Witness Name: Professor Isobel D. Walker
Statement No.: WITN4035001
Exhibits: WITN4035002-8
Dated: 5th November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ISOBEL D WALKER

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

I, Isobel Walker will say as follows: -

Section 1: Introduction

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

1.1 Name: Isobel Walker

1.2 Date of Birth: GRO-C 44

1.3 Home Address: GRO-C

Glasgow GRO-C

1.4 Professional Qualifications:

- 1967 MB ChB, University of Glasgow
- 2003 MD University of Glasgow

- 2005 MPhil (Medical Law), University of Glasgow
- 1974 Member, Royal College of Pathologists
- 1977 Specialist Accreditation in Haematology
- 1986 Fellow, Royal College of Pathologists
- 1987 Fellow, Royal College of Physicians, Edinburgh
- 2003 Fellow, Royal College of Physicians and Surgeons, Glasgow

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 Training Posts:

- Pre-registration House Officer General Surgery Aug 1967-Jan1968 and General Medicine Feb1968-July 1968 Southern General Hospital Glasgow
- Senior House Officer Infectious Diseases Aug 1968-Mar 1969 Ruchill Hospital Glasgow
- Senior House Officer then Registrar Haematology Apr 1969-Dec 1973 Glasgow Royal Infirmary
- Senior Registrar Haematology Jan 1974-Oct 1978 Greater Glasgow Health Board

2.2 Consultant Posts:

- Consultant Haematologist Oct 1978-Oct 2009 Glasgow Royal Infirmary and Glasgow Royal Maternity Hospital then Princess Royal Maternity Hospital

- Director UK National External Quality Assessment Scheme for Blood Coagulation (Consultant Haematologist grade) Feb 2005 -current Sheffield Teaching Hospitals

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 British Society of Haematology:
Member of Committee 1991; Secretary 1992-1995; 1995-1998; President Elect 1998-1999; President 1999-2000.

- British Committee for Standards in Haematology (BCSH):
Chairman BCSH1998-2001; Member Haemostasis and Thrombosis Task Force 1989-1992; 1992-1995; Chairman Haemostasis and Thrombosis Task Force 1995-1998

- UK National External Quality Assurance Scheme for Blood Coagulation (NEQAS BC):
Chairman NEQAS BC Steering Committee 1996-1999;1999-2002
Secretary NEQAS BC Steering Committee1990-1993;1993-1996 Member UK NEQAS BC Steering Committee 1990-1993;1993-1996; 2005-current

- Intercollegiate Haematology Committee:
Member Intercollegiate Haematology Committee Haematology 1997-2000;2000-2003

- Scottish Regional Council, Royal College of Pathologists:
Vice Chairman Scottish Regional Council Royal College of Pathologists 2001-2004
Chairman Scottish Regional Council Royal College of Pathologists 2004-2006

- Examiner for Royal College of Pathologists 1990 2010

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

4.1 I gave a brief statement in a letter to the Penrose Inquiry which I attach to this statement (WITN4035002).

Section 2: Decisions and actions of those treating patients with bleeding disorders at the Glasgow Royal Infirmary

5. Please describe the roles, functions and responsibilities of the haemophilia centre ("the Centre") at the Glasgow Royal Infirmary ("the GRI") during the time that you worked there, and how they changed over time.

5.1 The West of Scotland Haemophilia Centre was set up within the University Department of Medicine at GRI in the 1950s as a reference centre to deal with difficult clinical problems in patients with suspected congenital bleeding disorders and to act as a laboratory reference centre. With the development of Haematology as a specialty in the 1960's the Centre had two Co-Directors. Dr Stuart Douglas was based in the University Department of Medicine and provided clinical services for diagnosis, treatment and review and a coagulation research laboratory. Dr George MacDonald was based in the NHS Haematology laboratory and provided routine blood tests and monitoring, including a Blood Bank for provision of blood, plasma and other blood products. When I joined the staff of the GRI Haemophilia Centre in 1991, it provided 24 hour Consultant led diagnostic and clinical services for patients with heritable bleeding disorders registered with the Centre and multidisciplinary outpatient clinics for routine review and management of the bleeding disorder and, in collaboration with other specialists, for management of hepatitis, HIV, and other problems. It also had important roles in educating, counselling and supporting patients and their families.

5.2 As I remember it, in 1991 the majority of patients were males. This majority changed as time went on and the number of women attending for counselling, investigation and management increased.

6. Please identify senior colleagues at the Centre and their roles and responsibilities during the time that you worked there.

6.1

Consultant Vascular Physician Co-Director	Professor Gordon Lowe
Consultant Haematologist Co-Director	Professor Isobel Walker
Consultant Haematologist Co-Director	Professor Campbell Tait
Associate Specialist	Dr Arif Alvi
Haemophilia Specialist Nurse	Sister Ishbel McDougall
Haemophilia Specialist Nurse	Sister Pamela Wicks
Operational Manager	Ms Nancy Brodie
Consultant Gastroenterologist	Dr John Mackenzie
Consultant Hepatologist	Dr John Morris
Consultant in Infectious Diseases	Dr Andrew Seaton
Consultant Rheumatologist	Dr Rajan Madhok

7. Please describe:

a. your role and responsibilities at (i) the GRI, and (ii) the Centre and how, if applicable, this changed over time;

b. your work at (i) the GRI, and (ii) the Centre insofar as it involved the care of patients with bleeding disorders and/or patients infected with

hepatitis and/or HIV in consequence of infected blood or blood products.

7.1 I am primarily a Laboratory Haematologist, trained at a time when entry into the Specialty did not require post graduate qualifications in General Medicine. Throughout my training, like other trainees in the Department of Haematology at GRI, I had no access to the Haemophilia Centre. Furthermore my experience in general medicine is very limited and my clinical expertise was mainly in managing venous thrombotic disorders particularly in women.

a(i) Consultant Haematologist Glasgow Royal Infirmary with Responsibility for Glasgow Royal Maternity Hospital and later Princess Royal Maternity Hospital

7.2 In October 1978 I was appointed Consultant Haematologist. I had limited duties at Glasgow Royal Infirmary (GRI) as my appointment was with special responsibility for the Haematology Services at the associated Glasgow Royal Maternity Hospital (GRMH) and latterly the Princess Royal Maternity Hospital (PRMH). I had no access to in-patient beds and no access to the Haemophilia Unit. I developed an interest in the aetiology of thrombosis establishing tests to investigate potential risk factors for venous thrombotic disorders. I established an outpatient clinic at GRI (Thrombophilia Clinic) for patients with a personal or family history of venous thrombosis and to investigate women with a history of recurrent pregnancy loss potentially linked to underlying thrombophilia.

7.3 Prior to my appointment in 1978, haematology at GRMH had been restricted to a very basic laboratory service. My task was to introduce to the laboratory on the GRMH site a broad spectrum of haematology laboratory methods appropriate for a large teaching maternity hospital and, in collaboration with obstetric, midwifery and paediatric staff, to introduce consultative clinical haematology services.

7.4 I developed a comprehensive haemostasis service for GRMH to investigate potential bleeding or thrombotic disorders in women. Pregnancies in these women were managed by a multidisciplinary team led by Professor Ian Greer (obstetrician) and including myself. Latterly I organised the integration of GRMH's haematology laboratory services into the haematology laboratory at GRI ahead of the transfer of GRMH obstetric services to the new Princess Royal Maternity Hospital (PRMH) on the GRI site.

7.5 I was appointed Administrative Head of the Department of Haematology (GRI and associated hospitals) in October 1996.

7.6 Glasgow University awarded me a Personal Chair in Perinatal Haematology in 2003 in recognition of my expertise in the investigation and management of women around conception, pregnancy and the puerperium.

7.7 In February 2005 I was appointed Director of the UK National External Quality Assessment Scheme for Blood Coagulation (UK NEQAS BC) employed by Sheffield Teaching Hospitals at Consultant Haematologist grade. This is a part time non-clinical post and on appointment was for 2 sessions per week. I accepted this post with the support of my employers at GRI and with their agreement ceased providing a General Haematology outpatient clinic at GRI. Since I retired from GRI in October 2009 I have continued as Director of UK NEQAS BC increasing my commitments to 4 sessions per week.

a(ii) Co-Director West of Scotland Comprehensive Care Haemophilia Centre.

7.8 In 1991, when Dr George MacDonald retired, I was appointed Co-Director (with Professor Gordon Lowe) of the West of Scotland Comprehensive Care Haemophilia Centre.

7.9 In view of my limited and very different clinical experience my primary remit as a Centre co-director was to ensure delivery of essential haemostasis tests and assays, to make sure that these tests were not only accurate, done promptly throughout the working day and, if necessary, available as an emergency out of normal working hours and to instigate development of new tests and assays as clinically required.

7.10 Clinically my interests within the Haemophilia Centre were limited and revolved around the provision of services for women - the female relatives of haemophiliacs and women with other bleeding disorders. Protocols for the management of pregnancy and the puerperium and for ensuring that, where appropriate, neonates are tested and if necessary referred to the Royal Hospital for Sick Children, Yorkhill were updated. Protocols for the investigation and management of women with menorrhagia were also developed and implemented.

b(i) Consultant Haematologist Glasgow Royal Infirmary with Responsibility for Glasgow Royal Maternity Hospital and later Princess Royal Maternity Hospital

7.11 I do not recall having any patients at GRI or GRMH/PRMH that I knew to be infected with hepatitis and/or HIV in consequence of infected blood or blood products in these settings.

b(ii) Co-Director West of Scotland Comprehensive Care Haemophilia Centre.

7.12 I had no office or clinic space in the Haemophilia Centre. Consequently I did not participate regularly in the Centre's weekly routine review Clinic but saw the women referred to me in the Haemophilia Centre on an ad hoc basis. I only very rarely saw a male patient in the Centre. Thus, although I was very aware that some of the patients attending the Haemophilia Centre had been infected with hepatitis and/or HIV in consequence of infected blood or blood products I very seldom met any of these patients and cannot remember any of them specifically.

8. Approximately how many patients with bleeding disorders were under the care of the Centre when you began your clinics there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

8.1 I have no clear idea of how many patients were registered at the Haemophilia Centre but would estimate around 120 when I joined the staff there in 1991. Over the years, as female patients were increasingly encouraged to attend the Centre, the total number of patients registered increased and I estimate was 5 or 6 fold the number in 1991 by the time I retired in 2009.

9. The Inquiry understands that adult patients were treated at GRI and children at Yorkhill. Please confirm whether or not this is correct. If it is, please explain how care was transferred once a child reached adulthood (and when that was assessed to be). Were any children with haemophilia treated at GRI during your time working there?

9.1 I confirm adults with heritable bleeding disorders were treated at GRI and children at Yorkhill. When I joined the Haemophilia Centre staff in 1991, transfer from Yorkhill to GRI

happened at age 16 years after informal liaison between Professor Lowe and the Consultant in Charge of the Yorkhill Unit, Dr Brenda Gibson. Dr Campbell Tait when he was appointed accepted responsibility for developing the transfer arrangements to allow a more 'gentle' transition from the environment and staff team at Yorkhill to the Centre at GRI. Transfer still usually happened around the age of 16 but could be flexible. Dr Tait visited Yorkhill to introduce himself to the patient and his/her family and to discuss the proposed transfer with them.

10. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? 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?

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

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

d. What if any involvement did you have?

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

10.1 When I joined the Haemophilia Centre in 1991 most of the blood products for the management of patients with bleeding disorders were prepared by the Scottish National Blood Transfusion Service (SNBTS) at their Plasma Fractionation Centre (PFC) in Edinburgh. The Scottish and Northern Ireland Haemophilia Centre Directors met regularly with senior staff from the PFC to inform PFC of predicted quantity requirements and discuss what products were currently available and proposed product development.

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

10.2 With the banning of fractionation of plasma from UK donors in 1998 as concern mounted about the risk of transmission of vCJD by blood products, SNBTS imported plasma to fractionate but already the Haemophilia Centre Directors were discussing how to move away from plasma derived products to the new recombinant concentrates. The Co-chairs of the Haemophilia Directors of Scotland and Northern Ireland Organisation (Professors Lowe and Ludlam) met with the Chief Medical Officer (CMO) for Scotland to request that the NHS in Scotland develop a procedure to progressively replace SNBTS produced plasma derived factors with commercial recombinant concentrates. To this end, a Consortium was established and most of the patients with haemophilia registered with Haemophilia Centres in Scotland had been transferred to recombinant products, funded by Health Boards throughout Scotland and purchased following a tendering process organised by NHS National Services Division (NSD)Scotland, by 2002.

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

10.3 Of course financial considerations were taken into account but other factors including, evidence of safety, efficacy, availability and shelf life were also considered.

d. What if any involvement did you have?

10.4 I was involved in the discussions with other Scottish Haemophilia Directors, the Consortium and with NSD.

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

11.1 In 1991 when I joined the staff of the Haemophilia Centre at GRI the majority of patients with haemophilia A were treated with the intermediate potency FVIII produced by the PFC and called Z8. Patients with haemophilia B were treated with DEFIX (FII, FIX and FX). I believe a small quantity of commercial plasma derived products was purchased e.g. Profilate and Monoclate-P for managing some patients with haemophilia A who tolerated Z8 poorly and FEIBA (FVIII inhibitor bypassing activity) for patients with haemophilia A with inhibitors.

11.2 By 1991 arrangements were in hand to provide the Haemophilia Centres in Scotland with a high potency FVIII (HP FVIII) concentrate using technology developed in France. This was a phased process using initially HP FVIII prepared in Lille from French plasma, followed by a period when the Lille Fractionation Centre produced HP FVIII from Scottish plasma and finally with transfer of the technology to the PFC the PFC produced HP FVIII from Scottish plasma.

11.3 Desmopressin (DDAVP) was used in the treatment of mild and some moderate haemophilia A patients with minor bleeding and in patients with von Willebrand disease but is ineffective in severe haemophilia A in haemophilia B or in circumstances where there is severe bleeding or a risk of major bleeding.

11.4 With the recognition in the late 1990s that blood derived products may transmit vCJD a programme of transferring patients on to recombinant products was initiated using Recombinate (Baxter), Kogenate (Bayer) and Helixate (CSL Behring) for haemophilia A patients and Benefix (Pfizer) for haemophilia B patients.

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

12.1 The Haemophilia Centre was not directly involved with the pharmaceutical companies manufacturing/supplying blood products. I am confident that the Centre's decisions and actions were not influenced by any relationship with the pharmaceutical companies manufacturing/supplying blood products.

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

13.1 Following discussions with the CMO Scotland a Consortium of representatives of all Scottish Health Boards was formed with the aim of fairly distributing the cost of funding the purchase of products across all Scottish Health Boards. In discussion with the Consortium and NHS Scotland NSD the Haemophilia Directors agreed the predicted total quantities of each type of product required to treat the patients with haemophilia registered with Haemophilia Centres in Scotland.

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

14.1 By the late 1990s when the Centre at GRI was able to obtain recombinant products a third Co-Director (Dr Tait) had been appointed and I had very little direct clinical involvement in the Centre. I cannot recall actively participating in discussions about which products to use for individual patients or if patients were offered a choice.

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

15.1 I did not become involved with the Haemophilia Centre until 1991 but in the 1970s and 1980s I was recommending a variety of products for patients with surgical, traumatic or post partum bleeding. These products included Fresh Frozen Plasma and pools of Cryoprecipitate. Antifibrinolytic agents EACA (epsilon amino caproic acid) and tranexamic acid were also being used for post dental extraction bleeding and for some women with menorrhagia.

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

16.1 Cryoprecipitate had the advantage of being prepared from single donors but it had several major disadvantages for treatment. As with Fresh Frozen Plasma, the FVIII level in a single unit of cryoprecipitate was not known, recovery in the circulation was variable and unpredictable and there was an appreciable incidence of allergic reactions (including life-threatening anaphylactic shock). Cryoprecipitate had to be stored frozen at -20ºC and the thaw time was long (about 30 minutes in a 37 ºC water bath). The FVIII available in a single donation was not enough to treat a bleed and it was usual to prepare pools of 10-15 bags of thawed cryoprecipitate by spiking individual bags with a tube, draining the contents into one pool bag before washing out each individual bag to drain the last of the contents and adding the washouts to the pool. This was time consuming and the delay could be critical for an acutely bleeding patient and the process of pooling introduced a risk of contamination.

16.2 The synthetic vasopressin analogue, desmopressin (DDAVP) raises blood levels of the FVIII: von Willebrand factor (vWF) complex, by releasing vWF from vascular endothelium. Such elevations are sufficient to treat minor bleeding (for example, nosebleeds), and to

prevent bleeding following dental extractions or other minor surgery in patients with mild haemophilia A or mild von Willebrand disease (vWD). Adverse effects include facial flushing, tachycardia and fall in blood pressure (due to vasodilatation). It has the major advantage of not being a blood product. However, it has the disadvantage of not inducing a predictable rise in the concentration of FVIII and, on repeat dosing over a period of a few days, the response wanes. In some patients its side effects are quite unpleasant with headaches, palpitations and changes in blood pressure. DDAVP rarely causes cerebral oedema from hypo-osmolality due to the drug's antidiuretic effect

16.3 The anti fibrinolytic agents epsilon amino caproic acid (EACA) and tranexamic acid also have the advantage of not being blood products and they can be administered orally or transnasally but they have the disadvantage of predisposing to thrombus development.

16.4 Prior to the 1990s cryoprecipitate was used for the treatment or prevention of serious bleeding in patients with haemophilia A or von Willebrand disease. DDAVP was used as the treatment of choice for less serious bleeding in patients with mild haemophilia A and the majority of patients type 1 and type 2 (except 2B) vWD.

16.5 EACA and tranexamic acid were used to treat or minimise the risk of post dental extraction bleeding in patients attending the Centre and to manage menorrhagia in some haemophilia carriers and in women with type 1 and type 2 (except 2B) vWD.

16.6 Wherever possible alternatives to plasma derived products were used as all the Haemophilia Centre staff were highly conscious of the risk infection from blood and blood derived products.

17. What was the Centre's policy and approach 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 had with external parties?

17.1 In 1991 when I joined the staff of the Haemophilia Centre at GRI cryoprecipitate was no longer being used widely. Patients with moderate to severe haemophilia A were treated with the intermediate potency FVIII produced by the PFC and called Z8. Patients with haemophilia B were treated with DEFIX (SNBTS FII, FIX and FX complex) and patients' mild haemophilia A and those with type 1 and type 2 (except 2B) vWD were usually managed with DDAVP for minor bleeds and invasive procedures.

a. Did that policy and approach change over time?

17.2 The policy and approach with regard to cryoprecipitate use had already changed by the time I joined the Centre staff.

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

17.3 I don't know because I was not involved.

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

18.1 I believe that a major remit of the Centre's Nurses in the 1980s was to train adult patients with severe haemophilia who had frequent bleeds to self-administer home treatment whenever they suspected bleeding. When I joined the Centre staff in 1991 most patients on home treatment collected their supplies directly from the Centre. A few who were geographically distant had supplies delivered to them. Patients on home treatment were asked to keep a diary of their product usage and return this information to the Centre. This process was inconvenient for some patients and in some cases it proved difficult to obtain accurate records of a patient's bleed history and product use.

18.2 Once the majority of patients had been transferred to recombinant products, many of GRI's youngest patients were already used to home treatment prior to their transfer from Yorkhill and an increasing number of the older patients were asking to be considered for home treatment. After discussion with Haemophilia Directors throughout Scotland it was agreed that we should employ a commercial health services delivery service to deliver products. A programme of training more patients on safe injection procedures was instituted for those who had not already been benefitting from a home treatment programme. To remain in the home treatment programme patients were required to send the Haemophilia Centre records of usage and to attend the Centre for scheduled follow up visits.

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

19.1 Children were not treated at GRI and during the time I was on the staff of Haemophilia Centre at GRI (and bearing in mind that I retired from there in 2009) I was not aware that the GRI Centre had a specific policy for prophylactic treatment of its adult patients, other than for invasive procedures, although I believe that some individual patients on home treatment may have been given advice about prophylaxis in some circumstances.

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

20.1 No children were treated at the GRI Centre.

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

21.1 DDAVP was used as the treatment of choice for mild bleeding and in some cases of moderate bleeding in patients with mild haemophilia A, haemophilia A carriers and the majority of patients with von Willebrand disease. (Type 1 and Type 2 excluding 2B). It is ineffective in severe haemophilia A, most patients with moderate haemophilia A, haemophilia B and Type 3 von Willebrand disease. At diagnosis patients with mild haemophilia A, haemophilia A carriers and the majority of patients with von Willebrand

disease were test dosed with DDAVP to assess their response. Plasma concentrate was considered for 'poor responders' to DDAVP or if the bleeding was severe, in a critical site, did not respond to local measures - eg local pressure, application of thrombin soaked swabs or failed to settle after a repeat dose of DDAVP.

21.2 EACA and tranexamic acid were used to treat or minimise the risk of post dental extraction bleeding, in the management of epistaxis in patients attending the Centre and to manage menorrhagia in some haemophilia carriers and in women with von Willebrand disease.

22. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at the Centre's in consequence of the use of blood products?

22.1 I have a recollection that a patient may have been tested for parvovirus.B19. I am really not certain when, but possibly in the mid 1990s and I don't know the outcome.

Section 3: Knowledge of, and response to, risk

General

23. When you began work at the Centre, 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?

23.1 When I was a junior doctor in the 1970s, I recall hearing about an outbreak of hepatitis B (HBV) in Edinburgh. Vaccination against HBV was introduced in the mid 1980s and recommended to all NHS staff and patients who were at risk and non-immune.

23.2 A number of adults attending the Haemophilia Centre at GRI had already been diagnosed as HIV positive in the 1980s ahead of the time I joined the Centre's staff. I was already aware from reports in the press that there was a risk that an asymptomatic donor infected with the virus could donate blood which may be processed into a pool used to produce a product which may then be given to many recipients.

23.3 A few months ahead of the time I joined the staff of the Haemophilia Centre, a paper was published in the New England Journal of Medicine reporting that hepatitis C virus (HCV) was the predominant agent of transfusion associated non-A non-B hepatitis (NEJM 1989; 321 p1494) (WITN4035003). Discussions about testing blood donors were initiated and as far as I can recall an exercise to trace and test recipients of blood from donors found to be HCV positive established. Throughout the 1990s HCV infection was on the agenda of many meetings that I attended.

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

24.1 I believe HCV testing was added to routine surveillance for hepatitis in the Haemophilia Centre from 1991. Patients with positive tests were given information on the virus and its possible effects; and advice on precautions with blood and sex, testing of sexual partners, minimising alcohol intake and the need for regular follow-up. This was supplemented with leaflets from the British Liver Trust and/or the UK Haemophilia Society. Further counselling and support was available from the Centre's nurses and social workers.

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

25.1 (i) By the time I joined the Haemophilia Centre in 1991 I understood that it was unlikely that the SNBTS heat treated FVIII or DEFIX transmitted HIV or hepatitis.

25.2 (ii) I have limited knowledge of transmission of infection by commercial factor concentrates and do not feel competent to comment on the relative risks compared with SNBTS products.

Hepatitis

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

26.1 Vaccination against HBV was introduced in the mid 1980s and recommended to all NHS staff and patients who were at risk and non-immune thus I was aware of the risk of infection from blood.

26.2 A few months ahead of the time I joined the staff of the Haemophilia Centre, a paper was published in the New England Journal of Medicine reporting that hepatitis C virus (HCV) was the predominant agent of transfusion associated non-A non-B hepatitis (NEJM 1989; 321 p1494) (WITN4035004). Discussions about testing blood donors were initiated and as far as I can recall an exercise to trace and test recipients of blood from donors found to be HCV positive established. Throughout the 1990s HCV infection was on the agenda of many meetings that I attended.

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

27.1 HCV testing was added to routine surveillance for hepatitis in the Haemophilia Centre from 1991. Patients with positive tests were given information on the virus and its possible effects; and advice on precautions with blood and sex, testing of sexual partners, minimising alcohol intake and the need for regular follow-up. This was supplemented with leaflets from the British Liver Trust and/or the UK Haemophilia Society. Further counselling and support was available from the Centre's nurses and social workers.

27.2 By 1993, Scottish and Northern Ireland Haemophilia Centre Directors had completed a previously-untreated patient (PUP) study of SNBTS Factor VIII concentrate, which showed that no patient had developed abnormal liver function tests, or antibody to HCV.

28. What, if any, actions did you and/or the Centre take to reduce the risk to patients of being infected with hepatitis (of any kind)?

28.1 Every effort was made to reduce the use of blood and plasma derived concentrates. All patients were advised to practise safe sex (eg use condoms). Patients not naturally immune to Hepatitis A or B were strongly advised to seek vaccination.

28.2 In 1996, UKHCDO recommended that recombinant FVIII concentrate was the treatment of choice for those with FVIII deficiency. The Co-chairs of the Haemophilia Directors of Scotland and Northern Ireland met with the Chief Medical Officer for Scotland to request that the NHS in Scotland develop a procedure to progressively replace SNBTS blood derived factor concentrates with recombinant concentrates. This was agreed, and a consortium established for this purpose. The great majority of patients with haemophilia in Scotland were transferred to recombinant concentrates by 2002, several years before the rest of the UK.

29. 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?

29.1 Blood was known to transmit jaundice/hepatitis from the 1940s when the blood transfusion was introduced.

29.2 Hepatitis B (HBV) came to my attention when I stared my training in haematology because there was an outbreak in a dialysis unit in Edinburgh. It is common throughout the world but most adults are able to clear the virus within a few months. However, children and some adults risk developing chronic HBV which can lead to cirrhosis and to liver cancer. Laboratory staff and staff and patients in specialties where blood transfusion was common were regularly tested for hepatitis B. Blood donors were hepatitis B antigen tested from 1969. Although these measures reduced the risk of transmission of HBV by blood, some patients in Edinburgh who had received SNBTS cryoprecipitate or Factor VIII concentrate in the 1970s were found to have been infected. Hepatitis B vaccination was introduced in the 1980s, and recommended to all healthcare workers at risk and to those patients receiving regular blood or blood product transfusion.

29.3 Hepatitis A (HAV) is usually transmitted faecal-orally and is usually transient, lasting a few months, but it can be severe and even life threatening. In 1992, following reports of transmission of hepatitis A from some non-UK factor concentrates, UKHCDO recommended HAV vaccination for patients who were not naturally immune. In a study published in 1995 73 patients attending the GRI Centre, were tested for anti-HAV: 40% were positive, comparable with the local prevalence rate for natural immunity. 30 patients were subsequently treated with SNBTS high purity FVIII concentrate: no cases of seroconversion occurred (Haemophilia 1995; 1: p194) (WITN4035004).

29.4 Hepatitis C (HCV) was discovered in 1989 and it was established that this was the major cause of non-A, non-B hepatitis (NANB). HCV infection may be asymptomatic or cause only mild flu-like symptoms. The minority of affected patients clear the virus. Chronic HCV infection causes long term symptoms and may cause cirrhosis and hepatocellular cancer. Routine screening of blood donations was introduced throughout the UK in September 1991, using second generation ELISA and RIBA tests. In the GRI Haemophilia Centre, HCV testing was added to routine surveillance for hepatitis (HBV, HAV, liver function tests) from 1991.

HIV and AIDS

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

30.1 By the time I joined the staff of the Centre in 1991 it was already known that some patients with haemophilia attending the Centre at GRI had seroconverted and were HIV positive.

30.2 From reading reports I understand that in 1984 a retrovirus, subsequently named the Human Immunodeficiency Virus (HIV) was shown to be the cause of AIDS and it was realised that there was a risk that an asymptomatic donor infected with the virus could donate blood which may be processed into a pool used to produce a product which may then be given to many recipients.

30.3 Also I have read that in a collaborative study, with a group in Denmark, the GRI Haemophilia Centre reported that HIV antibody positivity was directly correlated with the consumption of concentrate imported from the US, but not of locally produced concentrate (Lancet 1984; ii: p 1444) (WITN4035006). While these findings initially suggested relative safety of SNBTS-produced Factor VIII concentrates compared to commercial concentrates, the Haemophilia Centre Director in Edinburgh, reported to SNBTS in November 1984 that a number of patients, tested for HIV antibody were positive, and had all received one batch of SNBTS Factor VIII concentrate, which had subsequently been withdrawn.

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

31.1 I was aware from reports in the press in the 1980s that there was a risk that an asymptomatic donor infected with the virus could donate blood which may be processed into a pool used to produce a product which may then be given to many recipients. I was aware of the Edinburgh cohort of patients with haemophilia infected with HIV apparently from a single batch of SNBTS FVIII concentrate.

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

32.1 I joined the staff of the Haemophilia Centre in 1991 by which time there was awareness of the risks of transmission of HIV/AIDS by blood and blood products and already the number of the Centre's patients with haemophilia who had been infected with HIV was known.

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

33.1 I was not involved in the Haemophilia Centre in the 1980s when the risk of transmission of HIV by blood products was initially described so I do not know from personal experience what actions were taken by the Centre at that time.

33.2 I know from reports that meetings between SNBTS and Haemophilia Centre Directors in November and December 1984 resulted in a decision to withdraw current batches of SNBTS FVIII concentrate and replace it with heat-treated concentrate from January 1985. Heat treatment of SNBTS Factor IX concentrate was introduced in October 1985. (Penrose Inquiry, Final Report).

33.3 Letters to GRI Haemophilia Centre patients who had received blood products, informing them of these developments; advising that all patients treated with blood products should take care with sex and blood to minimise risk of transmission; and advising that at review appointments the risk of AIDS would be discussed, and in due course HIV testing would be performed, once reliable tests had been established at the Regional Virus Laboratory (Penrose Inquiry, Final Report). Routine NHS HIV testing by the Regional Virus Laboratory was established by October 1985. All patients who were HIV positive were managed jointly with Consultants from the Infectious Diseases Department at Ruchill Hospital. Patients had access to developing AIDS support services, including access to counselling.

34. In the enclosed minutes of a meeting of the West Scotland Consultant Haematologists Group held on 22 November 1984 [PRSE0004852], which you attended, it is noted at paragraph 17 that Dr Mitchell outlined '*moves to prevent dissemination of AIDS by blood products'*. It is further noted that '*This programme appears to be progressing satisfactorily and to date no cases have been reported resulting from infusions of products from the Scottish Protein Fractionation Centre.'* What efforts were made to prevent dissemination? What if any, efforts were made by the Centre in particular?

34.1 Over the years clinicians have been frequently reminded that blood and blood product transfusion carry the risk of infection from agents both known and unknown. I do not remember what steps may have been taken at GRI/GRMH specifically following this meeting.

34.2 I had no involvement with the Haemophilia Centre in 1984 so cannot comment from personal experience on any action they may have taken.

35. How often did the West Scotland Consultant Haematologists Group meet? What was the purpose of its meetings?

35.1 I don't recall how often the West of Scotland Consultant Haematologists Group met but my impression was that it met infrequently. Its purpose was to keep Consultant Haematologists in the region up to date with issues of importance.

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

36.1 I did not join the staff of the Haemophilia Centre until 1991 so cannot comment on what the Centre did when it first became evident that blood and blood products could transmit HIV. By the time that I did join the Centre staff, huge efforts were being made to develop products with as low a risk of virus transmission as technically possible. The Centre Co Directors' focus was always on trying to obtain supplies of safe products.

36.2 I understand from reading that meetings between SNBTS and Haemophilia Centre Directors in November and December 1984 resulted in a decision to withdraw current batches of SNBTS Factor VIII concentrate and replace it with heat-treated concentrate from January 1985. Heat treatment of SNBTS Factor IX concentrate was introduced in October 1985. (Penrose Inquiry, Final Report).

Response to risk

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

37.1 I was not involved with the Haemophilia Centre until 1991 but I understand from reading that in January and in April 1985, two letters were sent to GRI Haemophilia Centre patients who had received blood products advising that all patients treated with blood products should take care with sex and blood to minimise risk of transmission; and advising that at review appointments the risk of AIDS would be discussed, and in due course HIV testing would be performed, once reliable tests had been established at the Regional Virus Laboratory (Penrose Inquiry, Final Report).

37.2 The April letter enclosed a Haemophilia Society information and advice booklet, "AIDS and the Blood" (WITN4035005). Meanwhile, Centre staff aided by an experienced HIV counsellor had the difficult task of telling the patients who had tested positive for HIV their result (Penrose inquiry, Final Report).

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

38.1 I understand that meetings between SNBTS and Haemophilia Centre Directors in November and December 1984 resulted in a decision to withdraw the then current batches of SNBTS Factor VIII concentrate and replace it with heat-treated concentrate from January 1985. Heat treatment of SNBTS Factor IX concentrate was introduced in October 1985. (Penrose Inquiry, Final Report). Since I had no involvement with the Centre at that point in time I cannot comment on which categories of patients received heat treated products.

39. Please refer to the minutes of the 30th meeting of the Haemophilia Reference Centre Directors' meeting held on 5 September 1988 [HCDO0000431], which you attended. The minutes (p.3) record a discussion in which "reservations were expressed about the Scottish factor VIII, 8Z [sic]." Dr Lowe is recorded as asking the English Haemophilia Centre Directors "if they were therefore prepared to make 8Y available for previously untransfused patients in Scotland". The meeting notes that this was not accepted.

a. Please explain the background to this discussion, and your recollection of it.

b. What reservations were expressed at this time about 8Z/Z8? Did you share those reservations?

c. What explanation was given for the apparent refusal of this request?

d. Did you and/or your Centre seek the provision of 8Y for previously untreated Scottish patients at any other times? If so, why, and what was the outcome?

39.1 I attended this meeting in 1988 as a deputy for Dr MacDonald. I was not at that time involved in the Haemophilia Centre and I do not recall having received any briefing on this issue ahead of the meeting. As a result, I do not feel competent to answer any of these questions.

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

40.1 I have no idea if it would have been technically possible to produce heat-treated products earlier but I note that in 1986, following evidence that the degree of heat treatment of SNBTS factor VIII concentrate (68 degrees C for 24 hours) was insufficient to eliminate transmission of viral hepatitis, SNBTS heat treatment was intensified (80 degrees C for 72 hours) and available for clinical use April 1987 (Penrose Inquiry Final Report). The Penrose Inquiry (Final Report) noted that "...Scotland appears to have been the first country in the world that was able to supply all of its haemophilia patients with a Factor VIII product that did not transmit Hepatitis C."

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

41.1 I was not involved in the Haemophilia Centre until 1991 so cannot answer the question posed.

42. Do you consider that the decisions and actions of the Centre in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

42.1 I consider that the actions of the Centre in response to any known or suspected risks of infection were adequate and appropriate for the time. I believe that the Centre's staff were acting within the limits of the then current scientific knowledge and technology and

strenuous and timeous efforts were made to ensure that patients were kept informed about the known or suspected risks of infection.

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

43.1 I am not aware of any decisions or actions the Centre could and/or should have avoided, or brought to an end earlier. In 1996, UKHCDO recommended that recombinant Factor VIII concentrate was the treatment of choice for those with haemophilia A, being free from human pathogens. Representatives of the Haemophilia Directors of Scotland and Northern Ireland met with the Chief Medical Officer for Scotland to request that the NHS in Scotland develop a procedure to progressively replace SNBTS factor concentrates with recombinant concentrates. The great majority of patients with haemophilia in Scotland were transferred to recombinant concentrates by 2002, several years before the rest of the UK.

44. 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?

44.1 I have no suggestions to make in response to these questions.

45. 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?

45.1 I cannot answer these questions because I have no in-depth knowledge of the science and technology needed to inactivate viruses in blood or blood products or what was possible prior to 1980.

Section 4: Treatment of patients at the Centre

Provision of information to patients

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

46.1 I saw only a few patients in the Centre. However, whenever I did I took great care to explain the advantages and disadvantages of any proposed treatment. This was always my practice when dealing with patients in any setting.

47. 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.

47.1 Since my clinical practice in the Centre was largely limited to carriers of haemophilia or females with vWD, the majority of interventions which I was recommending were not factor concentrates and I was frequently providing information about DDAVP, EACA, tranexamic acid, progestogen releasing intrauterine devices and hormonal contraception. I also made a point, where appropriate, of discussing pre-pregnancy the possible requirement for blood or blood products to manage deliveries. The products available obviously changed over time requiring updating of the information offered but in every setting where I was discussing with patients the possibility that they may require blood or blood products, I informed them that 'blood is dangerous' because of the risk of infection and stressed that every effort would be made to minimise the risk.

48. 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?

48.1 Because of the nature of my clinical practice, I do not recollect ever personally discussing home treatment with any patient and I do not remember what information the Centre provided.

HIV

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

49.1 I don't recall discussing AIDS or HIV (HTLV-III) with any patients attending the Centre who had not already been diagnosed with HIV and was not already attending an Infectious Diseases Specialist.

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

50.1 When I joined the staff of the Haemophilia Centre in 1991, I learnt that a number of patients attending the centre had been found to be HIV positive a few years previously.

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

51.1 I believe an experienced AIDS counsellor worked with the Centre staff from the mid 1980s and know that latterly the Centre collaborated with the Infectious Diseases Unit.

52. 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?

52.1 I had no involvement in the process of telling patients that they had been infected with HIV because I did not join the centre until 1991.

52.2 However, I believe that in January and in April 1985, two letters were sent to GRI Haemophilia Centre patients who had received blood products, advising that at review appointments the risk of AIDS would be discussed, and in due course HIV testing would be performed, once reliable tests had been established at the Regional Virus Laboratory (Penrose Inquiry, Final Report). The April letter enclosed a Haemophilia Society information and advice booklet, "AIDS and the Blood" (WITN4035005). The patients who had tested positive for HIV were individually informed of their result by the Centre Director aided by an experienced counsellor (Penrose inquiry, Final Report).

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

53.1 I was not involved in the Haemophilia Centre until 1991 so was not involved in the counselling of the HIV infected patients.

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

54.1 I was not involved in the Haemophilia Centre until 1991 so was not involved in the counselling or testing of partners/family members of people known or suspected to be infected with HIV.

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

55.1 I was not involved in the Haemophilia Centre until 1991 and do not know what information or advice was provided by the Centre to partners or family members of people who were at risk of infection with HIV or were infected with HIV in the 1980s. Later the Centre collaborated with the Infectious Diseases Unit who provided this information and advice.

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

56.1 All HIV positive patients were managed jointly with Consultants from the Infectious Diseases Department initially at Ruchill Hospital, later at the Beatson Infectious Diseases Centre. Through this collaboration, patients had access to developing AIDS support services, including access to counselling and a psychologist.

57. How many patients at the Centre 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 were children?**

57.1 I don't have access to records. I don't know how many patients at the Centre were infected with HIV and I have no idea how many in the groups a-e. No children attended the GRI Haemophilia Centre.

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

58.1 I did not join the Centre until 1991 so I don't know what work was done to establish the time period during which patients seroconverted but in a report published in 1985 on HIV antibody status in stored serial plasma samples dating back to 1974 from HIV positive patients from the Glasgow Centre, seroconversion occurred from 1981 onwards (Lancet 1985:I p524) (WITN4035007).

Hepatitis B

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

59.1 As far as I can recall, I had no personal experience of dealing with any patient infected with hepatitis B. Transmission of hepatitis B to sexual partners was recognised as a risk so the Centre's policy was to repeatedly educate patients about the need to practise safe sex (e.g. to use condoms even when other means of contraception were being used) and when I joined the staff of the Centre in 1991 it was already established policy to advise HBV vaccination for Centre patients not immune to HBV who may be exposed to blood or blood products.

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

60.1 I don't know how many patients at the Centre were infected with hepatitis B.

NANB Hepatitis/Hepatitis C

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

61.1 I do not know how patients were informed about NANB hepatitis. I did not join the staff of the Centre until 1991 by which time the agent responsible for causing the majority of cases of NANB hepatitis has been identified as what was named the hepatitis C virus.

62. When did the Centre begin testing patients for hepatitis C? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in

person, by letter or by phone? What if any involvement did you have in this process?

62.1 The first tests for HCV antibody introduced in 1991 were unreliable and replaced by the more specific RIBA-2 test in 1992. The GRI Haemophilia Centre commenced routine testing of all patients who had received blood products with the RIBA-2 test in 1992 and from 1994 introduced routine testing of all patients who had received blood products using a PCR test. Patients were informed of results in person by medical or nursing staff at their next hospital visit. I do not recall personally having told any Centre patient their HCV test result.

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

63.1 I don't recall the exact steps taken but all patients attending the Centre who had received blood or blood products were seen at regular intervals and repeatedly counselled about the risk of virus transmission from blood products. HCV antibody testing was offered at these routine review clinics and efforts made to chase up defaulters.

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

64.1 Specialist Haemophilia nurses had been part of the multidisciplinary team at the Centre since the beginning of the 1980s and they played a major role in educating patients, their families and partners about haemophilia and the risk of viral infection from transfusion of blood and blood products. This education began at first referral and was ongoing at every visit. Patients were informed about the Haemophilia Society and encouraged to join.

64.2 Patients who tested positive for HCV were given information on the virus and its possible effects; and advice on precautions with blood and sex, testing of sexual partners, minimising alcohol intake and the need for regular follow-up. This was supplemented with leaflets from the British Liver Trust and/or the UK Haemophilia Society. Further counselling and support were available from the Centre's nurses and social workers. Patients with clinical evidence of progressive liver disease were referred for further investigation and treatment including consideration of treatment with interferon or liver transplantation to a specialist led Gastroenterology Clinic. From 1996, patients were seen at a weekly Haemophilia/Hepatitis C clinic by a Consultant Hepatologist and a Viral Hepatitis Nurse Specialist Sister and a Specialist Haemophilia Sister and Staff Nurse.

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

65.1 I don't know the number because I no longer have access to records.

Delay/Public health/Other information

66. 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.

66.1 Every effort was made to notify patients in person of the results of tests as promptly as possible.

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

67.1 Patients who tested positive for HIV, AIDS, hepatitis B, NANB hepatitis and/or hepatitis C were given information on the virus and its possible effects and advice on precautions with blood spillage, safe sex, testing of sexual partners, minimising alcohol intake and the need for regular follow-up. This information and advice was offered repeatedly by both medical and nursing staff.

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

68.1 In addition to the up to date and updated information about the risk of infections associated with transfusion of blood or blood products offered by staff on a personal basis to individual patients at their visits to clinic, Haemophilia Society posters and leaflets and information leaflets from other relevant organisations were available in the waiting room or on request.

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

69.1 Patients who tested positive for HIV, AIDS, hepatitis A, hepatitis B, NANB hepatitis and/or hepatitis C were given information on the virus and advice on general hygiene and precautions with blood spillage and the requirement to practise safe sex to minimise the risk of infecting sexual partners. (e.g. use condoms even if other methods of contraception were being used).

Consent

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

70.1 Blood samples were taken for patient management at most clinic visits - Full Blood Counts to measure haemoglobin, total and differential white blood cell counts and platelet counts; coagulation screening tests and factor assays; coagulation factor inhibitor tests; liver function tests to assess presence or degree of liver damage; urea and electrolytes to assess renal function and virology if appropriate. I assume at some points some patients were also asked if they would be willing to participate in studies however I don't know specifically what studies.

70.2 Personally I always made a point of telling patients exactly the purpose of each sample I intended to collect. Thereafter if samples were being collected for routine investigations I accepted their tacit response to my approach with sample tubes as implied consent. I cannot recall if I ever collected samples for a research study in Haemophilia Centre patients but when I was conducting studies elsewhere I was conscientious about repeating details of the study purpose and procedures before checking that written consent had been obtained and proceeding to venepuncture.

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

71.1 Patients under my care or under the care of my colleagues at the Centre were not treated with factor concentrates or other blood products without their express and informed consent, except, I presume (because I was never involved in such a case), in the rare emergency when the patient lacked capacity. I don't recall how, or where, patient consent was recorded. I don't recall ever being responsible for initiating a treatment regimen in the Haemophilia Centre.

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

72.1 No patient under my care was tested for HIV or hepatitis or for any other purpose without their express and informed consent. In fact, I do not recall testing any patient in the Haemophilia Centre for the presence of HIV or hepatitis virus, thus I don't recall what the procedure for recording consent was.

PUPS

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

73.1 Patients attending the Centre at GRI were very rarely previously untreated (PUPs). I do not recall personally being involved in making decisions or taking action with regard to a PUP and I do not know the decisions and actions taken at the Centre by colleagues with regard to PUPs.

74. Please consider the report of the Coagulation Factor Working Party for Scotland and Northern Ireland on 30 April 1993 [PRSE0001520] and the minutes of the Haemophilia Centre Directors Scotland and Northern Ireland dated 1 May 1991 [GGCL0000114], which refer to PUP studies conducted. Were you involved in any of the noted PUP studies? Were any patients from the Centre recruited to the

studies referred to in these meetings? If so please detail your involvement in the study or in recruiting patients from the Centre to the study.

74.1 As far as I can recall, I was not involved in any of the noted PUP studies. I don't know if any patients from the Centre were recruited to the studies referred to in these meetings.

High purity products and recombinant products

In answering the below questions, you may be assisted by consideration of [GGCL0000164], [GGCL0000122_003], [LOTH0000089_010], [LOTH0000024_004] and [SBTS0000388_011].

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

75.1 I did not join the staff of the Haemophilia Centre until 1991. I was not involved until then in the choice of the treatment for HIV positive patients. I note that at the Coagulation Factor Working party meeting on 30 April 1993 *Study HPVIII 013* was reported as designed to assess the effect of SNBTS high purity FVIII on the immune system in 40 HIV positive patients. I am unaware of the progress or outcome of that study.

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

76.1 In 1996, UKHCDO recommended that recombinant Factor VIII concentrate, being free from human pathogens was the treatment of choice for haemophilia A. In 1998 the Co-chairs of the Haemophilia Directors of Scotland and Northern Ireland met with the Chief Medical Officer for Scotland to request that the NHS in Scotland develop a procedure to progressively replace SNBTS factor concentrates with recombinant concentrates. This was agreed, and a consortium which included representatives from all Scottish Health Boards was set up to discuss funding.

76.2 Discussions at the consortium meetings were sometimes difficult when it was realised that no additional funding would be available and Health Boards who did not have any patients resident within their geographic area registered with a Haemophilia Centre had to be persuaded that they would have to contribute to the fund to purchase recombinant factors on a population basis as an 'insurance policy' against the time that they did have an affected patient living in their area.

76.3 In 1999 there were shortages of recombinant FVIII and delay in allocating patients to recombinant FVIII and a number of patients who had been transferred to treatment with recombinant FVIII had to be temporarily changed back to plasma derived FVIII concentrate. The great majority of patients with haemophilia in Scotland were transferred to recombinant concentrates by 2002.

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

77.1 The great majority of patients with haemophilia in Scotland were transferred to recombinant concentrates by 2002. I don't believe that this could have been achieved any sooner.

78. When were recombinant products available to patients treated at the GRI? If the recombinant rollout was staged at the GRI, please explain which category of patients were given priority and why.

78.1 The transfer of patients attending the Centre at GRI to recombinant factors commenced in 1998-1999.There was a detailed protocol for the rollout of recombinant factors agreed by all the Scottish Haemophilia Centre Directors. Top priority was given to PUPs, followed by patients who were 'virus negative' in age defined tranches from youngest to oldest and finally 'virus positive' patients in age defined tranches from youngest to oldest.

Research

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

a. Describe the purpose of the research.
b. Explain the steps that were taken to obtain approval for the research.
c. Explain what your involvement was.
d. Identify what other organisations or bodies were involved in the research.
e. State how the research was funded and from whom the funds came.
f. State the number of patients involved.
g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.

79.1 I was never Principal Investigator on any study in the Haemophilia Centre so I cannot provide the information needed to answer questions a-g.

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

79.2 Hambley H, Davidson JF, Walker ID, Small M, Prentice CRM. Freeze dried cryoprecipitate: a clinical evaluation. Journal of Clinical Pathology 1983; 36: 574-576 (WITN4035008).

79.3 Clark P, Cameron SO, Walker ID, Lowe GD. Seroprevalence of total antibodies to hepatitis A virus in haemophiliacs in the West of Scotland. Haemophilia 1995; 1: 194-195 (WITN4035004).

80. 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.

80.1 I was never Principal Investigator on any study in the Haemophilia Centre and I cannot answer this question.

81. The Inquiry understands that you contributed to or were involved in or provided data for an article published in November 1997: "Mortality from liver cancer and liver disease in haemophilic men and boys in UK given blood products contaminated with hepatitis C" [HCDO0000264_150]. Please set out what you recall of this study and explain the involvement you had with it.

81.1 I was, at the time the paper was being prepared, a Co-Director of a Haemophilia Centre which contributed mortality and morbidity data to this study which was coordinated by UKHCDO. I had no other involvement in it and don't recall any detail of it.

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

82.1 Not as far as I am aware.

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

83.1 Not as far as I am aware.

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

84.1 Not as far as I am aware.

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

85.1 Clark P, Cameron SO, Walker ID, Lowe GD. Seroprevalence of total antibodies to hepatitis A virus in haemophiliacs in the West of Scotland. Haemophilia 1995; 1: 194-195.

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

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

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

86.1 **a.** I did not join the staff of the Centre until 1991 by which time patients who were HIV positive were managed jointly with Consultants from the Infectious Diseases Department at Ruchill Hospital, and latterly at the Beatson Infectious Diseases Unit. Through these Departments patients had access to developing AIDS support services, including access to counselling and a psychologist.

86.2 **b.** I don't recall because these were discussed and decided at the specialist Infectious Diseases Units.

86.3 **c.** I don't know because these were discussed and decided at the specialist Infectious Diseases Units.

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

87.1 They were followed up at special HIV clinics by Consultants in Infectious Diseases.

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

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

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?

88.1 I did not join the staff of the Centre until 1991 by which time patients who were HBV positive with clinical evidence of progressive liver disease were referred to a Gastroenterology Clinic for further investigation and treatment. I don't know what treatment options were offered. A Consultant Gastroenterologist/Hepatologist was responsible for informing patients about the treatment options, risks, benefits and side effects.

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

89.1 Patients with clinical evidence of progressive liver disease were referred to a Gastroenterology/Hepatitis Clinic for further investigation and treatment.

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

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

b. What treatment options were offered over the years?

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

90.1 I cannot answer these questions because I did not join the staff of the Centre until 1991.

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

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

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?

91.1 **a.** Patients with clinical evidence of progressive liver disease were referred to a Gastroenterology Clinic for further investigation and treatment, including consideration of treatment with interferon or liver transplantation. From 1996, patients were seen at a weekly Haemophilia / Hepatitis C clinic by a Consultant Hepatologist and a Viral Hepatitis Nurse Specialist, a Specialist Haemophilia Sister and a Specialist Haemophilia Staff Nurse.

91.2 **b.** I don't know the details because I never attended a Haemophilia / Hepatitis clinic.

91.3 **c.** I don't know because I never attended a Haemophilia / Hepatitis clinic.

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

92.1 Patients with clinical evidence of progressive liver disease were referred to a Gastroenterology Clinic for further investigation and treatment, including consideration of treatment with interferon or liver transplantation. From 1996, patients were seen at a weekly Haemophilia / Hepatitis C clinic by a Consultant Hepatologist and a Viral Hepatitis Nurse Specialist and a Haemophilia Sister MacDougall and Staff Nurse.

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

93.1 No children were seen at the GRI Centre and I don't know the arrangements which were made at Yorkhill for the care and treatment of children infected with HIV or hepatitis.

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

94.1 Counselling, psychological support and social work support were available from the Centre's medical staff, specialist nurses and social workers. Patients who were HIV positive were managed jointly with Consultants from the Infectious Diseases Department at Ruchill Hospital and later the Beatson Infectious Diseases Unit. Through this Department, patients had access to developing AIDS support services, including access to counselling and a psychologist. Patients who were HCV positive were given information on the virus and its possible effects; and advice on precautions with blood spillage and sex, testing of sexual partners, minimising alcohol intake and the need for regular follow-

up. This was supplemented with leaflets from the British Liver Trust and the UK Haemophilia Society.

95. Did the Centre receive funding from the government or from any other source to help with the counselling of patients infected with HIV?

95.1 Not that I am aware of but I did not join the Centre until 1991.

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

96.1 I do not know how funding was achieved prior to 1991 and I am unaware of problems obtaining funds for treating patients with HIV or HCV when I was a member of the Centre's staff.

Records

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

97.1 I don't know what the Centre's policy in regard to recording information on death certificates when a patient had been infected with HIV or hepatitis were. I never had cause to sign a death certificate for a patient registered at the Centre.

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

98.1 I cannot recall what the retention policies of the Centre in regards to medical records during the time I was practising there were.

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

99.1 The Haemophilia Centre kept records of the patients registered at the Centre in the Haemophilia Centre to allow rapid access to information about the patients' diagnoses and treatments in an emergency when the main hospital Record Department was closed. I retired from the Centre in 2009 and don't know where these records are now.

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

100.1 I never kept records or information (e.g. information being used for the purpose of research) about any of my patients at my home or anywhere other than the Centre.

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

101.1 No I don't hold records or information about any patients.

Section 5: UKHCDO

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

102.1 By dint of being a UK Haemophilia Centre Doctor, from 1991 onwards I was a member of UKHCDO but I rarely attended any of their meetings and only in the capacity as a deputy for whoever was our Centre's designated representative. I was never involved with any of its working parties, committees or groups.

103. 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 decisions were taken by UKHCDO.**
- **e. How information or advice was disseminated by UKHCDO and to whom.**
- **f. Any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to:**
  - **i. the importation, purchase and selection of blood products;**
  - **ii. the manufacture of blood products;**
  - **iii. self-sufficiency;**
  - **iv. alternative treatments to factor products for patients with bleeding disorders;**
  - **v. the risks of infection associated with the use of blood products;**
  - **vi. the sharing of information about such risks with patients and/or their families;**
  - **vii. obtaining consent from patients for the testing and storage of their blood, for treatment and for research;**
  - **viii. heat treatment;**
  - **ix. other measures to reduce risk;**
  - **x. vCJD exposure; and**
  - **xi. treatments for HIV and hepatitis C.**

103.1 **a.** The aims of UKHCDO are; to preserve, protect and relieve persons suffering from haemophilia and other inherit bleeding disorders; to advance the education of the medical profession, the nursing profession, professions allied to medicine and the general public in the knowledge of haemophilia and other inherited bleeding disorders and their treatment; and to promote or assist in the promotion of audit and research into causes, prevention, alleviation and management of haemophilia and other inherited bleeding disorders and to disseminate the useful results of such research.

UKHCDO is the custodian of the National Haemophilia Database which is a register of patients residing in the UK who suffer from bleeding disorders.

103.2 **b.** I was not involved in any committee or working group. I do not know the role structure or composition of these groups.

103.3 **c.** I have no information on this and never had.

103.4 **d.** I have no information on this and never had.

103.5 **e.** UKHCDO has representation on a number of committees eg the Thrombosis and Haemostasis Task Force, the Steering Committee of NEQAS BC

103.6 **f.** I was not involved in any policies, guidance, actions or decisions related to any topic i to xi above.

Section 6: Scottish National Blood Transfusion Service

104. Please set out the interactions and dealings you had in relation to SNBTS as the director of the Centre, insofar as relevant to the Inquiry's Terms of Reference. (If you had relevant dealings and interactions with any other national or regional blood service within the UK, please also provide information about those and answer the questions set out below in relation to other national or regional blood services as well as SNBTS).

104.1 The Haemophilia Centre Directors of Scotland and Northern Ireland met formally with senior staff members of SNBTS PFC several times a year to discuss the requirements of each Scottish Centre and to be updated by PFC staff on product development. I no longer have access to any of these records as I retired from clinical practice more than 10 years ago.

105. What discussions or meetings or interactions did you have with SNBTS 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?

105.1 The Centre Directors met senior staff from SNBTS PFC regularly several times a year and the risk of infection from blood products and minimising the risk were always amongst the topics discussed.

105.2 **a.** By 1991 when I joined the Centre it was known that HCV was likely to be the main cause of non-A non-B hepatitis and it had been established that the heat treatment of SNBTS FVIII concentrate used in the early 1980s was inadequate to eliminate transmission of viral hepatitis. As a result, SNBTS heat treatment process had been intensified in the late 1980s. Our meetings with the PFC staff covered their plans for donor screening and virus inactivation in their products but I don't recall the time scales of these discussions

105.3 **b.** Screening of donated blood for HIV was already in place by 1991 when I joined the Centre

105.4 **c.** Patients attending the GRI Centre were advised to be vaccinated against hepatitis A and hepatitis B and given advice about precautions to be taken with blood spillage and practising safe sex.

106. What involvement did you have with any decisions or actions taken by SNBTS in response to the risks arising from blood and blood products?

106.1 I was involved in the discussions which the Haemophilia Centre Directors had with PFC staff. I was part of the team of Scottish Haemophilia Centre Directors who along with staff from the PFC visited CRTS Lille in 1991 to assess their process for viral inactivation of plasma.

107. What system was followed for keeping records of the blood or blood products used in Scotland (both in relation to source and use)?

107.1 Each Centre and its allied Blood Bank was responsible for keeping detailed records of product source and use. These records (of both SNBTS product and commercial product ordered and used) were submitted on a monthly basis to the PFC to aid their planning. Stocks of blood and blood products were carefully controlled and great care taken not only to ensure traceability of each and every individual dose but also to ensure that no stock out-dated. Any unused stock was returned to SNBTS and the return recorded.

108. Why was the Coagulation Factor Working Party for Scotland and Northern Ireland established, and what was your role within it?

108.1 The Coagulation Factor Working Party for Scotland and Northern Ireland was established long before I joined the staff of the Haemophilia Centre and met around 2 to 3 times a year to discuss the current studies of PFC blood products.

109. The Inquiry understands that after Dr Davidson's retirement in 1996, Dr Tait and you were in charge of the Blood Bank for Glasgow Royal Infirmary. Please outline your responsibilities in this role, and any difficulties you faced in regards to inadequacy of supplies to meet patient needs.

109.1 On his appointment Dr Tait was in charge of the Blood Bank for Glasgow Royal Infirmary. I was administrative Head of the Department of Haematology which incorporated the Blood Bank and was therefore responsible for ensuring that the service was properly managed. Although from time to time supplies of SNBTS blood products were limited, I am not aware of any instances when there were insurmountable difficulties faced in regards to inadequacy of supplies to meet patient needs.

Section 7: Pharmaceutical companies/medical research/clinical trials

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

110.1 No, not that I can recollect.

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

111.1 No

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

112.1 No, not that I can recollect.

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

113.1 No

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

114.1 No

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

115.1 No

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

116.1 I have always been very conscious of my legal and ethical responsibilities and would never have consciously breached any regulations, requirements or guidelines in any dealings I may have had with any pharmaceutical company.

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

117.1 No

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

118.1 I believe that I was involved in a study of an anticoagulant shortly before I retired but I cannot remember anything about this study as I was not a Principal Investigator.

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

119.1 I cannot recall ever receiving personal funding from any pharmaceutical company for medical research

Section 8: vCJD

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

120.1 I cannot remember the exact circumstances but I was aware of vCJD by 1997-98 when I heard Professor James Ironside from the CJD Surveillance Unit in Edinburgh talk about it and by 1998 I had heard preliminary discussions about the need to leukodeplete blood for transfusion.

121. Please refer to the minutes of the Haemophilia Centre Directors for Scotland and Northern Ireland dated 2 December 1997 [LOTH0000079_008] which discusses the recommendation to switch to recombinant factor in light of the potential risk of blood borne transmission of CJD. It is noted that you pointed out "the near inevitability that other batches of British plasma derived factor concentrates will have to be withdrawn with all the associated problems of patient counselling". Please describe what the associated problems of patient counselling were, and how this impacted the withdrawal of plasma derived concentrates.

121.1 I was concerned that with the passage of time there may be further cases of vCJD found at autopsy of persons who had been blood donors and that if this worried me might it not worry patients? This was a personal opinion. I cannot comment on any problems encountered in patient counselling about CJD since I do not recall having personally counselled any patient about CJD. To the best of my knowledge, in spite of the concern that I had voiced, patient counselling did not impact the withdrawal of plasma derived concentrates.

122. Please refer to the minutes of the 11th meeting of UKHCDO dated 20 March 1998 which you attended [HCDO0000466]. It was noted that BPL and PFC made arrangements for alternative plasma to be sourced following the CSM announcement that plasma products should be made from non-UK plasma. Dr Ludlam said it was for individual Centres to decide, in consultation with each

patient, the most appropriate concentrate to use. What decisions regarding treatment were made at the Centre following this meeting? Were patients consulted when deciding the appropriate concentrate to use?

122.1 SNBTS sourced non-UK derived plasma for fractionating but I cannot recall when these products became available to the Centre. Meanwhile there had been increasing discussions about seeking funding to purchase supplies of recombinant FVIII for patients with haemophilia A. The emergence of vCJD added weight to these discussions. The Directors of the Haemophilia Centres in Scotland met annually with representatives of the Haemophilia Society. I can't recall exactly when but the issue of moving patients from plasma derived FVIII to recombinant FVIII was discussed at least one of these meetings and of course once supplies became available the patients were individually informed of the benefits of recombinant products and asked if they wished to transfer to a recombinant FVIII.

123. The minutes of the 9th meeting of the UKHCDO dated 6 February 1998 record a conversation about the issue of consent in relation to surveillance of vCJD by collecting blood and tissue samples prospectively [HCDO0000464]. It was noted that consent may be difficult to obtain without causing unjustified alarm due to the "extremely emotive nature of vCJD" and clinicians were unlikely not to participate for this reason. What actions did the Centre take in relation to surveillance of vCJD in or around this time? Did you and/or the Centre take part in research involving collecting blood and tissue samples prospectively for testing for vCJD? If so, what was the Centre's approach to obtaining consent for testing? Was their consent recorded and if so how and where?

123.1 I was not present at the 9th Meeting of UKHCDO on 6 February 1998 so was not a party to this discussion. I cannot recall what actions specifically were taken by the Centre in relation to surveillance of vCJD at this time. I do not recall being personally involved in research collecting blood or tissue samples for testing for vCJD and I don't know if anyone else in the Centre was.

124. Please refer to the letter dated 25 October 2002 from Professor Lowe, co-director of the Centre, to Dr E M Armstrong, Chief Medical Officer [GGCL000152_001]. This letter refers to Haemophilia Directors in Scotland and Northern Ireland learning that a donor who had subsequently died of vCJD had contributed to batches of SNBTS coagulation factor concentrates. The letter states that the Directors had subsequently prepared information sheets, but there had then been an eight month delay during which time there had been *"an absence of any comment from the Banner committee."* The letter goes on to inform Dr Armstrong of the steps that the Haemophilia Directors intend to take to inform patients. See also: the attached *"potential statement"* to be issued by an NHS Trust: [GGCL000152_002]; the attached proposed letter to patients dated 31 October 2002 co-written by you: [GGCL000152_003]; the response to Professor Lowe's letter of 25 October 2002 from Dr A Keel (response dated 29 October 2002): [GGCL000152_004]; a related template letter co-written by you concerning the discovery of a blood donor with vCJD whose plasma was used to make factor concentrate products in England [GGCL000148_001].

a. Were you involved in the letter written by Professor Lowe to Dr Armstrong dated 25 October 2002?
b. Was the proposed statement from the Trust made, and was the proposed letter sent to patients?
c. Why, to the best of your knowledge, was there such a delay between the production of the information sheets and a final decision on whether or not they should be published?
d. Are you aware of any patients from the Centre subsequently being diagnosed with vCJD? If so, was the source of the infection established (and if so, what was it)?

You may be assisted by a template letter (seemingly for distribution across the UK dated February 2009 that informs patients that a person with haemophilia had been found to have evidence of the infection that causes vCJD [GGCL000157].

124.1 **a.** I have no clear recollection of this but I think it likely that at very least he would have mentioned it to me.

124.2 **b.** I do not remember whether or not the Trust made the proposed statement but I believe that the proposed letter was sent to patients.

124.3 **c.** The Haemophilia Directors prepared information sheets in February 2002 but by October 2002 had had no response to their request for comment and advice from the Banner Committee because according to the letter dated 29 October from Dr Keel, Dr Armstrong (CMO Scotland) was waiting for a response from the Incidents Panel.

124.4 **d.** As far as I am aware no patients from the Centre have been diagnosed with vCJD.

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

125.1 Although I do not recall if I personally counselled any patient who had been informed that they might have been exposed to vCJD, I know that Professor Lowe and Dr Tait arranged to see and counsel each individual patient attending the Haemophilia Centre who had been informed that they might have been exposed to vCJD.

126. Please refer to the enclosed template letter dated February 2009 from you, Professor Lowe and Dr Tait, informing patients that based on their records, they have not received UK sourced plasma products between 1980 and 2001 [WITN2288008]. What difficulties, if any, were encountered by the Centre in tracing whether patients had received UK sourced plasma based on records available?

126.1 I was not personally involved in trying to trace this information so cannot comment.

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

127.1 Patients who may have been exposed to vCJD were sent a letter in February 2009 containing advice on how to reduce the risk of spreading vCJD to other people and offered the opportunity to make an appointment to come and see one of the Centre's clinical team for further discussion.

127.2 There was also considerable discussion around how to ensure that the records of those patients who may have been exposed to vCJD were coded in a manner such that clinicians under whose care they may at some point fall could be made aware of this fact without risking any inappropriate breach of any patient's confidentiality. I cannot recall the eventual solution to this problem.

127.3 I believe the Haemophilia Centre organised the purchase of some equipment e.g. endoscopes and some dental instruments to be used specifically for these patients to ensure that they were not disadvantaged by clinicians reluctant to perform invasive procedures because of the risk of contaminating equipment.

Section 9: The financial support schemes

128. 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?

128.1 I had no involvement in any Trust or Fund set up to support people who had been infected.

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

129.1 Medical and Nursing staff and our Social Work department were very diligent about informing patients and their relatives about Trusts and Funds offering financial support. I never personally discussed these Trusts or Funds with any patient or family member largely because I saw very few patients at the Centre but also because I was not well enough informed to be a reliable source of advice about them.

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

130.1 I don't remember.

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

131.1 I cannot answer this because I was never involved in seeking assistance from a Trust or Fund on behalf of a patient.

132. Did the Centre, or any of their staff, act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

132.1 I don't know the answer to this.

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

133.1 I don't know.

134. Based on your own dealings with any of its 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?

134.1 Since I had no dealings with any Trust or Fund offering financial assistance to infected patients seeking financial assistance, I cannot comment.

Section 10: Other organisations

135. Please provide details of your involvement with the Haemophilia Society. In particular, please describe the work undertaken as a member of the Society's Medical Advisory Panel and its Policy Committee, insofar as relevant to the Inquiry's Terms of Reference. What advice was provided by the panel/expert working group?

135.1 I was a member of the Haemophilia Society and paid annual membership fees. I attended the Annual meeting that the Scottish and Northern Ireland Haemophilia Centre Directors had with representatives from the Haemophilia Society in Scotland. I had no other involvement with the Haemophilia Society and I do not know what advice was provided by the panel/expert working group.

Section 11: Other issues

136. 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.

136.1 I am unaware of any complaints made against me.

137. 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.

137.1 I have nothing to raise in response to this request.

Statement of Truth

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

Signed

GRO-C

Dated 5th November 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
17th June 2010	Letter to Penrose Inquiry	WITN4035002
30th November 1989	H.J Alter et al. *Detection of antibody to hepatitis C virus in prospectively followed transfusion recipients with acute and chronic No-A, Non-B hepatitis*	WITN4035003
16th January 1995	P. Clark et al. *Seroprevalence of total antibodies to hepatitis A virus in haemophiliacs in the West of Scotland*	WITN4035004
April 1985	Haemophilia Society, information and advice booklet: "*AIDS and the Blood*".	WITN4035005
December 1984	M. Melbye et al. *HTLV-III seropositivity in European*	WITN4035006

	Haemophiliacs exposed to Factor VIII concentrate imported from the USA	
2nd March 1985	*R. Madhok et al. HTLV-III antibody in sequential plasma samples: from haemophiliacs 1974-84*	WITN4035007
4th January 1983	H. Hambley et al. *Freeze dried cryoprecipitate: a clinical evaluation*	WITN4035008