Witness Name: Dr Brenda Gibson
Statement No.: WITN3528002
Exhibits: Nil
Dated: 3 December 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR BRENDA GIBSON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 8 September 2020.

I, Dr Brenda Gibson, will say as follows: -

Section 1: Introduction

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated the 8th September 2020. However for a variety of reasons I did not receive the hard copy of the Rule 9 until 24th September. Whilst I appreciate the seriousness and urgency of this request I am still working full time with many other calls on my time. Furthermore the current data manager for the haemophilia service is on long term sick leave and not in a position to provide some of the information requested. Within these restraints I have done my best to answer the questions within the Rule 9 Request to the best of my ability.

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

1.1. Name: Professor Brenda Elizabeth Simpson Gibson: OBE

1.2. Address: GRO-C Glasgow GRO-C

1.3. Date of birth: GRO-C 1949

1.4. Professional qualifications: MB ChB, FRCP, FRCPCH, FRCPath, DFM

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. 1984-present -Consultant Paediatric Haematologist - Royal Hospital for Children (RHC), Glasgow; (previously known as the Royal Hospital for Sick Children)

2.1.1. Lead Clinician

2.1.2. Director of Haemophilia Unit - August 1987 – 1996/97

2.1.3. Director for the Haematopoietic Stem Cell Transplant Programme

2.2. From 1984 – 1987 my main responsibilities were for general clinical and laboratory haematology, leukaemia and stem cell transplantation. I provided cover for haemophilia care. I had a short sabbatical to McMaster University Medical Centre to work with Dr Maureen Andrews's group. She was a world leader in neonatal haemostasis. I brought her laboratory methodology back to RHSC setting up neonatal coagulation studies, which had not been previously available in Scotland.

2.3. From 1987 – 1996/97 – in addition to the responsibilities listed above, I assumed responsibility for haemophilia care and became the Haemophilia Director. In this respect I worked with a very experienced Clinical Assistant, Dr Anna Pettigrew, who had worked with my predecessor, Professor Ian Hann. Dr Pettigrew left in January 1989.

2.4. Since 1996/97 my main responsibilities have been providing care for children with leukaemia in the West of Scotland and the national stem cell transplantation programme for Scotland. I demitted responsibility for haemophilia in a transitional manner after that date.

2.5. I was joined by Dr Elaine Simpson, a consultant haematologist in 1988. She spent a brief sabbatical period in Philadelphia, was on maternity leave on two occasions, and sadly had a prolonged period of absence in 1995 for health reasons. During these periods I returned to being a single handed consultant. We were joined in 1996 by Dr Elizabeth Chalmers who replaced me as the Haemophilia Director.

2.6. Prior to my appointment as a Consultant I held the following trainee posts:

2.6.1. 1973-1974- JHO posts in general medicine and paediatric surgery – Aberdeen Royal Infirmary and Aberdeen Children's Hospital.

2.6.2. 1974-1975 – SHO at the Oxford Haemophilia Centre. Responsible for the day to day care of inpatients and outpatients with bleeding disorders under consultant supervision. I had no involvement in the selection of blood products. The Centre was run by Dr Charles Rizza, who ran a world class haemophilia service and was dedicated to the care of patients with bleeding disorders. The Centre incorporated a large research and diagnostic laboratory which was visited by many international doctors and scientists.

2.6.3. 1975-1977 – Medical rotation at Ninewells Hospital, Dundee – no involvement with haemophilia care.

2.6.4. 1977- 1984 – Haematology trainee at Glasgow Royal Infirmary which included two years at McMaster Medical Centre, Hamilton, Canada. McMaster Medical Centre was internationally known for

its work in thrombosis and was a world leader in neonatal haemostasis. At this time haemophilia care at Glasgow Royal Infirmary was provided by the Department of Medicine and not the Department of Haematology and therefore I had no involvement with this patient group during my haematology training, until my final rotation to the RHSC, which I think was for a period of 9 months. During this training period I was only marginally involved with haemophilia care during daytime, because the service was managed on a day to day basis by Professor Ian Hann in conjunction with a very experienced Clinical Assistant, Dr Anna Pettigrew and the Haemophilia Sister. I did provide out of ours cover at trainee level. I had no involvement with decisions about blood products or the organisation of the service.

2.7. I spent a short sabbatical to both Manchester Children's Hospital and Great Ormond Street Hospital to gain more experience in solid tumours but can't remember if this was before or just after I took up my consultant appointment.

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

3.1. Member of the Scotland and Northern Ireland Haemophilia Centres Directors Working Party – 1987 -1996/97

3.2. Member of the Factor FVIII/ Coagulation Factor Working Party for Scotland and Northern Ireland - 1987-1996/97

3.3. Member of the UKHCDO- 1987-1996/97

3.4. President of the British Society of Haematology – 2007-2009

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

4.1. I have previously provided written evidence to the Penrose Inquiry.

4.2. I believe the Inquiry has copies of my evidence to the Penrose Inquiry.

5. **Please consider the evidence that you gave to the Penrose Inquiry, which is attached to this letter [PRSE0004047; STHB0000852; PRSE0003869; GGCL0000225 and PRSE0000914]. Please confirm whether the contents of the above statements are true and accurate. If there are any matters contained in the above statements that you provided to the Penrose Inquiry <u>that you do not consider to be true and accurate, please explain what they are.</u>**

5.1. I have reviewed my written evidence which is correct with the exception of:

5.1.1. I have already acknowledged my error in stating that I did not attend a Scottish Haemophilia Directors Meeting in 1984 and indeed not until 1988. I made this error in good faith. When asked about my attendance at this meeting, I assumed that Professor Hann would have attended as the Haemophilia Director at that time.

5.1.2. I also recognise the discrepancy in Professor Hann's leaving date. I have stated August 1988 which is the information given to me by my HR department for the Penrose Inquiry, but I accept that it could be wrong and that the date could have been 1987. My HR

department cannot confirm the date. In this response I have given the date of August 1987.

Section 2: Decisions and actions of those treating patients with bleeding disorders the RHSC

6. **Please describe the facilities, organisation, roles, functions and responsibilities of the haemophilia unit at the RHSC during the time that you worked there and how they changed over time. In respect of this question, and those that follow, the Inquiry is aware of the evidence that you gave to the Penrose Inquiry on this matter, to which you should feel free to make reference.**

6.1. I was attached to RHSC as a trainee sometime in 1983 for a period of 6-9 months and appointed Consultant Haematologist in July 1984. I continue to work there. At that time the haematology / haemophilia service had variable access to beds on two paediatric wards for inpatient care. The majority of haemophilia care was outpatient based and patients were seen in a general Paediatric Day Care Unit (DCU). The DCU was geographically separate from the inpatient beds. In 1988 one of the paediatric wards was refurbished and became a dedicated haematology unit for children with both benign haematological and malignant disease. An area at one end of this ward was converted to a DCU and boys with haemophilia attended there. In 1996, another service vacated their facility and this was refurbished to provide a bone marrow transplant unit, generous inpatient facilities, a large DCU with a dedicated Haemophilia Office and consulting room, parent accommodation, data management, school room, pharmacy, social work and office accommodation. In 2015 the RHC was co-located on the QEUH campus. Accommodation is less generous but includes inpatient facilities and a Haemophilia Office within the DCU. Dedicated data management is co - located with data management for leukaemia and solid tumours.

6.2. The haemophilia unit has always provided care for children with haemophilia and a range of bleeding disorders in the West of Scotland and transitioned patients to the adult unit at GRI. The haemostasis service also provided support to other areas of the hospital particularly neonatal services, PICU, ECMO and maternity services prior to their relocation in 2002. The haemophilia unit is a Comprehensive Care Centre staffed by a multidisciplinary team. This includes a Lead Clinician for Haemophilia/Haemostasis, who is the Haemophilia Director, a Haemophilia Clinical Nurse Specialist (CNS), dedicated data management, social work support, physiotherapy and dental support. In the 1980/90's there was an orthopaedic surgeon with an interest in haemophiliac arthroplasty, but since the advent of prophylaxis this is a rare complication. The team has expanded and since 2014 two consultants work in bleeding disorders. A full range of coagulation laboratory tests has always been available on site as has genetic counselling.

7. Please identify senior colleagues at the RHSC within the haemophilia unit and their roles and responsibilities during the time that you worked there.

7.1. From 1983 to August 1987 Professor Ian Hann was the Lead Clinician for Haemophilia and the Haemophilia Director. As such he was responsible for all aspects of the care of patients with haemophilia. I succeeded him in 1987 until 1996/97.

7.2. Dr Anna Pettigrew was a Clinical Assistant until January 1989. She was mainly responsible for the day to day management of patients with haemophilia.

7.3. Dr Elizabeth Chalmers was appointed Consultant Haematologist and took up her post in January 1996. She became the Haemophilia Director after a period of transition. She was joined by Dr Fernando Pinto in 2014, who shares responsibility for haemophilia care.

7.4. There has always been a full time Haemophilia CNS – previously referred to as the Haemophilia Sister.

8. Please describe:

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

8.1. Between 1984 and 1987 my areas of responsibility were clinical and laboratory haematology and the leukaemia and bone marrow transplant services. My responsibilities for haemophilia were confined to on call / out of hours cover for acute clinical problems and I did not have the responsibility for the organisation of the service or decisions around the choice of blood products. In 1987 I assumed responsibility for patients with haemophilia and a range of bleeding disorders.

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

8.2. In 1987 I assumed responsibility for patients with haemophilia and a range of bleeding disorders. This included all aspects of care for this patient group – not only treatment of their bleeding disorder but management of any complication of treatment including blood product transmitted infection.

9. In your first witness statement [WITN3528001] and in your evidence to the Penrose Inquiry, you explained that you did not assume responsibility for haemophilia care until 1988, when you were appointed as the Haemophilia Director at the RHSC. Please confirm whether you treated any patients with haemophilia (or other bleeding disorders) at any stage prior to 1988. In respect of each stage of your career, please set out how much of your time (approximately) would be spend treating patients with haemophilia. Please also describe your involvement with the care or treatment of patients with bleeding disorders during your period as a senior registrar in training between 1982 and 1984.

9.1. I was employed as a SHO in 1974 -75 at the Oxford Haemophilia Centre where my responsibilities were the day to day and out of hours care for patients with haemophilia attending the Centre. I would assess patients and prescribe and deliver the factor concentrate / blood product already agreed for any individual patient. As I recall a blood product was assigned to each patient and when on call I would deliver the assigned blood product. I worked a few afternoons per week in the coagulation laboratory, but the rest of my time was dedicated to clinical care. As a senior registrar I was not involved with haemophilia care until I rotated to RHSC in 1983. I would have seen inpatients on ward rounds but my main involvement was reviewing patients who attended out of hours.

10. Approximately how many patients with bleeding disorders were under the care of the RHSC when you first started working there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

a. The Inquiry understands that adult patients were treated at Glasgow Royal Infirmary ("GRI") and children at the RHSC. Please explain how care was transferred once a child reached adulthood (and when that was assessed to be). Were any adults with bleeding disorders treated at the RHSC during your time working there?

10.1. I am afraid that I cannot provide the number of patients with bleeding disorders in 1984. The hospital has relocated and the data manger is on long term sick leave. However there are presently (2019) – 206 (including carriers with a factor level of < 45%) – and the same population base is served.

10.1.1. No with haemophilia A– severe 28: moderate 7: mild 45

10.1.2. No with haemophilia B – severe 4: moderate 6: mild 15

10.1.3. No with vWD – severe 10: mild 91

10.2. There was /is a good relationship between the paediatric and adult haemophilia Units within the city. My recollection is that patients were seen in a transition manner on a few occasions and the age of transition varied between 15-17 years depending on maturity and family wishes. I have no recollection of any adult patients being treated at RHSC.

11. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the RHSC, 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?

11.1. My understanding is that prior to 1983 imported commercial concentrate had been used, but was withdrawn in 1983 in favour of the current SNBTS product for patients who required concentrate. This was based on concerns of the safety of concentrate produced from plasma from paid donors. My recollection is that during my time as the Haemophilia Director which product should be used was based on collegiate decisions made by the SNBTS and the Scotland and Northern Ireland Haemophilia Director's and Factor VIII / Coagulation Working Parties and followed guidance from the UKHCDO and national and international practice.

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

11.2. Availability, safety, efficacy, UKHCDO guidance.

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

11.3. At a hospital level, I am not aware that commercial/ financial considerations played any role.

d. What if any involvement did you have in these matters, (i) in the period before your appointment as Director in 1988, (ii) following your appointment as Director in 1988?

11.4. I don't recall any involvement before becoming the Haemophilia Director. By the time of my appointment as Haemophilia Director patients were treated with SNBTS heat treated factor VIII - Z8 - which was in use at RHSC from June 1987. I attended Scottish Haemophilia Director's and Factor VIII /Coagulation Working Party meetings with other Haemophilia Directors where decisions about blood product selection and use were discussed and agreed nationally. The need for ever increasingly safe and efficient factor concentrates was recognised and emphasis was always on safety. However, I was not a member of the UK Haemophilia Reference Centre Directors so did not attend national meetings and benefit from UK discussion.

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

12.1. Prior to 1983 commercial product was used for patients with severe haemophilia because this facilitated home therapy. This practice was phased out in 1983. The choice of product followed recommendations from the UKHCDO. In principle blood products were avoided wherever possible. Desmopressin was used for mild/some moderate FVIII deficiency (those who raised their FVIII level into a haemostatic range) and patients with von Willebrand Disease. It was ineffective in patients with severe haemophilia A, many with moderately severe haemophilia A and in all patients with haemophilia B. Furthermore desmopressin was not recommended for use in small children because of the recognised risk of water intoxication and hyponatraemia which can lead to seizure activity. When the UKHDCO recommended in late 1983 that cryoprecipitate be used for previously

unexposed or mildly exposed patients, I am confident that this guidance was followed. However, cryoprecipitate was not practical for boys already established on home treatment and many continued to use concentrate, rather than abandon home treatment.

12.2. Cryoprecipitate has to be stored below - 20 degrees. A domestic freezer has a temperature of -18 degrees. The families would have had to have a freezer capable of maintaining a temperature below - 20 degrees which would have had to be monitored and alarmed should the temperature rise above - 20 degrees. The cryoprecipitate would have had to be delivered in a refrigerated van and packed in dry ice in a way to maintain this temperature. When required the boy's mother would have had to thaw the bags of cryoprecipitate to 37 degrees in a temperature controlled water bath. The thermometer would have had to be regularly calibrated. In a hospital Blood Bank water baths are temperature mapped annually for the detection of hot spots and the thawing of cryoprecipitate is the responsibility of a Health Care Scientist Associate Practitioner. After thawing the cryoprecipitate the mother would have had to draw the cryoprecipitate into syringes and inject it. Dependent on the injury, the FVIII level required and the size of the child this would involve several bags of cryoprecipitate. Patients can have an allergic reaction/anaphylaxis to cryoprecipitate and should this have happened the mother would have had to deal with this medical emergency until medical help arrived. This is a totally unreasonable responsibility to place on a mother and we never did it. I hope that this illustrates some of the difficulties of using cryoprecipitate as home treatment; something which we never did. A family who wished to revert to cryoprecipitate would have had to attend hospital for treatment.

12.3. The current SNBTS product was used for severely affected boys who were on home treatment. This was heat treated from 1984 with serial intensification of the heat treatment process. By the time I became Haemophilia Director the product was Z8 which was heat treated to 80 degrees for 72 hours from July 1987 and did not transmit HIV or HCV. When high purity (Liberate) and recombinant concentrate became available

children were always the first to benefit. Cryoprecipitate was not used after May 1988 following the advice of the UKHCDO that cryoprecipitate no longer be used unless the haemostatic efficacy of factor concentrate to treat von Willebrand Disease was in doubt.

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

13.1. I am not aware of any relationship between RHSC and pharmaceutical companies manufacturing blood products.

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

14.1. By 1985 Scotland was self-sufficient in plasma. Product selection followed UKHCDO guidance and discussion and agreement at SNBTS/ Scotland and Northern Ireland Haemophilia Director and Coagulation Working Party meetings. Factor concentrate was shipped to us from the SNBTS who in turn received this from PFC, Edinburgh.

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

15.1. I made no decisions about products for individual patients until I became the Haemophilia Director. By this time Scotland was self-sufficient in plasma and concentrate was heat treated. In principle blood product was avoided if an alternative was available and UKHCDO guidance followed. Safety, efficacy and availability drove decisions. The rationale for choice in terms of non-blood product, cryoprecipitate or concentrate was explained to parents (patients). The Haemophilia Directors of Scotland and Northern

Ireland worked collegiately in decisions involving SNBST products. A small amount of commercial factor was purchased for use in inhibitor patients.

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

16.1. FFP, cryoprecipitate, desmopressin, tranexamic acid and thrombin.

17. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the RHSC 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?

17.1. I believe that the policy at RHSC was to minimise the risk of viral transmission and alternatives to factor concentrates were used where appropriate. All non-virally inactivated blood products carried a risk of viral transmission, accepting that pooled products carried the greatest risk. Whilst FFP contains all coagulation factors it cannot be given in a sufficient volume to achieve haemostatic values. Cryoprecipitate was unsuitable for home treatment / prophylaxis. In my answer to Q 12 I have described the difficulties of using cryoprecipitate out with the hospital setting. In Haemophilia A prophylaxis is given three times weekly and attending hospital at this frequency would be challenging for any family. Only Desmopressin carried no risk of viral transmission and was used in patients with mild/moderate haemophilia who had an adequate response (achieved haemostatic levels of FVIII) and who did not develop tachyphylaxis and for patients with von Willebrand Disease. However, it was unsuitable for small children because of the risk of hyponatraemia seizures. Tranexamic acid prevents clot from breaking down but does not promote clot and was mainly used for dental extraction and in mucous membrane bleeding. Thrombin was used for localised mucosal bleeding.

18. What was your/the RHSC'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?

18.1. The UKHCDO recommended the use of cryoprecipitate for previously untreated and mildly exposed patients in late 1983. My recollection is that this recommendation was discussed with families and followed. Patients with minimal requirements for blood product support may have been offered cryoprecipitate prior to this guidance.

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

19.1. By the time I became Haemophilia Director my recollection is that most, if not all, severely affected boys were on home treatment after an age when cannulation by the child's mother was possible. Over time home treatment was converted to prophylaxis, thereby preventing bleeds rather than treating them promptly. The age at which prophylaxis was started fell with the use of central lines.

20. What was your/RHSC's policy and approach in relation to prophylactic treatment? Did the policy and approach change over time and if so how? In answering this question you might wish to refer to the minute of the Coagulation Factor Working Party Meeting held on 3 November 1994 where you noted that "prophylaxis according to the published guidelines, was gradually being introduced for some of [your] young patients" [LOTH0000051_002].

20.1. The RHSC's policy was to introduce prophylaxis at as early an age as possible to allow the boys as normal a life as possible and not restrict activities unreasonably. I don't recall exactly what I meant by this statement but the recognised benefits of prophylaxis meant that prophylaxis was

introduced at an early age. Pre the use of indwelling central catheters prophylaxis was started at an age when the child's veins were easily cannulated and the mothers were trained to do so. With the wide spread availability of indwelling central catheters the age at which prophylaxis was started progressively fell because the problem of cannulating tiny veins was overcome. This statement acknowledges the UKHCDO guidance on prophylaxis.

21. At a meeting of Haemophilia Directors and SNBTS representatives held on 29 November 1984 [PRSE0002066] you reported that "imported factor VIII had been used until relatively recently". When did the RHSC stop using "imported" factor VIII? What product was used in its place? What was the reason for the change?

21.1. I don't remember the exact date that the use of "imported" factor VIII stopped but I believe that it was phased out in 1983. This was done because of concerns of viral transmission by a product prepared from paid donors. The currently available SNBTS product was used in its place.

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

22.1. Patients with mild or moderate bleeding disorders were treated with factor concentrates when this was the only means of achieving haemostatic levels of FVIII or FIX and of maintaining a haemostatic level for the required length of time. This would have been unusual in a patient with a mild bleeding disorder.

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

23.1. I am not aware of the transmission of any other viruses to patients at RHSC, but we were aware that HAV, parvovirus and CJD could be transmitted.

Parvovirus is common in children and it would be difficult to establish the route of acquisition.

Section 3: Knowledge of, and response to, risk

In answering the following questions please refer to your evidence provided to the Penrose Inquiry, specifically in relation to Topic C5 [GGCL0000225 and PRSE0003869] as well as your earlier witness statement [WITN3528001] provided in response to professional criticisms made against you, and please make any corrections, amendments or additions that you feel to be necessary.

General

24. When you began work at the RHSC (as a Senior Registrar in training), what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

24.1. I was aware of the risk of hepatitis having spent a year at the Oxford Haemophilia Centre, where a number of patients had been infected with hepatitis B and many had abnormal live function tests. I also had colleagues who had acquired hepatitis B, presumably from needle stick injuries. I was training in haematology which included blood transfusion and the risk of infection associated with blood and blood products was part of that training. My understanding increased with time based on personal experience, information from meetings and the literature.

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

25.1. The risk of infection from blood and any individual blood product was always considered and their use avoided where possible. This was part of the training of a haematologist. However no blood product was completely safe.

Alternatives to blood products were used where appropriate. UKHCDO guidance was followed. NHS/SNBTS blood products were accessed at a national level. Patients were regularly monitored for hepatitis by testing for specific virus, where this was possible and by monitoring liver function tests otherwise.

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

26.1. I understand this question to relate to the period prior to viral inactivation. Commercial products were made from larger pools of plasma than NHS/SNBTS products and donors may have been paid. Scottish donors were not paid, but were voluntary, and Scotland had a low incidence of HIV compared to other countries. For these reasons I understood NHS/SNBTS blood products to carry a lower risk of transmitting infection than commercial product but all carried a risk.

Hepatitis

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

27.1. I had been aware of the risk of hepatitis since my time at the Oxford Haemophilia Centre, where a number of patients had been infected with hepatitis B and many had abnormal live function tests. Although my first re exposure to haemophilia was when I rotated to RHSC, experience/training in blood borne infection was part of haematology training. Knowledge of the clinical impact of NANB was changing and my understanding increased with time based on personal experience, information from meetings and the literature.

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

28.1. I/RHSC stayed abreast of evolving information on hepatitis via discussion with colleagues, attendance at scientific meetings, the literature and guidance where available from the UKHCDO. I/RHSC participated in viral surveillance studies of NHS/SNBTS products. The study of viral safety of SNBTS factor VIII/IX concentrates published in Transfusion Medicine in 1993 reported that Z8 and DEFIX did not transmit HIV or HCV and recipients did not develop hepatitis.

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

29.1. The use of imported commercial factor VIII concentrate was phased out and the use of cryoprecipitate introduced in line with UKHCDO guidelines. Patients were treated with non-blood product where possible and where not with SNBTS concentrate sourced from Scottish plasma and heat treated. Patients were appropriately vaccinated.

30. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

30.1. My understanding was that HIV was the most serious form of hepatitis with the potential to lead to AIDS and death. Hepatitis B was the next most serious before the vaccine became available. My understanding of the severity of non A, non B changed overtime as evidence emerged, and in particular for any individual patient when tests allowed the distinction between exposure to hepatitis C and carriage of the virus with the potential for cirrhosis or liver cancer.

HIV and AIDS

31. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products during your time working at the RHSC (including any time as a Senior Registrar)? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

31.1. I joined RHSC in 1983. HIV/AIDS had been reported in a small number of patients with haemophilia in the US and by 1983 the association with factor concentrates and haemophilia was emerging. The first case in the UK was in late 1983. My knowledge came from colleagues who attended UKHDCO meetings where this was being discussed and from the literature. This increased as evidence emerged.

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

32.1. Whilst I was a Senior Registrar at RHSC, I think. This was becoming generally known within the haematology /blood transfusion community.

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

33.1. I understand that patients who had received factor concentrates / blood products for bleeding disorders were tested for HTLV antibodies and later a confirmatory antigen test when it became available.

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

34.1. RHSC phased out the use of imported factor VIII concentrate in 1983, substituting with NHS/SNBTS concentrate, which was heat treated in

Scotland by the end of 1984 and this product did not transmit HIV. The use of cryoprecipitate for unexposed or minimally exposed patients was introduced in line with UKHCDO guidelines.

35. Did the RHSC continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why, and which products did you use?

35.1. I understand that NHS/ SNBTS concentrate was used. This was sourced from Scottish plasma and FVIII concentrate was heat treated from the end of 1984 and FIX concentrate from October 1985. Neither product transmitted HIV.

Response to risk

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

36.1. Information evolved. My recollection is that boys who were infected with HIV had already been informed, or their parents had been informed, in 1984, before I became the Haemophilia Director and I thankfully never had to give this information to a family. From my time as Haemophilia Director parents of boys with haemophilia received information on the best treatment for their son, including all treatment options, if more than one existed. As part of that discussion the benefits and risks of treatment were discussed and parents (patients) routinely informed of the risks of HIV, hepatitis B and NANB hepatitis/HCV. By this time heat treated factor VIII concentrate was in use which did not transmit HIV and it was hoped would reduce the risk of transmission of other viruses associated with hepatitis. The risk of hepatitis was explained by medical staff and regularly reinforced by the haemophilia nurse specialist. Patients were managed by a multidisciplinary team with the haemophilia nurse specialist playing a pivotal role in counselling and education. The mothers were trained by the haemophilia nurse specialist to

give factor concentrate at home and this training included precautions on how to avoid transmission of infection whilst preparing and administering the factor concentrate. This included the use of disposable gloves, safe disposal of needles, syringes and concentrate. Bins for disposal of needles, syringes etc. were issued with factor concentrate to mothers of boys on home treatment in line with good clinical practice. The families were well cautioned and educated on the risk of hepatitis from needle stick injuries and blood spills and trained to deal with both scenarios. The haemophilia nurse specialist carried out school visits to educate staff about haemophilia, which included the safe handling of a blood spill because of the risk of transmitting hepatitis. Parents knew of these school visits. Patients and mothers who were administering clotting factor concentrates at home were vaccinated against hepatitis B, when the vaccine became available and later hepatitis A (1992). They would have understood that each vaccine gave specific immunity and not protection against all causes of hepatitis. Families were encouraged to become members of the Haemophilia Society which provided literature on haemophilia, its treatment and complications of treatment, including hepatitis. This literature was available within the Unit. The Social Worker held parent support groups where treatment and its complications were discussed. The Haemophilia Society held local meetings and at least one was focused on hepatitis. I note that in his evidence to the Penrose Inquiry Professor Gordon Lowe stated that on transition to adult services that all patients/parents knew about hepatitis. The boys had regular 4 monthly liver tests, which prior to the identification of, and ability of a test for hepatitis C, was the only way of monitoring NANB hepatitis. The mothers of boys on prophylactic treatment would bring the blood samples to a clinic visit to prevent an unnecessary venepuncture and would have understood why these bloods were being checked. All concentrate, whatever the source, had information leaflets in the boxes, and this information included the possibility of transmitting hepatitis.

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

37.1. My understanding is that heat treated NHS/ SNBTS concentrate was available from the end of 1984 for patients with Haemophilia A and October 1985 for those with Haemophilia B and those who required concentrate subsequently received a heat treated product. The degree and duration of heat treatment was sequentially increased until Z8 which was heated to 80 degrees for 72 hours from July 1987. My recollection is that this was not restricted to any specific group of children but any child who required treatment with factor concentrate. Children were always given preference.

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

38.1. Heat treated factor VIII concentrate for patients with Haemophilia A became available from the end of 1984 and before I became the Haemophilia Director with responsibilities for product use in August 1987. Whilst the initial heat process prevented transmission of HIV, it did not prevent the transmission of NANB hepatitis until heated to 80 degrees for 72 hours in July 1987. The earlier introduction of heat treatment to this degree might have reduced HCV transmission.

39. Please describe your involvement in the production and use of the Scottish Factor VIII, 8Z/Z8. (In answering this question you might be assisted by referring to the letters between you, Professor Lowe and Dr Crawford dated November - December 1987 included in Dr Ludlam's Submission for a Product Licence Variation for SNBTS Factor VIII Z8 - Expert Report on the Clinical Documentation [PRSE0000129 pp. 24; 28 and 29] and the article that you co-authored "Study of viral safety of Scottish National Blood Transfusion Service factor VIII/IX concentrate", Transfusion Medicine, 1993 [PRSE0000082]).

39.1. I was not involved in the production, but in the use. My recollection is that this product was already in use at RHSC before I became the Haemophilia Director. I identified some previously untreated patients who were serially tested for the development of NANB hepatitis and other viruses. These

patients would have been vaccinated against hepatitis B. No patient developed hepatitis or seroconverted to HIV or HCV and the study found no evidence of viral transmission.

a. In your letter to Dr Crawford dated 30 December 1987 [PRSE0000129 p 29] you state that "our impression is that all batches of Z8 have been incriminated". What did you mean by this?

39.2. A number of the mothers reported that they had to administer more units of Z8 to control bleeding episodes than they had with the previous product. This did not appear to be batch specific. The word "incrimination" did not refer to viral transmission, but to efficacy.

b. You also state that "Most of these patients are HIV positive". Was your understanding that your patients were infected with HIV before or as a result of being treated with 8Z/Z8?

39.3. Patients were infected with HIV in the early 1980s and not as a result of using 8Z/Z8. No patients in the PUP study of 8Z/Z8 developed HIV.

40. Did the RHSC 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?

40.1. My recollection is that this decision preceded my time as Haemophilia Director and followed guidance from the UKHCDO in late 1983 which recommended that previously unexposed, or minimally exposed, patients might receive cryoprecipitate. My understanding is that this guideline was followed and reverting to cryoprecipitate discussed with parents (patients) but was unsuitable for patients who wished to continue on home treatment.

41. Do you consider that the decisions and actions of the RHSC, and your own decisions and actions, 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.

41.1. In the early 1980's imported factor VIII concentrate was used. This was stopped when the risk of HIV transmission became apparent. In all other aspects I think that the decisions and actions at RHSC were appropriate to the level of knowledge at that time, availability of product and consensus of the Haemophilia Directors of Scotland and Northern Ireland and UKHCDO guidelines.

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

42.1. The use of imported factor VIII carried an increased risk of HIV transmission, but the decision to use this product was founded on the desire to facilitate home treatment. It was replaced with NHS/SNBTS concentrate in early 1983 before the risk of transmitting HIV through blood products was truly appreciated, because of the view that commercial product - produced from paid donors - might carry a greater risk of viral transmission than NHS/ SNBTS product. All UKHCDO guidance was followed.

43. 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?

43.1. The use of imported commercial FVIII concentrate probably increased the risk of HIV infection, although this was done to facilitate home treatment which brought many benefits. The earlier introduction of effective heat treated concentrate derived from Scottish donors may have reduced the risk of NANB hepatitis.

Section 4: Treatment of patients at RHSC

In answering the following questions please refer to your evidence provided to the Penrose Inquiry, specifically in relation to Topic C5 [GGCL0000225 and PRSE0003869], including making any corrections, amendments or additions that you feel to be necessary.

Provision of information to patients

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

44.1. Some patients had already received treatment prior to presentation at the Haemophilia centre. For example, they may have developed a scalp haematoma at birth and received FFP or cryoprecipitate in the neonatal nursery. I cannot comment on what information was given to these families about the risk of such blood products. Neither can I comment about information given prior to becoming the Haemophilia Director. By this time heat treated factor concentrate was available. The parents of newly presenting patients were given information about the need for treatment, which treatment was appropriate for their son and the risks associated with this treatment, including the risk of hepatitis transmission. This however was a great deal of information for new parents to absorb after being given a diagnosis of a disorder of such severity as haemophilia, during a period of emotion and pride at the arrival of a new baby son.

44.2. New patients fell into one of three categories:

44.2.1. Infants of known carriers of haemophilia who had a 50% chance of being affected. However much these mothers expected an affected son confirmation was still upsetting. These mothers were

informed about treatment and its risks and the hope that prophylaxis would prevent the haemophilia arthroplasty/arthritis that their brothers suffered. They were perhaps the group most able to understand the risk of hepatitis associated with treatment.

44.2.2. Infants of mothers with no family history. Many of these mothers had never heard of the disorder of haemophilia and the concept of a bleeding disorder was foreign. Their main concern was that their son would live a normal life, could attend a normal school, could play football, grow up and get married; in essence have a normal life.

44.2.3. Toddlers who presented with excessive bruising when they started walking. Some parents had been involved with social services about concerns of non-accidental injury and were very angry at the time of diagnosis.

44.3. Whilst all patient were told about the risk of hepatitis associated with blood products, I accept that new parents may have prioritised other issues. This is why counselling about the treatment and its risks, including hepatitis, is not a single event but an ongoing process.

44.4. New patients may have been offered recruitment to a viral surveillance study of previously untreated patients and this required consent which could only be obtained after discussion of the risk of viral transmission. New haemophiliacs were vaccinated against hepatitis B and hepatitis A.

44.5. As our understanding of NANB improved, the information given reflected this.

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

45.1. Parents (patients) were told that suitable treatments were dependent on the severity of haemophilia. The alternatives to factor concentrate were cryoprecipitate or desmopressin. Tranexamic acid could be used for mucosal bleeding. However only mildly affected, or a few moderately affected, boys with haemophilia A and those with von Willebrand Disease could be treated with desmopressin. Desmopressin did not raise the factor VIII level to a haemostatic level in severely or most moderately affected boys and could not be used in small children because of the risk of hyponatraemia and associated seizure activity. UKHCDO guidance on the use of cryoprecipitate was discussed with parents and followed.

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

46.1. I understand this question to primarily relate to viral transmission. However, mothers would first have been taught when it was appropriate to use home treatment and when it was appropriate to attend hospital for treatment. Information evolved with our understanding of risks. All patients were vaccinated against hepatitis B when a vaccine became available. Heat treated concentrate was in use when I became the Haemophilia Director. The risk of hepatitis was explained by medical staff and regularly reinforced by the haemophilia CNS who played a pivotal role in counselling and education. The mothers were trained to give factor concentrate at home and this training included precautions on how to avoid transmission of infection whilst preparing and administering the factor concentrate. This included the use of disposable gloves, safe disposal of needles, syringes and concentrate. The families were well cautioned and educated on the risk of hepatitis from needle stick injuries and blood spills and trained to deal with both scenarios. The haemophilia CNS carried out school visits to educate staff about haemophilia, which included the safe handling of a blood spill because of the risk of transmitting hepatitis. Parents knew of these school visits. Patients and mothers who were administering clotting

factor concentrates at home were vaccinated against hepatitis B. They would have understood that each vaccine gave specific immunity and not protection against all causes of hepatitis. Many families were members of the Haemophilia Society which provided literature on hepatitis. This was available within the Unit. The boys had regular 4 monthly liver tests, which prior to the identification of, and ability to test for hepatitis C, was the only way of monitoring NANB hepatitis. The mothers of boys on prophylactic treatment would bring the blood samples to a clinic visit to prevent an unnecessary venepuncture and would have understood why these bloods were being checked.

HIV

47. When did you first discuss AIDS or HIV (HTLV-III) with any patients or their families at the RHSC? What did you tell them?

47.1. I understand this question to refer to positive HIV tests and not the clinical development of AIDS. I was never involved in discussions about HIV test results or in informing families of a positive test result.

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

48.1. Sometime in 1984.

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

49.1. I was not involved in HTLVIII/HIV testing so cannot comment on pre- test counselling.

50. At the meeting of Haemophilia Directors and SNBTS representatives held on 29 November 1984 [PRSE0002066] you reported that five out of ten patients already tested at the RHSC were HTLV-III antibody positive. What discussions can you recall taking place about this at the RHSC at the time?

50.1. I understand this to refer to how families were informed of a positive test result. I was fortunate in never having to give this information and cannot comment on how it was done.

51. How and when and by whom were patients and their families 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?

51.1. I had no involvement in this process and cannot comment further than it is my recollection that they were told individually and in person by Professor Ian Hann and perhaps Dr Anna Pettigrew.

52. At the meeting of Haemophilia Directors and SNBTS representatives held on 29 November 1984 [PRSE0002066] you reported on the anxiety felt by parents of patients at the RHSC regarding certain of your patients having tested positive for HIV. If parents or guardians were told without the patient present, what guidance were they given about when and how to inform their child about the diagnosis?

52.1. I never had to tell a family that their son had tested HIV antibody positive, so can't comment.

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

53.1. As above. I believe it to have been consistent with current knowledge at that time. Many families chose to remain silent about their son's infection.

54. What was the RHSC's/your 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 understand that HIV testing was offered.

55. What, if any, information or advice was provided by you or colleagues at the RHSC 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 but my recollection is that parents/ family members were educated on the routes of transmission of HIV, what precaution should be taken when administering concentrate, how to avoid a needle stick injury and how to deal with a blood spill. They would have known that HIV could be transmitted sexually and I remember that they were cautioned about sharing tooth brushes etc.

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

56.1. The Haemophilia Social worker and the Clinical Nurse Specialist/ Haemophilia Sister were sources of counselling for the families. My recollection is that there were a number of individuals, including a counsellor Patricia Wilkie and Dr Fiona Logan (psychology/psychiatry) who helped with counselling.

57. How many patients at the RHSC 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 am afraid that I can't answer this question in the detail requested. I understand from evidence given to the Penrose Inquiry that 21 boys were infected at RHSC, but by the time of testing only 10/11 were still being treated at RHSC. The others had transitioned to adult services. My recollection is that most had severe Haemophilia A. I don't think that any had von Willebrand Disease. All were children.

58. Was work undertaken at the RHSC or elsewhere 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 understand that stored samples were tested to establish the time period of seroconversion. Some fresh samples may have been used. Seroconversions were thought to have occurred by 1982.

Hepatitis B

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

59.1. I don't know the number of cases of hepatitis B prior to my appointment as Haemophilia Director. Boys were tested regularly and parents (patients) would have been informed of any seroconversion. They would have been given information on the significance of this finding and the management as available at that time. Z8 heated to 80 degrees for 72 hours did not transmit hepatitis B and boys were vaccinated against hepatitis B. A patient with Haemophilia A tested positive in March 1988. A number of batches were implicated and no other recipient of these batches seroconverted but no other risk factor was identified in the index patient. He had received two

of a planned three doses of Engerix B in February and March of 1988. His parents would have been informed that he had tested positive, that we were trying to identify the incriminated batch and told about the significance and management. I do not remember that he had long term effects. All patients were vaccinated against hepatitis B.

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

60.1. See answer to Q59.

NANB Hepatitis/Hepatitis C

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

61.1. Parents (patients) were aware of the risk of NANB hepatitis as part of their education about the complications of the treatment of haemophilia. In my time as Haemophilia Director, I would have been responsible for discussing this risk with the families, but we worked as a multidisciplinary team, and the Haemophilia CNS would have reinforced this information. The families knew that we were monitoring liver function tests for abnormalities which most likely reflected NANB hepatitis. I would have been responsible for discussing any abnormal liver function tests with families and this would have been done in person at a clinic visit. However, the reliability of tests for hepatitis C evolved. Parents/patients would have been given their results, but also told that there was some uncertainty about what a test result meant. It was not until there was a reliable test which could distinguish between a patient who had been exposed to the virus and one who was a carrier, that it was possible to inform families of the significance or prognosis or to identify those patients who required discussion about treatment options and management. Furthermore, most of the information

on the severity of NANB hepatitis came from adult experience. Initially (at least prior to 1985) NANB was not thought to be a serious problem. Even when it became apparent that NANB could progress to cirrhosis and liver cancer in adults, the significance was less clear in children because they had none of the co-morbidities common in adults such as alcohol consumption, other drugs, co-infection.

62. When did the RHSC begin testing patients for hepatitis C? How, when and by whom were patients and their families 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. RHSC tested in line with national guidance as serial tests of reliability came on board. This followed the same time frame as adults which in turn followed recommendations from the UKHCDO. The initial tests for hepatitis C antibody were unreliable and replaced by the improved RIBA-2 test followed by an antigen test which distinguished those who had been exposed from and those who were carriers and at risk of significant sequelae. Patients and their families were given their test results in person, by myself, at their next clinic visit or next return to the department after the result was available. All patients were given their test result irrespective of whether it was positive or negative.

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

63.1. Parents of boys who were hepatitis C antibody positive were informed that their son had been previously exposed to hepatitis C virus through treatment with clotting factors or cryoprecipitate and that this had likeliest happened with their earliest treatments. They were told that this did not necessarily mean that they were a chronic carrier of hepatitis C but hopefully a test would become available which could make this distinction. They were told that their child's liver function tests would be carefully

monitored and older boys were told to avoid alcohol. Parents of boys who were hepatitis C antigen positive were told that their son was probably a chronic carrier of hepatitis C and at risk of developing chronic liver disease. Patients and their families were informed of the potential sequelae of hepatitis C carrier status although much of the data came from adults and it was difficult to know if the outcome for children would be similar or milder, because of the absence of co factors such as alcohol consumption. They were offered referral to a paediatrician with an interest in liver disease and to an infectious diseases doctor for consideration of antiviral therapy.

63.2. Parents/patients were given information sheets published by the UK Haemophilia Society and /or the British Liver Trust, which discussed the complication of hepatitis and provided advice. The recommendations of the UKHCDO first guideline on hepatitis C were well in place at RHSC before those guidelines were published in 1995.

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

64.1. Patients with bleeding disorders were tested at their next clinic visit. My recollection is that there was a national initiative lead by SNBTS to trace other patients who had received blood products.

65. In your witness statement to the Penrose Inquiry on Topic C5 [GGCL0000225] you state that the "recommendations of the UKHCDO's first guideline on Hepatitis C were well in place at RHSC, Glasgow before these guidelines were published in 1995". Please describe the steps that had been taken at the RHSC in relation to hepatitis C before the guidelines were published and provide a copy of any relevant documents.

65.1. Recommendations from the UKHCDO were generally known to the treating community before their publication which always post-dated the Committee's agreement on their content. In this respect RHSC

implemented the recommendations of the guideline earlier than some centres and there was absolutely no delay in implementation. I have no relevant documentation to forward.

66. How many patients at the RHSC were infected with hepatitis C?

66.1. This information was collated for the west of Scotland and for the Penrose Inquiry and should be available to you. In the absence of a data manager I cannot give you an accurate number.

Delay/public health/other information

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

67.1. My recollection is that the results of test for hepatitis were notified to the patients and their families as they became available and generally at their next clinic visit or visit to the department. However, the significance of these results were not always known at that time and only became apparent as information accumulated.

68. 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 and their families or what treatment to offer patients?

68.1. The advice offered to a child /family was based on generic safety and the ability to allow as normal a life as possible. Patients and their families were given advice and educated on how to minimise risk of transmission when administering blood products, how to avoid needle stick injuries and blood spillage and how to deal with these two scenarios should they arise. They were told not to share toothbrushes and how to deal with cuts. Schools were

visited by the clinical nurse specialist and staff educated about how to deal with a blood spillage. Older boys were made aware of the risk of sexual transmission.

69. What information was provided to patients and their families about the risks of other infections?

69.1. They would have known about the risk of hepatitis A and were vaccinated in 1992. They would have been aware of the risk of CJD from blood products sourced from UK plasma. I don't know if they were aware of the risk of Parvovirus but this is a very common infection in children who have never received any blood product. These issues cascaded through the haemophilia community.

70. What information was provided to patients and their families about the risks of infecting others?

70.1. See answer to Q68.

Consent

71. How often were blood samples taken from patients attending the RHSC and for what purposes? What information was given to patients and their families about the purposes for which blood samples were taken? Did the RHSC obtain informed patients' informed consent (or in the case of children, the consent of their parents or guardians) to the storage and use of the samples? Was the consent recorded and if so how and where?

71.1. Boys were routinely screened for complications of haemophilia and treatment by blood samples taken at 4 monthly intervals. This included a full blood count to detect anaemia from occult blood loss, abnormalities of liver (hepatitis) and renal function, inhibitor formation, immunity post vaccination, viral transmission and lymphocyte numbers to detect any abnormality of immune function. My understanding was that the families

were aware of this and these bloods were either taken at a clinic visit or brought to clinic by the mothers of boys on home treatment to prevent an unnecessary venepuncture. This was considered routine clinical management and did not require consent.

71.2. I am not aware of what samples were stored and do not recall that consent was taken for storage if that happened or that it was considered necessary. The Medical Defence Union of Scotland advised that consent for hepatitis C testing was not required.

72. Were patients under the care of the RHSC treated with factor concentrates or other blood products without their express and informed consent (or in the case of children, the consent of their parents or guardians)? If so, how and why did this occur? What was your approach to obtaining consent to treatment? If it is your position that patients (or their parents/guardians) did give express and informed consent to treatment with factor concentrates, please explain the basis for that position and set out the information that was provided to them. Was their consent recorded and if so how and where?

72.1. Explaining the benefit and risks of treatment to patients and their families is an everyday occurrence in paediatric haematology, often involving complex chemotherapy protocols for children with leukaemia. Therefore giving detailed information on treatment and it risks was/is standard practice in all areas of paediatric haematology. Severe haemophilia is a potentially fatal disease from intracranial haemorrhage, or at best a lifelong crippling disease, in the absence of effective treatment. Counselling about the risks of viral transmission / hepatitis was part of the general information given to patients and their families. I will confine my response to after August 1987 when I was the Haemophilia Director and Z8 – heat treated concentrate - was in use at RHSC. The need for treatment and the most appropriate treatment with its risk, including hepatitis, were discussed with parents. Consent evolved as it did in all areas of medicine. Initially it was implied, but still informed by the information provided. From 1988 new patients, previously untreated, were given information on, and invited to participate

in a clinical trial of virally – inactivated SNBTS clotting factor concentrate whose aim was to demonstrate that such concentrates had a low risk of transmitting NANB hepatitis /hepatitis C. This goal was achieved. Extra blood sampling was required and parents would have understood this. Similarly, there was a safety trial for the successor high purity product – Liberate. My recollection is that a Patient Information Sheet was available for all trials and consent taken. Children were the first to receive recombinant concentrates when they became licensed and again an Information Sheet was available and my recollection is that consent was taken.

73. Were patients under your care tested for HIV or hepatitis or for any other purpose without their/their parents or guardians' 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?

73.1. By August 1987 patients were vaccinated against hepatitis B and heat treated concentrate was in use since June 1987. This product did not transmit HIV. Testing after this period was therefore for hepatitis C and the advice of the Medical Defence Union was that consent was not required for HCV testing.

PUPS

74. In your earlier witness statement [WITN3528001] provided in response to professional criticisms made against you, you state that after becoming responsible for haemophilia care you were "involved in 'Previous Untreated Patient (PUP) studies for heat treated Factor VIII concentrate, followed by High Purity Factor VIII and recombinant Factor VIII concentrates". Please detail all decisions and actions taken at the RHSC by you or with your involvement with regard to PUPS including, but not limited to, the "Study of viral safety of Scottish National Blood Transfusion Service factor VIII/IX concentrate" 1993 [PRSE0000082].

74.1. I understand this question to refer to consent for PUPS to be included in trials. Patients who have not been previously exposed to factor concentrates are those who will benefit most from blood products which do not transmit infection or are not associated with any other detrimental side effect and should be prioritised for such products. Equally their lack of infection demonstrates the viral safety of a product. The families would have been informed that this product was being processed in a way which we hoped would reduce the risk of viral transmission although this could not be guaranteed. The potential benefits and risks were explained as was the requirement for participation in terms of monitoring and blood sampling. It is my understanding that the inclusion of PUPs in studies was done with fully informed consent. An information sheet for families was available and studies carried out under the correct regulatory procedure.

High purity products

75. Please set out your involvement in the debate about the need for and/or use of high purity products for HIV positive patients, including details of any studies that you were involved in/undertook. You may wish to consider the following enclosed documents: Minutes of the meeting of the SNBTS Directors held on 21 July 1989 [PRSE0004188 and PRSE0004030]; Dr Ludlam's Submission for a Product Licence Variation for SNBTS Factor VIII Z8 detailing the study being undertaken by the Haemophilia Directors in Scotland and Northern Ireland, in conjunction with the Factor VIII Working Party regarding the safety of Factor VIII Z8 [PRSE0000129]; Letters between you, Dr Ludlam and Mr Pettet dated September - October 1990 regarding High Purity Factor VIII [LOTH0000028_003 and LOTH0000028_004]; Report regarding the Multicenter Prospective Cohort Study comparing Immune-Function in Patients treated wither with SNBTS high-potency Factor VIII Concentrate or with Monoclonally Immunopruified Factor VIII Concentrate in terms of which you were an Associate Investigator [LOTH0000084_001; LOTH0000084_002 and LOTH0000084_003]; Letter from Dr Ludlam to Mr McIntosh dated 19 November 1990 on behalf of the Haemophilia Directors for

Scotland and Northern Ireland regarding plans to manufacture a high purity factor VIII concentrate [SBTS0000706_224] and Letter from Dr Ludlam to Monsieur Golde dated 26 March 1991 [SBTS0000300_026].

75.1. Z8, an intermediate purity, F VIII concentrate was in use at RHSC from June 1987 and was the product in use when I was appointment as the Haemophilia Director. This proved itself to be an extremely safe product in terms of viral safety, but was of low purity. By the time of my appointment regular meetings (3 monthly) were well established between the Haemophilia Directors of Scotland and Northern Ireland and SNBTS (with representation from PFC) where developments in concentrates, including the need for a high purity product, were discussed. This concern escalated when evidence started to emerge that high purity or very high purity concentrates might slow the decline in CD 4 cells and the progression to AIDS in patients who were HIV positive and lead to a collaboration between SNBTS and the fractionation centre in Lille to produce an ion exchange high purity concentrate, later to be known as Liberate. My involvement was at the level of the Scottish Haemophilia Directors debate. However, 5 of the 18 UK Regional Haemophilia Centres Directors' Committee who produced the Recommendations for the Choice of Therapeutic Products for the Treatment of Non – Inhibitor patients with Haemophilia A, haemophilia B and von Willebrand Disease were also members of the Scotland / Northern Ireland Haemophilia Directors group and we had the benefit of their attendance at wider meetings. The Scotland/Northern Ireland Directors agreed to give HP FVIII to all PUPS and children under 5 years in addition to HIV positive patients. I was involved in two strands of studies –

75.1.1. Those associated with Liberate - viral safety, inhibitor formation and effect on immune system of HIV positive patients. I don't remember the number of children involved, but they would not have been involved in studies of recovery which could be carried out on adults alone.

75.1.2. The reports of benefit for high purity concentrates in HIV positive patients were restricted to monoclonal purified concentrates. To establish that ion exchange HP FVIII carried the same benefit a study was proposed to compare the immune function in patients treated with either SNBTS HP FVIII concentrate or monoclonal immunopurified FVIII concentrate.

Research

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

76.1. I am afraid that I can't remember the detail, but I would have been involved in all studies of new factor concentrates – intermediate purity, high purity and recombinant.

a. Describe the purpose of the research.

76.2. The purpose would have been to demonstrate efficacy and safety; the latter in terms of both viral transmission and the development of inhibitors.

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

76.3. Each study would have gone to my Ethics Committee for approval.

c. Explain what your involvement was.

76.4. My involvement would have been to identify suitable patients, explain the potential benefits and risks, obtain consent, and to oversee the trial at my site.

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

76.5. SNBTS/PFC. I think that I recall being involved in some studies of recombinant factor concentrate and the relevant drug company would have been involved, but I can't remember which company.

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

76.6. Non recombinant factor studies were academic and I don't remember any funding coming to the hospital but it may have gone to R&D.

f. State the number of patients involved.

76.7. I don't remember how many patients were involved.

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

76.8. The purpose, potential benefits and risks would have been discussed with parents who would have been given the information sheet for the study.

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

76.9. Study of the viral safety of Scottish National Blood Transfusion Service factor VIII/IX concentrate. Haemophilia Directors for Scotland and Northern Ireland: B Bennett, A.A Dawson, B.S Gibson, A Hepplestone , G.O Lowe, C.A Ludlam , E.E Mayne and T. Taylor *Transfusion Medicine*, 1993.3.295-2987

76.10. Children with haemophilia were no more disturbed than their diabetic or healthy peer controls, despite the identification of HIV infection within the clinic and the widespread publicity associated with AIDS and HIV infection: Logan FA, Maclean A, Howie CA, Gibson B, Hann IM, Parry-Jones WL *BMJ* 1990.301.1253-6

76.11. The only epidemiological studies which I remember were about numbers of patients with HIV and hepatitis C in Scotland. Data were collated to understand the extent of the problem but was anonymised.

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.

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

77.1. I do not believe so.

78. 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?

78.1. I don't believe patient data was used for research. Anonymised data would have been collated to understand the extent of any problem and identify resource for management. Consent would not have been taken for the use of anonymised data for this purpose at that time. Similarly data was sent to the Oxford registry. This is similar to what happened in many diseases and continues to happen.

79. 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?

79.1. I do not believe that data - anonymised or otherwise – was shared with third parties, if this term refers to commercial organisations.

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

80.1. At Q76h.

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

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

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

81.1. Patients were referred to one of two consultants who specialised in infectious diseases and who were known to the Unit because of involvement with other patient groups. These individuals had experience of HIV/AIDS management in other high risk patient groups.

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

81.2. The only treatment that I recall was azacytidine. In addition specific treatments of any infections which arose because of immunodeficiency.

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

81.3. This would best be answered by the Infectious Diseases clinicians who oversaw these treatments.

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

81.4. Patients had 4 monthly screening of lymphocyte numbers and subsets to monitor for reduction / progressive loss of immune function. They were also assessed in respect of the development of clinical manifestations of AIDS. RHSC offered open access at all times.

82. How was the care and treatment of patients with hepatitis B managed at the RHSC? 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 and their families about the risks and benefits of specific treatments and about side effects?

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

82.1. I only remember one patient testing positive for hepatitis B. His liver function tests were serially monitored as was serology. I don't remember any patients developing symptoms requiring treatment or referral.

83. How was the care and treatment of patients with NANB hepatitis managed at the RHSC? 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 and their families about the risks and benefits of specific treatments and about side effects?

83.1. Patients with NANB hepatitis as evidenced by abnormal liver function tests were not referred for specialist care. The significance of these abnormalities was not known particularly in children. Liver function tests fluctuated within patients and although NANB was thought the likeliest cause, there were

other potential causes such as concomitant drugs. The experience came from adults who may have had co factors which affected liver function such as alcohol or drug use. I don't recall any child having such concerning liver abnormalities that would have required referral in their own right. In the absence of knowing the cause of these abnormalities, no treatment was appropriate.

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

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

84.1. When a reliable test for distinguishing a patient who had been exposed to hepatitis C from a carrier of the virus became available, patients who were carriers of the virus and at risk of sequelae were offered referral to a paediatrician with expertise in liver disease.

b. What treatment options were offered over the years?

84.2. Treatment with Interferon was offered.

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

84.3. The risks / benefits and side effects of treatment were discussed with patients and their families as they were known at that time. This would have been done by the multidisciplinary team at RHSC, but primarily guided by Infectious Disease doctors and by the Hepatologist. Drug information was available and the British Society for Liver Disease and the Haemophilia Society produced literature which was available within the Unit.

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

84.4. This would have been done in conjunction with, and been led by, the Hepatologist. They had regular monitoring of their liver function and radiological investigation as indicated.

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

85.1. I recall that the majority of counselling and support came from the medical and nursing staff, but also from the haemophilia Social Worker.

86. Did the RHSC receive funding from any external source to help with the counselling of patients infected with HIV? If so please provide details.

86.1. The only funding that I am aware of was for a counsellor at the adult unit at GRI, who may also have had sessions at RHSC.

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

87.1. I don't recall any difficulties.

88. What if any involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details. In answering this question you may wish to refer to the following:

a. Your evidence provided to the Penrose Inquiry on Topic C5 [GGCL0000225];

b. a letter from Robert Stuart to you dated 31 May 1991 regarding clinical trials of HPVIII [PRSE0004266];

c. SNBTS Product Services Department: Clinical Trials Update Report produced by the Haemophilia Society, dated January 1996 [NIBS0001573];

88.1. RHSC involvement was limited to clinical trials to demonstrate the efficacy and safety of concentrates which had been treated to prevent viral transmission rather than trials of treatments for HIV and /or hepatitis. I don't recall if interferon therapy was part of a trial or not.

Records

89. What was the policy or practice of the RHSC with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis?

89.1. The deaths that I am aware of were from HIV and not hepatitis C. Some of boys infected with HIV had transitioned to the adult service. Terminally ill patients were in Ruchill Hospital (Infectious Disease Hospital) and the death certificates would have been completed according to its policy.

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

90.1. GGC Board worked to Scottish Government Records Management Code of Practice. My Records Department have provided the following information for the period 1980-1996, which I understand to be the relevant period.

90.1.1. 1980-1993- 6 years after date of last attendance or 3 years after death

90.1.2. 1993-1996- until 25th birthday or 3 years after death.

90.2. I understand that this latter retention policy still operates.

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

91.1. No separate files were kept.

92. 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 at RHSC? If so, why, what information and where is that information held now?

92.1. No.

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

93.1. No.

Section 5: Self-sufficiency

94. In December 1974 the Department of Health announced additional funding with the primary aim of making the NHS self-sufficient in Factor VIII blood products within two to three years. Please answer the questions in this section to the extent that you are able to (the Inquiry recognises that you did not take up a haematologist post until 1984).

a. When did you become aware of this announcement?

94.1. I don't know when I became aware of this statement.

b. What did you understand the term "self-sufficiency" to mean? In particular, did you understand it to mean self-sufficiency in providing Factor VIII blood products prophylactically, or solely in response to bleeding incidents?

94.2. I understood it to mean all requirements for factor concentrates – both on demand and prophylactic treatment.

c. Did your understanding of what "self-sufficiency" meant change at any time? If so, when and why?

94.3. No. The above was always my understanding.

d. What was your understanding of how others defined "self-sufficiency?

94.4. I assume similar to myself.

e. What if any role did you play, at any time, in any arrangements or initiatives designed to help achieve self-sufficiency?

94.5. Scotland was self- sufficient by the time I became a Haemophilia Director.

95. How were estimates made of how much Factor VIII blood product would be required for use in Scotland? In particular:

a. What was your role as the director of the RHSC in making such estimates, and how did this change over time?

95.1. The estimates of usage were based on the previous year's use and any predicted increase, which was usually predicted at 10% increase. I was responsible for forwarding the data to the SNBTS. This was originally in paper form and later electronically.

b. What was the role of UKHCDO and how did this change over time?

95.2. The UKHCDO produced guidelines for treatment which could have influenced usage i.e. prophylaxis. I believe that the UKHCDO supported the Oxford Registry.

c. What assumptions would underpin the estimates (including assumptions as to how the blood products would be used)?

95.3. A 10% increase each year was predicted. The number of new cases would be reasonably constant but the number of patients with inhibitors less predictable and this could influence usage, Changes in prophylaxis guidance also influenced usage.

d. How would the estimate be made (e.g. by whom were they made, when and through what process)?

95.4. Centres forwarded data on usage to SNBTS and the Oxford Registry.

e. How were the estimates shared with other interested parties?

95.5. I am not aware that this data was shared.

f. How did any of these processes change over time?

95.6. I don't recall any change during my period as Haemophilia Director.

96. How were annual figures derived for how much Factor VIII blood product had been used over the course of a year?

a. What was your role as the director of the RHSC in providing such figures, and how did this change over time?

96.1. Data on usage was transferred to SNBTS by each centre every month.

b. What was the role of UKHCDO and how did this change over time?

96.2. UKHCDO supported the Oxford Registry.

c. How would the calculations be made (e.g. by whom were they made, when, through what process and using what data)?

96.3. In understand that in Scotland this was done by SNBTS on behalf of PFC who would have received the data for each Scottish centre.

d. How were those figures broken down geographically (e.g. by region or any other unit)?

96.4. By centre.

e. How were the figures shared with other interested parties?

96.5. I don't know that they were shared.

f. How did any of these processes change over time?

96.6. Collection and transfer became electronic.

97. Were there significant differences between the estimates that were made and actual use? If so, why?

97.1. Yes there were differences between estimates and actual use. In a small centre such as RHSC one patient requiring surgery or developing an inhibitor in any one year could significantly increase usage.

98. Please refer to the thread of correspondence between you and the SNBTS about the use of commercial factor concentrates at the RHSC dated June - July 1985 [SBTS0000682_077; SBTS0000682_076 and SBTS0000164_007]. Please explain what you recall about the context of this discussion? Why was there concern about the NBTS material being "needlessly thrown away" at the RHSC?

98.1. This statement referred to SPPS – which is albumen solution. The biggest users at RHSC were neonates. A standard dose would be 10 ml/kg. Many of these neonates were less than 2 kg and were using less than 20 mls. Some infants were larger but the volumes used were small. SNBTS equivalent product came in 400ml bottles. The SNBTS product was not being needlessly thrown away. The volume was inappropriate for our needs. In my correspondence I stated that we had used 35 bottles of 50 mls and 6 bottles of 250mls. It was wasteful to take small volumes out of a 400mls bottle.

99. Please refer to the thread of correspondence between the Glasgow and West of Scotland Blood Transfusion Service and the Scottish Haemophilia Directors dated June to September 1990 [PRSE0000264; SBTS0000339_010; PRSE0000557 and PRSE0001978] regarding Factor VIII distribution in Scotland.

a. Why was the RHSC considered to be an "unpredictable user of factor VIII"?

99.1. I think that the phrase "unpredictable user of factor VIII" merely refers to the fact that in a small centre like RHSC it only takes one patient to require unexpected surgery, develop an inhibitor or have a serious bleed to significantly increase factor VIII usage. This would be particularly so if the affected patient was a teenager / significant weight. Children are more active than adults and injuries/ accidents unpredictable.

b. Did you agree with the issuing of whole batches to RHSC to minimise the number of batches to which each patient was exposed and minimise the number of patients receiving each batch? Was this approach effective in minimising the risk of infection?

99.2. I did agree with whole batches / batch dedication minimising the number of batches any patient, and therefore the number of donors, that any patient was exposed to. This approach also minimising the number of patients

exposed to any batch should that batch transmit virus. I don't know if this reduced infection but in theory it should have.

c. What is meant by "whole batches"?

99.3. This could best be answered by SNBTS / PFC. However, I understood it to mean that this was a volume / entire batch of factor VIII made from the same pool of donors.

d. What is meant by the "whole system"? Please describe the operation of the "whole system"?

99.4. I am not sure what was meant by the "whole system" and can't see it referenced. Perhaps this could best be answered by SNBTS/PFC

100. At the meeting of the SNBTS Directors on 15 September 1988 [PRSE0004647] there was a discussion regarding the "Comments on the Current Difficulties in the Supply of Factor VIII for the Scottish Health Service by the SNBTS and Proposals for Re-assertion of Self-Sufficiency" and reference to a letter from you in this regard. Please explain what you can recall about this discussion and provide us with a copy of the letter if you have it.

100.1. I am sorry but I can't recall anything of this discussion and do not have a copy of the letter.

101. To what extent (if at all) do you consider that Scotland achieved, or made progress towards achieving, self-sufficiency in blood products and when?

101.1. By the time I became Haemophilia Director in 1987 Scotland had achieved self- sufficiency. I believe this to have been achieved in 1985 and ahead of England.

Section 6: Scottish National Blood Transfusion Service

102. Please describe the relationship between the RHSC and the SNBTS over the years in which you worked at the RHSC.

102.1. My recollection is that relationships were good and mutually helpful.

103. Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, during the time that you worked at the RHSC.

103.1. I interacted at regional level about the number of vials of concentrate that I required and at a national level about the type and amount of concentrate required via the SNBTS/ Scottish Haemophilia Directors meetings,

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

104.1. My involvement would have been via SNBTS/ Scottish Haemophilia Directors meetings, I have no recollection about discussion to increase the supply of cryoprecipitate, but by the time I became Haemophilia Director Z8 was in use which was heat treated.

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

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

105.1. Regular meetings of the SNBTS/ Scottish Haemophilia Directors Working Party.

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

105.2. Regular meetings of the SNBTS/ Scottish Haemophilia Directors Working Party.

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

105.3. Regular meetings of the SNBTS/ Scottish Haemophilia Directors Working Party.

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

106.1. As my answer to Q105.

107. What was the system at the RHSC for keeping records of the blood or blood products that were used?

107.1. They were originally written in a ledger and later recorded electronically.

108. Why was the Factor 8 Working Party for Scotland and North Ireland established, and what was your role within it? You may wish to refer to the minutes and annual reports of the Working Party attached to this letter.

108.1. My understanding is that Factor 8 Working Party for Scotland and Northern Ireland was established to consider safe and effective coagulation factors for both countries as early as possible. My role was that of a Haemophilia Director,

109. Have you held any positions at the Scottish National Blood Transfusion Service (SNBTS), and if so what were your role and responsibilities in any such positions?

109.1. No.

Section 7: UKHCDO

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

110.1. I was an ordinary member of UKHCDO but don't remember being a member of any working parties, committees or groups. I am aware that I was invited by Brian Colvin to join the UKHCDO's Recommendations on Choice of Therapeutic Products for the Treatment of non- Inhibitor patients with Haemophilia A, Haemophilia B and von Willebrand Disease in 1996. However I can't remember this group and can't find an output by a literature search. I may also have attended a UKHCDO Committee meeting to represent Professor Lowe.

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

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

111.1. To give guidance on the diagnosis and management of bleeding disorders. Including complications of treatment.

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

111.2. I was not sufficiently involved to comment.

c. The relationships between UKHCDO and pharmaceutical companies.

111.3. I don't know.

d. How decisions were taken by UKHCDO.

111.4. I don't know.

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

111.5. Information was disseminated to all Haemophilia Directors in written form.

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

- the risks of infection associated with the use of blood products;

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

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

- heat treatment;

- other measures to reduce risk;

- vCJD exposure; and

- treatments for HIV and hepatitis C.

When addressing this question, please include a description of your involvement in the production of UKHCDO's Recommendations on Choice of Therapeutic Products for the Treatment of Non-Inhibitor Patients with Haemophilia A, Haemophilia B and Von Willebrand's Disease (third edition enclosed by way of example, [PRSE0003809] as well as letter from you to Dr Colvin dated 21 February 1996 confirming willingness to join the Task Force preparing these recommendations [BART0000922_032]).

111.6. I don't recall any involvement with any of the issues listed under 111F.

111.7. I was invited to be involved in a committee to produce UKHCDO's Recommendations for the Choice of Therapeutic products for the Treatment of Non – Inhibitor Patients with Haemophilia A, Haemophilia B and von Willebrand Disease but do not remember this work and can't find any publication.

Section 8: Pharmaceutical companies/medical research/clinical trials

112. 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.

112.1. No.

113. 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.

113.1. No.

114. 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.

114.1. No.

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

115.1. No.

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

116.1. No.

117. 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.

117.1. No.

118. 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?

118.1. I was funded to attend a small number of scientific meetings on factor concentrates and followed the procedures of my Trust.

119. 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.

119.1. Recombinant FVIII may have been supplied on clinical trial and if so I would have had to supply appropriate data.

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

120.1. As above.

121. 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?

121.1. I have had no financial involvement with pharmaceutical companies other than funding for attending meetings which was common practice.

Section 9: Involvement with the financial support schemes

122. 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?

122.1. None other than providing information to parents (patients) to apply for financial assistance and responding to requests from these Trusts for confirmatory information with patient/parent consent.

123. To the extent that you had any involvement with the trusts or funds or with the applications made by patients for assistance, please answer the following questions:

a. To what extent did the RHSC and its staff (including you) inform patients and their families about these different trusts or funds?

123.1. All were given information on how to apply for financial support.

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

123.2. My recollection is that all patients were advised by medical and nursing staff and the Social Worker to apply.

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

123.3. Help was given for completion of forms and requests were responded to with patient/parent agreement to do so.

d. Did the RHSC, or any of its staff (including you), act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

123.4. No.

e. Was the RHSC or any of its staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

123.5. No.

f. In your letter dated 31 July 1989 to Mr J Williams (Administrator of the Macfarlane Trust) [MACF0000175_033] you confirmed that "all of our HIV positive boys are registered with the Macfarlane Trust". Please outline the context of this letter.

123.6. I am sorry but I can't provide additional information. I can only assume that this was in response to a query from Mr J Williams.

g. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of the RHSC's 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?

123.7. Much of this was devolved to Social Work who would be best to respond.

Section 10: vCJD

124. 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?

124.1. I cannot remember exactly when, but it was discussed at meetings of the Haemophilia Directors and SNBTS when the risk was recognised. I was also working with children and it was recommended that those borne before 1996 and as a result not exposed to vCJD in the food chain should not be exposed to UK plasma.

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

a. What steps were taken/put in place a process at the RHSC for informing patients and their families about possible exposure to vCJD?

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

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

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

125.1. The information about the risk of vCJD rapidly spread through the haemophilia community. There was a great deal of press coverage, not

just in relation to the blood supply but the food chain. The risk was difficult to quantify and we answered patients as best we could.

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

126.1. During my time as Haemophilia Director we had no affected patients.

Section 11: Other Issues

127. 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.

127.1. None.

128. 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.

128.1. I am still working full time but have not been involved with haemophilia care for 20-25 years. However, I have had a career with children who have leukaemia and those who have undergone a stem cell transplant. I therefore have significant experience in giving bad news, in discussing the risks of treatment, in obtaining consent, and in being completely honest with parents/patients.

128.2. Much of the information, particularly of NANB hepatitis, evolved over time. This is not unlike COVID 19 where information continues to evolve.

128.3. I believe that all clinicians sought to do their best for their patients and are desperately upset by the consequences that they suffered from their treatment which was given with the best of intentions.

Statement of Truth

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

Signed GRO-C

Dated 03 December 2020