working party.

3.5. World Federation of Hemophilia (WFH) – Member (from 1994)

3.5.1. Elected to the executive committee of the WFH October 2004 and re-elected for a further 4-year term in July 2008. Meetings twice a year in Montreal.

3.5.2. Chair of the data and demographics committee until 2012 – formulating changes to data collection and leading on the publication of the annual Global Survey and I continue to review data for the annual Global Survey

3.5.3. Chair of the rare bleeding disorders committee until 2010

3.5.4. This involved conducting meetings by international telephone conferences about 3 times a year for each committee shaping education materials and planning sessions at the international WFH Congresses (held alternate years). This executive committee membership terminated July 2012 after 8 years (maximum allowed).

3.5.5. I reviewed abstracts for World Federation of Hemophilia meetings between 2002-2008. I organised a session on 'Evidence based practice in Haemophilia' for the WFH meeting 2004 and a session on von Willebrand disease 2008. Presented at meetings in 1988, 2000. Invited speaker 1998, 2008 and 2012. I chaired the international General Assembly of the WFH on three occasions 2008, 2010 and 2012

3.5.6. *WFH Twinning*: In 1999 I initiated twinning programme between Alder Hey Children's Hospital and Ismailovsky Children's hospital in Moscow winning the WFH 'Twin of the Year award' in 2003. In April 2003 I led the first national Coagulation workshop in Moscow with participants from across the Russian Federation. A subsequent twinning programme was established between Manchester Royal Infirmary and St. Petersburg ending in 2009.

3.5.7. *International Haemophilia Training Centre status*: Manchester Royal Infirmary became an International Haemophilia Training Centre for the WFH in 2008, 5 fellows completed training visits under my supervision up to 2011 when I changed job.

3.6. 2012 to 2020 Specialist advisor to the Care Quality Commission

3.7. 2015-2018 Member of external advisory board to the Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation. This was a 3-year European Joint Action programme funded by the European Commission under the 2014-2020 Health Programme

3.8. In 2019 I advised the Healthcare Safety Investigation Branch about a case of 'wrong blood in tube'. https://www.hsib.org.uk/documents/147/hsib_report_wrong_patient_details_blood_sample.pdf

3.9. In 2019 I worked with the British Society for Haematology preparing material for their 60th anniversary in 2020.

3.10. November 2017 to November 2020 Chair, Royal College of Pathologists Transfusion Medicine Specialty Advisory Committee. Through this I am a member ex officio of the National Blood Transfusion Committee and the Intercollegiate Committee on Haematology.

3.11. Research interests:

3.11.1. I researched for 25 years into the bleeding disorder, Factor XI deficiency, including two large studies in London (hence my attachment as clinical research fellow at the Royal Free Hospital) and the North West (Manchester and Liverpool) and recently supervised a PhD student who took this work further. Her PhD was awarded December 2016 and resulted in 4 peer reviewed

papers (one in Blood) and an oral presentation at ASH. I was an invited speaker in the ASH Educational Session on FXI in 2009.

3.11.2. I have been an examiner for 3 PhD, 1 DSc and 3 MD theses (for UCL, Cambridge, Liverpool, Manchester Metropolitan and Birmingham Universities)

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. In my role as Medical Director of Serious Hazards of Transfusion haemovigilance scheme in 2014 I gave written and spoken evidence (26 March 2014) to the Science and Technology Committee 'After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob disease'. I do not have a copy of the written evidence but it can be found in this list: https://publications.parliament.uk/pa/cm201415/cmselect/cmsctech/327/32712.htm

4.2. I have not provided evidence to nor been part of any other inquiries, investigations, criminal of civil litigation in relation to HCV, HIV, HBV or vCJD.

5. **It is the Inquiry's understanding that other than haematology roles at Addenbrooke's Hospital, Cambridge, in 1975-1976 and Swansea Hospital in 1979-1980, your haematology career has involved positions as Registrar at University College Hospital ("UCH") during 1980-1986; Senior Registrar, Consultant and Director at Alder Hey Children's Hospital ("Alder Hey") during 1987-2003; and Consultant (and possibly Director for a time) at**

Manchester Haemophilia Centre ("the Manchester Centre") from 2003. Please confirm if that is correct. The questions below focus, as appropriate, on your time at UCH, Alder Hey and the Manchester Centre. Some questions focus on one or two rather than all three of these locations, but if you have information concerning the other(s) relevant to the period or issue to which the question relates, please include that in your response. Insofar as your earlier experiences in Cambridge and Swansea are relevant to the questions asked, please include reference to these too.

5.1. The above details are not quite correct. I was a part time registrar at UCH working 2 sessions per week from 1980 to 1983, then working 5 sessions per week with on-call responsibilities until late 1986. In April 1986 I was promoted to Senior Registrar. As I was now on a formal training programme this period included a 4-month attachment to the Transfusion Centre at Brentwood. The details about 1987 to 2003 are also incorrect; I was attached to Alder Hey as a Senior Registrar for 12 months 1987 to 1988. I then returned to the Royal Liverpool Hospital to continue my training and was not responsible for Alder Hey again until December 1991 when I took up a locum consultant post, and in December 1992 was appointed to a permanent part-time consultant post there.

Section 2: Decisions and actions of those treating patients with bleeding disorders at UCH, Alder Hey and the Manchester Centre and your decisions and actions

6. In relation to your work at (a) UCH, (b) Alder Hey and (c) the Manchester Centre please:

a. describe the facilities, organisation, roles, functions and responsibilities (insofar as relevant to the Inquiry's Terms of Reference) of the hospital/centre during the time that you worked there, and how they changed over time;

b. identify senior colleagues at the hospital/centre (insofar as relevant to the Inquiry's Terms of Reference) and their roles and responsibilities during the time that you worked there;

c. describe your role and responsibilities at the hospital/centre and how those changed over the years.

6.1. **My role at UCH**. This was 35-40 years ago and therefore my memory of the time that I spent at UCH may not be accurate. My answers relating to UCH are therefore given with this caveat.

6.1.1. Facilities and organisation. The haemophilia patients would usually be seen as outpatients in the haematology department. As far as I recall there was no formal haemophilia centre at UCH.

6.1.2. **Senior colleagues**: As my role was as a part-time Registrar at UCH, I was supervised by the consultants (Drs Goldstone and Richards) and Dr Sam Machin at the Middlesex. My recollection is that overall supervision of haemophilia and bleeding disorders was provided by Dr. Machin.

6.1.3. **Role and responsibilities**: I was a part time trainee :2 sessions a week from 1980 to 1983, then 5 sessions per week with on call responsibilities . I concentrated on coagulation, and attended the Regional Haemophilia Directors meetings in London on behalf of UCH. There were several other trainees (senior registrars) in the department who shared in the management of patients with bleeding disorders. Patients would attend outpatient clinics or had drop-in visits to the haematology department. My role would have included writing treatment plans for patients with bleeding disorders who were undergoing surgery and the treatment of outpatients presenting with bleeding. Around 1980 I believe that I suggested the introduction of desmopressin for mild haemophilia and von Willebrand disease in preference to plasma products,

which was agreed by Dr. Goldstone. I was assisted by the Senior MLSO in coagulation, Linda Wilkinson. I do not recall any haemophilia nursing support for outpatients.

6.2. **B. My role at Alder Hey**. This was from 17 to 31 years ago and therefore my memory of the time that I spent at Alder Hey may not be accurate. My answers relating to Alder Hey are therefore given with this caveat.

6.2.1. a. **Facilities**: when I was attached as Senior Registrar my recollection is there was no consultant haematologist at Alder Hey and no specific facilities for patients with bleeding disorders. They would have been seen for acute bleeding problems on the oncology ward and followed in general haematology outpatients. Whilst I was there a haemophilia centre was developed, initially in Ward 2. The was later moved to an annex to the main building with improved facilities.

6.2.2. b. **Senior colleagues**: haemophilia patients would have been under the care of Dr. John Martin, consultant oncologist, and additionally managed by rotating senior registrars in haematology, with advice as required from haematology consultants at the Royal Liverpool Hospital. I think that Dr Lynne Ball was appointed as consultant paediatric haematologist in 1989. She then had maternity leave from 1991-1992 and so I was appointed locum consultant. I subsequently took up an additional part time substantive post in 1992. I became responsible for the children with bleeding disorders and for the transfusion service.

6.2.3. c. **My role and changes over time:** When I started there, the children with bleeding disorders would be seen as needed on the oncology ward, C3. There was no separate haemophilia centre. Treatment was given by oncology staff (nurses and doctors). I think that decisions about treatment products would have been made by staff at the adult centre (Royal Liverpool Hospital). I also

believe that the concentrates would have been supplied from there. Children with haemophilia A had been treated with a variety of FVIII concentrates (I think that the adult centre director was Dr. BA McVerry). Until the appointment of a consultant haematologist these patients would have been under the care of a consultant oncologist – Dr John Martin.

6.2.4. A haemophilia centre was then established in a different part of Alder Hey away from the oncology ward. A haemophilia sister – Nicola Mackett - was employed- who would manage home treatment training and supplies. Later other nursing staff were appointed including Cathy Benfield and Julie Bowman and there was also access to a social worker – John Donnelly. I applied to the UKHCDO for haemophilia comprehensive care centre (CCC) status which was granted (jointly with the adult centre at the Royal Liverpool University Hospital) in 1994. There would have been regular follow up clinics. I do not remember the details, but these will be available in the haemophilia centre audit reports held by the UKHCDO. We had helpful support from the biomedical scientists in Alder Hey coagulation laboratory.

6.2.5. I was engaged in the strategy for the management of children with bleeding disorders, and the implications for their families including genetic counselling. Haemophilia care also required negotiations with health authorities over cost of treatment (e.g. particularly use of recombinant blood products in 1995-6).

6.2.6. I organised teaching and outreach across the North West Region and North Wales and a clinic at Glan Clwyd hospital. I also liaised with the local hospitals and produced a discussion paper on the management of haemophilia and other bleeding disorders in October 1998.

6.2.7. I understand that in the early 1980s a number of children were infected with HIV. These children would have come under my care in about 1987 when I started my attachment as Senior Registrar. I do not remember how many children there would have been at this time. Alder Hey should be able to provide more details of the number of patients. Regular reviews and follow up of these patients would have been undertaken to ensure their symptoms were appropriately managed, any infections treated, and that they and their parents could be updated with developments in treatment. They had been diagnosed in 1986 when HIV testing was introduced. I do not know what information they and their parents were given at that time.

6.3. C. My role at Manchester Royal Infirmary (MRI)

6.3.1. I was appointed as consultant haematologist with an interest in haemostasis and thrombosis in 2003. MRI has a haemophilia centre. I was the consultant for half of the patients with bleeding disorders who had previously all been under the care of Dr. Hay alone.

6.3.2. **Facilities:** The haemophilia centre was staffed by two haemophilia sisters (Lorraine Birtwistle and Paula Mohn) who would manage home treatment and who would review drop-in patients with help from junior haematology staff and consultants. There would be weekly haemophilia clinics on Wednesday afternoons. Such clinics would be for new and follow up appointments. As a routine, patients with more severe haemophilia would seen on a 6 monthly basis (or more often if needed). Patients with mild disorders would generally be seen annually. These clinics included patients with all types of bleeding disorders.

6.3.3. **Senior colleagues**: Dr Charles Hay, Dr. Michael Nash; Dr. Martin Prince (hepatologist) and Dr. Ashish Sukthankar (lead HIV specialist)

6.3.4. As the management of HIV and HCV infections became more complex a joint clinic with HIV specialists was started to manage the HIV-infected patients once a month and a link was developed with a hepatologist to obtain advice about HCV treatment. I do not recall the dates that arrangement began. The patients with HCV that I saw would be seen jointly with the hepatologist (Dr Martin Prince).

6.3.5. **Changing roles**: A third consultant was appointed in haemostasis and thrombosis, Dr. Michael Nash. There was a weekly team meeting with joint ward rounds a week.

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

7.1. I do not know how many patients there were at UCH with bleeding disorders when I worked there. Evidence from a 'business case written for a full-time grade G nurse for the haematology treatment centre' (WITN4160002) shows that in 1995-6 there were 167 patients with bleeding disorders registered at Alder Hey. I do not remember how many there were at Manchester Royal Infirmary. These data will be available from the national database which has UKHCDO Annual Returns from all centres.

8. **What decisions and actions were taken, and what policies were formulated, at (a) UCH and (b) Alder Hey regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:**

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

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

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

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

e. What involvement did you have?

8.1. UCH – I do not recall exactly what products were available. In the early years I remember treating haemophilia and von Willebrand disease patients with cryoprecipitate. Some patients were on home treatment with cryoprecipitate. Concentrate was becoming available both from the NHS and commercial companies. I did not have any authority to decide which concentrates were to be used, but the focus was to use NHS-derived concentrates if possible. At this time the concentrates were not heat-treated. The data about what was used will be available in the UKHCDO Annual Returns submitted to UKHCDO.

8.2. **Alder Hey**. In the absence of a haematologist,

8.2.1. I believe that treatment product decisions were made for the children and the supplies received from the Adult Centre. When Lynne Ball and then I became the Centre Director we made the decisions and aimed to use the safest available products.

8.2.2. I do not know on what basis the choice of products was made in the time before I worked at Alder Hey. In the 1990s heat-treated factor VIII and IX concentrates of increasing purity became available; then recombinant FVIII from 1992 but this was more

expensive and so we had a struggle to obtain approval for its use. Plasma-derived products from different companies appeared to have equivalent activity and safety profiles.

8.2.3. We preferred to source from all companies (for example, BPL, Armour, Baxter and Alpha) in case of any unexpected problems with supply. All concentrates were understood to be safe from viruses once heat treated to an adequate temperature and time (1985-6 onwards). It was thought best not to switch patients between different products. It was possible that exposure to new products may increase the risk of inhibitory antibody development (that is, antibodies which interfere with factor VIII function and render the treatment less effective).

8.2.4. My understanding was that Haemophilia Centres purchased supplies individually, negotiating with the individual companies until a national contract was negotiated. I do not recall when that was (I believe that Dr Charles Hay was key negotiator in this). I tried to ensure that patients had the best available treatment. Guidance was taken from the UKHCDO and its expert committees who would review the most recent studies and evidence.

9. What products were used for treating patients at (a) UCH and (b) Alder Hey, over what period of time and for which categories of patients? How were decisions taken at the hospital/centre as to which products to use for individual patients? What involvement did you have in such decisions? Were patients given any choice, or involved in any discussions, as to which products to receive?

9.1. UCH – I do not remember

9.2. Alder Hey – as above. I do not recall discussing the different products that were available but there would have been some discussion about the available treatment.

10. What was the relationship between (a) UCH and (b) Alder Hey and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?

10.1. UCH – I have no knowledge of this

10.2. Alder Hey – my recollection now is that no single concentrate had advantage over the others for haemophilia A, and so the aim was to have equal relationships with the main providers of concentrates. Given equivalent safety of products, the aim was to treat all the companies the same.

11. If the responsibility for the selection and purchase of blood products at the hospital/centre lay with an external organisation, please specify which organisation and provide as much information as you can about its decision-making.

11.1. To the best of my recollection now responsibility for selection and purchase of blood products did not lie with external organisations.

12. What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders?

12.1. In the 1970s I believe that concentrates gradually became available. Otherwise Haemophilia A was treated with cryoprecipitate and haemophilia B with plasma.

12.2. Factor concentrates became available in the 1980s for both haemophilia A and B so the use of cryoprecipitate gradually diminished. Some FVIII concentrates were also effective for more severe forms of von Willebrand disease. Desmopressin was used for mild haemophilia A and mild von Willebrand disease (vWd) in the early 1980s.

12.3. In both decades antifibrinolytics were available and used for example for dental extractions as additional treatment, or as sole treatment for nose bleeds and heavy menstruation (oral contraceptive pills were also useful for menorrhagia).

13. What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at (a) UCH and (b) Alder Hey? 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?

13.1. Desmopressin is a non-blood product.

13.2. I introduced this in preference to concentrate for mild haemophilia and mild von Willebrand disease (vWd).

13.3. Desmopressin probably was not in use for these disorders at Alder Hey until after 1988-9 but the UKHCDO Annual Returns can clarify this. Antifibrinolytics were standard of care for mucosal bleeding with or without additional products depending on the patient disease and severity. When Desmopressin was used Alder Hey, it was initially as an IV infusion but later by subcutaneous injection.

14. What was the policy and approach at (a) UCH and (b) Alder Hey as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?

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

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

14.1. **UCH:** Cryo was used for patients with von Willebrand disease and for some patients with haemophilia A but I do not recall the policy. Concentrates were introduced once they were available and this policy was not decided by me.

14.2. **Alder Hey:** As far as I recall, cryo was not in use for patients with haemophilia or vWd at Alder Hey from the time I was there. The sequence of introduction of the different concentrates will be evident from the UKHCDO Annual Returns.

15. What was the policy and approach at (a) UCH and (b) Alder Hey in relation to home treatment? So far as you are aware, when was home treatment introduced? Did the policy and approach change over time and if so how?

15.1. **UCH:** I do not remember when it was introduced and do not know what the policy was.

15.2. **Alder Hey:** We aimed to get patients with severe haemophilia A and B on home treatment when they and the parents were willing and trained. I do not remember when this was first introduced.

16. What was the policy and approach at (a) UCH and (b) Alder Hey in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

16.1. **UCH** I do not recall any policy for this at the time I was at UCH

16.2. **Alder Hey** The experience of benefit of long term primary prophylaxis published from Sweden (reduced bleeding episodes, better joint outcomes) convinced UKHCDO and haemophilia treaters internationally that this was an important advance in haemophilia care, and that children should be started on this as soon as they and their parents could tolerate it. This became national policy. There was resistance to this due to the increased cost. I put a case in writing for this to the Research and Development (R&D) committee (chaired by Professor David Lloyd) and it was rejected as too

expensive and there was, at that time, insufficient evidence for it, i.e. no randomised controlled trials. I was not invited to attend in person. WITN4160003 'Prophylaxis for patients with severe haemophilia' outlines the evidence for prophylaxis (June 1996) and includes some comments received from other Centre Directors after the rejection by the R&D committee. The evidence of benefit from prophylaxis was later published by Manco-Johnson in 2007 following a randomised trial (prophylaxis vs episodic treatment).

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

17.1. I do not recall treating many children at UCH. I can recall one. They would normally have been managed from Great Ormond Street Hospital. I do not recall what the protocols or policies were for children, but I would have been guided by the UKHCDO.

18. To what extent, and why, were people with mild or moderate bleeding disorders treated at (a) UCH and (b) Alder Hey with factor concentrates?

18.1. **UCH** – factor concentrates were used for mild haemophilia until the introduction of desmopressin in the early 1980s. This was not suitable for factor IX deficiency nor patients with moderate haemophilia A. Factor IX concentrate was preferable to fresh frozen plasma for haemophilia B at all levels of severity where replacement therapy was required.

18.2. **Alder Hey** – the answer is similar to above. Over time the use of desmopressin, first given intravenously and later subcutaneously became the standard treatment for mild haemophilia and von Willebrand disease (of appropriate subtypes). Children with moderate and severe haemophilia required concentrates.

19. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at (a) UCH, (b) Alder Hey and (c) the Manchester Centre in consequence of the use of blood products?

19.1. I do not recall any specific details about this at a. UCH, b. Alder Hey or c. Manchester centre.

Section 3: Knowledge of, and response to, risk

General

20. When you began work at UCH, 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?

20.1. When I worked at UCH, I became aware that there could be infections associated with blood products The sources of information would have been medical meetings, medical literature, UKHCDO and colleagues.

21. What advisory and decision-making structures were in place, or were put in place, at (a) UCH and (b) Alder Hey and/or within the area they covered and/or nationally, to consider and assess the risks of infection associated with the use of blood and/or blood products?

21.1. UKHCDO meetings and local policies. The UK Haemophilia Centre Directors shared information as it became available. The UKHCDO annual meeting was a useful source of updates and recommendations. The UKHCDO Annual Returns collated data on all patients registered with bleeding disorders.

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

22.1. There was some evidence that the risk of infection with hepatitis viruses and HIV was increased with commercial concentrates sourced from the USA compared with NHS, but infections were also transmitted by UK products, both concentrates and cryoprecipitate.

Hepatitis

23. When you began work at UCH, what was your knowledge and understanding of the risks of the transmission of hepatitis (including HBV and NANB hepatitis) from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

23.1. When I worked at UCH I became aware that there was a risk that some blood products could transmit hepatitis. See above under 20 and 22.

24. What, if any, further enquiries and/or investigations did you carry out or cause to be carried out or were carried out at (a) UCH and (b) Alder Hey in respect of the risks of the transmission of hepatitis? What information was obtained as a result?

24.1. I cannot now recall what enquiries and/or investigations were undertaken at UCH.

24.2. At Alder Hey children with bleeding disorders would have had their liver function tests and hepatitis status monitored regularly, and HCV testing when it became available.

25. What, if any, actions did you, UCH or Alder Hey take to reduce the risk to patients of being infected with hepatitis (of any kind)?

25.1. All newly diagnosed children at Alder Hey were vaccinated against HAV and HBV at diagnosis and this prevented infection with these viruses. Newly diagnosed adults at UCH were also vaccinated against HAV and HBV.

26. What liver function tests and/or other forms of monitoring were undertaken at (a) UCH and (b) Alder Hey and how did that change over time? What was the purpose of such testing and monitoring?

26.1. At UCH hepatitis B markers would have been tested regularly (probably annually) or after evidence of a new infection – jaundice or elevation of liver enzymes.

26.2. Similar routine regular testing would also have taken place at Alder Hey. Patients would also have been tested prior to and then regularly after starting blood product therapy, usually annually. Once HCV was identified in 1991 and testing became available in 1992, patients would be screened for evidence of seroconversion. Most patients exposed to HBV in the past developed evidence of immunity and a few had markers of chronic infection with or without deranged liver function tests. In due course reviews as required were set up with an adult hepatologist from the Royal Liverpool Hospital as there was no paediatric experience with HCV management at Alder Hey.

27. 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?

27.1. HAV would usually be a mild infection with full recovery and subsequent immunity. It had rarely been transmitted by blood products.

27.2. Evidence of past HBV infection was not uncommon in adults and children treated with blood products prior to heat treatment but was mostly asymptomatic and with evidence of immunity.

27.3. The impact of NANB hepatitis was not fully appreciated for some time. It became apparent that a number of patients with NANB developed evidence of chronic liver damage.

HIV and AIDS

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

28.1. it was known before the virus was identified, that the condition could be transmitted by blood transfusion, so it was not surprising to find evidence of immune dysfunction and illness in haemophilia patients in the early 1980s (before the virus was identified in 1983-4 and a test developed in 1984-6). Understanding and knowledge of HIV and AIDS evolved as further research was published and information shared at the UKHCDO and other meetings.

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

29.1. I cannot now be certain but I would say the early 1980s. Bruce Evatt from the Center for Disease Control in Atlanta USA had cases reported to him in 1982, e.g. haemophilia patients diagnosed with pneumocystis pneumonia. There were also papers in Lancet 1984 and NEJM 1984.

30. What steps did you and UCH take in light of that awareness?

30.1. My recollections now are that there would have been caution in the management of venepuncture and IV treatment, adopting the same procedures as for HBV, i.e. gloves for venepuncture and treatment, double bagging of samples and labelling them as high risk with yellow hazard stickers.

31. What, if any, enquiries and/or investigations were carried out at UCH in respect of the risks of transmission of HIV or AIDS? What was your involvement? What information was obtained as a result?

31.1. I cannot now recall specific dates, however I think that testing for HTLV-3 became available from Richard Tedder's laboratory in 1984 so we would have been able to test for evidence of infection when this test became available. At this time it was not known what positive test results meant in terms of risk of developing illness in the patient.

32. What, if any, actions were taken at UCH to reduce the risk to the patients of being infected with HIV?

32.1. I cannot recall specifics but the general approach would have been, do not give treatment unless indicated, use desmopressin where possible, try to use NHS rather than commercial concentrate and then heat-treated product as soon as it became available.

33. Did you and your colleagues at UCH continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?

33.1. These would have been used as the alternatives were less effective for bleeding complications. As far as I recall Haemophilia A patients were not reverted to cryoprecipitate. I do not remember what was decided for children as I was not generally treating children at UCH. It should not be forgotten that the reason for treating these patients was that they were at a very real risk of death and serious complications from bleeding had they not been treated.

34. If you are able to provide information about the steps, enquiries, investigations and actions taken by Alder Hey in relation to HIV, based on what you learnt on or after taking up your position there in 1987, please do so.

34.1. When I began working at Alder Hey in 1987 the children had been tested for HIV when the test became available (1986). Follow up for these children and their families was arranged. In subsequent years many of the patients

developed serious infections and several died. It was clear that they needed much support and a place of their own in the hospital. It became clear that what was required was a haemophilia centre.

35. At the 9 November 1983 meeting of the North East Thames Region Association of Haematologists haemophilia working party [BART0000678], it was recorded that no cases of AIDS had been identified at the Royal Free.

a. Please describe the Association's work, purpose and structure, as well as the dates of your membership and role within it. Please also describe the role of the Working Party on Haemophilia in the North East Thames Region and the purpose of the Working Party's meetings.

b. Had any possible AIDS cases, and if so how many, been identified at UCH at the time of the 9 November 1983 meeting? Dr Kernoff told the meeting that all haemophilia centres should remain alert for possible cases – what actions or steps did you/UCH take to ensure that you were alert to possible cases of AIDS amongst your patients?

c. So far as you can, please explain the reasoning behind the suggestions at the meeting that "blood samples from suspected or possible AIDS cases should be handled as for hepatitis B; that the use of blood products in the treatment of mild haemophilia should be avoided and that DDAVP and tranexamic acid should be used whenever possible". Did UCH follow these recommendations, in particular in relation to the treatment of mild haemophiliacs? If not, why?

35.1. The meeting that you refer to was 37 years ago and so my recollections are somewhat historical now. As far as I recall, this group would meet to share information about haemophilia and blood products as a subgroup of the local association of haematologists. I attended for UCH.

35.2. As far as I remember no patients with AIDS had been identified. As I have said this was 37 years ago and so I cannot recall anything specific but we

would have been alert to note any unusual infections which might signify immune deficiency and to investigate and treat accordingly.

35.3. Again this was 37 years ago and the document says what it says. As far as I can now recall, this advice would have been followed.

36. The enclosed minutes of the 13 December 1984 meeting of the North East Thames Region Association of Haematologists Haemophilia Working Party [BART0000676] include an update and discussion on AIDS.

a. So far as you are aware, what was the basis/evidence for the suggestion that the risk of AIDS in treated haemophiliacs in the USA was 1:300 and less than 1:800 in the UK?

b. Please explain the reasoning behind the five agreed points for the treatment of haemophiliacs until heat treated factor VIII became available from BPL. Was the agreed approach implemented by UCH? If so, when? If not, why not?

36.1. I am being asked about the reasoning behind minutes of a meeting that took place 36 years ago. I cannot recall what happened at this meeting. I refer to my answer to 22 above.

36.2. I am being asked about the reasoning behind minutes of a meeting that took place 36 years ago. I cannot recall what happened at this meeting. However, in general terms since AIDS was thought to be a blood transmitted infection, the 5 agreed points appear to be a logical approach to reducing the risk of infection. I have no reason to believe that this type of process was not adopted at UCH but I do not recall now.

Response to risk

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

37.1. Unfortunately I cannot provide any specific detail of what information was provided to patients, I suggest that the respective institutions are approached for this.

38. When did you begin to use heat treated factor products and for which categories of patients? From where did you obtain heat treated products? Did you experience difficulties in obtaining such products? Did you return non-heat treated products or did you continue to use them?

38.1. The aim was to use these as soon as they were available. I do not recall how these were obtained for patients at UCH, nor can I recall how non-heat-treated products were used at this time. The only information I have is that provided in the minutes of the association of haematologists of NE Thames haemophilia working party (BART0000676). By the time I was at Alder Hey all patients were receiving heat treated products.

39. In the enclosed 1 February 1985 letter to Dr Snape at BPL [CBLA0011265], you applied for heat-treated Factor VIII for two patients. Please explain the process for obtaining heat-treated product from BPL, what you can recall about BPL's protocol for the product and how you decided which patients you would request heat-treated product for.

39.1. In relation to the **correspondence with Dr Snape in February 1985**, I do not remember the process for obtaining heat-treated product nor the protocol.

40. In a further 18 February 1985 letter to Dr Snape [BPLL0010626], you wrote that you had previously only included the names of the patients you thought would fulfil the protocol criteria.

a. Please confirm whether requests for heat-treated product were made for patients who did not meet the protocol criteria?

b. You also stated that you/UCH were "of course keen to treat all our haemophiliac patients with heat-treated factor VIII NHS concentrate." Please detail the products you/UCH were otherwise using to treat your/UCH's patients.

40.1. I do not remember if any requests were made for patients "who did not meet the protocol criteria"

40.2. I do not remember what products UCH was using.

41. In the enclosed 12 July 1985 letter to Dr Snape at BPL [BPLL0010516], you proposed a patient for a "*new high-purity concentrate*": 8Y heat-treated Factor VIII. Also enclosed is Dr Snape's 26 July 1985 reply [BPLL0010515], in which he agreed to supply 8Y for your patient.

a. Why did you consider that the information you provided showed the patient to be particularly suitable for this product?

b. What was the basis for your understanding that, if the 8Y concentrate was allocated in the way that BPL proposed, it would "have a significant effect on the distribution of NHS concentrate in the Region", which "would also affect the budget for individual hospitals"? So far as you are aware, did it have such an effect?

c. What if anything did you learn about the views of other Haemophilia Directors on this issue?

41.1. The details of the patient in this letter BPLL0010516 are obscured. I have no recollection of this patient or this letter and therefore any answer would be speculation.

42. At the 21 October 1985 UKHCDO meeting [PRSE0001638] Dr Craske stated that it "appeared from initial reports that dry-heating was not effective in destroying the hepatitis virus(es)". In response Dr Perry "reminded Dr

Craske that there were 3 different types of dry-heating and suggested it was unwise to make generalised statements including all types of heating together."

a. Which hepatitis virus or viruses did you understand Dr Craske to be referring to?

b. What, at the time, did you understand the three types of dry-heating referred to by Dr Perry to be? So far as you understood at the time, which, if any, of them was effective in destroying the hepatitis virus(es)?

c. What, if anything, did you/UCH do in response to Dr Craske's report at the meeting?

42.1. I have no recollection of this meeting and therefore any interpretation of the record of the meeting would be speculation.

42.2. I do not know specifically which hepatitis viruses are referred to here.

42.3. I do not remember what types of dry heat I knew of at that time but according to the literature (Evatt BL 'The AIDS epidemic in haemophilia patients II: pursuing absolute viral safety of clotting factor concentrates 1985-1988' Haemophilia 2012, 18, 649-654) the types of dry heating that were undertaken were: dry heat at 60°C for 72h (Hyland), dry heat at 60°C for 30h (Armour), dry heat at 68°C for 72h (Cutter). I do not remember what I thought at the time about relative effectiveness of these in destroying hepatitis viruses.

42.4. I do not remember if I did anything as a result of Dr Craske's report at this meeting.

43. In the enclosed 9 July 1986 letter [BAYP0000008_276], a Cutter representative outlined a study which was said to show that Koate HT carried no risk of LAV/HTLV III transmission and a low risk of transmitting NANB

hepatitis, and another study on the partition and inactivation of HTLV III virus during the Cohn-Oncley fractionation procedure.

a. How much confidence did you/UCH place on the reliability of these studies?

b. Did you begin to use/continue to use the products referred to by Cutter after receiving this information?

43.1. I cannot comment in the reliability of these studies

43.2. I do not remember what products were used at UCH or when any changes were made other than in the literature that the Inquiry has supplied to me.

44. In a 29 October 1986 letter [ARMO0000618], Armour referred you to a 13 March 1986 letter from Dr Harris on the effectiveness of its viral inactivation measures [ARMO0000512].

a. Armour's letter was addressed to you at Brentwood Transfusion Centre. What was your role at Brentwood? Over what period did you work there?

b. The 13 March 1986 letter set out Armour's donor screening and viral inactivation process for Factorate and its effect on HTLV III risk. How much confidence did you/Brentwood/UCH place on the reliability of this process?

c. The 13 March 1986 letter included the following passage: ""*However, it should not be overlooked that there may be material in centres, or in the home that is not derived from donors tested for anti-HTLV-III. We do appreciate that this information would aggravate the potential for distress to the haemophiliac, because of the patient's inference that non-donor tested material may be less safe with regard to the AIDS risk. Further, we recognise that any decision to give a patient this information rests with you as the unit director.*" What did you understand this passage to mean? Did you provide patients with the information outlined in the letter? Please explain why either way.

44.1. I was at Brentwood Transfusion Centre to continue my training in haematology. I was there for 4 months in 1986 but do not remember the exact dates. During that time, I was not responsible for management of patients at UCH.

44.2. I do not remember how much reliability if any I would have placed on the process for Factorate.

44.3. As I said in the response to 44a above, I was not responsible for management of patients at UCH whilst at Brentwood and so I was not in a position to provide information to patients at this time.

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

45.1. I have no views on this question.

46. Did you 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?

46.1. I do not remember if we reverted to treating some patients with cryo. This information would be available in the UKHCDO Annual Returns.

47. Do you consider that your decisions and actions, and the steps taken at (a) UCH and (b) Alder Hey, 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.

47.1. I believe that the actions taken at UCH were appropriate. We kept updated with developments in viral safety and chose the most appropriate treatment that we could.

47.2. Alder Hey – by the time I was working there in 1987 onwards the children were receiving heat treated products.

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

48.1. I was not at Alder Hey, between 1980 and 1986. Details of the products used might be in the UKHCDO Annual Returns for Alder Hey if these were completed in those years.

49. 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?

49.1. I believe that the most significant point was the UK not becoming self-sufficient in Factor VIII production. Haemophilia treaters had urged the government to do this. Dr. Biggs wrote in her paper in Br J Haematology 1977 (WITN4160004) *'We have the scientific and technical knowledge to make all of the factor VIII that is needed within the United Kingdom using blood that is collected in the United Kingdom. The sooner this objective of self-reliance is reached the less costly will the treatment for haemophilia A patients become. There are reasons other than cost which should encourage every effort to have the supply of factor VIII made from United Kingdom blood. For one thing our haemophilic patients should not be dependent on commercial blood donors recruited in other countries. Also, blood from these donors may be more likely to transmit infection than the blood of voluntary donors'.* As patients used greater amounts of product the proportion of commercial concentrate increased. This is clearly shown in the report on 'Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80: report on behalf of the directors of haemophilia centres in the UK' BMJ March 19, 1983, by Rizza and Spooner WITN4160005. In this paper the increased use of commercial concentrates

compared to NHS factor is clear. In 1980 commercial FVIII concentrate made up 60%. The authors wrote *'..in 1980 [NHS FVIII] represented a quarter of all factor VIII used. This low usage almost certainly reflected the relatively low output from the NHS fractionation laboratories and not a preference for commercially prepared concentrates'*. In retrospect it is clear that this was associated with increased risk of hepatitis and HIV infection. It is my understanding that the children at Alder Hey did not have the benefit of a consultant haematologist on site with haemophilia expertise. This might have made a difference in the years when HIV transmission occurred.

50. 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?

50.1. I cannot answer this question.

Section 4: Treatment of patients

Provision of information to patients

51. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at (a) UCH and (b) Alder Hey 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.

51.1. General principles: I always aimed to keep patients and their families informed about the benefits and risks of treatment. This would have been verbal and age appropriate, and this would usually backed up with written material.

51.2. I do not specifically recall starting any patients on new treatment at UCH.

51.3. At Alder Hey the same principles applied. Following a new diagnosis of haemophilia, I would have spent time with the parents and child going

through the implications and available treatment products together with their risks. A great deal of support would have been provided by the haemophilia team in addition with further opportunities for discussion both in the centre and on home visits. This information would have been regularly updated as new products became available.

52. 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.

52.1. Alternatives would have been discussed where appropriate, such as the use of desmopressin. However, early adequate factor replacement was the only effective treatment for bleeding episodes in severe haemophilia.

53. 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?

53.1. Home treatment was encouraged for children with severe haemophilia A as it resulted in a much better life-style and quicker treatment. The risks as well as benefits would have been explained. To the best of my knowledge heat treated factor VIII products were available for children which were considered low risk. The risk of inhibitor development would have been explained and the need to screen regularly for that. Parents and children would have had a programme of education for home treatment mainly provided by the haemophilia sisters. They could have contact by telephone for any queries. Prophylaxis was easier with home treatment. Parents varied in their abilities but with encouragement and training they were able to achieve it. At appropriate ages (variable) the child would learn to administer their own treatment.

HIV

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

54.1. UCH – I do not remember the details, but the principle would have been to give as much information as we had at the time, and to update this as new understanding came.

54.2. At Alder Hey see below.

55. Please describe how and when you learned that patients under your care/the care of UCH had been infected with HIV. What tests were undertaken, where and over what period of time? (If you are able to answer the questions in paragraphs 55-58 by reference to Alder Hey as well as UCH, please do so).

55.1. As cases of AIDS in people with haemophilia were reported in the USA, it became apparent that this was a risk for UK patients.

55.2. Testing became available at UCH in about 1984 by Richard Tedder's laboratory but this was not a generally available test. I do not remember the details. There are references to this in the minutes of the UKHCDO that you have provided for December 1984, BART0000676.

55.3. It is my understanding that children with haemophilia at Alder Hey were tested when the test became generally available, probably in 1986

56. What if any arrangements were made for pre-test counselling?

56.1. Pre-test counselling would have been done by the doctors looking after the patients. I do not recall any other specific arrangements.

57. 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?

57.1. At UCH the patients would have been told in person.

57.2. The children at Alder Hey were tested before I worked there. I understood that they/their parents would have been informed by letter.

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

58.1. UCH – we had very little knowledge at the time what the result meant other than that the patient had been exposed to HIV. It was not at all clear what would happen as this was a new disease. We did not know how many would become severely immunosuppressed nor how many would die.

58.2. Alder Hey – similarly we did not know the outcome.

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

59.1. I do not remember.

60. The minutes of the 21 October 1985 UKHCDO meeting [PRSE0001638] record that there was no agreed policy as to whom directors should disclose HTLVIII antibody results and that there was particular concern regarding children. What was your, UCH's and Alder Hey's policy on this issue? Did it change over time? If so, how and when?

60.1. UCH I do not remember

60.2. At Alder Hey when I started seeing the children and families with HIV we would have suggested that they should not discuss the results outside the

family as there was much fear and misunderstanding, and there had been some very unpleasant targeting of children and parents where the information got out.

61. What was the 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?

61.1. I do not remember any particular policy relating to family members at UCH but I think we offered testing to partners if so desired. We did not have a policy for testing family members at Alder Hey as the virus was only transmitted by sexual intercourse or by blood products.

62. The minutes of the 21 October 1985 UKHCDO meeting [PRSE0001638] record differences of view as to the appropriateness and validity of a proposed survey of HTLVIII antibody prevalence in household/sexual contacts. What was your view on this issue? Did you/UCH participate in the survey?

62.1. I do not remember the proposed survey of prevalence in household contacts.

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

63.1. I do not remember what advice was provided to partners or family members.

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

64.1. I do not remember any specific arrangements for post-test counselling. The patients would have been seen by haemophilia doctors and nursing staff.

65. The enclosed 28 February 1986 Armour memorandum [CGRA0000515] records visits by a representative to Lewisham Hospital to follow up patients who had seroconverted following treatment with heat-treated Factorate, or whose potential seroconversion was being followed up. The memorandum also records that the representative intended to discuss with you whether a patient continued to test negative for HTLV-III. Please describe the nature and purpose of any discussions you had with Armour representatives about potential or confirmed seroconversions. Were patients informed of such discussions and of Armour's investigations? If not, why not?

65.1. I do not remember any discussion or meetings in relation to this

66. At the 7 October 1991 UKHCDO meeting [PRSE0002012], it was recommended that directors should continue to test HIV negative patients at six monthly intervals. What was your understanding of the purpose of this? Did you/Alder Hey implement this recommendation? If not, why not?

66.1. The purpose of this was to ensure there were no new infections with products then in use. We did continue to test children at Alder Hey.

67. How many patients at (a) UCH and (b) Alder Hey were infected with HIV? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many at UCH were children?

67.1. The numbers of infected patients will be found in the UKHCDO Annual Returns. I do not have any of this information.

68. Was work undertaken at (a) UCH and (b) Alder Hey to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached.

68.1. I do not remember any specific work on the time period of seroconversion for UCH. For the children at Alder Hey we could review their treatment records and speculate but there was no definitive way of knowing.

69. To the best of your knowledge, did any of the partners or other family members of patients of (a) UCH and (b) Alder Hey became infected with HIV, and if so how many?

69.1. As far as I know,

69.1.1. UCH no partners were identified as infected

69.1.2. Alder Hey – no family members were infected.

69.2. However, I would suggest contacting the respective institutions for a definitive answer.

Hepatitis B

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

70.1. Patients would have been informed of their infection and the risk of transmission to others if they were antigen positive. I do not remember any

discussions with patients about the prognosis, treatment options or management.

71. How many patients at (a) UCH and (b) Alder Hey were infected with HBV?

71.1. I do not have the answers to this question, but these data are collected in the UKHCDO Annual Returns.

NANB hepatitis

72. 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 involvement did you have in this process?

72.1. I do not know the answers to these questions.

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

73.1. Testing for HCV became available in 1991 or 1992. Parents and children would have received age-appropriate information before testing and would have been informed of the results in person by me or Dr Lynne Ball.

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

74.1. Testing for HCV – I do not remember what else was done to trace patients who might have received blood products (other than blood transfusion see later).

75. At the 7 October 1991 UKHCDO meeting [PRSE0002012], Professor Preston made a number of recommendations with regard to HCV testing on behalf of the chronic liver disease working party, including that all haemophiliacs should be tested for HCV, and that all those tested by first generation tests should be retested using second generation tests. Did you/Alder Hey implement these recommendations? If so, when? If not, why not?

75.1. At Alder Hey there would have been implementation of the recommendations for HCV testing according to the UKHCDO. I do not remember the dates.

76. At the 18 September 1992 UKHCDO meeting [HCDO0000248_013], Professor Preston reported that, of the 100 Haemophilia Centres that had responded to a questionnaire, 77 carried out HCV testing, "*46% indicated that they discussed the results with their patients but 8% said the results were not discussed*".

a. If you/Alder Hey carried out HCV testing at this time, did you discuss the results with your patients? If not, why not? So far as you are aware, why did a significant number of Haemophilia Centres either not carry out HCV testing or not discuss the results with their patients?

b. It was also agreed at the meeting that patients should be tested annually for HCV. Did you/Alder Hey implement this measure and what was its purpose?

76.1. HCV testing was carried out and results were discussed with the patients/parents. I do not know why some haemophilia centres did not test or discuss the results.

76.2. My best recollection is that patients would have been tested annually to check whether infections had occurred.

77. At the 25 March 1994 meeting of the Alder Hey Blood Transfusion Committee [AHCH0000039], you informed the committee of a proposal to test potential

anti-coagulant clinic patients for hepatitis C antibodies. Please provide further details on the nature of this test and when it was introduced. Why was the introduction of a finger prick method not suitable for "*high risk patients*" and how were such patients identified? What was the basis/evidence for your advice that it was likely that there would be a very low number of infected patients? How many patients, if any, were found to be infected following this testing? Please also provide a copy of the information sheet and consent form referred to in the minutes if available; alternatively describe them as far as you can.

77.1. The blood test done by finger prick results in blood drops that are not enclosed in a container and therefore carry an increased risk of transmission of blood borne viruses to the person performing the test. People positive for HCV (HBV or HIV) would not be suitable for this testing method and would need to be tested by the regular closed venepuncture method. The majority of children requiring anticoagulation were those who had had major cardiac surgery in infancy and were likely to have received multiple blood components (red cells, plasma and platelets). Any transfused from HCV-positive donors detected once screening was introduced in 1991 should have been detected by the Blood Transfusion Service look-back study. This is why I suggested it would be a low number. I do not have any information about the results of this study nor copies of the information sheet or consent form.

78. At the 11 September 2000 meeting of the UKHCDO advisory committee [BART0000940], Dr Hill circulated a letter "*regarding offering testing to patients to try to ensure that everyone who wished [had] been tested*". By this stage, had any of your/Alder Hey's patients not been offered an HCV test and if so, why not?

78.1. I do not remember any Alder Hey patients not being offered HCV testing.

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

79.1. I do not have copies of information provided to HCV-infected patients. It would have been explained that this could cause chronic liver disease which they would need to be monitored for, and a link was established with a hepatologist at the Royal Liverpool hospital – Professor Ian Gilmore (as there was no experience of HCV in the paediatric setting). He would have seen patients with HCV at Alder Hey as and when required. Once these young people reached 16 years of age, they would have been referred on to the Adult Haemophilia Centre and would continue their HCV follow up there.

80. In the enclosed June 1996 edition of the Haemophilia Society Bulletin [HSOC0023013], you responded to a reader's question about whether their son's school should be told he was HCV positive. Were you asked similar questions by parents of your patients at Alder Hey? Did your advice ever differ from the response in the enclosed article and/or change over time?

80.1. I was probably asked similar questions by other parents and would have given similar answers. As far as I can now recall there would have been no change over time.

81. How many patients at Alder Hey were infected with HCV?

81.1. I do not remember how many patients were HCV-infected.

Delay/public health/other information

82. 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.

82.1. The results of any tests performed under my care would have been passed to the patients/parents as soon as possible.

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

83.1. I am not clear what this question means. Patients and parents were given advice about appropriate hygiene, clearing up blood spills etc.

84. What information was provided to patients about the risks of other infections in consequence of treatment with infected blood or blood products?

84.1. Those with HIV infection and damaged immune function would have been warned about potential for unusual infections and to get in touch if they developed any symptoms, particularly of chest infections.

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

85.1. Patients/parents would have been told there may be a risk of infecting others. They would be warned about the potential for transmission by sexual intercourse and given advice about management of blood spillage.

Consent

86. How often were blood samples taken from patients attending (a) UCH, (b) Alder Hey and (c) the Manchester Centre and for what purposes? What information was given to patients (or their parents) about the purposes for which blood samples were taken? Were patients/their parents asked to consent to the storage and use of the samples? Was their consent recorded and if so how and where?

86.1. At UCH – I do not remember.

86.2. Alder Hey – routine samples at annual intervals as indicated in the registration form WITN4160006; other tests as required

86.3. Manchester Centre – routine samples at annual intervals similar to b.
For both Alder Hey and Manchester patients the reasons for testing would have been explained to patients and parents and verbal consent obtained. Written consent would be required for long term storage or other tests.

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

87.1. Patients would not be treated without their/their parents' consent unless they attended with a life-threatening bleed and were unable to consent. When children were first diagnosed the parents would have had several meetings with the haemophilia staff to discuss the diagnosis and treatment options. These discussions would have been recorded in the case notes and in correspondence to the general practitioner.

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

88.1. Patients would not be tested for HIV, hepatitis or for other reasons without their consent. This information would be recorded in the case notes. Reasons for regular testing would have been explained at the time of diagnosis.

89. The minutes of the 30 January 1995 meeting of the Regional Haemophilia Centre Directors' Committee [HCDO0000453] record a discussion on

consent to treatment, including whether written consent should be obtained before a first dose of treatment and where there was a change in the type of treatment. The minutes also refer to whether consent to blood transfusion was required. What was your/Alder Hey's approach to consent at this time, both with respect to treatment with concentrates and blood transfusion?

89.1. Treatment decisions and changes would have been recorded in the case notes. Written consent would not necessarily have been required for transfusion.

90. The enclosed minutes of the 5 June 1995 meeting of the Regional Haemophilia Centre Directors' Committee [HCDO0000454] record a further discussion on consent to treatment, including obtaining written consent, during which Dr Hill said there was a special situation with children. What was your/Alder Hey's approach to consent around this time? Did change over the years that you worked there and if so how?

90.1. I do not now recall what the process was for consent other than there would have been an appropriate discussion with the families and an appropriate record would have been made in the case notes.

91. Consent to treatment was discussed again at the 18 June 1996 meeting of the UKHCDO Executive Committee [HCDO0000458_003]. Dr Giangrande did not think formal consent forms would be useful and considered it best to rely on good note taking in patient records, while Dr Ludlam thought general consent forms would be useful. What was your/Alder Hey's position on the use of consent forms? Why did the meeting agree that the matter should not be discussed further for the time being?

91.1. I have nothing further to add on this subject of consent.

92. During the 6 February 1998 UKHCDO Executive Committee meeting [HCDO0000464], it was considered that the informed written consent of a patient or their relatives would be required to collect blood and tissue

samples prospectively for vCJD testing, including for autopsy samples. What was your/Alder Hey's policy and practice on this issue?

92.1. The issue of consent for a study in relation to vCJD would require written consent but I do not recall any such instances for patients at Alder Hey.

93. The enclosed minutes of the 21 May 1998 UKHCDO meeting [HCDO0000466] record a further discussion on consent and testing tissue samples obtained during autopsies and surgery for vCJD. During the meeting, you asked whether patients would be informed of the results if samples taken during surgery were subsequently used in studies (including a potential tonsillectomy study), and whether ethical approval was needed. Were any samples from your patients used in such studies? If so, was ethical approval obtained? Were the patients informed of the results?

93.1. I do not recall any samples from my patients being used for the national vCJD studies.

PUPS

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

94.1. These are adults or children not previously exposed to blood products. My approach was to provide the most suitable treatment with follow up, which would include screening for viral transmission and screening for development of inhibitory antibodies. Patients should be kept on a single product as long as possible.

95. The enclosed minutes of the 25 June 1986 meeting of the North East Thames Region Association of Haematologists Haemophilia Working Party [BART0000673] record a discussion about the "*urgent need to include 'first exposure' patients who were to be treated with concentrate in one of the*

***current prospective 'safety' studies established to assess risk of hepatitis/HTLV-3 transmission.*" Please describe any involvement you had in such studies. Did you, UCH and (after you moved in 1987) Alder Hey agree with Dr Kernoff's view that the only Factor VIII concentrates which could be ethically assessed at that time were NHS 8Y and Alpha Profilate (as well as Armour monoclonal-purified factor VIII when it became available)? Did you/UCH/Alder Hey share Dr Machin's reservations about using 8Y due to a lack of evidence of safety?**

95.1. I do not remember the particular discussions referred to here nor my views at the time about the products discussed there.

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

96. How was the care and treatment of patients with HIV/AIDS managed at (a) UCH, (b) Alder Hey and (c) the Manchester Centre? In particular:

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

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

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

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

96.1. I do not remember how these patients were treated at UCH

96.2. Alder Hey – there was a group of HIV-infected children. They were seen regularly and had their immune function monitored.

96.2.1. Advice was sought from relevant clinicians including a fungal expert in Manchester, Dr David Denning.

96.2.2. Treatment with antiretroviral drugs would have been given as they became available, AZT and DDI. An HIV expert in London at the Westminster Hospital (Brian Gazzard) was consulted for advice and guidelines would have been considered as they were published.

96.2.3. Patients and families would have been informed about risks, benefits and side effects as known from the literature and other haemophilia colleagues.

96.2.4. I do not remember other details.

96.3. Manchester Centre – the patients would have been seen regularly. A close liaison was developed with the HIV specialists, for example seeking advice about combination therapy and resistance testing with the aim of offering each affected patient optimal therapy. I do not remember details of the regimes used.

97. How was the care and treatment of patients with HBV managed? In particular:

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

b. What treatment options were offered over the years?

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

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

97.1. As far as I can recall I had no children who needed referral for specialist HBV care.

97.2. As far as I can recall there were no children who needed treatment for HBV.

97.3. I do not remember any issues in adults with HBV at Manchester Centre.

97.4. I do not recall what arrangements were in place for follow up in respect of adult patients infected with HBV

98. How was the care and treatment of patients with NANB hepatitis managed at (a) UCH and (b) Alder Hey? In particular:

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

b. What treatment options were offered over the years?

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

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

98.1. UCH – I do not remember any specific management

98.2. Alder Hey – I do not recall any issues with NANB hepatitis. There was no specific treatment until later.

98.3. I do not recall what information was provided to patients about the risks and benefits of specific treatments or side effects

98.4. As far as I can recall any patients infected with NANB hepatitis would have been regularly reviewed with monitoring of their liver function tests

99. How was the care and treatment of patients with HCV managed at (a) Alder Hey and (b) the Manchester Centre? In particular:

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

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

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

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

99.1. In general terms when HCV infection was confirmed in patients at Alder Hey, they would be monitored and would be reviewed by a consultant hepatologist (Professor Ian Gilmore). No treatment was required. Regular monitoring would be by liver function tests.

99.2. Manchester Centre: as indicated earlier patients with HCV would be reviewed by a consultant hepatologist who advised on treatment if necessary and any further investigations. I do not remember the details and do not recall when a patient was first given interferon.

99.3. Treatment options evolved over the years. At all times any treatment would have been explained including side effects and probability of success.

99.4. Patients would be monitored with liver function tests and where appropriate, ultrasound or other imaging of the liver.

100. At the 18 September 1992 UKHCDO meeting [HCDO0000248_013], after Dr Savidge and Professor Bloom had said they would use Interferon for patients with significant hepatitis, the consensus of opinion "*seemed to be that the*

***use of an unlicensed product was not justified"*. What was your/Alder Hey's policy and practice on using interferon at this time?**

100.1. Policy for use of interferon at Alder Hey in 1992. I do not recall having a policy for this as I did not have patients with significant hepatitis.

101. The Inquiry understands that you were involved in the following presentation at the 4 April 2006 British Society for Haematology ("BSH") annual scientific meeting: "Treatment of hepatitis C with peginterferon and ribavirin in adult haemophiliac patients: a single centre experience". Please describe your experience of treating patients with Peginterferon and Ribavirin. (If you are able to provide a copy of the presentation or any available documents that relate to it, please do so).

101.1. The presentation at the British Society for Haematology meeting in 2006 was made by a registrar based on experience with Manchester patients. He collated data from patients between 2000 to 2005 and other than this I did not have a role in this presentation. The abstract is attached: Watt et al. BSH abstract on HCV WITN4160007. Part of the time covered was before I took up my post in June 2003.

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

102.1. UCH I do not remember responsibility for any children with either HIV or hepatitis

102.2. The Manchester Centre only manages adult patients. There is a separate paediatric centre in Manchester and I was not responsible for any children there

103. What if any involvement did you and/or colleagues at (a) Alder Hey and (b) the Manchester Centre have with any clinical trials in relation to treatments for HIV and HCV?

103.1. I do not recall participation in any clinical trials for HIV or hepatitis C at either Alder Hey or Manchester.

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

104.1. There was a very good social worker at Alder Hey. Other than this support was provided by the medical and specialist nursing staff. There was no regular psychological support but it was possible to arrange for children to be seen if required.

105. Did UCH, Alder Hey or the Manchester 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?

105.1. I do not remember any financial support for assistance with counselling of patients with HIV at any of the three centres, UCH, Alder Hey and Manchester.

106. The enclosed minutes of the 25 June 1986 meeting of the North East Thames Region Association of Haematologists Haemophilia Working Party [BART0000673] record that the Royal Free had received a DHSS grant of £45,000 for 1986/87 to support AIDS counselling for haemophiliacs. Was Dr Kernoff correct to presume that the funds could be used for patients treated in the North Thames supra-region generally rather than the Royal Free specifically? If so, were they used for UCH patients? Please comment on the use of the funds recorded in the minutes, including whether you considered it to have been effective.

106.1. I do not remember this grant.

107. What if any difficulties did you encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or HCV?

107.1. I do not remember obtaining any funding for treatment of people infected with HIV and/or HIV.

Recombinant

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

108.1. Recombinant: Please see *Current treatment strategies in Haemophilia A* WITN4160008 for information about available products in 1996 and the reasons for changing patients to these.

109. Please explain your involvement, and that of UKHCDO, with efforts to obtain recombinant blood products for patients with haemophilia. What difficulties were encountered and why?

109.1. Please see attached letter to the BMJ 1997, WITN4160009 about problems with funding for recombinant products. I do not know if this was ever published but it outlines the difficulties.

110. When were recombinant products available to patients (and which categories of patients) treated at Alder Hey? Were they available throughout your time at the Manchester Centre?

110.1. When were recombinant products available at Alder Hey? The paper *'Current treatment strategies in Haemophilia A: June 1996'* WITN4160008 from June 1996 shows that two patients had been started in 1994 and I recommended change to recombinant for 10 others at this time. We had

difficulty in getting agreement for this. I do not remember what was available when in Manchester. Dr Charles Hay will be able to answer this.

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

111.1. Recombinant products were perceived to be the safest available treatment, however the high purity monoclonally purified FVIII concentrates were effective with a good safety profile. Some therefore considered that the gains from changing to recombinant were marginal and at greatly increased cost and so could not be justified.

112. The Inquiry understands that you were a member of a multidisciplinary group in the mid-1990s which considered decisions about recombinant Factor VIII in the North West. Please outline your involvement in the group and the conclusions it reached.

112.1. Dr Hay and I were members of a group which met with the purchasers to discuss coagulation factors. I do not remember the details. One of the main problems was that repeated re-organisations of health services meant that we had to keep educating different groups about haemophilia, a very rare disorder with expensive treatment, and the rationale for treatment. Managers and purchasers found it difficult to take a life-time perspective (eg. that prophylaxis now for children will result in fitter adults later who would be likely to remain in good health and contribute actively to the workforce).

113. In the enclosed June 1996 paper [DHSC0020815_060], you outlined treatment strategies in relation to haemophilia A and their implications for patients at Alder Hey. What was the context and purpose of the paper? How were decisions taken as to which categories of patient would receive recombinant?

113.1. The June 1996 paper (DHSC0020815_060) is an extract from a longer paper '**Current treatment strategies in Haemophilia A**' (WITN4160008) that I

prepared for Alder Hey managers to explain why we should change the treatment for the patients with haemophilia from plasma-derived to recombinant concentrates. It also details the cost impact. Page 7 provides details of which patients should receive this and the rationale. It also includes the reasons for prophylaxis and the cost implications. The outcome was that I had to apply to individual purchasers to fund the recombinant products. Newly diagnosed previously untreated patients should receive recombinant products.

114. The minutes of the 3 February 1997 UKHCDO meeting [HCDO0000460] record a discussion around the implementation of UKHCDO's recommendations on the use of recombinant, including: "*Dr Bolton-Maggs said that she had eight purchasers. The Trust said that the patients should not be switched from one material to another and that she should follow her conscience regarding the materials to be received by new patients*." Please explain this passage further, including the Trust's suggestion that you should follow your conscience regarding materials for new patients. The minutes of the 6 February 1997 UKHCDO Paediatric Working Party meeting, at which these issues were discussed again, are also enclosed for reference [BART0002208].

114.1. Re the **UKHCDO minutes of February 1997** (HCDO0000460): there was resistance to the introduction of recombinant FVIII concentrate due to the cost and the perceived safety of the available plasma-derived concentrates. I do not know what the Trust meant that 'I should follow my conscience'.

115. The enclosed March 1997 correspondence between you and Dr Ludlam [HCDO0000277_025 and HCDO0000277_026] concerns a 7 March 1997 letter from Alan Sharples, Alder Hey's director of finance [HCDO0000277_027].

a. Please explain the circumstances which led to you treating a patient with recombinant while waiting for confirmation of South Cheshire's funding position.

b. Did you treat any patients with plasma derived rather than recombinant products as suggested by Mr Sharples?

c. Dr Ludlam queried whether informed consent to treatment could be obtained if patients were not offered the professionally recommended range of options. Did you consider that informed consent could be obtained in such circumstances?

d. Following Mr Sharples' letter, did you use plasma-derived or recombinant products to treat new patients?

115.1. My view was that newly diagnosed children with haemophilia A should receive recombinant factor VIII.

115.1.1. The patient may present with an acute bleeding episode and need treating immediately and not in time for me to obtain permission from the health authority. This may be what happened in this instance. The associated letters show that there was a delay of at least 3 months between my meeting with Alan Sharples and his response with regard to advice from North Cheshire.

115.1.2. I do not recall whether I had to go against national guidelines for newly diagnosed children after this.

115.1.3. I do not recall what action I took in regard to informed consent.

115.1.4. I do not remember what action I took for subsequent new patients. This information should be available in the UKHCDO Annual Returns

116. In the enclosed 3 September 1997 letter to Dr Langlands of the NHS Executive [HSOC0020683], you and Dr Stevens outlined inequalities in access to recombinant Factor VIII across the UK, and explained that whether children at Alder Hey could be treated with it depended on their postcode.

Did access to recombinant change for your/Alder Hey's patients following this letter? If so, when and how?

116.1. I do not now recall the outcome/response following the letter.

117. In the enclosed 6 February 1998 letter to Haemophilia Centre Directors [BART0002234], you described the results, received by 30 October 1997, of a survey by the paediatric working party, regarding the implementation of UKHCDO guidelines on the use of recombinant Factor VIII.

a. So far as you are able to, please describe the reasons why there existed a wide variation in policy across the UK and why Directors of Public Health in different regions came to opposite conclusions.

b. You noted that you "did not yet know whether the publicity surrounding variant CJD [had] altered the attitudes". Did it alter attitudes and if so when and how?

c. You also stated: "Sadly, there are at least two instances where a pregnant mother is likely to give birth to a severely haemophiliac son whose H.A.s are refusing to agree rVIII if the child is affected." Did you consider those refusals to agree recombinant Factor VIII to be unjustified? If so, please explain why.

117.1. I cannot say factually what the reason was for the wide variation in policy across the UK. However, from my experience in my own area and discussions with wider colleagues, this was probably due to some Health Authorities not funding this product. The reason for this was, in all probability, cost, which was higher (e.g. from 27-33p per unit for plasma-derived and 45-52p per unit for recombinant – see '**Current treatment strategies in Haemophilia A** WITN4160008). Directors of Public Health had finite resources. I think they perceived that the available plasma-derived materials were safe and effective and that the perceived benefits of switching were outweighed by the increased cost.

117.2. I do not remember if this had an effect on attitudes, but the publicity about vCJD was another indication that unknown agents may be transmitted by plasma-derived concentrates. This might increase fear of using these particularly on the background of HIV and hepatitis infection.

117.3. I wanted to use recombinant FVIII for newly diagnosed patients in line with national recommendations. However, the use of plasma-derived products could be supported according to views above.

118. You reported on the outcome of the recombinant survey at the 1 October 1998 UKHCDO meeting [BART0000947]. Please provide a copy of your written report if available or summarise what you found. Did it highlight similar issues to those identified in your 6 February 1998 letter?

118.1. I do not have a copy of this survey and cannot comment further on this. It was listed as Appendix A in the UKHCDO minutes (BART0000947) so should be available from UKHCDO.

Research

119. Please list all research studies that you were involved with during your time at UCH, Alder Hey and Manchester insofar as relevant to the Inquiry's Terms of Reference and please:

a. Describe the purpose of the research.

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

c. Explain what your involvement was.

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

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

f. State the number of patients involved.

g. Provide details of 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.

119.1. See the list under 119.9.

119.2. Purpose of the research generally was to understand bleeding disorders better. In the later 1980s with development of heat treated concentrates it was important to obtain information on their efficacy and safety. The optimal study patients were those with no previous transfusion history. As a treater of children, I had the opportunity to enter newly diagnosed children into such studies. In addition to demonstrating viral safety it was important to find out if they were associated with an increased risk of inhibitor development

119.3. All research studies were subject to local ethical approval through the relevant committees as detailed below. This was not required for simple observational studies at the time

119.4. Where I was first author, I led the research. Where I was not the first author I contributed, e.g. patient data or material (where necessary with patient/parental consent)

119.5. Some of these studies related to information available in the national haemophilia database collected from our UKHCDO Annual Returns or other surveys made by UKHCDO and its working parties

119.6. Factor XI research in Manchester and Liverpool was funded by grants received from Mersey Regional Health Authority, Alder Hey Children's Hospital Research Advisory Group, the Haematology Research Fund at Alder Hey, and the Haemophilia Society. The factor XI research performed in London was funded through the Royal Free Haemophilia Centre and not by external funds

119.7. Numbers of patients involved are reported related to each of the publications listed below.

119.8. The factor XI studies: all patients gave written consent as approved by the Manchester and Liverpool ethics committees and the London study through the ethics committees at the Royal Free Hospital and UCH. Patients would have also received written reports summarising their own results and if newly identified to be FXI deficient would be registered with their haemophilia centres and the national database, with their consent. There was also a simple overall summary for patients of the study. The two FXI studies contributed to my Doctor of Medicine thesis for the University of Oxford (2008).

119.9. Publications

119.9.1. Bolton-Maggs, P. and L. S. Wilkinson (1984). "Mild bleeding disorders: review of 120 patients." Clin Lab Haematol **6**(3): 247-256. *(This was a retrospective review of case notes)*

119.9.2. Bolton-Maggs, P. H., B. Young Wan-Yin, A. H. McCraw, J. Slack and P. B. Kernoff (1988). "Inheritance and bleeding in factor XI deficiency." Br J Haematol **69**(4): 521-528. *(164 individuals studied)*

119.9.3. Bolton-Maggs, P. H., D. A. Patterson, R. T. Wensley and E. G. Tuddenham (1995). "Definition of the bleeding tendency in factor

XI-deficient kindreds--a clinical and laboratory study." Thromb Haemost **73**(2): 194-202. *(172 individuals studied)*

119.9.4. Rugman, F. P., P. T. Mannion, C. R. Hay, P. Bolton-Maggs, D. Roberts and K. J. Mutton (1989). "Cytomegalovirus, serum beta 2 microglobulin, and progression to AIDS in HIV-seropositive haemophiliacs." Lancet **2**(8663): 631. *(I do not have a copy of this paper and do not know the details)*

119.9.5. Bolton-Maggs, P. H., P. D. Rogan, J. K. Duguid, K. J. Mutton and L. M. Ball (1991). "Cold agglutinins in haemophiliac boys infected with HIV." Arch Dis Child **66**(6): 732-733. *(In this study we looked for irregular red cell antibodies in 11 boys with haemophilia and HIV, and 9 boys not infected. Blood samples were those taken at their regular clinic visits. There are no details related to consent or ethical issues. This study was consistent with investigative practice at the time and sought to understand better the effects of immune disturbance in HIV infection)*

119.9.6. Bolton-Maggs, P. H., R. T. Wensley, P. B. Kernoff, C. K. Kasper, L. Winkelman, R. S. Lane and J. K. Smith (1992). "Production and therapeutic use of a factor XI concentrate from plasma." Thromb Haemost **67**(3): 314-319. *(This paper describes manufacture of FXI concentrate and the use from 1985 in 30 patients undergoing 31 procedures. When this heat treated (80 degrees C for 72h) FXI concentrate was first produced it did not undergo any formal trial but was used on a named patient basis. Data contributed from individual patients was therefore with their consent. This describes use in 30 patients on 31 occasions with FXI levels and viral markers followed up)*

119.9.7. Stowell, K. M., M. S. Figueiredo, G. G. Brownlee, P. Jones and P. H. Bolton-Maggs (1993). "Haemophilia B Liverpool: a new British family with mild haemophilia B associated with a -6 G to A

mutation in the factor IX promoter." Br J Haematol **85**(1): 188-190. *(this paper describes a new mutation in the FIX gene in a family. The investigations were performed with informed consent and contribute towards our understanding of FIX genetics and why it is important to do genotyping in all FIX-deficient families. This identified a type of FIX deficiency that improves with age)*

119.9.8. Bolton-Maggs, P. H., B. T. Colvin, B. T. Satchi, C. A. Lee and G. S. Lucas (1994). "Thrombogenic potential of factor XI concentrate." Lancet **344**(8924): 748-749. *It was important to report this unexpected side effect in 4 patients which resulted in publication of guidelines for use and dosage on behalf of the UKHCDO - Guidelines for the use of factor XI concentrate .Bolton-Maggs PHB, Colvin B, Lee CA on behalf of the UKHCDO, issued to haemophilia centre directors September 30, 1994, revised November 1997.*

119.9.9. Imanaka, Y., K. Lal, T. Nishimura, P. H. Bolton-Maggs, E. G. Tuddenham and J. H. McVey (1995). "Identification of two novel mutations in non-Jewish factor XI deficiency." Br J Haematol **90**(4): 916-920. (*a report in two families of novel FXI mutations. Part of research when I was developing methods for genetic analysis in Liverpool. Participants gave consent for these investigations)*

119.9.10. Khan, R. U., C. Y. Tong, S. Bloom, I. T. Gilmore, C. H. Toh, P. H. Bolton-Maggs, N. J. Beeching and C. A. Hart (1997). "Evaluation of two simplified methods for genotyping hepatitis C virus." J Med Virol **52**(1): 35-41. *This study was designed to look at HCV genotyping. Ethical approval and informed consent was obtained for inclusion of some paediatric samples. There were 39 haemophiliacs in this study but I do not remember how many were children. Samples used would have been part of those already taken for routine monitoring of HCV status)*

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

a. "Effect of dry-heating of coagulation factor concentrates at 80C for 72 hours on transmission of non-A, non-B hepatitis", The Lancet, 8 October 1988.

b. A proposed study, with Professor Whitehouse, of the neuropsychological effects of HIV infection in haemophiliac children in the late 1980s to early 1990s.

c. A trial of the Armour product Mononine in the early 1990s.

d. "Mortality before and after HIV infection in the complete UK population of haemophiliacs', Nature, Vol 377, 7 September 1995.

e. "The importance of age at infection with HIV-1 for survival and development of AIDS in UK haemophilia population", The Lancet 1996, 347: 1573-1579.

f. "Mortality from liver cancer and liver disease in haemophilic men and boys in UK given blood products contaminated with hepatitis C", The Lancet, 1997, 350: 1425-31.

g. "Immune status in HIV-1 infected men and boys with haemophilia in the United Kingdom", AIDS, 1998, Vol 12 No 8.

h. "Treatment of haemophilia in the United Kingdom 1981-1996", Haemophilia, 2001, 7, 349-359.

Please set out what you recall of these research studies and explain what involvement you had in them.

120.1. Lancet 1988: This was an early study of a heat-treated concentrate before the agent for NANB hepatitis was discovered. Suitable patients were scarce. I entered a single patient into this study as shown in the analysis DHSC0001084. The patient had factor IX deficiency and was previously untreated with concentrate. Such studies had ethical approval and the patient would have given consent for inclusion

120.2. A study with Professor Whitehouse was performed: A longitudinal MR imaging study of neurological manifestations of HIV infection in a cohort of HIV positive haemophiliac children. Smith SR, Bolton-Maggs PHB, Whitehouse GH, Smith TE, Ball LM. This was presented by me as a paper at the annual congress of the British Institute of Radiology, Brighton, April 1991.

120.3. A study of Mononine – I do not have any information about this study.

120.4. Studies d to h were performed using data submitted to the UKHCDO Annual Returns or other Working Party surveys. I do not recall any other involvement in these

121. Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference and please provide a copy (if you have one) of "Optimal haemophilia care versus the reality", British Journal of Haematology", 2005; 132: 671-82.

121.1. I have contributed to several reviews of Factor XI deficiency and to national guidelines on transfusion. These include **national guidelines** published by the **British Committee for Standards in Haematology/British Society for Haematology**

121.1.1. Paediatric **and neonatal transfusion guidelines 2004,updated 2016**. Gibson, B. E., A. Todd, I. Roberts, D. Pamphilon, C. Rodeck, P. Bolton-Maggs, G. Burbin, J. Duguid, F. Boulton, H. Cohen, N. Smith, D. B. McClelland, M. Rowley, G. Turner and g.

British Commitee for Standards in Haematology Transfusion Task Force: Writing (2004). "Transfusion guidelines for neonates and older children." Br J Haematol **124**(4): 433-453.

121.1.2. New, H. V., J. Berryman, P. H. Bolton-Maggs, C. Cantwell, E. A. Chalmers, T. Davies, R. Gottstein, A. Kelleher, S. Kumar, S. L. Morley, S. J. Stanworth and H. British Committee for Standards in (2016). "Guidelines on transfusion for fetuses, neonates and older children." Br J Haematol **175**(5): 784-828.

121.1.3. **Use of FFP and cryoprecipitate 2004, updated 2018** O'Shaughnessy, D. F., C. Atterbury, P. Bolton Maggs, M. Murphy, D. Thomas, S. Yates, L. M. Williamson and B. T. T. F. British Committee for Standards in Haematology (2004). "Guidelines for the use of fresh-frozen plasma, cryoprecipitate and cryosupernatant." Br J Haematol **126**(1): 11-28.

121.1.4. Green, L., P. Bolton-Maggs, C. Beattie, R. Cardigan, Y. Kallis, S. J. Stanworth, J. Thachil and S. Zahra (2018). "British Society of Haematology Guidelines on the spectrum of fresh frozen plasma and cryoprecipitate products: their handling and use in various patient groups in the absence of major bleeding." Br J Haematol **181**(1): 54-67.

121.1.5. **Blood component administration guidelines 2018** Robinson, S., A. Harris, S. Atkinson, C. Atterbury, P. Bolton-Maggs, C. Elliott, T. Hawkins, E. Hazra, C. Howell, H. New, T. Shackleton, K. Shreeve and C. Taylor (2018). "The administration of blood components: a British Society for Haematology Guideline." Transfus Med **28**(1): 3-21.

121.1.6. Updated guidelines for indications for irradiated cellular components in press 2020

121.1.7. Guidelines for the UK Haemophilia Doctors' Organisation on Rare Bleeding disorders (published in Haemophilia and in the top ten most downloaded papers for more than 10 years) and a separate one on inherited platelet disorders.

121.1.8. Other papers:

121.1.8.1. Bolton-Maggs, P.H., et al., *Difficulties and pitfalls in the laboratory diagnosis of bleeding disorders.* Haemophilia, 2012. **18 Suppl 4**: p. 66-72.

121.1.8.2. Bolton-Maggs, P., et al., *FXI concentrate use and risk of thrombosis.* Haemophilia, 2014. **20**(4): p. e349-51.

121.1.8.3. Pike, G.N. and P.H. Bolton-Maggs, *Factor XI-related thrombosis and the role of concentrate treatment in factor XI deficiency.* Haemophilia, 2015. **21**(4): p. 477-80.

121.1.8.4. Pike, G.N., et al., *In vitro comparison of the effect of two factor XI (FXI) concentrates on thrombin generation in major FXI deficiency.* Haemophilia, 2016. **22**(3): p. 403-10.

121.1.8.5. New, H.V., et al., *Guidelines on transfusion for fetuses, neonates and older children.* Br J Haematol, 2016. **175**(5): p. 784-828

121.1.8.6. Green, L., et al., *British Society of Haematology Guidelines on the spectrum of fresh frozen plasma and cryoprecipitate products: their handling and use in various patient groups in the absence of major bleeding.* Br J Haematol, 2018. **181**(1): p. 54-67

121.1.8.7. Optimal haemophilia care versus the reality. Br J Haematol 2005; 132: 671-82 is attached WITN41600010

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

122.1. Ethical principles that should guide research are defined on the internet as follows – these should include respect for all participants, their right to refuse to participate, protection of the interests of children. Research should be performed only if likely to provide benefit to either the individual or wider community. It must include appropriate informed consent (usually written). Arrangements should include confidentiality and data protection. There should be no conflict of interest (i.e. no personal financial gain). These are the principles I applied to all research.

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

123.1. **Patients involved in research studies**: Children would be given an age-appropriate explanation and parents invited to give informed written consent according to ethical principles at the time of the study. I am not aware of any patients being involved in research studies without their/their parents express and informed consent

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

124.1. The National Haemophilia Database organisers would need to be consulted about this.

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

125.1. Where necessary as shown in the Lancet study above, patient data were shared with BPL in the investigation of their heat-treated concentrates. This would be anonymised data on factor recovery, development of inhibitors and viral studies.

126. The enclosed April 1991 memorandum from JK Smith [BPLL0005964] refers to a practice whereby the Protein Fractionation Laboratory ("PFL") provided certain products, mostly free of charge, on the understanding that clinical data would be provided in return. You were included on the list of Factor XI users. Did you provide clinical data to PFL in return for Factor XI that was free or at a reduced charge? Did you do the same for Factor VIII or Factor IX? If so, what was the nature of the clinical data you provided?

126.1. Factor XI concentrate is unlicensed and was available on a named patient request and I did provide patient data. I also gathered data from other users and wrote up a study of the use of this concentrate, see under 119 h above. The type of data included is shown in that publication and includes factor XI levels achieved, half-life data and viral markers where available. I do not recall doing this for other concentrates.

Records

127. What was the policy at (a) UCH, (b) Alder Hey and (c) the Manchester Centre as regards recording information on death certificates when a patient had been infected with HIV or hepatitis? You may wish to consider the discussion at section 8 of the enclosed minutes of the 1 October 1993 UKHCDO meeting [HCDO0000493].

127.1. UCH – I had no role in recording deaths at UCH

127.2. Alder Hey – the death certificate should record the cause of death and contributory causes such as HIV infection. As far as I can recall there were no deaths related to hepatitis in my time there.

127.3. I believe that HIV and hepatitis would have been recorded as indicated on the death certificates. As far as I recall I did not complete any myself.

128. What were the retention policies of (a) UCH, (b) Alder Hey and (c) the Manchester Centre relation to medical records during the time you were practising there?

128.1. I am not clear what this question means.

128.2. I do not know the policy for UCH records

128.3. I do not know what the policy was for records at Alder Hey

128.4. I do not know what the policy was for records at Manchester

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

129.1. I do not recall keeping separate files for patients at any of the three hospitals. Please also see the response to 130 below.

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

130.1. I did not keep hospital records at home at any time.

Section 5: Blood Services and BPL

131. Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, and/or with BPL during the time that you worked at (a) UCH and (b) Alder Hey.

131.1. UCH I do not remember any particular interactions with the blood services nor with BPL

131.2. Alder Hey – I was responsible for setting up the hospital transfusion service and participated in regular meetings with the local blood transfusion service in Liverpool to discuss their service and our needs. I was invited to join a national group on the appropriate use of blood, chaired by Angela Robinson, the Medical Director of the National Blood Service. My interactions with BPL related to provision of their factor concentrates and my work with Factor XI deficiency.

132. Do you know what if any consideration was given to increasing production of cryoprecipitate, or producing a product with lower risk, in response to the risks associated with factor products, and what if any involvement did you have with any blood service (regionally or nationally) and/or BPL in relation to this?

132.1. I had no personal involvement with the blood services or BPL in relation to discussions about increased production of cryo

133. What if any discussions or meetings or interactions did you have with any blood service (regionally or nationally) and/or BPL in relation to:

a. the risk of infection with hepatitis from blood products;

b. the risk of infection with HIV/AIDS from blood products;

c. the steps to be taken to reduce the risk of infection?

133.1. Other than above and my participation in meetings of the UKHCDO, I do not remember any discussions, meetings or interactions with blood service or BPL in relation to

133.1.1. Risks of infection with hepatitis

133.1.2. Risk of infection with HIV/AIDS

133.1.3. Steps to be taken to reduce the risks of infection

134. What if any involvement did you have with any decisions or actions taken by any blood service (regional or national) and/or BPL in response to the risks arising from blood and blood products?

134.1. Other than my participation in meetings of the UKHCDO I do not recall any involvement with decisions or actions taken by any blood service or BPL in response to the risks arising from blood and blood products

135. What was the system at (a) UCH and (b) Alder Hey for keeping records of the blood or blood products that were used?

135.1. I do not remember what system was used at UCH for keeping records of blood or blood products except that any use of materials for patients with bleeding disorders (cryo or concentrates) would have been recorded and could then be used for completing the UKHCDO Annual Returns.

135.2. Alder Hey: records of treatment products used for patients with bleeding disorders would have been recorded and could then be used for completing the UKHCDO Annual Returns. It was a requirement for children on home therapy that forms be completed at home to account for their product use. This included type of concentrate and manufacturer and the batch, date of infusion and reason. Cryoprecipitate used for these patients was also recorded with the donor numbers. Records of blood transfusion in all patients across the hospital required improvement when I took up my post and so I generated a new blood transfusion policy and transfusion prescription record to promote the proper recording of all blood and blood components from the transfusion services and so ensure these were traceable.

Section 6: UKHCDO

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

136.1. As a haemophilia centre director I was a member of this organisation and attended the annual meetings together with any other relevant educational events. In addition, I participated in the following working parties but do not recall the exact dates.

136.2. I was chair of the Rare Disorders Working Party and led the writing group for guidelines for the diagnosis and treatment of rare bleeding disorders and the guidelines for platelet disorders:

136.2.1. Bolton-Maggs, P. H., E. A. Chalmers, P. W. Collins, P. Harrison, S. Kitchen, R. J. Liesner, A. Minford, A. D. Mumford, L. A. Parapia, D. J. Perry, S. P. Watson, J. T. Wilde, M. D. Williams and Ukhcdo (2006). "A review of inherited platelet disorders with guidelines for their management on behalf of the UKHCDO." Br J Haematol **135**(5): 603-633.

136.2.2. Bolton-Maggs, P. H., D. J. Perry, E. A. Chalmers, L. A. Parapia, J. T. Wilde, M. D. Williams, P. W. Collins, S. Kitchen, G. Dolan and A. D. Mumford (2004). "The rare coagulation disorders--review with guidelines for management from the United Kingdom Haemophilia Centre Doctors' Organisation." Haemophilia **10**(5): 593-628.

136.3. I was a member of the Paediatric working party.

136.4. I was a member of the Genetics Working party and contributed to production of guidelines.

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

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

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

c. **The relationships between UKHCDO and pharmaceutical companies.**

d. **How UKHCDO was funded.**

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

f. **Any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to matters relevant to the Inquiry's Terms of Reference.**

137.1. The UKHCDO started in 1968 when it was recognised that there was benefit for doctors looking after people with rare bleeding disorders in sharing experience and working together to generate standards of care and optimal treatments. Subsequently the organisation drew together haemophilia centre representatives from across the UK and expanded to include patient representation (the haemophilia society), haemophilia nurses, social workers and physiotherapists. Full information about UKHCDO can be found on their website: http://www.ukhcdo.org/about-us/

137.2. The purpose is to optimise care of people with bleeding disorders

137.3. the evolution of the organisation and subcommittees is described in their minutes. I do not recall the details

137.4. Relationship with pharmaceutical companies – they were not part of UKHCDO but could be invited when relevant

137.5. Funding – each haemophilia centre director paid a small annual fee; I think it was £20. This is confirmed in the Minutes of UKHCDO advisory committee 11 September 2000 (BART0000940) I do not remember any other details for the early years. The original secretariat was in the Oxford Haemophilia Centre which I think funded Rosemary Spooner

137.6. Dissemination of information was by peer reviewed publications in journals including British Journal of Haematology. These included guidelines for treatment and a regularly updated registry of treatment products. There is an annual meeting and minutes of meetings and other educational materials were circulated to all haemophilia treaters.

137.7. Policies, guidance and decisions.

137.7.1. I wrote guidelines (with Christine Lee) for the management of FXI deficiency after the emergence of thrombotic complications

137.7.2. I was lead author on two guidelines for bleeding disorders

137.7.3. I led a survey on the uptake of recombinant FVIII concentrate

National haemophilia database

138. Please describe the establishment and operation of the National Haemophilia Database, its purpose and objectives, your involvement in it, the range and kind of data recorded in the Database and how data is (or was during your involvement) collected and organised.

138.1. A national database was established in about 1978 in Oxford; haemophilia centres were encouraged to register their patients and submit UKHCDO Annual Returns about treatment use and complications. This was an important source of information for doctors, patients and the NHS. Originally the records were collected on paper and later through electronic systems. The history and functions are described on the UKHCDO website. The

database moved to Manchester in 2002. My role was to ensure that the UKHCDO Annual Returns were completed fully when I was at UCH and later at Alder Hey.

139. Please explain how the work of the National Haemophilia Database was funded during your involvement in it and what if any financial contributions were offered or made by (a) pharmaceutical companies and (b) the Department of Health.

139.1. I do not remember how the database was funded. The Department of Health had interest in the information that was collected, and I think makes a contribution now but I do not know the details. There is reference to a DoH grant in the minutes of the UKHCDO Executive Committee 11 February 2000 (HCDO0000473). There is also mention there of an offer of funding from Wyeth and notification that this £30,000 was accepted for upgrading the National Database in the minutes from 11 September 2000 (BART0000940).

140. Please explain how the question of patient consent in relation to the National Haemophilia Database was approached over the years that you were involved in it. Please address in your response the extent to which there were differences of opinion and approach amongst Haemophilia Centre Directors in relation to this issue. As well as the documents referred to below, you may wish to consider the minutes of the 11 February 2000 UKHCDO Executive Committee meeting [HCDO0000473] and the 11 September 2000 UKHCDO Advisory Committee meeting [BART0000940].

140.1. Verbal consent was obtained from the outset in line with good medical practice at the time. The issue had to be reconsidered with each iteration of Data Protection legislation. The general approach was that inclusion of data in the national database was for the benefit of patients. I do not remember the discussions or difference of opinion in 2000.

141. The enclosed minutes of the 29 September 2000 UKHCDO meeting [HCDO0000500] record a discussion about the Data Protection Act 1998 and the National Haemophilia Database. Following a question on whether the Act gave an age for consent, you said that you "*presumed that the Data Management's Group's leaflet would be suitable for children*", prompting a discussion during which several views were put forward. Please explain the reason for your comment. So far as you can, please describe the views put forward by other attendees at the meeting as well as you own.

141.1. Patient information: Leaflets written for adults may not be suitable for children who require age-appropriate written information. I do not remember any details about the discussion.

142. Why was it agreed, at the 7 February 2002 meeting of the UKHCDO Data Management Group [HCDO0000005_014], that written permission from patients "*would be very difficult (in fact impossible) to obtain*"? Was this comment referring only to inclusion of patients' data in the National Haemophilia Database or also to other uses? In your experience, how successful was the patient information sheet discussed at the meeting in informing patients as to how their data would be used?

142.1. This comment on written permission from patients only referred to inclusion in the National Database and not to any other studies. The leaflet was satisfactory in its explanation to patients on how their data would be used.

<u>Section 7: Pharmaceutical companies/medical research/clinical trials</u>

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

143.1. I have provided consultancy services and advice to pharmaceutical companies over several decades and cannot remember all the details. This

was common practice for haemophilia centre directors. These include BPL and LFB particularly about factor XI concentrate, and probably Novonordisk, Centeon and Baxter.

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

144.1. I have not received any pecuniary gain from pharmaceutical companies.

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

145.1. I have participated in advisory boards for several companies involved in the manufacture, importation or sale of blood products. I no longer have details of these, but they may include BPL, Novonordisk, Immuno, Centeon, Alpha.

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

146.1. I have not received any financial incentives to use particular blood products.

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

147.1. I have not received any non-financial incentives from pharmaceutical companies to use particular products. I have been a guest of several companies and with other haemophilia centre director colleagues received hospitality and travel to national and international educational and scientific meetings These were declared to the Trusts I was working in at the time and taken as approved study leave.

148. 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.

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

149. What regulations or requirements or guidelines were in place (at any time relevant to your answers above) concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

149.1. I do not recall what the regulations were, but Trusts where I worked required annual declarations of interest which I completed. All meetings were taken as study leave and full details supplied. The UKHCDO also required an annual declaration of interest to be submitted.

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

150.1. **Medical research:** I participated in studies (clinical trials) of factor concentrates as described above for BPL, FIX and Factor XI.

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

151.1. I provided information about use of Factor XI concentrate to the NHS plasma fractionation laboratory (BPL) in order to write up the use of this concentrate (Bolton-Maggs P et al. Production and therapeutic use of a factor XI concentrate from plasma – Thrombosis and Haemostasis 1992 67(3); 314-319). This included patients treated by several clinicians who

had obtained the concentrate on a named patient basis. I do not recall if I participated in PUP studies at Alder Hey.

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

152.1. I do not recall receiving funding for research from pharmaceutical companies. If I did, I would have declared it to my employing organisation.

Section 8: vCJD

153. When and in what circumstances did you first become aware of the risks of transmission of vCJD associated with the use of blood and blood products? How did your knowledge develop over time?

153.1. I do not recall how I first became aware of the risks of vCJD associated with blood and blood products. This was probably through the Blood Transfusion service, the Department of Health and the UKHCDO meetings and updates. Knowledge developed over time with further publications and notifications.

154. Please describe your involvement in decisions as to what information to provide to patients about vCJD at (a) Alder Hey and (b) the Manchester Centre. Please also answer the following questions:

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

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

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

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

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

154.1. I do not remember how I decided to provide information to patients at either hospital. I would have been guided in my answers to questions a. to e. by vCJD surveillance centre in Edinburgh and the UKHCDO

154.2. Alder Hey – Please see my response at paragraph 154.1.

154.3. Manchester Centre – Please see my response at paragraph 154.1

155. The minutes of the UKHCDO Advisory Committee meeting on 15 January 2001 [BART0000938] record disagreement over whether and how to inform patients about a blood donor who had been diagnosed with vCJD. What was your/Alder Hey's position on this issue?

155.1. I have reviewed the information in the minutes of the UKHCDO advisory committee for 15 January 2001 (BART0000938) and cannot add to this

156. Enclosed is a generic September 2004 letter from you and Dr Hay [WITN0165007], forwarding Department of Health information on vJCD risk. In your experience, how did your/the Manchester Centre's patients react to being sent this information?

156.1. **WITN0165007**: This was a letter to be sent out as instructed by the Department of Health. Patients varied in their reactions. Some were alarmed, others were philosophical already being infected with HIV and or HBV. Some could see that they were not at risk.

157. In the enclosed 31 March 2005 letter to Professor Hill on the implications of vCJD advice from the Department of Health [HCDO0000622], you described a patient having surgery postponed while disposable equipment was purchased.

a. Were you aware of similar incidents involving other patients?

b. Did you then, or do you now, consider the Department of Health's vCJD advice to have been deficient? If so, how and why?

157.1. **HCDO0000622 – postponement of cataract surgery**. The DoH advice noted increased risk of transmission of vCJD from instruments used for eye surgery and endoscopy. I think this was the only incident related to eye surgery but there were problems described below for endoscopy.

158. At the 16 May 2005 meeting of the UKHCDO Advisory Committee [BART0000924] Dr Hay reported *"the trouble Manchester is having with endoscopies"*. Please explain what problems the Manchester Centre was experiencing and how, if at all, they were resolved.

158.1. I do not remember the details. Patients with bleeding disorders suffer from gastrointestinal bleeding and then require investigation using endoscopes. As these required quarantining after use the hospital had to purchase additional endoscopes at considerable expense. It resulted in reluctance to perform endoscopy and potential delay in management for the patients.

159. Endoscopies and the need to quarantine instruments were discussed in more detail at the 13 October 2005 UKHCDO meeting [HCDO0000504]. Did the discussion and advice given by Professor Jeffries help to resolve the problems the Manchester Centre was experiencing?

159.1. Update on management of endoscopes is detailed in the minutes of 13 October 2005 (HCDO0000504). This lists which procedures could be

considered non-invasive and therefore the endoscopes do not need quarantining. This was helpful.

160. The enclosed 21 December 2010 letter from Lynne Dewhurst to Dr Giangrande [HCDO0000616_009] recorded that a patient of the Manchester Centre had been mistakenly notified as being at risk of vCJD and provided your details as the Centre's director. When were you informed of the mistaken notification and what if anything did you do in response? Were you the director of the Manchester Centre at this time? If so, when did you assume the role and were you co-director alongside Professor Hay? Were there other instances of mistaken notification? What was the impact on patients?

160.1. I do not remember this.

161. In the enclosed 23 June 2009 generic letter [WITN0010011], the Manchester Centre updated patients about the likely source of a haemophiliac patient's vCJD infection. In your experience, how did your/the Manchester Centre's patients react to being provided with this information?

161.1. I do not have any recollection of how the patients reacted to this information.

Section 9: Transfusion

162. The questions above have focused on the care and treatment of patients with bleeding disorders. The Inquiry understands that you have held a number of positions relevant to the transfusion of blood and the use of blood products other than those used for treating bleeding disorders. Please provide an outline of these aspects of your career. In doing so, please confirm whether the Inquiry is correct to understand that your positions have included the following (please include details and dates for each as well as any other relevant roles):

a. Chair/member of the Alder Hey blood transfusion committee.

b. Member of the National Blood Service's appropriate use of blood and blood services group.

c. Member of the British Committee for Standards in Haematology transfusion task force.

d. Contributor to Department of Health publications on "Better Blood Transfusion".

e. Member/observer of the Advisory Committee on the Safety of Blood, Tissues and Organs.

f. Member of the Medicines and Healthcare Products Regulatory Agency blood consultative committee.

g. Member, and more recently medical director, of Serious Hazards of Transfusion.

162.1. I set up and chaired the Alder Hey transfusion committee following the recommendations in the Health Service Circular (HSC) 1998/224 'Better Blood Transfusion'. The minutes of July 18th 1997 meeting [AHCH 0000033_001] show that we planned terms of reference and function of the committee based on advice from the Royal Colleges of Physicians and Pathologists, the British Society for Haematology and British Blood Transfusion Society. There was national recognition that standards of transfusion required improvement (HSC 1998/224). A National Blood Transfusion Committee and Regional Transfusion Committees were set up (2001). This was a successful network. Local actions included implementation of a formal transfusion record, mandatory transfusion training for medical staff including consultants and audits of transfusion practice.

162.2. I confirm that I was a member of the National Blood Service's appropriate use of blood group. I was invited originally to represent paediatric

transfusion but do not recall the date. I remained a member until it was disbanded more recently but do not recall when that was. Some of the work was to improve patient information leaflets and to generate materials suitable for children of all ages.

162.3. I confirm that I was a member of the British Committee for Standards in Haematology transfusion task force. This was during my employment as medical director of the Serious Hazards of Transfusion (SHOT) haemovigilance scheme so only in years between 2011 and 2018. This involved participation in review and selection of transfusion guideline topics. I led and contributed to the writing of several of these.

162.4. I do not recall contributing directly to the DoH publications on Better Blood Transfusion but attended national meetings where these were discussed.

162.5. I was an observer on the Advisory Committee on the Safety of Blood Tissues and Organs. I received the minutes but did not attend the meetings. This was ex officio as medical director of SHOT.

162.6. I confirm that I was a member of the MHRA blood consultative committee while medical director of SHOT. This committee met once or twice a year to discuss matters relating to the reporting of serious adverse events and reactions as defined by the EU.

162.7. From its inception in 1996 to 2003 I contributed data on behalf of Alder Hey to the Serious Hazards of Transfusion haemovigilance scheme. This was not a membership as such. I was employed as medical director from October 2011 to August 2018 when I retired. I oversaw the collection of national data, met regularly with the expert working group and steering group, generated an annual report which was published in July each year at a national symposium where we reported the main findings.

163. Please answer the following questions with reference to your time at UCH and Alder Hey (in particular, in relation to Alder Hey, the years between 1987 and 1991).

a. Please describe your involvement in decisions relating to blood transfusion.

b. Please describe your involvement in treating patients with blood products, other than for the treatment of bleeding disorders.

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

d. What (if any) information did you typically provide to patients and/or their parents/guardians about the risks of infection from transfusion?

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

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

g. Please describe your involvement with any patients who were infected with HIV or HCV in consequence of blood transfusion.

h. Please describe your involvement with any patients who were infected with HIV or HCV in consequence of treatment with blood products other than for the treatment of bleeding disorders.

163.1. I had no particular role in transfusion decisions at UCH. At Alder Hey between 1987 and 1991:

163.1.1. I do not recall any particular role in decisions about transfusion apart from individual clinical decisions at the bedside

163.1.2. I would have treated children with leukaemia and other haematological diseases with red cells and platelets

163.1.3. I do not remember whether I had conversations about risks from transfusion

163.1.4. I do not recall how I provided such patients or their families with information about risk of infection

163.1.5. I do not recall giving information about other blood products during this time.

163.1.6. I do not recall the discussions with colleagues about the risks of transfusion

163.1.7. I do not recall any involvement with patients with HIV or NANB hepatitis from blood transfusion during this period

163.1.8. I do not recall any patients infected with HIV or NANB from other blood products

164. Please detail the arrangements for purchasing or otherwise obtaining blood and blood products during your time at Alder Hey.

164.1. Blood and other labile blood components were provided by the National Blood Service through the Liverpool transfusion centre. There was an annual contract sent by the Blood Service to the Alder Hey finance director which I would review.

165. The enclosed minutes of the 16 May 1997 meeting of the Alder Hey Blood Transfusion Committee [AHCH0000045] include a discussion regarding

informed consent. Please explain why it was considered "*logical*" to have "*informed written consent for the transfusion of blood and blood products considering the hazard that these may pose.*" So far as you are aware, why had the Blood Transfusion Task Force decided in the past that, nationally, informed consent was not required? Did you consider that a different approach should be adopted at Alder Hey and if so why? If available, please provide a copy of the patient information leaflets referred to in the minutes.

165.1. The question of written informed consent was discussed at the Transfusion Committee as detailed in AHCH0000045. The context was that there was ongoing discussion in the Trust on informed consent. Children receiving transfusion would be expected to have a long life expectancy compared to transfused adults (peak age over 60 years) and the reminder at that time that transfusion could transmit infections led us to consider information and consent. I do not possess copies of the information leaflets. I cannot answer the question about the view of the Blood Transfusion Task Force.

166. The minutes of the same meeting refer to a recent case of HIV transmission in the North West Region, as well as to one other case since 1986 in Glasgow. As far as you are able to, please expand upon the account given in the minutes and describe how and when these transmissions occurred. Having discussed the availability of virally inactivated fresh frozen plasma ("FFP"), why was it "*felt strongly that a paediatric service should use virally inactivated FFP as soon as it was feasible due to the much greater safety*"?

166.1. The HIV transmission referred to in the transfusion committee minutes [AHCH0000045] was reported to SHOT and is found in the first report for 1996-7. I have no details from the case reported from Glasgow. These incidents were a reminder that despite testing of donors, viruses may still be transmitted, hence the discussion about virally inactivated fresh frozen plasma

167. The enclosed minutes of the 18 July 1997 meeting of the Alder Hey Blood Transfusion Committee [AHCH0000033_001] record a further discussion regarding informed consent.

a. Please explain why it was generally agreed that informed written consent would not be appropriate at that time, and why it "was not felt to be a particularly practical issue" for blood transfusion.

b. Why did you feel that "it was a slightly different issue with children facing elective surgery"? What did you consider to be the appropriate approach in such cases? Did other members of the committee agree with you and if not why not?

c. Why was a patient/parent information leaflet thought to be a good way forward? Please provide a copy of the leaflet if available. Was a leaflet used alongside or in place of written informed consent? Was it used in all cases and if not what was the alternative approach?

167.1. Where transfusions are given in an emergency it would not be practical to seek informed consent

167.2. Patients preparing for elective surgery would have time for a discussion and explanation of the procedure together with signed informed consent. This would present an opportunity to discuss the possibility of side effects and possible complications of blood transfusion at the same time

167.3. Written information is useful; I do not have copies of material generated more than 20 years ago

168. In the enclosed paper, written in September 1997 and revised in January 1998 [AHCH0000030_005], you and Dr Carswell outlined Alder Hey's options for the purchase of FFP and made a number of recommendations.

a. **When outlining the infectious risks of standard FFP, you referred to the recent HIV transmission in the North West region and to the 1986 transmission. Other than the enclosed paper, what if any steps did you/Alder Hey take in response to learning of the recent transmission?**

b. **After outlining two types of sterilised plasma and the available options, you recommended using virally inactivated FFP (methylene blue method) universally at Alder Hey. Were your recommendations accepted? If so, when were they implemented and if not, why not?**

168.1. **Options for the purchase of FFP** September 1997

168.1.1. I do not recall any other steps

168.1.2. I do not remember if our recommendations were accepted, however methylene blue treated plasma became standard of care for children

169. The minutes of the 17 July 1998 meeting of the Alder Hey blood transfusion committee [AHCH0000021_001] record further discussion regarding sterilised FFP. They note that the NBA decided not to move towards the use of pooled solvent detergent heated plasma using the Octaplas process but were developing methylene blue sterilisation of single units.

a. **So far as you are able to, please explain why the NBA "were very unhappy to use pooled plasma, particularly in light of anxiety about new variant CJD". Did you/Alder Hey share the NBA's views on the use of pooled plasma?**

b. **The minutes also record that the Trust was essentially in agreement to switch to Octaplas for children, that there was doubt about its use in cardiac surgery and that it was agreed you would produce a guideline on its use. Please explain why and in what circumstances Alder Hey used Octaplas and whether and if so how its approach differed from the NBA's.**

169.1. I do not recall what my opinion was on this at the time. However, in general terms, pooled plasma was considered to carry a greater risk of infection. If there was a single donor in a large pool that would have the potential to infect a larger group of patients.

169.2. I do not remember under what circumstances Octaplas was used.

170. Enclosed is an 11 May 1999 letter from Octaplas to the Office of Fair Trading [DHSC0031349] concerning the NBA's pricing policy, which refers to a draft statement [DHSC0041566_008] resulting from a 14 January 1999 meeting of senior haematologists. Please explain what led you to attend this meeting. Did you have any input into or otherwise approve the draft statement on the future provision of FFP?

170.1. Dr Sam Machin called a meeting in January 1999 of 14 consultant haematologists known to have an interest in FFP (as described in DHSC0041566_008). I was one of the consultants. The paper states that all the attendees listed approved this draft statement.

171. The minutes of the 22 September 2000 meeting of the Alder Hey Blood Transfusion Committee [AHCH0000011] record a discussion regarding transmission of vCJD by transfusion, prompted by a Lancet article.

a. Please explain why you advised the committee that, whenever children received any blood or blood products, there should be a good justification for usage recorded in the case notes.

b. During the discussion that followed, the committee concluded that standard fresh frozen plasma should continue to be used, rather than "S/D treated FFP", "apart from certain circumstances defined by the consultant haematologists, because our main use is in children being exposed to a large number of other blood products." How were the risks of infection addressed in "standard" FPP? In what circumstances was solvent-detergent treated

FFP used? What was meant by Alder Hey's "main use" being in "children exposed to a large number of other blood products"?

171.1. Good medical practice was for all treatments, including blood components to have an indication recorded in the medical case notes.

171.2. Risk of infection from standard FFP were low and described/defined by the Blood Service. The main use of FFP was in relation to cardiac surgery where the children would receive several other components, red cells and platelets. I do not remember how solvent-detergent FFP was used at that time but it would have been appropriate for treatment of bleeding in some non-haemophilia congenital coagulation deficiencies such as factor V, VII, X or XI.

172. At the 24 August 2001 meeting of the Alder Hey Blood Transfusion Committee [AHCH0000006], you reported having attended a national meeting to discuss the potential impact of a screening test for vCJD and noted that it was possible the test could result in a 50% loss of donors. Which national meeting were you referring to and what were the concerns being expressed? The committee's subsequent discussion emphasised the need to reduce the amount of transfusion and the importance of education in doing so. Please explain and expand upon what that meant and what it involved.

172.1. As the heading for that section of the minutes is 'blood shortage/towards better blood transfusion' this was probably a meeting in preparation for the second 'Better Blood Transfusion' letter issued as HSC 2002/009. The concerns are published there *'donated blood is a limited resource. As a result of further measures that may have to be taken to reduce the unknown risk of transmission of vCJD by blood transfusion, such as the introduction of a future screening test and limitations on the numbers of donors, blood supplies may be reduced'.* Several actions were identified in this and the previous 1998 circular. Our aim was to improve transfusion practice by education of medical and nursing staff in the hospital and to follow the

recommendations of this and the previous circular HSC 1998/224 December 1998.

173. At the 3 October 2003 BSH meeting [BSHA0000007_017], Professor Machin reported that the "*National Blood Authority (NBA), against professional advice, are purchasing plasma from North America from male un-transfused donors and that methylene blue treated US plasma is to be recommended for use for all children born after 1 January 1996*". So far as you are aware, why was this course of action "*against professional advice*" and who provided the advice? Please describe the reasons for the BSH's concerns about this and other issues reported in the minutes (including the lack of implementation of Better Blood Transfusion).

173.1. This likely refers to the view recorded in paper DHSC0041566_008 in 1999 where haematologists were in favour of solvent detergent pooled plasma. I do not recall the reasons for BSH concerns other than this, BSH minutes October 2004 BSHA0000007_004. I note the reference in these minutes to the lack of implementation of BBT HSC 2002/009. This circular included recommendations for hospitals to improve transfusion practice but I do not recall what the specific issues were referred to in these minutes.

174. At the 8 October 2004 BSH meeting [BSHA0000007_004] it was reported that there was an MSBT recommendation that all children under the age of 16 should receive non UK virally inactivated plasma and that there may be problems with sourcing sufficient non UK plasma for all UK requirements. Was this recommendation in response to vCJD risk? Was it implemented at the Manchester Centre or, so far as you are aware, anywhere else?

174.1. This was in relation to the possible risk of vCJD. Children were not treated at the Manchester Adult Centre.

Section 10: The Haemophilia Society

175. Please provide details of your involvement with the Haemophilia Society. In particular, please describe:

a. the work undertaken by you as a member of the Society's Medical Advisory Panel, insofar as relevant to the Inquiry's Terms of Reference;

b. the work undertaken by you as a member of the Society's Health Sub-Committee, insofar as relevant to the Inquiry's Terms of Reference.

175.1. I was a member for many years, 1988 to 2018. I do not remember the specific work in association with the medical advisory panel nor the health sub-committee. The society may have minutes from those meetings.

Section 11: The financial support schemes

176. 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) which were set up to provide financial support to people who had been infected? Please provide as much detail as you can.

176.1. I do not remember any details about the various funds.

177. To what extent, during your time at (a) Alder Hey and (b) the Manchester Centre, did staff (including you) inform patients about the different trusts or funds?

177.1. I do not remember what we did to inform patients about the different sources of support.

178. Did (a) Alder Hey and (b) the Manchester Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support? If so please provide details.

178.1. I do not remember if we had policies at Alder Hey or Manchester in relation to these funds.

179. What kind of information did (a) Alder Hey and (b) the Manchester Centre provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

179.1. I do not remember what information Alder Hey or Manchester was provided in making applications for assistance.

180. What kind of support or assistance was provided by you and/or (a) Alder Hey and (b) the Manchester Centre making applications for financial assistance?

180.1. I do not remember what support or assistance we provided at Alder Hey or Manchester

181. Did (a) Alder Hey and/or (b) the Manchester 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.

181.1. I do not remember if we acted as a gateway at either Alder Hey or Manchester

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

182.1. I do not know the answer

183. 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?

183.1. I do not remember and have no views on how these funds were run.

184. The minutes of the 13 September 2004 UKHCDO Advisory Committee meeting [BART0000928] record that members reiterated their concerns about the way in which the scheme for ex gratia payments for HCV had been set up. Please detail these concerns and explain which of them you shared. Were they borne out by the way in which the scheme operated?

184.1. I do not recall the concerns and cannot add to the information in the UKHCDO Advisory Committee minutes from 2004, BART0000928

Section 12: HCV look-back

185. In the enclosed 27 May 1995 letter to a cardiologist colleague [NHBT0085922_006], you provided the details of a patient who had been identified in a look-back exercise as having been transfused with a presumed HCV positive blood component. The Inquiry understands that you wrote a number of similar letters. Please outline your involvement in this look-back exercise generally, including whether you had any direct contact with patients.

185.1. The hepatitis C lookback was organised through the transfusion services. As a result of the new tests for HCV a number of donors were identified as HCV positive. The fates of their previous donations were traced; the hospitals to which these donations had been provided were sent lists of the donation numbers and asked to trace the fate/recipients of these potentially infected units. There were accompanying forms and standard letters to assist. I cannot recall how many patients I identified. I remember seeing one teenage patient who turned out to be HCV-positive and presumed

infected when they had been transfused in relation to cardiac surgery. I believe I saw them with the cardiologist. As with this case although we could identify for which patients units had been issued, it was not always possible to confirm that the unit had been transfused.

186. Please provide details of any involvement you had in the creation of, and/or enrolment of patients into, the National HCV Registry in 2002-2003, as well as HCV look-back programmes organised by the Department of Health in 2010 and 2013.

186.1. I do not recall any involvement in the creation or enrolment into the National HCV Registry nor the HCV look back programmes.

187. In the enclosed May-July 2003 email chain [NHBT0089588_001], you attempted to establish whether it was necessary to trace a patient who, as a baby, had received blood through a donor whose HCV test was equivocal. Please provide further details on the background to your queries regarding the general protocol at the time for the tracing of patients who were known to have received infected blood. Do you recall whether your queries in this instance were they ever answered and if so what was the outcome?

187.1. Email trail NHBT0089588_001. Other than the information in this email trail I do not have any further details.

Section 13: Current/recent haemophilia care and treatment

188. The Inquiry understands that you worked at the Manchester Centre until at least 2014. In answering the questions in this section, which 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 draw upon your practice at the Manchester Centre around the time that you stopped working there as a clinician, and where appropriate your earlier work and experiences.

188.1. I left the Manchester Centre in September 2011 not 2014 as stated

189. Please outline:

a. how the provision of care and treatment for bleeding disorders was organised at the Manchester Centre; and

b. the treatments provided to patients with bleeding disorders at the Manchester Centre.

189.1. Haemophilia care at the Manchester adult centre was organised around the requirements for a comprehensive care centre. Three consultant haematologists provided cover 24/7. Patients would have had had scheduled visits to clinics in association with additional specialities (HIV, hepatitis, gastroenterologists). The haemophilia centre was staffed appropriately with nurses and patients could attend there in an emergency.

189.2. Treatments – standard of care with appropriate concentrates and desmopressin where appropriate. I do not remember the details for 2011 when I left.

190. Please describe how, in recent years, you typically obtained your patients' consent to treatment. In particular:

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

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

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

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

190.1. I do not have details about consent for treatment but would have followed the guidelines in Good Medical Practice as provided from time to time by the General Medical Council.

191. Did you, in recent years, routinely take blood samples from patients attending the Manchester Centre? If so, what information did you provide to patients about the purposes for which the samples are being taken? Did you obtain patients' consent to the storage and use of the samples and if so how and was that recorded?

191.1. Patients would have had routine samples taken at regular follow up visits either at 6-month or 12-months. This was a haematology clinic. These would include blood counts, biochemistry, viral markers where relevant. The patients understood that these were for monitoring and for their benefit, which is the purpose of a haematology review clinic. I do not recall samples being taken for storage other than in research studies where written informed consent was obtained

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

192.1. I do not remember any specific methods for consent to testing other than explanations of the reasons for the tests and verbal consent. In my research into Factor XI deficiency I obtained written informed consent for the study including analysis of the factor XI gene.

193. How many patients at the Manchester Centre (at the time you stopped working there) (a) were infected with HIV through blood products; (b) were infected with HCV through blood products; (c) were infected with HBV through blood products; (d) were co-infected with HIV and HCV through blood products?

193.1. I do not know the answers to these questions

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

194.1. HIV and HCV – there were multidisciplinary clinics for these which were beneficial

195. What if any psychological services were available at the Manchester Centre in recent years? Did you have a psychologist as part of the staff team? Was there psychological support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

195.1. I do not recall any specific psychological support

196. What if any other support services were available at the Manchester Centre in recent years?

196.1. Patients could be referred for physiotherapy and dental review, and to any other specialists as needed.

197. What was the impact of the infection of patients with HIV and/or hepatitis through blood products:

a. upon patients at the centres/hospitals at which you worked (without identifying any individual patient);

b. upon the ways in which decisions about treatment and care were taken, and treatment and care were provided, at the centres/hospitals at which you worked?

197.1. **The impact on patients and their families** was devastating. I looked after several children at Alder Hey with HIV infection who died. At that time there was very little experience or knowledge about HIV infection in children. One mother lost two of her three haemophiliac sons to AIDS which caused difficulties with the undertakers and cemetery. Adults with HIV at Manchester – many have survived with the improved therapy, but others have died from complications of their infections including liver disease and cancer. The psychological effects were profound. Some have survived who thought they would die and spent all their savings.

197.2. **Impact on decisions and care, how they were taken and their provision**. The principles of good haemophilia care remained the same. Additional routines were introduced for treatment of blood samples (phlebotomy and in the laboratory) but it was later recognised that all blood samples should be treated the same. Additional access was required for advice about infections in this patient group as described elsewhere in this response. Members of the team (haemophilia nurses) had to become familiar with HIV disease and its complications. As far as I can recall there were no protocols for treatment of HIV in children at that time.

198. Did the infection of patients with HIV and/or HBV and/or HCV through blood products:

a. change or influence your professional practice and approach and if so how?

b. change or influence the practice and approach of your colleagues at the centres/hospitals at which you worked and if so how?

c. change or influence, in recent years, the way in which haemophilia care was provided and if so how?

198.1. This experience did influence my professional practice. I had not expected to take on a major role in HIV management. This was not just of the children with haemophilia but also other paediatric HIV infection because I was the

only consultant with experience, and it was a disease others did not wish to engage with. I also started up a clinic for other children with immune deficiency with collaboration from chest physicians and arranged consultant immunologist input from another hospital.

198.2. I did not notice any change in practice or approach of other colleagues other than in a.

198.3. I have not had a role in haemophilia care in recent years (none since 2011).

Section 14: Other issues

199. 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.

199.1. I have had no complaints against me

200. 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.

200.1. It is important to note that as physicians and haemophilia centre directors we did the best we could for our patients with the knowledge and resources that were available at the time. Without adequate replacement therapy haemophiliacs could become severely disabled.

Statement of Truth

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

Signed GRO-C Dated 17 November 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
	Business case written for a full-time grade G nurse for the haematology treatment centre	WITN4160002
	Prophylaxis for patients with severe haemophilia	WITN4160003
	Excerpts from '**Haemophilia treatment in the UK 1969-1977'** Br J Haematol 1977, 35, 487	WITN4160004
	Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80: report on behalf of the directors of haemophilia centres in the UK' BMJ March 19, 1983, by Rizza and Spooner	WITN4160005
	Registration form for children with disorders of haemostasis	WITN4160006
	Watt et al. BSH abstract on HCV 2006	WITN41600007
	Current treatment strategies in haemophilia A	WITN4160008
	Letter to the BMJ 1997	WITN4160009
	Optimal haemophilia care vs the reality. Br J Haematol 2005; 132: 671-82	WITN4160010