Witness Name: Professor Philip Cachia
Statement No.: WITN4028001
Exhibits: None
Dated: 20 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR PHILIP CACHIA

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 4 August 2020.

I, Professor Philip Cachia, will say as follows: -

Section 1: Introduction

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

1.1 Name: Philip Cachia
Address: GRO-C
Date of birth: GRO-C 1956

1.2 Professional qualifications:
MBChB (Edinburgh University) 1980,
MD (Edinburgh University) 1989,
MRCP (UK) 1983,
MRCPath (Haematology) 1990,
FRCPE 1995,
FRCPath 1998.

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 Employment History:

April 2015 – November 2019
Clinical Director of Training and Assessment
Royal College of Pathologists
6 Alie Street, London, E18QT

September 2004 – March 2015
Postgraduate Dean, the Scotland Deanery – East Region,
NES Executive Lead for Clinical Skills and Patient Safety

February 1992 – August 2004
Consultant Haematologist and Director of Haemophilia Services, NHS Tayside.
Honorary Senior Lecturer, Dundee University

October 1997 – September 2004 (two sessions per week)
Postgraduate Tutor, East Deanery the Scottish Council for Postgraduate Medical and Dental Education (SCPDME) (the precursor of NES) and NES

January 1991 - January 1992
Medical Research Council Training Fellow
Pre-Leukaemia Research Unit
University Hospital of Wales (Prof A Jacobs)

June 1988 – January 1991
Senior Registrar in Haematology
University Hospital of Wales, Cardiff
(Professor A Jacobs, Professor AL Bloom)

October 1985 –May 1988
Research Fellow and Honorary Registrar
Department of Pathology Lothian Health Board
University of Edinburgh (Professor C Bird)
MD Thesis: Immunoglobulin Idiotope expression in
B-cell Chronic Lymphoproliferative Disease

September 1983 – September 1985
Registrar in Haematology
Western General Hospital, Edinburgh (Dr N Allan)

Bangor General Hospital, West Lothian (Dr M Cook)

August 1982 – August 1983
Senior House Officer in Respiratory Medicine, Northern General Hospital, Edinburgh

August 1981 – July 1982
Medical Senior House Officer
Roodlands Hospital, Haddington, East Lothian

February 1981 – July 1981
Junior House Officer in Surgery
Royal Infirmary of Edinburgh

August 1980 – January 1981
Junior House Officer in Medicine
Eastern General Hospital, Edinburgh

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 Membership committees/associations/societies:

1. Haemophilia Directors of Scotland and Northern Ireland, member and secretary from 1993 - 2004
2. Coagulation Factor Working Party for Scotland, member from 1993 – 2004
3. United Kingdom Haemophilia Centre Directors' Organisation (UKHCDO), member from 1993 - 2004

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 (other than those which are enclosed with this letter).

4.1 Inquiries and litigation:

1. The Penrose Inquiry
2. No other investigations or litigation

5. Please consider the evidence which you gave to the Penrose Inquiry which is attached to this letter. Please confirm whether the contents of the written and oral evidence you gave to the Penrose Inquiry are true and accurate. If there are any matters contained within the written statements or in the oral evidence you provided that you do not consider to be true and accurate, please explain what they are.

5.1 Penrose evidence:

Item 3.4 on page 3 of my written statement should read 'The Haemophilia service predominately ……'

5.2 I can confirm that the evidence given by me to the Penrose Inquiry is true and accurate to the best of my knowledge and memory.

6. The questions below focus, as appropriate, on your time as a Senior Registrar in Haematology at University Hospital of Wales, Cardiff ("Cardiff") between 1988 and 1991 and as Consultant Haematologist and Director of Haemophilia Services, Tayside ("the Dundee Centre") between 1992 and 2004. Some questions relate to events that would have taken place before you began work at the Dundee Centre, but the Inquiry assumes that, as a consultant at and director of that Centre over a number of years, and given your evidence to the Penrose Inquiry, you will have some knowledge of its policies and practices before you began working there, and so if you have information concerning Dundee relevant to the period or issue to which the question relates, please include that in your response. If you have information arising from your work prior to 1988 which is relevant to the issues to which the questions relate, please also include that in your response. When answering the questions below, please make clear in your response which hospital(s) your answers relate to.

6.1 Cardiff and Dundee experience:

My answers to the questions set out in this statement are all based on my memories as a Haematology Senior Registrar in Cardiff from June 1988 to January 1992 and as a consultant Haematologist and Director of Haemophilia Services in Tayside from 1992

to 2004. In making this statement, I have not had access to any information or documentation from the South Wales or Scottish Health Authorities but have analysed the documents provided by the Inquiry with the Rule 9 request. I can also confirm that I did not retain any documents relating to my clinical practice or patient specific information on leaving my employment in South Wales and NHS Tayside.

Section 2: Decisions and actions of the Centres at Cardiff and Dundee and your decisions and actions

7. In relation to your work in Cardiff as Senior Registrar in Haematology please:

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

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

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

7.1 **a.** I trained as a senior registrar in the South Wales Haematology programme from June 1988 until January 1992. This time included a 1 year MRC Research Fellowship in the University Haematology department in 1991 when I took time out of the formal training programme. The Cardiff programme consisted of 4 monthly rotations round the different sections of the service (Haematology ward, day unit, Haemophilia Unit and coagulation laboratory, general laboratory, all based in the University Hospital of Wales; Cardiff Royal Infirmary, and Llandough Hospital).

7.2 **b.** Professor Arthur Bloom was the head of the Haemophilia and coagulation service in Cardiff with other consultants providing out-of-hours cover. Dr Has Dasani was a full time, permanent non-consultant staff grade doctor based in the Haemophilia Unit. There were also permanent (including Doreen Davies and Jenny Jones) and rotating nursing staff based in the Centre.

7.3 **c.** During my time in Cardiff I had two attachments in the Haemophilia Centre and coagulation laboratory when my daytime work and training were based in the Centre. This included seeing, assessing and treating patients with Haemophilia and other coagulation disorders attending for planned, elective visits and emergency problems.

I therefore had 8 months of daytime work and training in the Haemophilia Centre under the direct supervision of the senior doctors and nurses in the Haemophilia Centre.

7.4 In addition, I would see patients with Haemophilia and other coagulation disorders with emergency problems, when I was on out-of-hours duties throughout my 3 ½ years as a senior registrar in the training programme.

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

a. describe your understanding of how haemophilia care was provided within the Dundee Centre in the period prior to when you took up your post in 1992;

b. describe the facilities, organisation, roles, functions and responsibilities of the Dundee Centre during the time that you worked there and how they changed over time. It may be useful to describe the situation between 1992 and 1995 before a formal Centre was established; your review of care and recommendations that you made; and from 1995 once the Dundee Centre was established;

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

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

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

8.1 **a.** In 1992 when I was appointed as consultant in NHS Tayside, the Haemophilia service predominantly consisted of a 'crisis intervention service' providing emergency and in patient care in the event of acute bleeding or other medical problems. Medical staff in the Haematology department provided some pro-active Haemophilia care advice and routine assessment but this was on an opportunistic basis. There was no managed or organised system of routine care or prospective review of patients with inherited bleeding disorders in terms of their general health, joint disease or any of the complications of Haemophilia or its treatment. There was a named consultant Haematologist (Dr Heppleston) responsible for the care of patients but he was not a specialist in Haemophilia care and had a very heavy clinical load looking after patients with Haematological malignancies. There was also a named consultant Paediatrician

who provided continuous care for boys with Haemophilia but there was little formal communication or shared care with the Haematology service. Adult patients on home factor concentrate therapy received their supplies by contacting a technician in the regional Scottish National Blood Transfusion (SNBTS) laboratory based in Ninewells Hospital and were issued with the required product without regular medical supervision or formal review of their treatment. There were no formal liaisons between the Haematology department and key specialist services essential for the provision of comprehensive Haemophilia care including dentistry, the HIV service, hepatology, orthopaedic surgery, physiotherapy, social work or psychological counselling services. The Haematology coagulation laboratory provided a comprehensive coagulation service including factor and inhibitor assays required to monitor Haemophilia care although not every on call biomedical scientist was able to perform these assays as an emergency, out of hours procedure.

8.2 **b.** In developing the Haematology service, we obtained funding for an additional consultant post. In recruiting to this post, we agreed that my job plan should be modified and that I would become the named consultant responsible for the care of patients with Haemophilia and other inherited bleeding disorders and that the department should aspire to develop the service to deliver high quality, comprehensive care to UKHCDO standards.

8.3 **c.** Initially, I had no dedicated resources or staffing support other than a rotating Haematology trainee and general Haematology nursing support in the day unit and ward. I did, however, initiate a process of arranging for all the known patients with inherited bleeding disorders to meet me at a planned appointment in the Haematology Day unit to introduce myself, establish contact and start the process of regular, routine care and assessment of complications and to review and manage their factor concentrate issue and usage.

8.4 **d.** To achieve the goal of providing comprehensive care, I prepared a business case making the case for a dedicated unit/space in the department as a Haemophilia Centre, a full-time specialist Haemophilia nurse, data manager and administrative support. I cannot remember the precise details or timing but the business case was approved resulting in the establishment of a Haemophilia Centre, the appointment of a part-time specialist Haemophilia nurse (June Ward) in early 1995.

8.5 **e.** From early 1995, June Ward and I set about establishing the Haemophilia Centre and the delivery of comprehensive care in Tayside. Priority objectives included:

i. Establishing the Centre management, documentation and local protocols.

ii. Training and education for other haematology staff (medical and nursing) to ensure that the standards of care and treatment protocol would be delivered 24/7.

iii. Developing formal links with the local Haemophilia Society branch to engage with patients, parents and carers. This included our attendance at local meetings to explain our ambitions for improving care.

iv. Establishing a working relationship with the regional SNBTS Director and staff so that all requests for factor concentrates for home therapy came through June Ward or myself and were linked to formal review of each patient's bleeding history and factor concentrate usage.

v. The introduction of regular clinical reviews for all patients to include general health review, assessment of Haemophilia related joint disease, factor concentrate usage, viral status, education and social needs.

vi. Establishing formal links between paediatric and adult Haemophilia care to ensure consistency of clinical protocols and management of seamless continuity of care as the children with inherited bleeding disorders transferred to the adult service.

vii. Introducing prophylactic home factor concentrate therapy for boys with Haemophilia in Tayside as best clinical practice to prevent joint bleeds and the long term complications of arthritis.

viii. Developing the coagulation laboratory service and staff to ensure the 24/7 availability of all factor and inhibitor assays required for emergency Haemophilia care.

ix. Establishing formal agreements, clinical policies and access to shared care for patients with Haemophilia with:

1. Orthopaedic surgery
2. Anaesthetics
3. Physiotherapy
4. Dentistry
5. Hepatology
6. Infectious Disease and the regional HIV service
7. Obstetrics

8. Clinical Genetics
9. Social Work

x. Participation in SNBTS clinical trials of highly purified clotting factor concentrates as a member of the Scottish and Northern Ireland Haemophilia Directors group.

xi. Elective orthopaedic surgery. Elective surgery for the backlog of severe Haemophiliac arthropathy was a priority service development. At that time, all orthopaedic surgery was performed in Dundee Royal Infirmary while the Haematology clinical and laboratory services were in Ninewells Hospital. Given the need for close post-operative clinical and laboratory monitoring, I arranged with the Professor of Orthopaedics for a series of operating dates in Ninewells on a Friday morning, linked with my on call weekends so that I was available for the immediate post-operative management of factor concentrate doses and bleeding problems. I wrote protocols for the peri-operative and anaesthetic care of patients with Haemophilia. Over the next few years, this service provided elective joint replacement surgery for around 10 patients with severe joint disease often affecting several joints.

xii. At a later date (from memory 1997) when I became Postgraduate Tutor for two sessions a week. I used the backfill funding to employ a clinical assistant for 1-2 days a week to further develop the dedicated Haemophilia team and undertake routine clinical assessments on patients attending the Centre.

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

9.1 **a.** The Cardiff Haemophilia Unit was a comprehensive care centre which provided tertiary care for South Glamorgan and surrounding areas. From memory there were approximately 200 patients with inherited bleeding disorders and approximately 50 patients with severe Haemophilia registered at the centre.

9.2 **b.** From memory, there were around 25 patients with severe Haemophilia within our catchment area in Dundee. The numbers meant that we could not become a standalone comprehensive care centre (the UKHCDO requirements were for a

minimum of 30 patients with severe Haemophilia). We therefore had a formal link with the Edinburgh comprehensive care Haemophilia Centre but nonetheless succeeded in providing comprehensive care at the Dundee Centre, relying on advice from the Edinburgh Centre on occasions but without having to transfer patients with Haemophilia to Edinburgh for clinical care.

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

10.1 **a.** Cardiff - As a trainee Haematologist in the department, I had no involvement in the choice or purchase of factor concentrates used to treat patients with bleeding disorders. The product of choice for existing patients was recorded in their case notes and in the Haemophilia Centre. Treatment decisions on previously untreated patients would be decided by Professor Bloom and/or Dr Dasani. I have no knowledge of how policy on factor concentrate selection and purchase was determined.

10.2 **b.** Dundee – The selection, purchase and use of factor concentrates was managed on an all Scotland basis by the Scotland and NI Haemophilia Directors Group which worked closely with the Coagulation Factor Working Party (which consisted of Haemophilia Directors, SNBTS and the Protein Fractionation Centre (PFC) representatives and Scottish Executive Medical Directorate representation. There was a well-established agreement from all parties that Scotland should preferentially use factor concentrates manufactured by SNBTS from volunteer blood donors and that Scotland should aim to become self-sufficient in factor concentrate production and supply. Commercial factor concentrates were purchased in the event of supply shortages and for specific patients where indicated. It was agreed that in times of supply shortages of SNBTS products, the smaller Haemophilia Centres (Dundee, Aberdeen and Inverness) would be prioritised for the SNBTS products. From memory, I believe the Edinburgh and Glasgow comprehensive care centres purchased any commercial products through their Health Board financial systems. This system was well established in 1993 when I became Haemophilia Director in Tayside and joined the groups so I had no role in formulating the original policies.

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

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

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

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

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

e. What involvement did you have?

11.1 **a.** Cardiff - As detailed in my answer to question 10, the senior doctors determined the product of choice for individual patients and the Haematology trainees followed these decisions when treating patients in emergency circumstances. I had no involvement in the choice or purchase of blood products and have no knowledge of commercial or financial considerations in making these decisions.

11.2 **b.** Dundee – as detailed in my answer to question 10, the selection of factor concentrates and the purchase of any commercial concentrates required was managed on an all Scotland basis, primarily through the Scotland and NI Haemophilia Directors group in collaboration with the Coagulation Factor Working Party.

12. What products were used for treating patients at (a) Cardiff and (b) the Dundee Centre, over what period of time and for which categories of patients? How were decisions taken, at Cardiff and the Dundee Centre, as to which products to use for individual patients? What involvement did you have in such decisions?

12.1 **a.** Cardiff - As a Haematology Senior Registrar, I had no involvement in the selection of blood products available in the Centre or used for individual patients. I would follow the decisions made by senior doctors in treating individual patients. From memory, most of the factor VIII and IX concentrates used in the Cardiff Centre in 1988 were from the national NHS organisation Bio Products Laboratory (BPL). From memory, there were a number of commercial factor concentrates still used but I do not remember the details.

12.2 **b.** Dundee – Until the introduction of recombinant factor VIII and IX, all patients with Haemophilia attending the Dundee Centre were treated with SNBTS intermediate purity (Z8 and DEFIX) and later high purity (Liberate and HIPFIX) factor VIII and IX concentrates. Once the SNBTS Z8 was phased out and replaced with high purity Liberate, we maintained a stock of Haemate P for patients with VWD who required factor concentrate therapy (and who would previously have been treated with Z8).

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

13.1 **a.** Cardiff - As a Haematology trainee in Cardiff, I had no knowledge of involvement in relationships with commercial pharmaceutical companies.

13.2 **b.** Dundee – As the Haemophilia Director in Tayside, I had no regular meetings or involvement with representatives of pharmaceutical companies until the introduction of recombinant Factor VIII in the late 1990s. Once there were multiple recombinant factor VIII products on the market, pharmaceutical representatives would make appointments to see me (as with the other Haemophilia Directors) to promote their product even though purchasing decisions were made through the National Consortium.

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

14.1 Cardiff - As a Haematology Senior Registrar in Cardiff, I had no knowledge of external organisations with a role in factor concentrate selection and purchase.

14.2 Dundee – as explained in my answers to questions 10, 11 and 12, the decision to use SNBTS plasma derived factor concentrates was made on an all Scotland basis through the Scotland and NI Haemophilia Directors group and the Coagulation Factor Working Party. Once recombinant Factor VIII and IX were introduced funding decisions were made by the National Consortium established by the National Services Division on behalf of the Scottish Health Boards and Scottish Executive/Government.

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

15.1 a. Pharmaceutical agents

i. Desmopressin (DDAVP)

ii. Antifibrinolyitic agents such as Tranexamic acid

15.2 b. Blood products including

i. Fresh frozen plasma

ii. Cryoprecipitate

iii. Platelet concentrates

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

16.1 DDAVP can be used to treat patients with mild to moderate Haemophilia A and patients with mild Von Willebrand Disease (VWD) but is not effective in patients with severe Haemophilia A (0% baseline factor VIII activity) or severe VWD (type 3, 0% Von Willebrand Factor (VWF) activity). DDAVP is a pharmaceutical agent so there is no risk of blood borne viral infections. However, the therapeutic effect of consecutive doses decreases with each dose (tachyphylaxis) because the drug acts by releasing the patient's VWF stores which need time to replenish. It can cause side effects such as headache, nausea, flushing and upset stomach. DDAVP has no therapeutic use in Haemophilia B or any of the rarer inherited bleeding disorders.

16.2 Cryoprecipitate is a source of Factor VIII and can be used to treat patients with Haemophilia A and VWD. Cryoprecipitate has no therapeutic use in Haemophilia B or any of the rarer inherited bleeding disorders.

i. The only advantage of cryoprecipitate over Factor VIII concentrates is the much lower donor exposure for the equivalent rise in plasma Factor VIII or VWF activity following infusion. This was clearly a major advantage over untreated factor concentrates in the 1970s and early 1980s but diminished over time as effective viral elimination was introduced into factor concentrate manufacture. The risks and benefits of the reduced donor exposure compared to heat treated plasma derived Factor VIII concentrate from the late 1980s are

debatable given that pooled cryoprecipitate could not be effectively treated to eliminate viruses or contaminating bacteria (which would be eliminated in factor concentrates by terminal dry heat treatment).

ii. Factor concentrate is more efficient and effective than cryoprecipitate in achieving, maintaining and controlling high levels of factor VIII plasma levels over a period of time for patients who require sustained high levels of factor VIII to cover major bleeding complications or invasive procedures including surgery. In addition, cryoprecipitate therapy is associated with a greater range of potential side effects and complications (than Factor VIII concentrate) especially with prolonged treatment. These include fairly common side effects such as circulatory overload (increased risk in infants, older patients and those with pre-existing cardiac problems), febrile and allergic reactions and haemolytic transfusion reactions – the medical management of which will slow down factor VIII therapy and effective treatment of the bleeding problem. There are also some extremely rare but potentially fatal transfusion related complications – Transfusion Related Lung Injury, post-transfusion purpura and transfusion associated graft-versus-host disease.

16.3 The optimal treatment for a patient with Haemophilia A or VWD in the 1980s therefore depended on two factors: 1) the severity of the Haemophilia or VWD and 2) the severity of the bleeding problem being treated and/or the nature of the surgical or invasive procedure to be covered by the treatment including the duration of treatment and the Factor VIII plasma levels that need to be maintained to achieve haemostasis. For instance:

i. A life threatening bleed (e.g. a bleed in the brain) or major surgery can only be safely and effectively managed by raising the factor VIII and/or VWF level to normal or near normal factor VIII or IX levels (100%) for a sustained period of time and will therefore require continuous treatment for a week or more. Factor VIII concentrate treatment was (and still is) the most effective treatment option to reliably achieve this and minimise the risks of serious bleeding complications.

ii. A simple tooth extraction, on the other hand might well be covered with a single dose of DDAVP in patients with mild Haemophilia A or VWD or by cryoprecipitate in patients with more severe Haemophilia or VWD.

16.4 In both Cardiff and Dundee, DDAVP and cryoprecipitate were available and considered for patients undergoing minor invasive procedures where the reduced intensity of treatment levels did not compromise safety in terms of bleeding complications.

17. What was the policy and approach at Cardiff and at the Dundee Centre as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?

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

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

17.1 **a.** Cardiff – I cannot remember whether there was a written policy for cryoprecipitate use in the Cardiff Haemophilia Centre and am not aware of any changes in approach to using cryoprecipitate during the 3 1/2 years I was there. The treatment options for individual patients would be documented in their case records and known by the Haemophilia Centre staff (and patients and families). Patients with mild Haemophilia A or VWD would be assessed for each invasive procedure and a decision made, usually by Professor Bloom and/or Dr Hasani. In the case of a previously untreated patient (PUP), senior medical and nursing staff would be involved in making therapeutic decisions. I do not remember being personally involved in the managing a PUP during my time in Cardiff.

17.2 **b.** Dundee – When I arrived in Dundee in 1992, heat treated intermediate purity SNBTS Factor VIII (Z8) had an excellent safety profile and record so the choice between Z8 and cryoprecipitate for patients with mild Haemophilia A or VWD was marginal. My approach to managing an invasive procedure was as described in my answers to question 16 and 17a above with case by case risk assessment and recommendation depending of the severity of the Haemophilia A or VWD, the patient's previous blood product exposure and the severity of the bleeding symptoms and/or invasive procedure that required haemostatic cover. With the withdrawal of Z8 (in favour of Liberate) in the mid 1990s, I maintained a stock of Haemate P as the factor concentrate of choice for patients with VWD who required concentrate to cover a procedure and this became the treatment of choice (if DDAVP was not indicated) for patients with VWD who required Factor VIII replacement when UK plasma products were not advised because of vCJD concerns in the late 1990s.

18. What was the policy and approach at Cardiff and at the Dundee Centre in relation to home treatment? Did the policy and approach change over time and, if so, how?

18.1 In Cardiff, home treatment was well established and considered the norm for all patients with severe Haemophilia A and B. There was no change in policy during the 3 ½ years of my time as a senior registrar there.

18.2 In Dundee, the majority of adult and paediatric patients with severe Haemophilia were already on home treatment in 1992 but one of my early priorities was to implement regular medical review of their factor concentrate usage and bleeding problems. There was no change in policy during my time as Haemophilia Director.

19. What was the policy and approach at Cardiff and at the Dundee Centre in relation to prophylactic treatment? Did the policy and approach change over time and, if so, how?

19.1 Cardiff – routine prophylactic factor concentrate for children with Haemophilia (usually instituted after the first 'spontaneous' joint bleed) was only established as optimal treatment in the mid-1990s so was not routine practice in Cardiff when I was there. Prophylactic treatment for individual patients would be determined on a case by case basis and would be considered and recommended for patients who were going through a period of frequent 'spontaneous' joint bleeds, often recurring in a 'target joint'. In such cases, a prophylactic treatment regime could reduce the frequency of bleeds (and thereby prevent painful symptoms and further joint damage) and also reduce the overall factor concentrate usage. The prophylactic regime would be reviewed on a regular basis and discontinued if the precipitating bleeding problem could be resolved. I was not aware of any changes in policy during my 3 ½ years in Cardiff.

19.2 Dundee – Prophylactic factor concentrate therapy for boys with severe Haemophilia was introduced in Tayside from 1995 in response to the evolving evidence of the benefits in reducing long term joint damage and arthritis and the lifetime reduction in factor concentrate use.

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

20.1 Cardiff – I was not aware of specific policies in relation to treating children with Haemophilia in Cardiff. As a Haematology Senior Registrar, I had relatively little involvement in the management of children with Haemophilia and other bleeding disorders as their first line management was through the Paediatric service in liaison with Professor Bloom and the senior staff in the Haemophilia Centre.

20.2 Dundee – As described in my answer to question 19, prophylactic factor concentrate was introduced for boys with severe Haemophilia from the mid 1990s. The only other change in treatment policy and approach during my time as Haemophilia Director was the change from plasma derived to recombinant factor concentrate as the treatment of choice from 1998 as detailed in section 67.

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

21.1 Cardiff – During my time in Cardiff DDAVP, cryoprecipitate and factor VIII concentrate would all be considered as therapeutic options for patients with mild or moderate Haemophilia A or VWD depending on the severity of the bleeding problem and/or the type of invasive procedure for which treatment cover was required (as described in my answer to question 17). The patient's past treatment history would also be considered in recommending treatment and, where possible, DDAVP would be used to reduce exposure to blood products. For patients with Haemophilia B, factor concentrate was the only effective treatment available.

21.2 Dundee – I took a similar approach as Haemophilia Director in Dundee with DDAVP, cryoprecipitate and SNBTS Z8 (or Haemate P after Z8 was withdrawn) considered for patients with VWD on a case by case basis. DDAVP, Cryoprecipitate and Z8 or Liberate were considered for patients with mild Haemophilia A until the introduction of recombinant Factor VIII in the late 1990s which became the treatment of choice for all patients with Haemophilia A. Intermediate (DEFIX) or high purity (HIPFIX) SNBTS factor IX concentrates were the only effective treatments for patients with mild Haemophilia B.

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

22.1 **a.** Cardiff – I cannot remember from my 3 ½ years in Cardiff, specific instances or details of infections other than HIV, HCV and HBV transmitted to patients by blood products.

22.2 **b.** Dundee – High purity SNBTS Factor VIII concentrate (Liberate) was introduced in NHS Scotland in the early 1990s to replace intermediate purity Factor VIII (Z8). The viral inactivation process also changed from dry heat treatment (for Z8) to solvent/detergent inactivation (for Liberate). Solvent/detergent treatment is very effective at eliminating HIV, HBV and HCV, all of which have lipid based outer coats. There are, however, some non-lipid enveloped viruses (e.g. HAV and Parvovirus) which will not be inactivated by this process.

22.3 There were reports in the literature of HAV transmission by solvent/detergent inactivated high purity Factor VIII concentrates is the 1990s (when Liberate was being used in Scotland). This led SNBTS to develop a double viral inactivated (solvent/detergent and terminal dry heat treated) formulation of Liberate which was approved for a clinical trial in 1996. This trial did not take place in Scotland because of the decision not to use UK derived plasma (because of vCJD risks) and the move to recombinant Factor VIII in the late 1990s.

22.4 Parvovirus B19 infection is common in our population but became a concern because there was evidence of Parvovirus transmission by solvent/detergent inactivated high purity Factor VIII. Furthermore, Parvovirus B19 is associated with a potentially serious medical condition – pure red cell aphasia, which results in a severe form of anaemia. These concerns resulted in Haemophilia Directors prioritising patients who were negative for antibodies to Parvovirus (i.e. no natural immunity and therefore susceptible to potential Parvovirus contamination of any blood products) for recombinant Factor VIII.

Section 3: Knowledge of, and response to, risk

General

23. When you began work as a Senior Registrar in Haematology at Cardiff, what did you know and understand about the risks of infection associated with blood

and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

23.1 My Haematology registrar rotation in Edinburgh did not include the Haemophilia Centre, so I had no previous direct involvement in Haemophilia care.

23.2 My knowledge when I began in Cardiff would be based on reading contemporary Haematology journals and formal educational activities in the training programme. I would have been aware of infection risks associated with blood and blood products from my time and training in Blood Transfusion Medicine and was aware of problems of HIV infection in patients with Haemophilia from the scientific literature.

23.3 In Cardiff, this knowledge was enhanced by day to day discussion and training from the senior staff in the Haemophilia Centre. Detailed and up to date knowledge in preparation for sitting the MRCPath part 1 and 2 examinations in Haematology was obtained from various sources – textbooks, Haematology journals, attendance at Haematology conferences, tutorials and other teaching activities in Cardiff.

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

24.1 Cardiff – As a Haematology Senior Registrar, I was not aware of advisory or decision-making structures at a regional on national level in Wales.

24.2 Dundee – The advisory and decision making structures in Scotland were the Scotland and NI Haemophilia Directors group and the Coagulation Factor Working Party as described in my answers to questions 10, 11 and 12.

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

25.1 My understanding as a Haematology Registrar and Senior Registrar in the 1980s was that there was a broad consensus on commercial factor concentrates derived from systems that paid donors (particularly if including donations from high risk populations including those in prison) that they were likely to have higher risks of transmitting blood borne infections than voluntary blood donation systems. The UK Blood Transfusion

Services were generally considered to be of high quality and there was ongoing debate about how to achieve UK-wide self-sufficiency in factor concentrate production.

25.2 The decision to aim for Scotland to be self-sufficient in factor concentrates derived from voluntary Scottish donors and manufactured at the SNBTS Protein Fractionation Centre had been made before I took up my consultant post in Dundee in 1992. That aspiration had, to the best of my knowledge, the support of all stakeholder organisations and individual Haemophilia Directors.

25.3 The national policy to be self-sufficient in factor concentrate from UK derived voluntary donor plasma had to be reversed with the vCJD crisis in 1996 when it was decided to import plasma from the USA.

26. What decisions and actions were taken at Cardiff and at the Dundee Centre to minimise or reduce exposure to infection?

26.1 Cardiff – During my time in Cardiff, patients were kept on a single factor concentrate product unless there were supply problems or shortages or the patient developed an allergic reaction to a specific product. There was also a stock control process to ensure that individual patients were treated with a single batch while available and to reduce exposure to multiple batches where possible.

26.2 Dundee – Throughout the 12 or so years that I was Haemophilia Director in Tayside, I supported the all-Scotland approach to Haemophilia treatment mediated through the Scotland and NI Haemophilia Directors Group and the Coagulation Factor Working Party. I attended the meetings of these two groups, contributed to the discussions and decision making processes and implemented nationally agreed actions in the Dundee Centre expeditiously. Steps taken to minimise exposure to infection during this time include supporting and implementing the development of high purity double virally inactivated, plasma derived factor VIII and IX concentrates and their replacement with recombinant factor VIII and IX when possible. Within the Dundee Centre, the introduction of routine clinical review for patients with inherited bleeding disorders and regular review of home factor concentrate use was aimed at, amongst other things, ensuring appropriate treatment and minimising unnecessary exposure for all patients.

Hepatitis

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

27.1 In the 1970s, conventional teaching at medical school was that NANB hepatitis was known to be transmitted by blood but was thought to be a mild, self-limiting infection with no long term consequences. That was my understanding as I started my career as a junior doctor in the early 1980s. I would have gained some additional knowledge from Blood Transfusion Service attachments as a Haematology Registrar in Edinburgh but would not have gained deeper insight into issues relating to factor concentrate therapy before starting my senior registrar post in Cardiff.

27.2 As stated in my answer to question 23, my knowledge and understanding of the evolving evidence of long term liver dysfunction following NANB infection and the eventual discovery of the Hepatitis C virus was based on reading contemporary Haematology journals, formal educational activities in the training programme and from my time and training in Blood Transfusion Medicine and the Cardiff Haemophilia Centre. Detailed and up to date knowledge in preparation for sitting the MRCPath part 1 and 2 examinations in Haematology was obtained from various sources – textbooks, Haematology journals, attendance at Haematology conferences, tutorials and other teaching activities in Cardiff.

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

28.1 Cardiff – From memory, every effort was made to keep individual patients on the same factor concentrate product wherever possible. Patients would also be issued with concentrate from a single batch until this was no longer available as detailed in my answer to question 26. I am not able to comment on the development of policy and actions during the 1980s prior to my time as a Senior Registrar there.

28.2 Dundee - as detailed in my answer to question 26, the adoption and implementation of national recommendations made through the Scotland and NI Haemophilia Directors Group and the Coagulation Factor Working Party, included the development of high

purity, double viral inactivated plasma derived factor concentrates and the introduction of recombinant factor concentrates from 1996 onwards.

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

29.1 Cardiff – patients attended the Centre for routine 4 - 6 monthly clinical reviews. Blood was taken at that time to monitor liver function tests (including alpha-fetoprotein), full blood count, factor VIII or IX levels and inhibitor levels. Many patients had abnormal liver function tests, so the serial measurements were to detect trends and consider further investigations or referral if the tests were worsening in time. Serum alphafetoprotein was measured as a screening test for hepatocellular carcinoma. There was no change in the monitoring process during the 3 ½ years I was in Cardiff.

29.2 Dundee – The same liver function tests were monitored at regular 4-6 monthly clinical reviews as in Cardiff, based on standard practice for monitoring ongoing liver inflammation associated with HCV and to screen for hepatocellular carcinoma – a known complication of both HBV and HCV chronic infections.

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

30.1 As stated in my answers to questions 23 and 27, my knowledge and understanding of blood borne viral hepatitis developed through my commitment to lifelong learning. This included informal interaction with Haemophilia Centre staff, formal educational activities in the training programme, clinical attachments in Blood Transfusion Medicine and personal reading and preparation for the MRCPath examinations in Haematology.

30.2 As medical students in the 1970s, we were taught that Hepatitis B was a blood borne viral infection in which an episode of acute hepatitis at the time of infection could be followed by complete resolution and immunity to further infection or a carrier state in which the virus persisted and the patient remained infectious. It was recognised that there was a long term risk of liver disease and hepatocellular cancer in patients with persistent viraemia.

30.3 In the 1970s, the assumptions (and medical school teaching) that NANB hepatitis was a blood borne, self-limiting illness associated with acute hepatitis but no long term sequelae were gradually eroded by the evolving evidence of long term liver dysfunction in the 1970s and 80s. The cloning of the Hepatitis C virus and introduction of laboratory tests to identify the presence of the virus and antibodies against it in the early 1990s, enabled the causal link between Hepatitis C infection and long term liver disease and hepatocellular cancer to be established.

30.4 Hepatitis A (HAV) is not generally a blood borne infection but as a non-lipid coated virus, HAV is not easily eradicated by solvent/detergent inactivation. The addition step of terminal heat treatment of solvent/detergent inactivated Liberate in the mid 1990s was in response to reports of HAV transmission by solvent/detergent inactivated Factor VIII in the medical press.

31. At a meeting on 10 February 2000, you stated that between 1 September 1985 and 31 December 1988, only SNBTS products were used at the Dundee Centre [ARCH0003312_020]. Is this correct? Given that this period pre-dated your appointment at the Dundee Centre, how did you come to this conclusion?

31.1 From memory, I had asked the regional SNBTS service based in Ninewells Hospital to confirm from their records all factor concentrates issued in Tayside for the relevant period of time – 1 September 1985 to 21 December 1988 in preparation for this meeting. This was consistent with information I had collected on factor concentrate issue in Dundee from my 1992 review of Haemophilia services in Tayside. SNBTS and other Haemophilia Directors had confirmed that intermediate purity factor VIII (Z8) and factor IX (DEFIX) had been issued to patients with Haemophilia and VWD and I had not been informed of instances of commercial factor concentrates used for patients attending the Dundee Centre prior to my arrival in 1992.

32. At the same meeting, you stated that "different products presented different risks and benefits and that the procedures and clinical staffing levels at the five Centres would have varied. The procedures followed now would be much more detailed because of the present state of knowledge". Please explain what you meant by this, including what impact of the staffing arrangements in the Dundee Centre had on the products that were used and the information that was provided to patients.

32.1 It is challenging to think back to a meeting that took place over 20 years ago and comment with certainty on a quote from the minutes, without the context of the detailed discussions that would have taken place. However, the comments in relation to the risks and benefits of different products would almost certainly be a reference to the different forms of heat treatment to inactivate viruses in factor concentrates – pasteurisation vs terminal dry heat treatment and the different temperatures and durations of heat treatment.

32.2 The comment about clinical staffing levels and procedures across the five centres most probably related to the evolution of standardised approaches to Haemophilia care across Scotland and the evolution of scientific understanding and knowledge of factor concentrate safety from the 1980s.

32.3 The period in question was prior to the formal establishment of the Dundee Centre after my appointment in 1992, so there were no designated Haemophilia Centre staff.

Response to risk

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

33.1 In establishing comprehensive care in Tayside, June Ward and I set up regular clinical review for all patients registered at the Haemophilia Centre. A routine component of the clinical review process was discussion of their individual HCV and HBV status and contemporary developments in knowledge of the viral infections and treatment. We provided patients with information booklets produced by the Haemophilia Society and the Liver Trust. For patients with ongoing HCV infection, we established shared clinical reviews with Dr John Dillon, a Gastroenterologist with a specialist interest in liver disorders to ensure that patients had access to expert advice and the most appropriate therapy.

34. Please consider HSOC0012064. Did you prepare a medical report in relation to this individual? If so, please state who that person was and if available, please provide a copy of the report. Did you respond to the author of this letter or to Dr Ludlam about the issues raised and, if so, what was your response?

34.1 I am unable to remember details of the patient concerned, and/or whether I prepared a medical report. If there are any further documents or information the Inquiry can share with me that might provide further information, I will try to answer this question.

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

35.1 I do not have in depth knowledge of and had no personal involvement in the sequence of events and/or the decision making process involved in incorporating viral inactivation steps in the manufacture and licensing requirements of factor concentrates in the early 1980s. Furthermore, the development of heat treated concentrates was an evolving process rather than a single, defined event as different forms of heat treatment were evaluated.

35.2 I cannot, therefore, comment with authority on whether heat treated products should have been introduced earlier.

35.3 Nonetheless it may be of value to the Inquiry for me to share my recollections of the issues as discussed between Haematology trainers and trainees and between trainees at the clinical 'coalface' in the 1980s and my understanding of the issues relating to factor concentrate safety and the evolving scientific evidence:

i. As a Haematology Registrar and Senior Registrar in the 1980s, I was aware of the evidence of probable transmission of AIDS and hepatitis by infectious agents in factor concentrates and the identification of the HTLV III (HIV) virus as the causative agent of AIDS. I was also aware, from discussions with my trainers and other trainees and reading the medical literature of the debate and scientific investigation into how to inactivate viruses in factor concentrates without adversely affecting the clotting factor activity and supply of the product.

ii. One major concern in the early stages was the effect of heat treatment on the factor VIII and IX molecules in the concentrate. In particular, would the heat treatment denature or modify the Factor VIII or IX molecule in a way that would induce inhibitor (Factor VIII or IX antibodies) formation in treated patients. This would result in a major clinical problem with affected patients potentially unable to receive effective treatment for bleeding problems or prophylaxis for invasive procedures.

iii. Pasteurisation was generally considered to be less likely to cause protein denaturation than dry heat treatment but is, I understand, a more complicated process and has the disadvantage that the whole batch has to be pasteurised and then transferred to vial and freeze dried. There is, therefore, an increased risk of batch contamination by bacteria compared to dry heat treatment where the final vial of freeze dried concentrate is heat treated which will inactivate contaminating bacteria as well as blood borne viruses.

iv. With respect to dry heat treatment, there was ongoing debate in the 1980s about the optimal temperature and duration of dry heat treatment. This included taking into account the competing priorities and potential safety issues of viral inactivation, protein denaturation and the potential supply issues for a limited biological product given the reduction in total yield of factor VIII and IX units with all forms of heat treatment.

36. Do you consider that the steps taken at Cardiff and/or the Dundee Centre in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

36.1 Cardiff – I do not have knowledge of the steps taken in the Cardiff Centre in response to the evolving knowledge of blood borne viral infections and viral inactivation of factor concentrates throughout the 1980s.

36.2 Dundee – I do not have knowledge of the decisions taken in Dundee in the 1980s prior to my appointment as a consultant. I am aware of the general approach within Scotland of aiming for self-sufficiency in factor concentrates produced by SNBTS from voluntary Scottish donors and the introduction of dry heat treatment to inactivate blood borne viruses. However, I do not have detailed knowledge of evidence available to decision makers nor the option appraisals and risk assessments undertaken to comment on what different actions might have produced better outcomes. I can comment on the decisions taken through the Scotland and NI Haemophilia Directors Group and the Coagulation Factor Working Party from 1993. I consider the actions to improve the safety of factor concentrate therapy with the development of solvent/detergent treated high purity factor concentrates, the introduction of double viral inactivation into the manufacturing process, and the introduction of recombinant factor concentrate therapy

were pursued with safety and efficacy as the major objectives and were carried out with rigour and as expeditiously as scientific evidence and financial governance permitted. In addition, the response to the potential risk of vCJD transmission by factor concentrates in the late 1990s with the prompt decisions to withdraw UK plasma from concentrate manufacture, was also appropriate.

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

37.1 Cardiff – I do not have knowledge of the decisions and actions taken in the Cardiff Haemophilia Centre in response to the evolving evidence of transmission of blood borne viruses by factor concentrates prior to my arrival as a Haematology Senior Registrar in 1988.

37.2 As detailed in my answer to question 36, I do not have detailed knowledge of the decisions taken in Dundee and Scotland in the 1980s to comment.

38. 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?

38.1 I do not have sufficient in depth knowledge of the decisions and policy generation in relation to factor concentrate safety in the 1980s to make an informed comment on the decisions that were made at regional or national levels nor what could have been done differently given the rapidly evolving knowledge and evidence base.

38.2 As detailed in my answer to question 36, I do not have detailed knowledge of the decisions taken in Scotland or across the UK in the 1980s to comment.

Section 4: Treatment of patients

Provision of information to patients

39. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at (a) Cardiff and (b) the Dundee

Centre about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

39.1 a. Cardiff – From memory, information about factor concentrates and infection risk was discussed with patients by Haemophilia Centre staff and relevant information leaflets provided. Any change in factor concentrate product would be discussed with the patient but the majority of all the patients I saw for clinical consultations had been on factor concentrate treatment for a number of years. I do not know what information was shared with them (or their parents) at the time of first treatment. I was not involved in initiating factor concentrate therapy in a previously untreated patient during my 3 ½ years in Cardiff. All the patients with Haemophilia that I saw at the Haemophilia Centre already had an established treatment plan including their current product.

39.2 b. Dundee - As detailed in my answer to question 33, patients attending Dundee from 1992, were informed about the risks of infection through regular clinical review. As the Haemophilia service developed, there was also information from relevant specialist services (such as Hepatology) and through distributing standardised patient information leaflets. From memory, I do not think there were any previously untreated patients (PUPs) with Haemophilia in whom I initiated factor concentrate therapy. It is likely that some patients with VWD will have been treated with Haemate P for the first time but I cannot remember specific cases. I would have discussed the treatment options of DDAVP, cryoprecipitate, SNBTS intermediate purity factor VIII (Z8) and Haemate P (when Z8 was withdrawn) as outlined in my answer to question 16 in order to agree on a therapeutic intervention.

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

40.1 Cardiff – I am not aware of the information provided to patients about alternatives to factor concentrate therapy prior to my arrival as a Haematology Senior registrar in Cardiff in 1988. For patients with mild Haemophilia A or VWD requiring treatment for a bleeding problem or prophylactic cover for an invasive procedure, there would be a discussion between Haemophilia Centre staff and the patient about the options and

merits of DDAVP, cryoprecipitate and Factor VIII concentrate as detailed in my answers to questions 16 and 17.

40.2 Dundee – I do not know what information was provided to patients with mild Haemophilia A and VWD about the treatment options of DDAVP, cryoprecipitate or factor concentrate therapy prior to 1992. From 1992 onwards, I would discuss the treatment options with individual patients as outlined in my answer to question 16.

NANB Hepatitis/Hepatitis C

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

41.1 Cardiff – I am not aware of the processes for informing patients of NANB infection prior to my arrival as a Haematology Senior registrar in 1988. From memory, there were no new cases of NANB/HCV infection from blood products in the Haemophilia Centre during my time in Cardiff. As I described in my answer to question 27, I was in Cardiff when the HCV virus was first identified and a commercial HCV antibody test was available. I was, however, undertaking a research fellowship at that time and had no knowledge or involvement in when and how patients in the Haemophilia Centre were tested and counselled.

42. In your evidence to the Penrose Inquiry, you stated that when you arrived at the Dundee Centre, you were given a list of patients who had HCV based on frozen serum samples [PRSE0003777]. Please describe:

a. How you came to be given this list of patients;

b. Your understanding of the testing process that had been undertaken;

c. Your understanding in relation to the consent of the patients to this testing;

d. The steps you took after receiving the list of patients to inform them that testing had been undertaken; and

e. The steps you took after receiving the list of patients to inform them that they had HCV, including how, when and by whom were patients informed of their diagnosis of HCV? Were they told in person, by letter or by phone? What involvement did you have in this process?

42.1 **a.** In 1992, I undertook a review of Haemophilia care in the department at the request of Professor Pippard. Dr Heppleston was, at that time, the named consultant for all patients with inherited bleeding disorders. He provided me with a box of file cards containing the name and details of all patients with inherited bleeding disorders who had attended and/or been registered with the department. Dr Heppleston also had a list of around 30 of these patients, whose stored serum had been tested for HCV antigen when the first test was introduced in 1991. From memory, around 25 of these patients had tested positive.

42.2 **b.** Stored sera from patients with inherited bleeding disorders who had attended the department were analysed for HCV antigen with a commercial immunoassay kit.

42.3 **c.** Following discussion with Dr Heppleston and Dr Urqhuart (consultant virologist in the Ninewells Department), I concluded that the samples had been analysed without any patient's consent. I do not know whether the patients had consented to having their serum samples stored.

42.4 **d.** Appointments were arranged for all the patients to meet with me (and from 1995 June Ward and myself) to undertake a full review of their bleeding disorder and management. Counselling for blood borne virus infections and treatment risks were a part of this process. For each of the patients who had been tested for HCV, I explained what had happened and requested their consent to repeat HCV testing on a fresh blood sample.

42.5 **e.** Following a confirmatory HCV test, I met all the patients (and partners if appropriate) to explain the diagnosis and implications. From 1995, most consultations were undertaken by myself and June Ward, Haemophilia specialist nurse.

43. In relation to other patients who were not on the list that you described to the Penrose Inquiry, when did you begin testing patients for HCV? How, when and by whom were patients informed of their diagnosis of HCV? Were they told in person, by letter or by phone? What involvement did you have in this process?

43.1 From 1992, I started to review all patients (who could be traced) from Dr Heppleston's records (from memory, around 120) for clinical review in the Haematology Day Unit. Patients with the most severe bleeding disorders and most recent attendances in the

department were prioritised. All patients who had received blood products were asked for their consent to test HCV, HBV and HIV status and would be given a follow up appointment for me to give them their results in person.

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

44.1 As mentioned in my answers to questions 33 and 39, information on HCV infection, assessment of each patient's liver function and the treatment options was provided through clinical consultation with myself and June Ward, specialist advice and consultation from Dr John Dillon, and relevant Haemophilia Society and Liver Trust patient information leaflets.

45. How many patients at the Dundee Centre were infected with HCV?

45.1 From memory, there were around 25 patients with HCV infection attending the Haemophilia Centre in Dundee.

Delay/public health/other information

46. Were the results of testing for HIV and hepatitis (of all kinds) notified to patients promptly at the hospitals at which you worked, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

46.1 Cardiff – From memory, there were no new cases of HIV or viral hepatitis infection from blood products in the Haemophilia Centre during my time in Cardiff

46.2 Dundee - There were significant delays between the anonymous testing of stored sera (in 1991 I believe) and informing patients at clinical review from 1992 onwards as described in my answers to 42 above. From 1992 onwards, patients were seen as soon as possible to discuss test results.

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

47.1 In both Cardiff and Dundee, information about the public health implications was provided with an emphasis on the implications for the patient and their families and friends.

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

48.1 Cardiff – I am not aware of additional infection risks from factor concentrate therapy that arose during my 3 ½ years in Cardiff.

48.2 Dundee – I do not know what information was shared with patients in Dundee in the 1980s prior to my appointment. From the mid-1990s, we provided patients with information on the concerns of Parvovirus and nvCJD transmission by blood products and the actions required to mitigate the risk.

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

49.1 Cardiff – Patients and their partners were informed about the risks of sexual transmission of HIV and viral hepatitis and partners offered counselling and screening.

49.2 Dundee – patients and their partners were informed about the risks of sexual transmission and partners offered counselling and screening.

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

50.1 Cardiff and Dundee - Patients attending the Haemophilia service who had been infected with HIV and/or viral hepatitis through factor concentrate or cryoprecipitate therapy were counselled about the risks of sexual transmission and partners offered counselling and screening.

50.2 Patients potentially exposed to HIV and/or viral hepatitis through blood or blood component transfusion, were traced and managed through national Blood Transfusion Service systems.

51. At the Scotland and Northern Ireland Haemophilia Directors Group meeting on 28 January 2000, it was agreed that all centres would provide the Deputy Chief Medical Officer information about patients who had HCV and had likely been infected in the window of 1 September 1985 to 30 June 1987 as part of the HCV lookback exercise [GGCL000125]. What, if anything, did you tell your patients about this request? Was consent obtained to collate the data? How and when were patients informed of the lookback exercise and whether or not they may be infected? What actions did you take in relation to patients that were identified as having likely been infected in the relevant window but who were no longer treated at the Dundee Centre (in this regard, [GGCL000120_001] may be of assistance)?

51.1 From memory, no consent was obtained from patients about collating the data presented at this meeting. This would be on the basis that the data was already held by each Haemophilia Centre and the collated data would be anonymised. Furthermore, all patients with inherited bleeding disorders attending Haemophilia Centres, would already have been tested and, where positive, diagnosed with HCV. My understanding was that the purpose was not to identify undiagnosed cases but to identify patients who were infected by blood products during the years when heat treatment for factor concentrates was introduced and heating times and temperatures modified. I cannot remember any patients who were transfused factor concentrate or cryoprecipitate in Dundee during this period who were lost to follow up. From memory, there was a system in place to cross-check whether a patient was attending another UK Haemophilia Centre.

Consent

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

52.1 Cardiff – Blood samples were taken at routine 4-6 monthly clinical reviews as described in my answers to question 29. Patients were told about the clinical purpose in monitoring abnormal liver function tests (to analyse trends and potentially instigate further investigations) and the importance of intermittent checks for factor VIII or IX

inhibitors. Verbal consent for taking the blood samples would be obtained at the time of blood sampling. I do not know if written consent was obtained initially or whether consent was recorded. There may also have been blood samples taken from patients participating in clinical trials but I had no involvement in these.

52.2 Dundee – As described in my answer to question 29, samples were taken for liver function tests, alpha-fetoprotein, full blood count, coagulation factor and inhibitor assays and virology at 4-6 monthly intervals. These were standard/best practice tests for monitoring Haemophilia and the complications of blood borne viral infections. Verbal consent would have been obtained for the blood sampling at each clinic visit but not routinely recorded. From memory, it would not have been routine at that time to ask separate consent for storing serum samples. However, for samples required as part of SNBTS clinical trials of new or modified factor concentrates, separate written consent and explanation of the analyses to be performed would be obtained and recorded as per the trial protocols.

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

53.1 Cardiff – From memory, I did not encounter any circumstances in Cardiff where treatment with blood products occurred without patient consent. From memory, all the patients that I was personally involved in managing were already on a named blood product of choice and I would follow this when treating them in emergency situations or in the Haemophilia Centre. The initial consent process would have occurred prior to my time in Cardiff.

53.2 Dundee – From memory, there were no circumstances when I would not have obtained informed consent from patients when treating them with blood products during my consultant career in Dundee. (The only exception to this (for almost all doctors during our early training years) would be in the immediate resuscitation of patients with acute gastrointestinal bleeding or severe trauma where immediate blood transfusion is a life-saving intervention and the patient may not be conscious or able to have a discussion to obtain informed consent). My approach to obtaining informed consent for factor concentrate or blood product therapy was to explain the need for treatment to deal with a bleeding problem or cover an invasive procedure and explain the alternative

treatment options (where there were options) and the advantages and disadvantages of each and then make a recommendation and make a shared decision with the patient how to proceed. The treatment given would be recorded in their clinical records. Where a patient was being treated with a blood product for the first time (for instance Haemate P for a patient with VWD), the discussion with the patient and their consent would be recorded in their clinical records but not generally with a patient signature. For SNBTS clinical trials of new or modified factor concentrates, written consent would be obtained and recorded as per the trial protocol.

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

54.1 Cardiff – I was not aware of any patients attending the Cardiff Haemophilia Centre who were tested for HIV or viral hepatitis without their consent although the large majority of patients I was involved in would have been first tested before I arrived in Cardiff.

54.2 Dundee – As described in my answer to question 42, there was a cohort of around 30 patients attending the department whose stored sera were tested for HCV antigen when the new commercial assay was available in 1991. From my appointment in 1992, there were no other instances, that I am aware of, where patients were tested for HIV or blood borne viral hepatitis without their verbal consent. When seeing a new patient and/or testing for HIV, HCV and HBV for the first time, the explanation and the verbal consent of the patient would be recorded in their clinical records. Patients who were attending for routine follow up as described in my answer to question 52 would give their verbal consent for the repeat investigations but this would not generally be recorded.

PUPS

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

55.1 Cardiff – From memory, I was not personally involved in managing any previously untreated patients during my 3 ½ years in Cardiff.

55.2 Dundee – From memory, I did not manage any new cases of severe Haemophilia with factor concentrate during my time as Haemophilia Director in Dundee. It is likely that some new cases of VWD were treated for the first time under my care and that some previously diagnosed patients had their first dose of factor concentrate under my care but I cannot remember specific patients or instances.

56. Please consider item 4 in the minutes of the Annual Haemophilia / SNBTS Directors / SOHID meeting of 30 April 1993 [LOTH0000051_052]. Were you involved in any PUPS study? Were any of the Dundee Centre's patients recruited to the studies referred to here? If so, please detail your involvement in the study or in recruiting Dundee Centre patients to the study.

56.1 From memory, there was an SNBTS PUPs study and I would almost certainly have obtained ethical approval to enter patients into the trial but I cannot remember the details of the trial and cannot remember any new patients who were entered from the Dundee Centre.

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

57. How was the care and treatment of patients with HIV/AIDS managed at (a) Cardiff and (b) the Dundee Centre? In particular:
a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years to those infected with HIV?
c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

57.1 **a.** Cardiff – from memory, I was not involved in the care of any new HIV cases diagnosed in the Cardiff Haemophilia Centre during my time there as a senior registrar. Patients attending the Centre who had HIV/AIDS were being managed in respect of their HIV infection by the regional HIV service. I do not have knowledge of process of referral, the treatment options or the discussion and information provided for individual patients.

57.2 **b.** Dundee - In 1992, there were no Haemophilia patients with HIV infection registered with or attending the department in Dundee. (This is likely to have been a benefit of the all Scotland policy of aiming for self-sufficiency in factor concentrate treatment from voluntary Scottish donors and the Scotland and NI Haemophilia Directors' decision to maintain the supply of SNBT products to Dundee, Aberdeen and Inverness in times of shortage with Edinburgh and Glasgow purchasing commercial concentrate to cover any shortfall). At some time during my time as Haemophilia Director, we did care for a patient with Haemophilia who had HIV infection. The patient had been diagnosed and HIV treatment initiated at another centre, so was already established on anti-viral treatment. From memory, he attended our local HIV clinic while in Tayside.

58. How was the care and treatment of patients with HBV managed? In particular:
a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HBV?

58.1 **a.** Cardiff – from memory, I was not involved in the care of any patients attending the Cardiff Haemophilia Centre who had chronic Hepatitis B infection. When I arrived in Cardiff in 1988, most patients would be immune to hepatitis B through exposure to the virus through blood products or vaccination. From memory, patients with chronic hepatitis B infection would have been offered interferon therapy but I do not remember specific patients.

58.2 **b.** Dundee – From memory, there were no patients with chronic hepatitis B infection attending the Dundee Centre while I was Haemophilia Director. Testing for HBV antigen and antibody was part of the routine clinical screening as described in my answers to questions 29 and 52 with HBV vaccination offered to all patients who did not have natural immunity.

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

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

b. What treatment options were offered over the years?

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

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

59.1 **a.** Cardiff – All patients with evidence of ongoing hepatitis (presumed to be NANB) were followed up by Haemophilia Centre staff. I was not aware of the formal involvement of liver specialists in their care but I would not necessarily know what conversations Professor Bloom was having with local experts. There were no treatment options for NANB hepatitis in the 1980s. Interferon for HCV infection was not introduced until the mid 1990s after I had left Cardiff.

60. How was the care and treatment of patients with HCV managed at the Dundee Centre? In particular:

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

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

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

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

60.1 **a.** As described in my answers to questions 33 and 44, all patients attending the Centre from 1992 were tested for HCV status and those with active infection were counselled by myself and June Ward and referred to Dr John Dillon, consultant gastroenterologist. Dr Dillon made arrangements to see the patients in the Haemophilia Centre

60.2 **b.** From memory, Interferon therapy was offered from the mid to late 1990s as the evidence evolved and protocols reported and developed. Dr Dillon would be see and advise all patients on the treatment options, potential benefits and side effects. The HCV treatment was then managed and monitored in the Haemophilia Centre with regular follow up and monitoring as described in my answer to question 29.

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

61.1 Cardiff – as detailed in my answer to question 20, children with Haemophilia were managed primarily by the Paediatric service with input from the Haemophilia Centre in respect of the bleeding disorder. Involvement of Haematology trainees in their routine care was minimal and I do not know the details of HIV or hepatitis management.

61.2 Dundee – All the paediatric patients were seen and managed primarily by the Paediatric service. There were specific Haemophilia Paediatric clinics which June Ward and I would routinely attend to develop shared care with the Paediatricians. From memory, there were no children with HIV infection attending the clinics but some of the older children (who transferred to the adult service during my time as Haemophilia Director) did have HCV infection. Other than the involvement of parents in obtaining informed consent for minors, there were no differences in approach to the management of HCV infection that I can recall.

62. What if any involvement did you and/or colleagues at Cardiff and/or the Dundee Centre have with any clinical trials in relation to treatments for HIV and HCV?

62.1 Cardiff – Clinical trial involvement was managed by the permanent Haemophilia Centre staff in collaboration with relevant specialist services. As a Haematology Senior Registrar I had minimal involvement and cannot remember details of any clinical trial participation during my time in Cardiff

62.2 Dundee – From memory, we were not involved in any clinical trials for HIV or HCV treatment.

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

63.1 Cardiff – I cannot remember specific details of the counselling, psychological and social work support provided through the Haemophilia Centre or specialist services in Cardiff.

63.2 Dundee – Counselling support for patients with HCV attending the Dundee Centre from 1995, was primarily provided by June Ward, myself and John Dillon. The HIV service did have specialist counsellors although, as previously mentioned, there were no Haemophilia patients with HIV infection when I was establishing the service. The haematology department had access to social work support and we would refer individual patients to the social work department when appropriate but there was no specific service for the Haemophilia Centre.

64. Did any of the centres at which you worked receive funding from the government or from any other source to help with the counselling of patients infected with HIV?

64.1 Cardiff – I do not know the funding arrangements for HIV counselling services in Cardiff.

64.2 Dundee – the HIV service in Tayside had specialist counsellors but I do not know about their funding arrangements.

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

65.1 Cardiff - From memory, I was not aware of funding problems for HIV treatment for patients with Haemophilia during my time in Cardiff.

65.2 Dundee – From memory, there were no major difficulties in obtaining funding for interferon and/or ribaviron for our patients with HCV. Scientific publications on the efficiency of new treatments do generally precede licensing and funding arrangements and I do remember having to make individual requests for interferon for named patients in the early days. From memory, such requests had to be approved by the liver specialty consultants, which was not a problem as Dr Dillon would have already seen the patient and recommended treatment.

High Purity products

66. Please set out your involvement in the debate about the need for and/or use of high purity products for HIV positive patients.

66.1 In the early 1990s, there was some evidence to suggest that intermediate purity factor VIII concentrate had some negative impact on immune function in HIV positive patients. I can remember discussion on this topic in the Scotland and NI Haemophilia Directors Group and agreeing that it would be sensible to use high purity Factor VIII for such patients but my personal involvement in this issues was marginal.

Recombinant

67. Please provide (to the extent that you are able to from your own knowledge) a chronological account of the introduction of recombinant products in Scotland, and insofar as your knowledge extends to it, the rest of the UK.

67.1 The first recombinant Factor VIII product was licensed in the UK in 1994. From memory, the Haemophilia Directors in Scotland agreed that recombinant factor VIII should be the treatment of choice, certainly for previously untreated patients, and submitted a case for funding and a national approach across all Health Boards and Haemophilia Centres in Scotland around 1994.

67.2 From memory and from information in the papers sent by the IBI with this Rule 9 request, the Scottish Executive agreed to national funding for priority patients in 1998 to be overseen by a National Consortium that would be responsible for purchasing recombinant products, audit and financial governance. The Haemophilia Directors of Scotland were responsible for assigning patients to the clinically defined priority groups and collecting the relevant clinical data on factor concentrate usage. We attended the National Consortium meetings and gave advice on the different recombinant products on the market but were not responsible for the final decisions, negotiation with the commercial companies or the funding arrangements.

67.3 From memory, all patients with Haemophilia in Scotland were treated with recombinant factor VIII or IX from around 2002.

67.4 I do not have detailed knowledge of the timeline or funding arrangements for the introduction of recombinant factor concentrates in the rest of the UK.

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

68.1 As a Haemophilia Director and member of the Scotland and NI Haemophilia Directors group, I shared collective responsibility with the other Haemophilia Directors for submitting the case for funding to the Scottish Executive and for developing the clinical prioritising criteria for patients to receive recombinant factor VIII or IX.

68.2 I coordinated the collection of data required to utilise the available budget for priority patients by collating factor concentrate usage data from each of the Scottish Haemophilia Centres.

68.3 The main barrier to the use of recombinant factor concentrates was financial given that the recombinant concentrates were more expensive that plasma derived equivalents and health care planners rightly needed to be convinced about the added value of the increase in cost, given that plasma derived products in the late 1990s had an excellent safety profile.

68.4 Bridging the funding gap (between plasma derived and recombinant concentrate) in Scotland was complicated because Haemophilia Centres did not have a pre-existing budget for plasma derived products. Funding was top-sliced from Health Board budgets in order to centrally fund SNBTS to manufacture plasma derived concentrates in the Protein Fractionation Centre.

68.5 It is likely that the nvCJD crisis and the potential risk of transmission by blood transfusion was a significant catalyst in the decision to phase out plasma derived factor concentrates in favour of recombinant concentrates.

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

69.1 When recombinant factor VIII was licensed in 1994, the consensus amongst the Scottish Haemophilia Directors was that it should be the product of choice for patients with Haemophilia A, particularly for previously untreated patients, so the simple answer to the question is that all patients should have been offered recombinant therapy (subject to availability). There are, however, many competing priorities for limited NHS

funding and it entirely appropriate that due process including detailed option appraisal and cost benefit analyses, was conducted to inform NHS policy makers and funding decisions. As a Haemophilia Director, I wanted the best available treatment for our patients as soon as possible but I also wanted the best available treatment for my patients with leukaemia and lymphoma. Clinicians have to make the most cogent, evidence based case for therapeutic improvement but also have to accept that there are finite limits to NHS funding.

70. When were recombinant products available to patients (and which categories of patients) treated at the Dundee Centre? You may be assisted by consideration of [SBTS0000344_056], [GGCL000122_003], [GGCL000115_001], [GGCL000116_001], and [LOTH0000089_006].

70.1 a. From memory and from reviewing the papers sent by the IBI with the rule 9 request, Haemophilia Directors made a case to the Scottish Executive for funding for recombinant Factor VIII from around 1994. A national contract managed by the National Services Division was introduced in 1996 with recombinant Factor VIII funded for priority patient groups (for instance previously untreated patients, HIV, HCV and/or parvovirus negative, patients, children under the age of 15). I cannot remember which groups of priority patients were included for recombinant Factor VIII treatment in that first year nor how many of them attended the Dundee Centre.

70.2 b. A National Purchasing Consortium was formally established in 1997 to oversee the process as described in my answer to question 67.

70.3 c. Over the next 4 years or so, patients with Haemophilia were gradually transferred from plasma derived to recombinant Factor VIII or IX according to the agreed clinical prioritisation process until all patients were being treated with recombinant Factor VIII or IX by 2002. I cannot remember details of the numbers of patients attending the Dundee Centre transferring to recombinant Factor concentrate on a year by year basis.

70.4 d. From memory, there were 1 or 2 patients who were funded for recombinant Factor concentrate by NHS Tayside ahead of this national timetable. From memory, this was on the basis of the individuals concerned refusing to take plasma derived concentrates (because of concerns of vCJD transmission by blood products) and my

writing to the Health Board to explain the patients' request for recombinant Factor concentrate therapy and the consequences of them otherwise refusing treatment.

Research

71. Please list all research studies that you were involved with during you time at Cardiff and Dundee. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please:

a. Describe the purpose of the research.

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

c. Explain what your involvement was.

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

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

f. State the number of patients involved.

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

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

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

71.1 **a.** Cardiff – Clinical trials and research studies were organised by the permanent staff in the Haemophilia Centre with minimal involvement from Haematology trainees. I cannot remember details of the trials ongoing during my time in Cardiff.

71.2 **b.** Dundee – There were a series of national clinical trials of SNBTS factor concentrate products that were collaborations between SNBTS and the Haemophilia Directors, developed through the Coagulation Factor Woking Party.

71.3 **c.** From memory, I participated in national clinical trials of high purity solvent/detergent inactivated Factor VIII (subsequently licensed as Liberate) and high purity solvent/detergent and heat treated Factor IX (HIPIX). In order to meet licensing requirements, each trial consisted of initial pharmacokinetic studies on small numbers of patients followed by therapeutic trials in which the as yet unlicensed product was used to treat consenting patients under a clinical trials exemption certificate.

71.4 **d.** These national clinical trials were an important part of the Scotland wide policy of aiming for self-sufficiency in the production of plasma derived factor concentrates from volunteer Scottish blood donors. Given the finite resource of donated blood, SNBTS had to maintain manufacturing capacity for the licensed intermediate purity Factor VIII (Z8) and IX (DEFIX) concentrates as well as the unlicensed high purity trial Factor VIII and IX concentrates to ensure patients who did not participate in the trials would have continued access to their current licensed product. Funding for the development of the new product was included in the SNBTS central funding for factor concentrate production.

71.5 **e.** My personal involvement including contributing to the debate and trial design within the Scotland and NI Haemophilia Directors group and the Coagulation Factor Working Party; to obtain local ethical approval through the NHS Tayside Ethics Committee; to offer trial participation to eligible patients attending the Dundee Centre and to ensure the trial conditions were followed for those patients who chose to participate.

71.6 **f.** From memory, most of the patients with severe Haemophilia A or B chose to participate in the relevant therapeutic trial of high purity concentrate. That would be likely to be between 20 and 30 patients in total.

71.7 **g.** Patients had detailed explanations of the trial from myself and were given the trial patient information sheets to take and consider and/or discuss with their families. If they chose to participate in the trial, informed consent would be recorded in the trial documentation.

71.8 **h.** I was not directly involved in any SNBTS therapeutic trial publications and cannot remember details of publications.

71.9 I was not involved in any relevant epidemiological studies.

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

72.1 Cardiff – I do not have knowledge of clinical trial arrangements during my time in Cardiff.

72.2 Dundee – to my knowledge, no patients attending the Dundee Centre after 1992 were involved or registered in clinical research studies without their consent.

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

73.1 Cardiff – I do not have knowledge of data management during my time in Cardiff.

73.2 Dundee – Anonymised and collated data on total factor VIII and IX usage was shared on a regular basis with SNBTS and the Scottish Executive for the purpose of predicting and planning factor concentrate production on a year by year basis. Once recombinant factor concentrates started to be used from 1996, anonymised and collated data on factor concentrate usage was shared with the National Purchasing Consortium (membership of which included Scottish Executive Health Directorate, National Services Division and SNBTS) in order to predict the categories and numbers of patients who could switch from plasma derived to recombinant treatment and for audit and funding purposes.

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

74.1 Cardiff – I do not have knowledge of whether data was shared with third parties during my time in Cardiff.

74.2 As described in my answer to question 73, anonymised and collated data on factor concentrate usage was shared with the National Purchasing Consortium, SNBTS and the Scottish Executive Health Directorate.

75. Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference, including your work in 1998 with Dr Dow on Human Parvovirus and Haemophilia.

75.1 With the introduction of high purity SNBTS Factor VIII through a clinical trial in 1992, the viral inactivation step was changed from dry heat treatment (for intermediate purity Z8) to solvent/detergent treatment. As detailed in my answer to question 22,

solvent/detergent treatment is effective at eliminating lipid enveloped viruses (such as HIV, HCV and HBV) but concerns began to emerge about non-lipid enveloped viruses such as HAV and Parvovirus B 19. In view of reports of HAV transmission by solvent/detergent inactivated high purity Factor VII in the medical literature, steps were taken to add dry heat treatment as a second viral inactivation process in the manufacturing process.

75.2 Parvovirus B19 has the potential to cause severe ill health in a minority of patients and the study referred to was a collaboration between SNBTS and Scottish Haemophilia Directors to look at the percentage of susceptible patients amongst patients with Haemophilia in Scotland. I do not remember the detailed findings of this study but patients susceptible to Parvovirus B19 infection (i.e. no natural antibodies) were included as priority patients for recombinant factor concentrate therapy through the National Consortium contract.

Records

76. What was the policy at (a) Cardiff and (b) the Dundee Centre as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?

76.1 Cardiff – I am not aware of any specific policy regarding death certification for patients with HIV or hepatitis during my time in Cardiff.

76.2 Dundee – there was no Haemophilia Centre policy regarding death certification. From memory, there were no deaths of HCV positive patients attending the Dundee Centre while I was the Director but we would have followed normal practice in terms of accurately recording the cause of death and any contributing conditions.

77. What were the retention policies of (a) Cardiff and (b) the Dundee Centre in relation to medical records during the time you were practising there?

77.1 Cardiff – I do not have any knowledge of the policies regarding medical records retention during my time in Cardiff.

77.2 Dundee – medical records were managed on a regional basis by NHS Tayside. As far as I am aware, the policies were in accordance with NHS Scotland and legal requirements.

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

78.1 The Haemophilia Centre in Dundee utilised the hospital medical records. I did not maintain separate files for any of the patients.

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

79.1 I did not keep any records or data about any of the patients attending the Dundee Centre at home and only used the official hospital medical records.

Section 5: Scottish National Blood Transfusion Service

80. Please consider [SBTS0000429_008]. Please set out the work you were involved in as a Visiting Research Worker at the SNBTS in 1987 insofar as relevant to the Inquiry's Terms of Reference.

80.1 From October 1985 to May 1988, I took time out of Haematology training to undertake an MD thesis based in the Department of Pathology at Edinburgh University. The topic of my research was immunotherapy of lymphoproliferative disorders. As part of this research, I had to purify tumour specific immunoglobulin from cell culture. My supervisor put me in contact with Dr Pepper at the SNBTS lab as a local expert in protein purification. Dr Pepper provided me with both the expert advice and use of the lab's chromatography equipment in order to complete this work. I was therefore registered as a visiting researcher but not involved in any of Dr Pepper's work in relation to coagulation factors or Haemophilia.

81. Please set out the interactions and dealings you had in relation to SNBTS as the director of the Dundee Centre, insofar as relevant to the Inquiry's Terms of Reference. (If you had relevant dealings and interactions with any other national

or regional blood service within the UK, please also provide information about those and answer the questions set out below in relation to other national or regional blood services as well as SNBTS).

81.1 As Haemophilia Director and Haematologist in charge of coagulation laboratory services in NHS Tayside, I had a close working relationship with the Director and staff of the regional SNBTS service based in Ninewells Hospital. In relation to the Haemophilia Centre, my relationship centred around factor concentrate stocks and usage, individual patient usage, and keeping SNBTS informed of any changes in factor concentrate usage including increased requirements to cover elective orthopaedic surgery, for instance.

81.2 As a member of the Coagulation Factor Working Party, I met regularly with senior SNBTS staff involved with factor concentrate production from Scottish donor plasma at the Protein Fractionation Centre in Edinburgh.

81.3 From 1997, the National Purchasing Consortium (for recombinant factor concentrates) included representation from the Haemophilia Directors, SNBTS, the National Services Division and the Scottish Executive.

82. What 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 SNBTS in relation to this?

82.1 I have no personal knowledge of strategic decisions taken in NHS Scotland in relation to cryoprecipitate production or the development of virally inactivated factor concentrate prior to 1992. From 1993 and my involvement as a Haemophilia Director, modifications in factor concentrates to reduce the potential of viral transmission (e.g. the evolution of high purity concentrates, double viral inactivation processes and the role of recombinant factor concentrates) were frequent agenda items in the Coagulation Factor Working Party and the Scotland and NI Haemophilia Directors' meetings. Cryoprecipitate was easily available through SNBTS but the safety profile of virally inactivated factor concentrates was excellent and there was no evidence or desire from Haemophilia Directors in Scotland to increase cryoprecipitate use.

82.2 Any discussions about increasing the production of cryoprecipitate as the evidence of infection risk with factor concentrates evolved in the 1970s and 80s, would have been before I took up my consultant post in 1992.

83. What discussions or meetings or interactions did you have with SNBTS in relation to:
a. the risk of infection with hepatitis from blood products;
b. the steps to be taken to reduce the risk of infection?

83.1 a. As detailed in my answer to question 81, the Coagulation Factor Working Party was the formal and official forum where the Haemophilia Directors meet with senior staff from SNBTS and the Scottish Executive to discuss all aspects of factor concentrate use in NHS Scotland. Infection risk and how to reduce it, were regular minuted agenda items.

83.2 b. I cannot comment on the sequence and timing of the steps taken to reduce infection risk prior to my appointment as a consultant in 1992. As detailed in my answer to question 81, steps taken to reduce infection risk during the time included the development of solvent/detergent treated high purity Factors VIII and IX, the addition of dry heat treatment as a second viral inactivation step and the introduction of recombinant factor concentrate treatment.

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

84.1 During my time as Haemophilia Director, collective decisions in NHS Scotland were made primarily though collective decisions at the Coagulation Factor Working Party.

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

85.1 In 1992, when I started as a consultant in NHS Tayside, the Haematology Department did not keep any records of factor concentrate stocks, batch numbers, issues to patients or home treatment use. Details of factor concentrates given in Ninewells Hospital were inconsistently recorded in the relevant patient's medical records. This situation was in part due to the underdeveloped Haemophilia service as described in my answer to question 8. Secondly, there was the unusual circumstance of a regional

SNBTS service (situated in the main hospital) and providing services of both a regional transfusion centre (blood collection, donor management etc) and the local hospital transfusion and cross-matching services. To my knowledge Dundee and Aberdeen were unique in that the regional SNBTS service rather than the Haematology service delivered transfusion services to clinical users.

85.2 Once the Haemophilia Centre was established (as described in my answer to question 8), the Centre kept records of individual patient factor concentrate usage but the regional SNBTS service continued to manage and record factor concentrate stocks in the region (for the reasons given above and the absence of transfusion service and facilities within Haematology).

85.3 I cannot comment on the arrangements for recording blood or blood products usage across other Health Boards in Scotland.

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

86.1 The CFWP was well established when I took up my consultant post in 1992. I do not know about its origins or original remit and purpose.

86.2 During my time as Haemophilia Director, the CFWP was the established forum where decisions about factor concentrate development and use in Scotland were discussed and agreed by representatives of the Haemophilia Directors, SNBTS and the Scottish Executive Health Directorate.

87. 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?

87.1 The only position I have held in SNBTS was as a laboratory assistant during my school holidays in the late 1960s and early 1970s.

Section 6: UKHCDO

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

88.1 When I became Haemophilia Director for Tayside in 1993, I joined UKHCDO, principally as a means of keeping up to date with Haemophilia standards of care.

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

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

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

c. The relationships between UKHCDO and pharmaceutical companies.

d. How UKHCDO was funded.

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

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

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

ii. the manufacture of blood products;

iii. self-sufficiency;

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

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

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

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

viii. heat treatment;

ix. other measures to reduce risk;

x. vCJD exposure; and

xi. treatments for HIV and hepatitis C.

89.1 **a.** My understanding was that UKHCDO was an organisation of doctors working in Haemophilia Care across the UK which had the purpose of developing standards of care and promoting best practice across the UK, and to promote research, audit and education for relevant health care professionals involved in delivering Haemophilia care.

89.2 **b.** I was not involved in the management of UKHCDO and did not have detailed knowledge of its structures or committees.

89.3 **c.** I do not have any knowledge of any relationships between UKHCDO and pharmaceutical companies.

89.4 **d.** From memory, there was an annual membership fee but I have no knowledge of any other forms of income or funding the organisation received.

89.5 **e.** From memory, UKHCDO produced guidelines of clinical practice from working groups and produced information leaflets. From memory, I think UKHCDO coordinated an audit process but for comprehensive care centres only.

89.6 **f.** I was not personally involved in developing any UKHCDO policies or guidelines and did not participate in any of their working groups.

Scottish Haemophilia Database

90. Please describe the establishment and operation of the Scottish Database at Dundee. Please describe how it differed, if at all, from the National Database, its purpose and objectives, your involvement in it, the range and kind of data recorded in the Database and how data is collected and organised.

90.1 From memory, the Scottish Executive agreed to fund recombinant Factor VIII treatment for specific groups of priority patients through a national contract in 1996. There was finite budget for the year and published priority criteria (developed by the Haemophilia Directors) for patients to transfer from plasma derived to recombinant therapy. The agreement was that patients in the highest priority group would be transferred to recombinant therapy first and that subsequent priority groups and patients could then be transferred up to the limit of the total approved funding. Given that individual patients have widely varying annual concentrate use, the only way the Haemophilia Directors could calculate the numbers of patients who could be offered recombinant factor concentrate within the total available budget was to analyse individual patient factor concentrate usage referenced to the priority criteria and then to collate the individual Haemophilia Centre outputs to give an all Scotland prediction of factor concentrate usage by priority groups.

90.2 The national (UK) database coordinated from Oxford, did not have the facility to enter the Scottish priority criteria for recombinant factor. So the Scottish database was

initially established with the sole purpose of analysing factor concentrate usage by individual patients referenced to their priority for recombinant factor concentrate treatment and collated across all Scottish Centres. This was the only way we could allocate as many patients as possible to recombinant Factor VIII therapy and stay within the agreed national budget. I agreed to coordinate this initial activity as I had a data manager in Dundee with the computer skills and capabilities to set up and manage the database. This was initially established from existing personnel and resources.

90.3 The following year the National Purchasing Consortium was established to oversee recombinant factor concentrate purchase and eligibility for treatment. As the total budget for recombinant factor concentrate therapy increased, the same process of analysing anticipated factor concentrate usage by individuals referenced against priority criteria had to be repeated in order to transfer the maximum number of patients within the available budget.

90.4 This process was repeated annually until all patients were transferred to recombinant therapy.

91. Please explain how the work of the Scottish Database has been funded over the years; how it is currently funded; and what if any financial contributions have been offered or made by (a) pharmaceutical companies and (b) central government.

91.1 After the first year, the National Consortium provided some annual funding to cover our data manager's additional time.

91.2 There was no funding from any other source, including pharmaceutical companies.

91.3 I have no knowledge of what happened to the Scottish Database after I left Haematology in 2004 or whether it still exists, given its core purpose became redundant once all patients were transferred to recombinant factor concentrate therapy.

92. Please explain how the question of patient consent in relation to the Scottish Database has been approached over the years. Please address in your response the extent to which there have been differences of opinion and approach amongst haemophilia centre directors in relation to this issue.

92.1 From memory, the Haemophilia Directors did not believe there were consent issues in relation to the Scottish database and its use as described in my answer to question 90. The data was already held by each of the Scottish Haemophilia Centres in respect of their patients and the Scottish database only collated this information from an all Scotland perspective. Any information shared with third parties at the National Consortium was anonymised and collated.

92.2 I do not, however, have knowledge of the initial process of informed consent though which each Haemophilia Centre collected and held the source data on the Centre's patients.

Section 7: Pharmaceutical companies/medical research/clinical trials

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

93.1 I have never provided advice or consultancy services to any pharmaceutical company.

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

94.1 I have never received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company.

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

95.1 I have never sat on any advisory panel, board or committee of any pharmaceutical company.

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

96.1 I have never received financial incentives from a pharmaceutical company to use certain blood products.

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

97.1 I have never received non-financial incentives from a pharmaceutical company to use certain blood products.

98. 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.

98.1 I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company.

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

99.1 I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company.

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

100.1 I have never undertaken medical research for or on behalf of a pharmaceutical company.

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

101.1 I have never provided research results to a pharmaceutical company.

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

102.1 I have never received funding from a pharmaceutical company for research.

Section 8: vCJD

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

103.1 From 1996 onwards, concerns about vCJD were widely reported in the media and medical literature. The risks of transfusion related vCJD were routinely discussed and actions agreed in the Scotland and NI Haemophilia Directors meetings and the Coagulation Factor Working Party.

103.2 From memory, there was a well coordinated national approach to managing the issues with information and advice available from the National CJD Incidents Panel within the Public Health Authority in England and also the National CJD Surveillance Unit established in Edinburgh University.

104. Please describe your involvement in decisions as to what information to provide to patients about vCJD. You may be assisted by consideration of [HSOC0015115], [DHSC0038507_067], [GGCL000198] and [GGCL0000202]. Please also address in your answer the 2004 notification process. Please also answer the following questions:

a. What discussions took place (a) within UKHCDO, (b) with other organisations (including the Annual Meeting of the Scotland and Northern Ireland Haemophilia Directors, CJD Incidents Panel and UK Health Departments) and (c) within the Dundee Centre?

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

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

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

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

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

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

104.1 **a.** In 1997, the Haemophilia Directors in Scotland recommended to the Scottish Executive that the treatment of choice for all patients should be recombinant factor concentrate given the uncertainties and risks of blood borne vCJD transmission. In the absence of sufficient supplies of recombinant concentrate, plasma derived concentrate from non-BSE countries should be preferred to UK-derived products. This advice was followed in the Dundee Centre.

104.2 **b.** Patients at the Dundee Centre were informed in person at the Centre wherever possible. June Ward and I also attended a meeting of the local Haemophilia Society in December 1997 to explain what was known about vCJD and blood transfusion, to explain the actions recommended by the Scottish Haemophilia Directors and to answer questions.

104.3 **c.** From memory and reviewing the documents provided with the IBI Rule 9 request, some Scottish Haemophilia patients had been exposed to potentially contaminated plasma derived concentrate between 1987 and 1989. I have to assume that the donor implicated in the affected batches had developed sporadic rather that variant CJD but without access to further documents from the time, I cannot remember the details of this episode.

Section 9: Financial Support Schemes

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

105.1 Advice and support for patients to access financial support was provided primarily by a Social Worker. In 1992, there was a named social worker who dealt with all

Haematology patients and was actively involved in the department, attending our weekly case discussions. At some point, the named support was withdrawn and the service became noticeably more fragmented but I cannot remember when this happened in relation to support for patients with HCV attending the Haemophilia Centre.

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

106.1 Cardiff – I do not know what arrangements there were in Cardiff.

106.2 Dundee - Information for patients was primarily provided by June Ward, Haemophilia Nurse and Social Work.

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

107.1 Cardiff – I do not know what arrangements there were in Cardiff.

107.2 Dundee – The Haemophilia Centre did not have a written policy or guidance. There may have been such guidance in the specialist HIV and liver services but I do not know.

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

108.1 Cardiff – I do not know what arrangements there were in Cardiff.

108.2 Dundee – from memory, the department's named social worker was supportive and helpful to patients who required assistance in completing the relevant documentation. I am less certain about the level of service and support once the department lost our named social worker.

109. What kind of support or assistance was provided by you and/or Cardiff and/or the Dundee Centre to patients making applications for financial assistance?

109.1 Cardiff – I do not know what arrangements there were in Cardiff.

109.2 Dundee – My understanding is that patients were actively supported in completing the documentation as described in my answer to question 108.

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

110.1 Cardiff – I do not know what arrangements there were in Cardiff.

110.2 Dundee – to my knowledge, the Centre staff did not have any role as a gateway for determining eligibility.

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

111.1 Cardiff – I do not know what arrangements there were in Cardiff.

111.2 Dundee – I am not aware that any Haemophilia Centre staff were involved in determining the outcomes of applications.

112. Are you aware of any patients at the Dundee Centre who were unable to obtain financial assistance because medical records had been lost? If so, was this a widespread problem and what happened to their applications to the relevant trust or fund?

112.1 I am not aware of any difficulties that patients attending the Dundee Centre had in obtaining financial assistance because of missing medical records.

113. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of your patients in relation to the trusts or funds, do you consider that the trusts and funds were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way

in which they operated or in their dealings with beneficiaries and applicants for assistance?

113.1 I did not have any direct involvement in dealing with the relevant trusts and funds and am not, therefore, able to comment on these questions.

Section 10: Other issues

114. 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 Ombudsmen or to any other body or organisation which has a responsibility to investigate complaints.

114.1 I am not aware of any complaints made about me to my employers, the GMC or any other relevant organisation.

115. 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.

115.1 Having listened to some of the Inquiry hearings, I would like to comment on three areas that have been discussed with other Haemophilia clinicians:

1. Analysing decisions and actions from the 1970s and 1980s in the context of accepted practice and knowledge of that time whilst disregarding consequences that have only become apparent with hindsight and current knowledge and practice is a challenge. For instance, the concept of 'clinical freedom' probably was standard medical practice in the 1970s and 80s. Doctors' actions during those years should not, therefore, be judged against more modern concepts of evidence-based medicine and person-centred care which have largely replaced clinical freedom but would not have been known in the 1970s and early 80s.

2. In relation to the Inquiry's consideration of the evidence of long term liver damage with NANB hepatitis from the 1970s, it is important to appreciate that there is an unavoidable lag between research publications and changes in clinical practice. There are multiple reasons for this including the volume of scientific research that clinicians have to assimilate, the fact that different research groups and papers

can reach conflicting conclusions and therefore the need for confirmatory studies and evidence before evidence based decisions and recommendations can be agreed. Translating scientific findings into evidence-based recommendations and then into clinical practice may also require NHS policy development, prioritisation and funding decisions.

3. In considering the options for withdrawing some or all factor VIII concentrates in favour of cryoprecipitate in response to the risks of AIDS in the early1980s, it is important to recognise that factor concentrates are more effective than cryoprecipitate in treating life threatening bleeding and major surgery. A complete withdrawal of concentrate would almost certainly have resulted in worse outcomes (including deaths) from life threatening bleeding.

Statement of Truth

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

Signed GRO-C

Dated 10th Nov. 2020.

Table of exhibits:

Date	Notes/ Description	Exhibit number