Witness Name: Dr Julia Anderson
Statement No.: WITN4027001
Exhibits: WITN4027002 - 074
Dated: 19 March 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR JULIA ANDERSON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 22 July 2020.

I, Julia Anderson, will say as follows: -

Section 1: Introduction

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

1.1. Name: Julia A M Anderson

1.2. Address: Department of Haematology, 51 Little France Crescent, Edinburgh EH16 4SA

1.3. Date of birth: GRO-C 1964

1.4. Professional qualifications: MBChB BSc(Hons) MD FRCP Edin FRCPath

2. Please set out your employment history, including the various roles and responsibilities that you have held throughout your career and the dates when you held them.

2.1. Aug 1988 - Jan 1989: House Officer - Dunfermline and West Fife Hospital, Scotland

2.1.1. Specialities: General, Orthopaedic, Paediatric and Urology Surgery

2.2. Feb 1989 - Jul 1989: House Officer - Royal Infirmary of Edinburgh, Scotland General Medicine and Haematology (note: haemato-oncology and general haematology, haemophilia service not covered)

2.2.1. Specialities: Endocrinology, Diabetes, Cardiology and Haematology (Haemato-oncology)

2.3. Aug 1989 - Jul 1990: Senior House Officer - Falkirk & District Royal Infirmary, Scotland

2.3.1. General Medicine and Geriatric Medicine

2.3.2. Specialities: Cardiology, Endocrinology, Diabetes, Chest Medicine, Gastroenterology, Geriatric Medicine

2.4. Aug 1990 - Mar 1991: Senior House Officer – NHS Lothian Medical Training Rotation, Western General Hospital, Edinburgh, Scotland

2.4.1. Department of Clinical Neurosciences, Neurology

2.4.2. Specialities: Neurology and on-call Neurosurgery

2.5. Apr 1991 - Nov 1991: Senior House Officer - General Medicine, Renal Unit and Nuffield Surgical Transplant Unit, Western General Hospital, Edinburgh

2.6. Dec 1991 - Mar 1992: Senior House Officer - Coronary Care Unit and Department of Cardiology, Western General Hospital, Edinburgh

2.7. Apr 1992 - Jul 1992: Senior House Officer - Intensive Care Unit and Regional Head Injuries Unit, Western General Hospital, Edinburgh

2.8. Aug 1992 - May 1993: Senior House Officer - Department of Clinical Oncology, Western General Hospital, Edinburgh (Radiation Oncology and Medical Oncology)

2.9. Jun 1993 - Jun 1996: Registrar in Haematology: Lothian Rotational Training Scheme: Western General Hospital, Royal Infirmary, St John's Hospital, Royal Hospital for Sick Children, Edinburgh, Scottish National Blood Transfusion Service, Scotland

2.10. Aug 1996 - Sep 1998: Academic appointment as Research Fellow - Hamilton Civic Hospitals Research Centre, Hamilton, Ontario, Canada (affiliated to McMaster University, Hamilton, Ontario, Canada): laboratory project: effect of sulphated glycosaminoglycans on prothrombinase and intrinsic tenase, key components of the coagulation cascade.

2.11. Nov 2000 – July 2004: Consultant Haematologist with a specialist interest in haemostasis and thrombosis: The Royal Group of Hospitals NHS Trust and Belfast City Hospital NHS, Belfast, Northern Ireland, and Director of Northern Ireland Comprehensive Care Haemophilia Centre, Belfast, Northern Ireland, and Honorary Clinical Lecturer, Queen's University, Belfast, Northern Ireland.

2.12. Oct-Mar 2008: Staff (Consultant) Haematologist, Service of Clinical Haematology Hamilton Regional Lab Medicine Program (HRLMP), Hamilton General Hospital Hamilton, Ontario L8L 2X2, Canada, and Academic appointment as Assistant Professor, promoted to Associate Professor 2008, Department of Medicine, McMaster University, Division of Hematology and Thromboembolism, Hamilton, Ontario, Canada.

2.13. April 2008 to date: Consultant Haematologist (Full-time) Department of Clinical and Laboratory Haematology Royal Infirmary of Edinburgh, Little France Crescent, Old Dalkeith Road, Edinburgh EH16 4SA and, Honorary Clinical Senior Lecturer College of Medicine and Veterinary Science, Edinburgh University

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

3.1. Member of the UK Haemophilia Centre Doctors' Organisation, 2000-2004; 2008 to date

3.2. Member of the Scottish and Northern Ireland Haemophilia Director's Group, 2000-4

3.3. Member of the Scottish and Northern Ireland Coagulation Factor Working Party, 2000-2004

3.4. Member of the Scottish Haemophilia Director's Group, 2008 to date

3.5. Scottish Inherited Bleeding Disorders Network (SIBDN), managed clinical network, lead clinician, October 2017 – February 2021

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 the 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 that you provided.

4.1. I have not been involved in any other inquiries, investigations, criminal or civil litigation in relation to the 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.

Section 2: Decisions and actions of the haemophilia centres at which you worked

5. Please describe the facilities, organisation, roles, functions and responsibilities of any haemophilia centre at which you worked prior to your appointment to the Northern Ireland Haemophilia Centre. In relation to any such centre:

a. Please identify senior colleagues at the centre and their roles and responsibilities during the time you worked there.

b. Please describe your roles and responsibilities and how, if applicable, they changed over time.

c. Please 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 infected blood or blood products.

d. Please describe the centre's approach to the selection, purchase and use of blood products (in particular factor concentrates) during the time you worked there.

e. Please describe how decisions were taken as to which products to use for patients and your involvement if any in such decisions.

f. Please set out your knowledge as to whether patients at the centre were infected with (a) HIV, (b) HCV, (c) HBV (d) any other virus or infection (and if so what) in consequence of the use of blood products.

5.1. **a.** 1994: Edinburgh Haemophilia Centre: Dr Christopher Ludlam (Director); Dr Angela Thomas (Co-director);

5.2. 1999: Dr Edinburgh Haemophilia Centre: Dr Christopher Ludlam (Director); Dr Angela Thomas (Co-director);

5.3. From mid-1999: Dr Lishel Horn (Consultant Haematologist).

5.4. **b.** I held the position of trainee in haematology on a regional rotational training scheme from 1993 to 1999 (for the period of time August 1996 to October 1998, I was a research fellow in Ontario, Canada).

5.5. In 1994, I rotated to the Department of Haematology, Royal Infirmary of Edinburgh for a 6-month training attachment (from 1 February to 31 July 1994) and held the position of haematology registrar.

5.6. In 1994, the haematology in-patient ward was based in ward 25, Royal Infirmary of Edinburgh, and this busy in-patient ward encompassed care for patients with malignant disorders of the blood, as well as patients with inherited bleeding disorders. During this time I also gained experience in laboratory haematology, general haematology and malignant haematology.

5.7. Overall the majority of my work was spent managing patients with malignant haematological disorders on the ward, alongside laboratory reporting duties, although I was allocated to the haemostasis team for the first 12 weeks of this attachment. During this 12-week period, I attended ward rounds and managed in-patients with inherited bleeding disorders under the direction of Professor Christopher Ludlam, as part of a multidisciplinary team, alongside colleagues working at the Haemophilia Centre that was located a short distance from the ward (5 to 10 minute walk).

5.8. On occasion, I attended the Haemophilia Centre to assess paediatric and adult patients when the staff doctor was unavailable, and this was usually in the afternoons. The further management of an individual was then discussed with the consultant in charge of the patient.

5.9. In March 1999, I rotated back to the Department of Haematology, Royal Infirmary of Edinburgh, to train for a further 6-month period as a specialist registrar in haematology. Following a move of the haemato-oncology team to the Western General Hospital site around 1997, patients with inherited bleeding disorders continued to be managed at the Royal Infirmary of Edinburgh site, although the location of the ward changed to ward 22.

5.10. I held responsibilities for all aspects of haematology during this attachment, including, for example, on-call general queries from other clinicians, haematology liaison work, reporting of blood films and bone marrow aspirates in the laboratory and reporting abnormal coagulation screens. I was involved with the management of all haematology patients on the wards, including patients with haemophilia and other inherited bleeding disorders. I attended the registrar-led haemophilia clinic held on Friday mornings at the Haemophilia Centre. As this responsibility was also shared with other registrars allocated to the haematology department, the frequency of assisting at clinic was approximately once or twice per month to see return patients.

5.11. **c.** I was involved in the management of the following situations, under the direction of the consultant, Professor Christopher Ludlam:

5.11.1. the care of patients with bleeding disorders undergoing major and minor elective (planned), and emergency surgery;

5.11.2. the management of patients with acute bleeds requiring outpatient review, including during and also out with working hours on a 1:3 on call rota;

5.11.3. the management of in-patients on the ward, including the management of patients with inhibitors to coagulation factor concentrate;

5.11.4. the in-patient management of patients with inherited bleeding disorders, who had been infected with HIV. In 1994, some of the in-patients I managed were in the terminal stages of AIDS.

5.12. d. I was not a party to any discussions or decisions on this subject.

5.13. e. I was instructed as to which products to use for a given patient by the responsible consultant clinician in charge of the care of the patient.

5.14. f. I was aware that some patients at the Edinburgh Centre had been infected with human immunodeficiency virus (HIV) in consequence of the use of blood products.

5.15. I was aware that many patients at the Edinburgh Centre had been infected with hepatitis C virus (HCV) in consequence of the use of blood products.

5.16. I was not aware of any patients at the Edinburgh Centre having been infected with the hepatitis B virus (HBV) in consequence of the use of blood products.

5.17. I was aware that 1 patient had been infected with parvovirus in consequence of the use of blood products.

The Belfast Centre

6. Please describe the facilities, organisation, roles, functions and responsibilities of the Northern Ireland Haemophilia Centre ("the Belfast Centre") during the time that you worked there, and how they changed over time.

6.1. Background: During the time that I worked at the Northern Ireland Comprehensive Care Haemophilia Centre, the "Belfast Centre" was responsible for the diagnosis and management of all patients with hereditary haemostatic disorders in Northern Ireland. At the time, this was a region with a population of 1.5 million, of which approximately one third lived in Belfast.

6.2. The Belfast Centre was based in central Belfast, just off the Falls Road, at the Royal Hospitals site. To the best of my recollection, during my time as Director of the Belfast Centre, children under the age of 16 years were seen at the Royal Hospital for Sick Children and this service was supervised by Dr Sid Dempsey, Consultant Paediatric Haematologist. The adult services were based at the Royal Victoria Hospital and had been supervised by Dr Elizabeth Mayne until May 1999. At this time, as there was no replacement, Dr Frank Jones was the most senior doctor in post pending my appointment in November 2000.

6.3. In August 2001, the adult haemophilia service relocated to the Belfast City Hospital site, some 1.5 miles from the Royal Hospitals site, along with the rest of the Department of Haematology that had been based at the Royal Victoria Hospital. I was responsible for ensuring the adequate provision of space for the adult centre, distinct to the haemato-oncology service, including space for the specialist coagulation laboratory and haemophilia genetics service, in addition to the provision of all aspects of comprehensive care for the adult patients, following this move.

6.4. I will divide the response to this question into the following paediatric and adult sections, and refer to the UKHCDO Audit 1-2 June 2000 (**WITN4027002).**

6.5. Paediatric service:

6.5.1. Paediatric service: November 2000 – August 2004:

6.6. The adult section will be split into 3 sections, as set out below:

6.6.1. Adult service: November 2000 - June 2001;

6.6.2. Adult service: Issues pertaining to relocation of the Belfast Centre from Royal Victoria to City Hospital site, and how these challenges were overcome;

6.6.3. Adult service: June 2001 – August 2004

6.7. Paediatric service: November 2000 – August 2004:

6.7.1. The paediatric service was located at the Royal Belfast Hospital for Sick Children. To the best of my recollection, during the time that I was Director of the Belfast Centre, patients were transferred after their 16th birthday to the adult service.

6.7.2. The director of the paediatric service was Dr Sid Dempsey, who was supported by Dr Carole Cairns, Clinical Medical Officer, Dr McCarthy, Consultant Paediatric Oncologist, and supported by a full time paediatric registrar and a paediatric senior house officer.

6.7.3. There was excellent communication and links between the adult and paediatric services. When the adult service was based at the Royal Victoria Hospital I met almost weekly with Dr Dempsey to discuss matters pertaining to the combined haemophilia service, either face-to-face, or by telephone. Following relocation of the adult service to the Belfast City Hospital site, active links were maintained between the adult and paediatric units by monthly face-to-face meetings alongside the adult and paediatric haemophilia specialist nurse leads, and frequently with Dr Dempsey by telephone when needed.

6.7.4. When I started in November 2000 there was no dedicated paediatric haemophilia nurse specialist, but several ward nurses took an active interest in the children with inherited bleeding disorders, and a nurse, Staff Nurse Fionnuala Diamond, was trained into this role and appointed in 2003.

6.7.5. There were links to the in-patient paediatric physiotherapy team should physiotherapy be required; there was a paediatric dental unit which was described as "excellent" in the 2000 UKHCDO audit report, enabling review of all children every 12 to 16 weeks. There was a designated orthopaedic surgeon, if required, and there was access to a social worker for one session per week.

6.7.6. Haemophilia clinics were held twice monthly, within the outpatient department. In-patient facilities were based on the eight-bedded haematology ward, where children with haemophilia could be reviewed at any time. This was well signposted and accessible, and there was a direct telephone line to the ward. There were two refrigerators containing factor concentrates that were regularly re-stocked by the team from Belfast Links Laboratory. There were disabled parking spaces available, and there was a hospital bus system linking the hospital to the city centre.

6.7.7. In the UKHCDO 2000 audit, it is recorded in the section "Emergency Treatment": "Patients are able to obtain emergency treatment by telephoning the haematology ward and attending. Out-of-hours the patients will be seen by the Senior House Officer on call. There are excellent printed guidelines about what to do when a patient attends. Doctors are advised to seek senior help for every new bleed, and they are given advice on what treatment to give and where to find concentrate, as well as how to record it".

6.7.8. Paediatric medical records were housed within the Haematology Department. The quality of the notes was described as "excellent both in content and presentation" in the UKHCDO audit of 2000.

6.7.9. The 2000 UKHCDO audit records "All (paediatric) patients with haemophilia are on recombinant factor VIII or IX concentrates. The product usage is compatible with UKHCDO recommendations".

6.7.10. Three paediatric patients had portacaths (central indwelling catheters) for the administration of factor concentrate. Twenty two paediatric patients received prophylaxis with factor VIII or IX

concentrate, and the vast majority received the prophylaxis at home by their parents, although four patients attended the ward to receive their prophylaxis.

6.7.11. The paediatric service received excellent laboratory support from an on-site laboratory that could perform full blood counts and coagulation screens, and from the specialist coagulation laboratory, which until 2001 was located in the basement of the Royal Victoria Hospital, haematology laboratory. The specialist coagulation laboratory was a short walk from the Royal Belfast Hospital for Sick Children. From 2001 onwards, after the adult service, including the specialist coagulation laboratory, relocated to the Belfast City Hospital site, the Belfast Links Laboratory (combined laboratories for both the Royal Victoria Hospital and Belfast City Hospitals) trained laboratory staff to perform factor VIII, factor IX and VWF assays to provide support for adult patients undergoing procedures at the Royal Hospitals site, as well as a service for the paediatric haemophilia centre.

6.8. Adult service 2000 – 2001 (this section relates to the time that the adult service was based at the Royal Hospitals site):

6.8.1. Prior to my appointment in November 2000, the continuity of haemophilia care was provided by Dr Frank Jones, Consultant Haematologist and Dr Orla McNulty, Staff Grade Physician. The former director, Dr Elizabeth Mayne had retired in May 1999.

6.8.2. Sister Colette McAfee was the nurse specialist in haemophilia, and had been appointed as such in February 2000. Her salary was supplemented by Bayer plc. pharmaceutical company to enable Sister McAfee to hold this specialist position as it required a particular level of band (seniority) . Following discussion with senior management at Belfast City Hospital Trust I was grateful that this support was relinquished from September 2001, when Sister McAfee's salary became fully supported by the Belfast City Hospitals Trust.

6.8.3. There was a haemophilia specialist physiotherapist primarily for outpatient haemophilia clinics and outpatient physiotherapy, working on two days per week.

6.8.4. When I was appointed on 6 November 2000, there was no longer a dedicated dental service for adult patients with haemophilia in Northern Ireland, despite the excellent provision of paediatric dental care. Through links with the Scottish and Northern Ireland Dental Group, by January 2001, I was able to develop a haemophilia-dental service involving Mr David Russell, Consultant Dental Surgeon, who started to provide a conservative and restorative dentistry service at the Royal Dental Hospital, based at the Royal Hospitals site; and Mr Norman Campbell, Associate Specialist in Dentistry, who advised on preventive dental health issues and issues relating to simple dental extraction and dental hygiene issues, and who helped support care within the community dental service across Northern Ireland. Mr Campbell was based at the Belfast City Hospital site, and became closely integrated within the Centre following its relocation in 2001.

6.8.5. Patients with HIV were managed alongside a HIV specialist, Dr Michael McBride, based in the Infectious Diseases Unit, Royal Victoria Hospital and although prior to my appointment joint clinics were possible, there was such excellent liaison between teams that this had not been felt necessary. From May 2001, I developed joint HIV/haemophilia clinics that continued following the relocation of the adult service to the Belfast City Hospital site, with Dr Say Quah as the lead Consultant in Infectious Diseases.

6.8.6. Regarding the hepatology service, there was a limited service available from a part-time hepatologist, Dr Michael Callender. This service deficit had been noted in the UKHCDO audit, June 2000. **(WITN4027002)**

6.8.7. "Most adult haemophiliacs are infected with the hepatitis C virus. There is, at present, only very limited input from the hepatologists. The UKHCDO guidelines on the management of liver disease in

haemophiliacs recommend that patients are managed in conjunction with a hepatologist, and there should certainly be much more hepatology input in the management of these patients. The combination of interferon/ribavirin treatment is not available in the Centre for financial reasons, in common with many parts of the rest of the UK. A number of patients have been previously treated with the combination as part of a UK trial".

6.8.8. I will provide further detail about my actions to successfully develop a combined hepatology/haemophilia clinic by July 2004 in question 56.

6.8.9. There was an excellent and long-standing orthopaedic service offered by Mr Joe McClelland, who held considerable experience in haemophilia orthopaedic surgery, and had known many patients for years. At the time of my starting as centre director, in November 2000, patients were solely reviewed at Mr McClelland's orthopaedic clinic. From February 2001 a joint clinic was considered, but to the best of my recollection, it proved more fruitful to join up and create joint consultations as and when needed. These joint consultations enabled a joint approach to patient management, with ample time for discussion about any aspects of care with the patient.

6.8.10. When orthopaedic surgery was performed, the patient was managed for the first 48 hours on the orthopaedic ward, and then transferred to the haematology ward for the rest of their care to enable factor administration in a timely manner.

6.8.11. Between the time of Dr Mayne's retirement and my appointment, due to the lack of local expertise, no inhibitor surgery or major orthopaedic surgery could be safely undertaken, and this, alongside some outstanding vascular surgery procedures (mostly relating to the removal and re-insertion of port-a-cath central catheters) was addressed swiftly upon my taking up appointment.

6.8.12. There was provision of social work support for 18 hours per week, but no dedicated psychology service provision. Although supported

by the Medical Director of the Royal Victoria Hospital, who helped to set up a meeting between myself, Dr Nichola Rooney, Psychology Services Manager, and Patricia Donnelly, Director of Clinical Professions, on 5 February 2001, these early attempts on my part to address this service deficit were not immediately possible, with the need for a business case to justify funding. As the adult service was in the process of relocating between two hospital Trusts, my further attempts to develop a psychology service were made at the City Hospital following relocation and proved more successful.

6.8.13. The in-patient facilities were on the Haematology ward based at the Royal Victoria Hospital. The senior nursing staff knew many of the patients well. According to the 2000 Audit, there were written medical and nursing protocols available on the ward for reference. However, when I took up post, the Royal Victoria Hospital was in need of refurbishment, and there was commencement of a new build shortly thereafter.

6.8.14. In terms of out-patient facilities, the adult haemophilia centre was located in the Haematology Day Ward, and this was a purpose-built accommodation to the rear of the hospital and had been in place for around one year before my appointment.

6.8.15. This was a large portacabin that housed a spacious area that included a reception and administrative area, a kitchen, disabled toilets, a large room for the housing of haematology notes (including all haemophilia case notes and past volumes of case notes), and three private single-bedded rooms, as well as an open ward area with beds and curtains to draw around the bedside.

6.8.16. There were a small number of parking spaces, and disabled access with a ramp. The portacabin was approximately a five minute walk from the ward, and a further five minute walk from the administrative offices in the Department of Haematology and the Haematology Laboratory.

6.8.17. The Haematology Day Ward had a designated porter, who helped patients gain access to the Centre if in a wheelchair, and accompany patients to and from other parts of the hospital, such as the Radiology Department. The porter knew the haemophilia patients well, and later accompanied the Haemophilia Centre, as part of the multidisciplinary team, to the Belfast City Hospital site to assist patients in accessing the Centre.

6.8.18. There was a very friendly atmosphere on arriving at the Day Ward, with the kitchen area in the morning providing a hot breakfast for anyone who had travelled a long distance. I heard no complaints about the portacabin, despite the temporary nature of the accommodation. It was this pleasant and friendly ambience that I noted when I attended for a pre-interview visit that persuaded me to join the Belfast haematology team.

6.8.19. This ambience is echoed in the 2000 UKHCDO audit report:

6.8.19.1. *"Despite the temporary nature of the accommodation, the facilities are adequate, and probably superior to many provided by other Comprehensive Care Centres in the UK".*

6.8.20. When I arrived, I was allocated the same previous clinic days as my predecessor, Dr Elizabeth Mayne, and I worked with the Directorate Service Manager over the first few months to rearrange the clinic time slots and send out letters of invitation for patient review irrespective of the severity of haemophilia. The haemophilia clinics became noticeably busier over these first few months as patients returned for specialist opinion.

6.8.21. Emergency care was provided during working hours at the Day Ward, and walk in referrals were readily accommodated and seen and assessed by the on-call registrar, by the Staff Grade doctor in haemophilia, Dr Orla McNulty, or by myself. Out-of-hours, patients called the Haematology Ward and attended to receive treatment, with management overseen by a senior house officer, or a registrar,

and discussion with the on-call consultant. All patients were reviewed at Consultant level within a 24-hour period.

6.8.22. As I was single-handed in terms of being a haemostasis and thrombosis specialist within a team of predominantly haemato-oncology experts, I was fortunate that my colleagues, Dr Jones and Dr McMullin knew many of the patients with haemophilia and had gained great experience in managing patients with heritable bleeding disorders.

6.8.23. Medical records were handwritten, and kept meticulously. There was excellent administrative and secretarial support, and it followed that the filing was good, with the medical records kept within dividers in the case notes, and any written results were filed in separate sections. The patient's diagnosis and details were kept at the front of the file, along with any family pedigree available, and this was particularly well recorded. These case records were of superior quality to those I had seen at many other institutions I had worked at previously.

6.8.24. All medical records pertaining to patients with inherited bleeding disorders were kept within the Day Ward records department in a separate section to other records belonging to other haematology patients. All records were transferred to the temporary accommodation at Belfast City Hospital and later to the new Centre based in the Bridgewater Suite at the time of relocation in 2001. Some patients had many volumes of notes, and all volumes were retained. I personally oversaw the transfer of all volumes of case notes and relevant Blood Bank records from the Royal Victoria Hospital to the Belfast City Hospital at the time of the Centre's relocation.

6.8.25. I also introduced a typed record (as well as a handwritten note) of all patients attending for day case assessment, as well as outpatient assessment, to ensure good communication with the general practitioner, as well as a legible and clear record of the patient's care for future reference.

6.8.26. At that time, patients requiring factor products for "on demand" or prophylactic use would contact the Haemophilia Centre in advance to place an order. The order would then be made up by the Blood Bank, that was located adjacent to the Haematology Laboratory, and collected by the Day Unit porter to be taken to the Haemophilia Centre, where patients would come to collect it, and hand in their treatment record.

6.8.27. There was also an elegant system for the transfer of factor concentrate from the Royal Victoria Hospital Blood Bank to other district general blood banks throughout Northern Ireland, enabling patients to collect supplies from their local hospital to save a lengthy trip to Belfast if living at a distance from the Centre. This was so efficient and well received, that initially home delivery was not felt to be necessary in Northern Ireland when it was being introduced in Scotland and other regions of the UK. As the Blood Bank was recording supply and receipt of product, there was a full audit trail of product receipt in the event of any product recall, and this seemed a very safe and sensible aspect to the service.

6.8.28. In terms of laboratory support, there was a dedicated specialist haemostasis laboratory located in a basement laboratory of the main haematology laboratory, Royal Victoria Hospital until its relocation to the Belfast City Hospital site. The laboratory offered 24-hour a day factor VIII, factor IX, von Willebrand functional activity and inhibitor quantification. Multimeric analysis for the diagnosis of von Willebrand's disease was sent to the Royal Free Hospital. Platelet aggregometry was available with a basic agonist panel, but platelet nucleotide analysis was not available.

6.8.29. The Belfast Centre also received excellent molecular genetic support from a senior clinical scientist, Dr Paul Winter, who performed molecular genetics to identify carriers of haemophilia, and provided a regional service. An antenatal diagnostic service was available, with support from Dr Winter, and colleagues in the Department of Gynaecology at the Royal Maternity Hospital.

6.9. Adult services: Issues pertaining to relocation of the Belfast Centre from Royal Victoria to City Hospital site, and how these challenges were overcome;

6.9.1. The relocation of the adult Belfast Centre to the Belfast City Hospital site in 2001 posed some service challenges. Thankfully, as I was appointed in early November 2000, I was able to point out these potential issues to the Service Managers and colleagues during several service relocation meetings and they were actively addressed by the Belfast City Hospital team. In this regard, the helpful, creative and friendly support of Dr Brian Armstrong, and Chief Executive, Mr Quentin Coey enabled an adult haemophilia service to be re-developed that utilised the pre-existing services at the Royal Hospitals site, and brought in services available at the City Hospital sites such as preventive dentistry and dental hygiene, hydrotherapy, urology and general surgery, gynaecology and genetic counselling. Although many surgical operations continued to be undertaken at the Royal Victoria Hospital, the appointment of a second nurse specialist, Margaret O'Donnell, ensured the smooth delivery of care between the two hospital sites, as well as providing off-site support for operations at Musgrave Park Hospital, where elective orthopaedic surgery was often undertaken.

6.9.2. Centre staff and patient representatives met with the architect designing the new haemophilia centre and we were given the opportunity to design the space in a bespoke manner. There was attention to disabled access to the temporary centre based on level 1, and also to the permanent centre at the Bridgewater suite, as well as access to lifts and signposting, and provision of disabled toilets.

6.9.3. Dedicated space for the specialist laboratory and the haemophilia genetics laboratory, and the ongoing provision of access to specialist tests for the patients at the Royal Hospitals site, was discussed at Service meetings and agreed.

6.10. Adult service 2001 – August 2004 **(See acetates slides of presentation to NI Haemophilia Society AGM 14 June 2003 - WITN4027003)**

6.10.1. The adult service for the Belfast Centre relocated to Belfast City Hospital, off the Lisburn Road area of the city, on 31 August 2001.

6.10.2. The hospital is a tower block over 10 storeys tall. As the Bridgewater suite was being built, the service was temporarily located on Level 1 of the lower floors and was accessible by lift or by stairs.

6.10.3. A new car park had been constructed and had ground floor disabled parking. The hospital managers did not wish to have reserved spaces initially for patients visiting the haemophilia centre, but with later feedback, as car parking could be difficult, two spaces were allocated within the renal unit dialysis parking area.

6.10.4. The Centre was separate to the rest of the Haematology Day unit facilities, and had its own reception area and office space, that included a locked area to store case notes. A receptionist, Mrs Laura Ferris, was appointed, as well as the previous level of secretarial support (a part-time secretary to support the centre, Mrs Collette Diamond, and a part-time secretary, Mrs Anne Pollock, to support medical and nursing administrative work in general). Clinical records were maintained meticulously, with filing of all results by the administrative staff.

6.10.5. Patient representatives met with myself, and our nurse specialist, Colette McAfee, alongside the Chief Executive and lead service manager, Dr Brian Armstrong on 21 June 2001 (as identified in my 2001 work diary) to discuss the bespoke design of the adult Belfast Centre with the architect. I had earlier had the opportunity to meet the architect on 3 April 2001 with Colette McAfee. In particular, there was an emphasis on confidentiality within closed rooms, emphasis on ease of access for those with arthropathy and disabilities arising from recurrent joint bleeds, provision of disabled toilets and attention to signposting.

6.10.6. There was an acknowledgement that the busy lifts were not the best way to gain access due to jostling within the lifts. Such was the wait to gain access to the lifts, a separate lift (designed with specifications to accommodate a wheelchair) and stairwell were designed specifically for the Belfast Centre. A wheelchair, sponsored by the Bayer pharmaceutical company, was designated for the centre and was suitable for patients with bleeding disorders. The resident porter assisted patients with joint arthropathy or poor mobility from the car park to the Centre as the lifts were often busy and crowded.

6.10.7. The Bridgewater suite, located on the first floor of the Belfast City Hospital was built during 2001-2003, and was opened in May 2003 by Sir James Galway with an opening ceremony to which patient representatives were invited.

6.10.8. The 2003 UKHCDO audit noted:

6.10.8.1. "Given the previous concerns regarding the physical locality of the centre and the absence of a centre director for 2 years, the new Director, Dr J Anderson is to be congratulated in re-convening a first class multi-disciplinary service…This was evident from the inspection, from speaking to patients and staff on the day, and from the patient questionnaires. The auditors have absolutely no concerns regarding the standard of haemophilia care being delivered to patients by the Centre staff". **(WITN4027004)**

6.10.9. I provided an update on the service implications and the roles and function of the adult centre at Belfast City Hospital to the Northern Ireland Haemophilia Society on Saturday 14 June 2003. **(WITN4027003)**

6.10.10. In the 2003 UKHCDO audit the new purpose-built adult haemophilia centre was described as "exemplary". The front entrance to the Bridgewater Suite was stunning with coloured lighting and a circular

corridor. Patients for haemato-oncology were directed to the left hand side of the area, and patients heading for the Haemophilia Centre turned, if I recall, to the right. There was a short walk to the Centre. The furnishings were modern, with brightly coloured upholstery. We checked to ensure that despite looking modern and stylish, the chairs were comfortable for patients with joint arthropathy, and some special chairs were also purchased for those requiring assistance. The walls had been painted in delicate and complementary hues. A local artist, with links to the Centre, had donated paintings for the walls that were regularly changed. There were two waiting areas within a spacious corridor and a long sofa offered the chance for patients, who had known each other for years, to catch up – this had been a special request from the patients on leaving the Royal Victoria Hospital Day Hospital.

6.10.11. We had developed the Centre to incorporate one treatment room, with a bed and television facilities: two consulting rooms/assessment areas, a director's office, a nurse's room, an interview room for family counselling, a large reception area, incorporating an area for the storage of case records, a PAS computer system and an area for secretarial and administrative staff. The aromatherapist worked one day per week and used a quiet room, adjacent to the centre designed for therapists, and this room, and others were also used by physiotherapists, if required.

6.10.12. The relocated Belfast adult centre offered the same range of comprehensive care services, but also provided access to several new services including: the excellent hospital dental service, the departmental pharmacist, Mr Michael Jackson, an on-site gynaecology service (Dr Tharma and Dr Casement), an on-site urology service, an on-site dermatology service (Dr Corbett), an on-site genetics service with genetic counselling (Professor Morrison and Dr Shane McKee), an on-site ENT service, an on-site ophthalmology clinic, and the introduction of an aromatherapy service (supported in part by the Adult Centre endowments and in part by Bayer plc) to support patients and their families.

6.10.13. It was important for continuity of care to retain active links to the general surgery and vascular surgery units at the Royal Hospitals sites, for example for renewal of portacaths and indwelling lines, as the consultant surgeons knew individual patients well.

6.10.14. There were, therefore, general surgery (Mr Declan Carey) and vascular surgery services (Mr Lee and Mr Chandra) available at the Belfast City Hospital site and general surgery (Mr Clements and Mr Russell) and vascular surgery (Mr Hood and Mr Blair) at the Royal Victoria Hospital site, a radiology department, and a renal unit and oncology unit on site.

6.10.15. Haemophilia clinics were available on Tuesday and Friday mornings from 9am until 12.30pm, but if anyone had difficult attending the clinics, the centre was pleased to accommodate clinic reviews in the afternoons or early evening on any day of the week, and patents were encouraged to just ask. Sister McAfee set up evening clinics for patients who were working during daytime.

6.10.16. The orthopaedic service involved a quarterly joint clinic with Mr Joe McClelland at the Royal Victoria Hospital orthopaedic department. All elective operations took place at Musgrave Park hospital, and emergency procedures were undertaken through the fracture service based at the Royal Victoria Hospital (with expertise from Professor Marsh and Mr Nicholas). Along with Mr McClelland, who held expertise in knee and hip surgery, patients were offered opinion on hip surgery (Professor Nixon); ankle surgery (Mr Henderson); and elbow surgery (Mr Elliot).

6.10.17. In the 2003 UKHCDO audit, the dental service was described as being “of a high standard”. There was provision of services for oral surgery, restorative dentistry and dental hygiene services and care in the community was promoted to ensure access for all to good dental care. Specifically, I set up a service alongside Mr Norman Campbell, Associate Specialist in preventive dentistry, and dental check-ups and simple dental extractions were performed within the Centre. Mr David Russell continued to provide a service for

conservative dentistry and performed fillings and more complex dental procedures. He also provided an outreach service to Craigavon and Altnagelvin hospitals, with the support of local haematologists at these district general hospitals. A service was also available from the oral surgery department with Mr Marley based at the Royal Victoria Hospital, and Mr Ramsay Baggs at the Ulster Hospital. This expansion of the dental service and the collegiality of my dental colleagues enabled me to develop a keen interest in the provision of dental care for patients with inherited bleeding disorders.

6.10.18. The obstetric service continued at the Royal Maternity Hospital, based at the Royal Hospitals site, and involved an active liaison with Dr Ann Harper, Professor Dornan and colleagues. A service was available for antenatal diagnosis, and a carrier clinic was set up in 2004.

6.10.19. From circa 2002/3, a psychology service was provided with the support of Professor Robin Davidson and Dr Davies, and psychology support was offered within the haemophilia centre or at the Gerard Lynch Centre, Belvoir Park Hospital.

6.10.20. There was access to physiotherapy through the out-patient department if needed, and a case was made, and realised for specialist physiotherapy support in early 2004.

6.10.21. Regarding the hepatology service, following relocation, the Medical Director, Dr Ken Fullerton, and the Chief Executive, Mr Quentin Coey, were appraised by myself of the service deficiency for patients infected with hepatitis C in consequence of contaminated blood products, and were supportive in trying to address this issue. Dr Fullerton, like Dr Carson, Medical Director of the Royal Victoria Hospital liaised with contacts in the Department of Health about the matter. However, the hepatology input was described in the 2003 audit as "totally unsatisfactory and needs addressing immediately", and "However, the care of patients in respect of liver disease was not of an acceptable standard".

6.10.22. A specialist was being trained, and discussions commenced in May 2004 regarding a joint hepatology/haemophilia clinic following the appointment of Dr McDougall. Details from my work diary of 2004 show that a combined hepatology/haemophilia clinic with 6 patient slots was established from 28 June 2004 on a weekly basis. **(WITN4027005)**

6.10.23. The combined HIV-haemophilia clinic continued, and HIV specialist, Dr Say Quah would attend the adult centre to see patients with either myself or Dr McNulty, Staff Grade, on a quarterly basis.

6.10.24. On a near daily basis, clinical and nursing staff would walk over to the Royal Hospitals site to ensure smooth management of operations and procedures conducted at the Royal Victoria Hospital. This walk took around 15 to 20 minutes through a shortcut and I found it the quickest way to go between the two hospital sites, and the best way to ensure good overall care for the patient.

6.10.25. Staff also became familiar with the Musgrave Park site that offered surgical interventions including Ear Nose and Throat and orthopaedic operations. Patients would be transferred to Ward 10 North at the Belfast City Hospital for factor replacement therapy if necessary. The 2003 UKHCDO audit found "Nevertheless, whilst time consuming for staff we found no evidence that patient care was inadequate in this regard."

6.10.26. For this reason, immediately following the transfer of services to Belfast City Hospital, there was justification for a second nurse specialist to join the team, and Staff Nurse Margaret O'Donnell, an already experienced haematology nurse from the Royal Victoria Hospital Day Unit, joined the adult Belfast Centre as a full-time band F grade staff nurse having completed specialist training in haemophilia. In the 2003 UKHCDO audit, it is noted that "there are plans for a third nurse as there is an increasing workload in thrombophilia and obstetrics, which is detracting from the haemophilia service".

6.10.27. In terms of medical staffing, in the 2003 UKHCDO audit report it stated:

6.10.27.1. "Dr Anderson single-handedly provides the haemophilia service and in addition is responsible for thrombophilia and non-oncological haematology for which there is an increasing workload…a business case for a second consultant in haemostasis should be formalised and a formal commitment from the Trust to implement this post should be obtained with a proposed implementation date".

6.10.28. This matter was taken seriously by the Directorate, with meetings to ensure that the next consultant haematologist to be appointed should be one in haemostasis and thrombosis. **(WITN4027006 and WITN4027007)** In addition to Dr Orla McNulty, Staff Grade, there was a dedicated specialist registrar every 3 months on the training rotation.

6.10.29. The in-patient ward was based on Ward 10 North. Patients were admitted to the ward following assessment either at the haemophilia centre, or the Accident and Emergency Department. The Accident and Emergency Department received teaching and instruction about the emergency care and management of patients with inherited bleeding disorders, although patients were seen and assessed primarily by the Haematology registrar or senior house office on call. Patients were advised to call the centre in advance if possible, and also to bring their green haemorrhagic status card to show the Accident and Emergency staff.

6.10.30. The capacity of the ward to support both previous Belfast City Hospital and Royal Hospital site patients and a regional haemato-oncology service was under-estimated and frequently patients with inherited bleeding disorders could not be accommodated.

6.10.31. However, on a positive note, other wards in the hospital took great pride in looking after patients with haemophilia and bleeding

disorders, and were interested to learn, and received induction courses and teaching from the specialist nursing staff. Centre staff were very involved and took a lead role in the care of patients with haemophilia and other bleeding disorders once admitted to these wards.

6.10.32. The specialist laboratory was located in the main haematology department in a designated area, which was compact and small, and had Clinical Pathology Accreditation (CPA) accreditation. The service was deemed adequate, but it was noted that there was the need to increase the staff quota for specialist investigations, as there were only two whole-time equivalent biomedical scientists for the service and one whole time equivalent for molecular biology.

6.10.33. The main haematology laboratory at the Royal Victoria Hospital continued to perform factor VIII, IX and VWF assays 24 hours a day. The haemophilia genetics service had strong links to the Edinburgh haemophilia genetics team in relation to carrier detection, and antenatal molecular genetic studies. Factor assays were still available at the haematology laboratory, Royal Victoria Hospital, not only for the paediatric team, but also for any maternity cases and for surgery that was necessary at the Royal Hospitals site. However, more complex paediatric plasma assays were performed in the specialist laboratory at the Belfast City Hospital site.

6.10.34. To maintain strong links to the paediatric centre, there were monthly meetings with Dr Sid Dempsey, myself, Staff Nurse Fionnuala Diamond and Sister McAfee. The new appointment of staff nurse Fionnuala Diamond allowed free and easy communication with respect to transitioning young adults over to the adult centre.

6.10.35. The Blood Banks at both sites kept coagulation factor concentrates, and were responsible for the release of products from either site to ensure an audit trail for receipt of products. At the time of relocation of the adult service from the Royal Victoria Hospital site to Belfast City Hospital site, the stock ordering for factor products remained

unchanged because the system was viewed as highly robust. Factor products were then decanted from the Royal Victoria Hospital Blood Bank to the paediatric centre and the Belfast City Hospital Blood Bank.

6.10.36. At the time of the 2003 UKHCDO audit, the auditors summarised "the centre staff are highly regarded and patients feel they have good information and access to staff."

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

7.1. During the time that I worked at the Belfast Centre, I was a single-handed consultant with an interest in haemostasis and thrombosis. When I started work in November 2000, the Belfast Centre was based at the Department of Haematology, Royal Victoria Hospital. At that time, Dr Frank Jones, a Consultant Haematologist at the Royal Victoria Hospital, had been the interim lead for the haemophilia centre pending my appointment, following the retirement of Dr Elizabeth Mayne in May 1999. Dr Mary-Frances McMullin was also a Consultant Haematologist in the department, and both colleagues provided on call cover for the Belfast Centre, as part of a long-standing arrangement for cover of the service. To the best of my recollection, while I was Director of the Belfast Centre, children under the age of 16 were seen at the Royal Belfast Hospital for Sick Children and this service was supervised by Dr Sid Dempsey, Consultant Paediatric Haematologist.

7.2. Following the relocation of the Belfast Centre (and the Royal Victoria Hospital Department of Haematology) to the Belfast City Hospital site in 2001, Dr T C M Morris was the Departmental Clinical Lead, alongside Dr Frank Jones, and Dr Robert Cuthbert and Dr Paul Kettle were also consultants in the department. Later, circa 2002, Dr Mary Drake joined the Department of Haematology. The cover of the Belfast Centre if I was unavailable out-of-hours, rotated between two consultant "teams", comprised of these consultants.

7.3. The Charge Nurse/Nurse sister during my time in Belfast was Sister Colette McAfee. The Staff Grade Physician/Associate Specialist was Dr Orla McNulty.

8. Please describe your role and responsibilities at the Belfast Centre and how those changed over the years.

8.1. My role, from November 2000 to August 2004, was Consultant Haematologist with a specialist interest in thrombosis and haemostasis, and Director of the Northern Ireland Comprehensive Care Haemophilia Centre.

8.2. My responsibilities, relevant to the Inquiry, included:

8.2.1. Diagnosis and management of adult patients with inherited and acquired bleeding disorders at a regional level. Specifically, this included:

8.2.1.1. Liaison with the surgical, anaesthetic and operating teams, and dental practitioners and oral surgeons, for patients undergoing minor and major surgery, to ensure adequate haemostasis.

8.2.1.2. Diagnosis of in-patient and out-patient new referrals, and ongoing management.

8.2.1.3. Liaison and support to the Consultant Paediatric Haematologist in relation to the diagnosis and management of paediatric patients with inherited and acquired bleeding disorders, and the transition of patients after the age of 16 years (as far as I can recall) to the adult service.

8.2.1.4. Direction of the specialist coagulation laboratory within Belfast Links Laboratory, and support of the work of a clinical scientist within the Regional Haemophilia Genetics Service.

8.2.1.5. Provision of a liaison service to general practitioners in matters relating to haemostasis, including haemophilia and inherited, and acquired, bleeding disorders.

8.2.1.6. Teaching and training of undergraduate and postgraduate trainees in haematology, and in haemostasis and thrombosis.

8.2.1.7. Audit of the quality of service.

8.2.1.8. Attendance at the Scottish/Northern Ireland Haemophilia Directors' Group, the Coagulation Factor Working Party, and at the UKHCDO Advisory Panel to represent the Belfast Centre.

8.2.1.9. Attendance at meetings of the Regional Medical Consortium Blood Subgroup, to represent the Belfast Centre.

8.3. Apart from my role in overseeing and supervising the transfer of the adult service from the Royal Hospitals site to the Belfast City Hospital Trust site from 2000 to 2001, these roles and responsibilities did not change over the time that I was in employment at the Belfast Centre.

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

9.1. When I first started working at the Belfast Centre there were 153 patients registered with a bleeding disorder. There was roughly 2.2 : 1 split in adults to children. (Information source: from the UKHCDO audit report of 1-2 June 2000) **(WITN4027002)**

9.2. Paediatric service:

Diagnosis	Total patients	Severe patients
Haemophilia A	47	24
Haemophilia A carrier	1	0
Haemophilia B	4	4
Factor X deficiency	1	0
Von Willebrand's disease	15	0
Platelet abnormalities	7	0

9.3. Adult service:

Diagnosis	Total patients	Severe patients
Haemophilia A	106	40
Haemophilia A carrier	2	0
Haemophilia B	7	4
Haemophilia B carrier	1	0
Von Willebrand's disease	85	1
Platelet abnormalities	30	0

10. Over the years that you worked at the Belfast Centre:

a. What products were predominantly used for the treatment of patients with bleeding disorders?

b. Who was responsible for the selection and purchase of those products?

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

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

e. What was the relationship between the Belfast Centre and pharmaceutical companies manufacturing/supplying the products, and what, if any, influence did that relationship have on decisions regarding the selection and purchase of products?

10.1. **a.** I refer to the audit of factor concentrate use in Northern Ireland, an audit conducted by the Department of Public Health, Eastern Health and Social Services Board **(HCDO0000264_125),** in preparation for the change of adult patients with haemophilia A from plasma-derived to recombinant factor products.

10.2. During my time working at the Belfast Centre, a range of haemostatic treatments were offered and these varied according to the individual's condition.

10.3. Factor and blood product sparing treatments including desmopressin (DDAVP) and tranexamic acid had been, and continued to be, offered to patients with haemophilia A, von Willebrand disease, unidentified bleeding disorders, congenital thrombocytopenia and platelet function disorders, where applicable.

10.4. When I started to work at the Belfast Centre, to the best of my recollection, all inhibitor patients received recombinant factor VIIa.

10.5. To the best of my recollection, following my arrival, all patients with factor IX deficiency were treated with recombinant factor IX, BeneFIX, having previously been treated with plasma-derived factor IX.

10.6. To the best of my recollection, all children with factor VIII deficiency were offered treatment with either Kogenate (Bayer plc) or Recombinate (Baxter Healthcare). There was a preference to use Kogenate at the Paediatric Centre at the time, and to use Recombinate for those adults requiring small volumes of treatment to treat bleeds.

10.7. To the best of my recollection, one or possibly two adults with factor VIII deficiency were taking Refacto as they had been recruited into a clinical trial by Wyeth, and it was a condition of the trial arrangement to continue treatment after the trial concluded.

10.8. To the best of my recollection, patients with haemophilia A requiring factor VIII therapy infrequently, for example, to promote haemostasis around the time of an invasive procedure, would receive Recombinate, a recombinant form of factor VIII.

10.9. All other adult patients with factor VIII deficiency received either SNBTS-factor VIII (Liberate) or BPL-Replenate.

10.10. To the best of my recollection, at the Paediatric Centre, all children with factor VIII deficiency were receiving Kogenate.

10.11. I have recorded, in a talk given to the Northern Ireland Haemophilia Society on June 14 2003, that by that time, the Northern Ireland Department of Health had agreed to recurrent funding of recombinant factor VIII for all patients.

10.12. Once supplies were guaranteed by a tendering and contractual process, I was in a position to switch all adult patients with haemophilia A previously on home treatment programmes over to recombinant factor concentrate, if they wished.

10.13. To the best of my recollection, patients with von Willebrand disease requiring treatment with factor concentrate (where desmopressin (DDAVP) and / or tranexamic acid were not sufficient) were treated with plasma-derived von Willebrand factor concentrate, and the product used was Haemate-P, made by CSL-Behring. A recombinant product was not available at this time.

10.14. Patients with factor X deficiency were treated with DEFIX, a 4-factor plasma-derived concentrate manufactured by SNBTS. No recombinant product is available.

10.15. Patients with rare inherited factor deficiencies, such as factor XI deficiency or dysfibrinogenaemia or hypofibrinogenaemia, with the exception of severe factor VII deficiency, were treated with plasma-derived concentrates, if tranexamic acid was not sufficient to effect haemostasis. No recombinant product is available.

10.16. For those with severe factor VII deficiency, where treatment was deemed necessary, recombinant factor VIIa was used.

10.17. In situations such as factor XI deficiency, in those who had received tranexamic acid, fresh frozen plasma would be used (with virally inactivated Octaplas being used as a preference provided this did not unduly delay emergency treatment).

10.18. Patients with platelet function defects and heritable thrombocytopenia were treated with HLA-matched platelet transfusions (obtained from a single donor by apheresis) when tranexamic acid and / or desmopressin (DDAVP) were insufficient or not appropriate.

10.19. Patients with acquired haemophilia were treated with a combination of haemostatic agents depending on the clinical situation. Agents used included tranexamic acid, recombinant human factor VIII, recombinant factor VIIa and (plasma-derived) FEIBA. Intravenous immunoglobulin G was used in some cases of acquired haemophilia, and was used to treat acquired von Willebrand Syndrome.

10.20. **b.** A Regional Medical Consortium (RMC) Blood Subgroup was responsible for matters relating to factor products for Northern Ireland, and the selection and purchase of those products. To the best of my recollection, this consortium consisted of an independent chair from one of the 4 Health Boards (usually a chief executive or medical director), the 4 public health directors representing each Health Board, a finance director from the Eastern Board and a senior accountant, amongst others.

10.21. My role on this Consortium was to attend an annual meeting, as well as any other meetings requested, in order to update the Consortium about any clinical situations that might require high usage of factor concentrate, or use of the more expensive products such as recombinant factor VIIa or FEIBA. Such situations might, for example, include the development of a patient with an inhibitor requiring immune tolerance therapy, or the diagnosis of a patient with acquired haemophilia who required by-passing agents to enable cessation of bleeding. For further discussion about contract updates, anticipated volumes of products required per annum, and forthcoming operations that would use a high volume of product, a sub-group consisting of Mr Glenn Bell, Senior Accountant, Eastern Health and Social Services Board, Mrs Collette McBride, Accountant, Dr Sid Dempsey, Consultant Paediatric Haematologist and myself would meet, under the auspices of the RMC.

10.22. For example, at the first meeting I attended in January 2001 **(WITN4027008 Agenda for RMSC Project Team 18 Jan 2001),** I emphasised the need to move patients to recombinant factor as soon as possible once the market enabled guaranteed supplies, as well as the need to purchase from more than one supplier in the event of an acute shortage.

10.23. I was not personally involved in any tenders or commissioning of products.

10.24. **c.** From 2001 to 2004, when I was working at the Belfast Centre, recombinant products (where available) were favoured over plasma-derived products, irrespective of cost. The purchase of products was dependent on the availability of a given product, and the need for a guaranteed supply to Northern Ireland.

10.25. Apart from changes to the contracts for plasma-derived factor VIII, 50% of which was supplied by the Scottish National Blood Transfusion Service (SNBTS), and new contracts with manufacturers of recombinant factor products, there were no changes to existing contracts for products for other conditions during my tenure.

10.26. The further selection of one recombinant factor VIII product over another did not really become an issue during the time-frame I was in post, as in 2001 the issue was mainly one of supply and demand throughout the UK and the rest of Europe. All products were made from recombinant technology and appeared efficacious and safe in clinical trials, particularly from the point of view of inhibitor development.

10.27. However, the recombinant factor VIII product, Refacto, was a B-domain deleted product, and required a different factor VIII standard to monitor levels in the clinical laboratory. As this was more time-consuming to monitor from a laboratory perspective, there was slightly less inclination to use this product over the other recombinant products at the time.

10.28. **d.** Although the products were expensive relative to other medicines and drugs, and some coagulation factor products such as recombinant factor VIIa and FEIBA were much more expensive than other coagulation factor concentrates, I did not feel that financial considerations played any role in the selection and purchase of factor products. I was always reassured by the Regional Consortium in this regard, that the safest and most efficacious product for the patient should be used. To the best of my recollection, the establishment of contracts for, and the subsequent roll out of recombinant factor VIII, for adult patients with haemophilia A, was dependent on the availability of the recombinant products, and was not dependent on cost. I also wish to state that I felt that the Regional Consortium was very supportive

when considering high cost surgery and I cannot recall any requests being turned down or reconsidered, which in retrospect seems remarkable.

10.29. Product packaging and safety of reconstitution devices were an important point to consider, but in many circumstances there was only one recombinant product on the marketplace for some conditions and this was the main reason to choose a product.

10.30. If there was more than one plasma-derived product, these factors would have been taken into account. We would also take into account the issues involved in product switches for patients. During my time as Director of the Belfast Centre from 2000 to 2004, I did not recall any need to switch contracts for any plasma-derived therapies other than for those products used for haemophilia A (when we switched patients from plasma-derived to recombinant therapies).

10.31. All companies offered educational support for the multidisciplinary team, as well as for patients. As each company would have offered similar opportunities as part of a contract, this was not a reason to favour one product over another, and this played no role in the choice of product selected or purchased by the Regional Consortium when I was in post.

10.32. **e.** There was a collegial and friendly relationship between the Belfast Centre staff and all the pharmaceutical companies manufacturing and supplying the products. Pharmaceutical companies usually had to fly over to Belfast for the day, or drive from Dublin across the Irish border, and would go to both adult and paediatric centres and spend some time with staff, ensuring good education of staff regarding their products and an awareness of new products being developed. This was always felt to be very helpful, in a centre that could otherwise have become quite remote from other centres in the UK by virtue of geographic location.

10.33. As the Centre could be somewhat remote from other UK centres, it was very important for staff within the multidisciplinary team to attend educational symposia and meetings in other regions of the UK. There was support provided to several staff members (nursing, medical and laboratory staff, for example) to travel to major meetings that would have been well out with the study leave budgets that were offered from the Royal Hospitals and Belfast

City Hospital Trust. Different companies would sponsor different staff members meaning that the Belfast Centre was well represented at meetings, and enabled a close team to develop with a sense of camaraderie when attending meetings in the UK and abroad. To optimise the support offered from pharmaceutical companies, I met with the Chief Executive, Belfast City Hospital, Mr Quentin Coey to request a general fund to be set up for the Haemophilia Centre, so that any pharmaceutical sponsorship offered could be placed into a Trust fund in order that as many staff benefit, and also so that the funds could be used for other purposes within the Belfast Centre, such as the provision of aromatherapies and supportive therapies for patients and families.

10.34. In 2001, the Belfast Centre relocated to a different Trust at the Belfast City Hospital. Pharmaceutical companies sponsored the departmental educational seminar and provided support for a lunch, enabling staff to sit and listen to team presentations during their lunch break. Support was also offered from a pharmaceutical company (Bayer) to, in part alongside Centre endowments, support an aromatherapist to give sessions for patients and families, which was much appreciated. Support was also provided for the senior specialist nurse's salary in 2000-2001 by a pharmaceutical company (Bayer plc), and was subsequently taken over by Belfast City Hospital Trust following relocation of the adult Belfast centre to this site in the summer of 2001. Bayer also provided financial support to the Centre to purchase a wheelchair to help access to the Centre following the move to the Belfast City Hospital site.

10.35. This relationship, with all the pharmaceutical companies, had no impact on decisions regarding the selection and purchase of products.

10.36. This is because the selection and purchase of products was controlled by a Regional Consortium, consisting of representatives from the 4 Health Boards. At the time, this was the Eastern Health and Social Services Board, the Western, Southern and Northern Boards. Representatives included the Public Health Directors of each Board, a Finance Director from the Eastern Board and senior accountants, Mr Glenn Bell, and Mrs Collette McBride from the Eastern Board.

11. Were any viruses or infections, other than HIV, HCV and HBV, transmitted to patients at the Belfast Centre in consequence of the use of blood products during the time that you worked there, and if so what? As far as you are aware (from your knowledge of the patients that you treated at the Centre over the years), were any viruses or infections, other than HIV, HCV and HBV, transmitted to patients at the Belfast Centre in consequence of the use of blood products prior to the time you joined the Centre, and if so what?

11.1. During the time that I worked at the Belfast Centre, from November 2000 to August 2004, I am not aware of any viruses or infections transmitted to patients at the Belfast Centre in consequence of the use of blood products. A "quarterly return" was made to UKHCDO for haemovigilance purposes by myself, and I do not recall any viral transmission of any sort whatsoever being declared.

11.2. As far as I am aware (from my knowledge of the patients that I treated over the time spent at the Belfast Centre) prior to the time I joined the Centre, there were no viruses or infections, other than HIV, HCV and HBV, transmitted to patients at the Belfast Centre in consequence of the use of blood products.

The Edinburgh Centre

12. Please describe the facilities, organisation, roles, functions any responsibilities of the Haemophilia and Thrombosis Centre at the Royal Infirmary of Edinburgh ("the Edinburgh Centre") during the time that you have worked there, and how they have changed over time.

12.1. Haemophilia Centre Audit Report 1994 **(WITN4027009)**

12.2. **January - June 1994:**

12.2.1. As a trainee in haematology on the Lothian Haematology Training Rotation, I worked at the Department of Haematology, Royal Infirmary of Edinburgh for a 6 month period from 1 February until 31 July 1994.

12.2.2. Personal roles and responsibilities:

12.2.2.1. This rotational attachment involved attending the Haemophilia Centre to review outpatients presenting during working hours with an urgent issue, such as an acute joint bleed, if the Clinical Assistant was unavailable.

12.2.2.2. I was also involved with the provision of an on-call service at registrar level, reporting to the on-call consultant out with normal working hours on a 1:3 basis.

12.2.2.3. I was also involved in the management of in-patients, under the direction of the consultant, on Ward 25 of the Royal Infirmary of Edinburgh, and although the majority of the patients I attended had malignant conditions affecting the bone marrow, some patients had inherited and acquired bleeding disorders.

12.2.3. Facilities:

12.2.3.1. In 1994 the Royal Infirmary was located in the centre of the city of Edinburgh on Lauriston Place. The Haemophilia Centre was located on the first and second floors of a separate building to the main hospital, sited just off a quadrangle that linked to the main medical corridor of the hospital. In-patients were cared for in ward 25, situated on the medical corridor of the main hospital building that linked through a series of wide corridors to the Radiology Department, and then to the Surgery Department.

12.2.3.2. The haematology laboratory was situated in a separate building, around 3 minutes' walk from the ward requiring a short walk outdoors, and around 7-8 minutes' walk from the Edinburgh Centre. There was a vacuum tube system that connected the laboratory to the Centre to enable swift processing of blood samples taken at the Edinburgh Centre.

12.2.3.3. Access to the Centre was by a set of stone stairs, and I recall the stairwell was particularly dark when access was required by on-call medical staff at night. There was a lift, and audit reports from 1994 and 2000 refer to the lift as "inadequate for use by disabled individuals"; I never used this lift so am not able to comment, but recall the lift doors, which consisted of a heavy door and then an outer set of railings, would have been very heavy to shut.

12.2.3.4. The Edinburgh Centre consisted of a reception area; a waiting area with a tropical fish tank, and with toys for children; a parents' room; and a treatment room. There were two consultation rooms, one doctor's office, an office for the charge nurse, a seminar room and a blood fridge room.

12.2.3.5. There were designated parking spaces, and I recall that the centre was well sign-posted. The hospital dental unit was located on the floor above and enabled good communication with dental colleagues.

12.2.4. *Organisation*

12.2.4.1. In 1994, the Centre Director was Dr Christopher Ludlam and Dr Angela Thomas, Consultant Paediatric Haematologist, was shortly afterwards appointed as Co-director of the Edinburgh Centre. There were two Clinical Assistants, and a Clinical Lecturer (a haematology trainee who was doing a research project with the University of Edinburgh). There were two specialist nurses, and there was a receptionist with administrative duties.

12.2.5. *Roles, Functions and Responsibilities:*

12.2.5.1. The role of the Edinburgh Centre was, as far as I understood, to provide advice and care for the management of people with inherited and acquired bleeding disorders for Lothian and the surrounding regions of the Borders, and Fife, as well as Forth

Valley in some instances. The Edinburgh Centre also provided advice and support to other haemophilia centres located in the East Coast of Scotland, namely Dundee, Inverness and Aberdeen, and acted as a Comprehensive Care Centre. The Edinburgh Centre also provided care to people with inherited bleeding disorders living in some of the islands off the Scottish coast, including Orkney, Shetland and the Western Isles.

12.3. **February - November 1999 (WITN4027010)**

12.3.1. In 1999, I returned to further train as a haematology specialist registrar at the Royal Infirmary of Edinburgh.

12.3.2. At this time, the Edinburgh Centre remained at the Royal Infirmary site, and the hospital remained at the Lauriston Road site, in the city centre. The layout of the Edinburgh Centre had not changed from my description of the centre in 1994.

12.3.3. *Organisation:*

12.3.3.1. A further adult consultant haematologist had been appointed, Dr Peter Johnson (who had no role in the service for inherited bleeding disorders) at the time of my starting the attachment, and Dr Lishel Horn, was appointed as Consultant Haematologist with a specialist interest in haemostasis and thrombosis mid-way through my attachment in the summer of 1999.

12.3.3.2. There was a Clinical Assistant, Dr Rosie Dennis, who provided clinical service for six sessions per week. There was also a Clinical Lecturer post within the Department of Haematology.

12.3.3.3. Regarding nursing, there was a grade G Charge Nurse, and two Grade E Charge Nurses.

12.3.3.4. There was a business manager. There was an administrative assistant, who had joint roles as a secretary and receptionist.

12.3.3.5. Comprehensive care services included Professor Peter Hayes, Professor of Hepatology; Mr Malcolm MacNicol, Consultant Orthopaedic Surgeon; Mr Andrew Hazzard, Dentistry; Mrs Jenny Forsyth, Physiotherapist; Mrs Geraldine Brown, Social Worker; Dr Alison Richardson, Clinical Psychologist (dealing mostly with the viral complications of haemophilia); and Dr Ray Brettle, Consultant in Infectious Diseases (who worked from the Regional Infectious Diseases Unit based at the City Hospital).

12.3.3.6. Patients requiring admission were admitted to ward 22, an acute medical ward that developed expertise in nursing and managing patients with inherited bleeding disorders.

12.3.3.7. My personal recollection was that the Edinburgh Centre was well organised, and this is evident from a UKHCDO audit in 2000, that reports:

12.3.3.8. "Review of the notes showed them to be well organised with problem sheets prominent in the front of the notes and a tick list for vaccinations administered and investigations taken at clinic visits. Family pedigrees were documented in six out of seven patient records. There was evidence of appropriate clinical and disease monitoring of patients with viral complications. There was evidence of adequate communication with general practitioners, affiliated Haemophilia Centres and colleagues in secondary care. The records within the unit are greatly enhanced by the use of a computer database. This has records of patients from 1988. It includes records of concentrate administration and use at home, but in addition has clinical data of diagnosis, recommended treatment and the frequency of bleeding complications at home. The results of laboratory investigations, other than coagulation results, are downloaded directly from the pathology department computer system" (this system was known as "PROTON").

12.3.4. *Roles, function and responsibilities*

12.3.4.1. The roles, function and responsibilities of the Edinburgh Centre were unchanged from 1994.

12.4. ***2006 -2008:***

12.4.1. I did not work at the Edinburgh Centre from the end of 1999 until April 2008.

12.4.2. *Relocation of the Edinburgh Centre, 2006:*

12.4.2.1. In 2003 the hospital relocated to the Little France site, located on the south side of Edinburgh.

12.4.2.2. The Edinburgh Centre was relocated to the Outpatient Department 1 area of the "New" Royal Infirmary, as it was referred to. The Edinburgh Centre currently remains in this location, and is a ground floor location, offering direct access from the car park, and has two designated car park spaces.

12.4.2.3. My first impression of the new Haemophilia Centre on my return to work at the Royal Infirmary of Edinburgh in 2008 was of a spacious, bright and well-lit centre, with the outer windows surrounded by bushes, trees and landscaped gardens, in a quiet location within the hospital. The centre is located adjacent to the apheresis centre, the social work department and the hospital dental service, and has access from the Outpatient Department 2 back door, which has disabled access.

12.4.3. *Facilities and Organisation:*

12.4.3.1. The Edinburgh Centre is described in a 2007 audit report **(WITN4027011)** conducted under the auspices of the Scottish / Northern Ireland Haemophilia Directors' Group, as being

"…of a reasonable size with a good waiting area with toilets and disabled toilet facilities, email access/ answerphone and direct telephone access, and direct emergency access. There was clear sign-posting to the Centre from the main entrances and a mixture of office and treatment rooms: 2 treatment rooms, 3 consulting rooms, one of which is specifically decorated for children with toys and small chairs".

12.4.3.2. Within this audit report of 2007, it is noted –

12.4.3.2.1. "the treatment areas provide privacy and comfort, and there was evidence of universal cross-infection precautions in place. Other clinical and laboratory departments were noted to be situated within a reasonable reach of the centre, and the centre is adjacent to the Dental Department. The Centre included services for paediatric and adult patients, with Sick Children's hospital based still at Millerfield Place in the city centre. The paediatric treatment room has a video player and TV for diversional therapies".

12.4.3.3. This 2007 audit notes "satisfactory procedures for factor ordering, storage of concentrate, procedures for stock control, procedures for recording the concentrate issued to patients and a home delivery system in place with adequate recording of concentrate issuing by each company, as well as procedures for recording concentrate usage by patients on home treatment.

12.4.3.4. This audit documents evidence of appropriate routine review of patients, prompt review by junior medical staff out of hours, and availability of senior staff 24 hours a day for treatment advice".

12.4.3.5. Regarding services at this time, the audit records a full range of comprehensive care services including a receptionist/ secretary, data manager, dedicated social worker, dedicated

physiotherapist, psychologist (Alison Richardson being named in the UKHCDO triennial audit report of 2006) a dental service, orthopaedic surgeon, general and specialist surgical services, HIV physician (Dr Ray Brettle in 2006; Regional Infectious Diseases Unit that had moved to the Western General Hospital site), hepatologist (Wednesday morning clinics, Prof Peter Hayes), obstetric and gynaecology service, dietician and genetic counselling services and an antenatal diagnostic service.

12.4.3.6. In an audit of the Edinburgh Centre in 2006 (**WITN4027012**) conducted by UKHCDO as part of the triennial audit scheme, note keeping and the physical state of the case notes was complimented and, the auditor comments, felt to be "superior to any I have ever witnessed", with appropriate content and documentation of major issues.

12.4.3.7. The auditor comments: "There was evidence of appropriate HIV and HCV management in the notes of the 2 patients in whom this was relevant".

12.4.3.8. The auditor also states:

12.4.3.8.1. "The high quality of service provided by the Haemophilia Centre at the Edinburgh Royal Infirmary is impressive. Care is provided by an enthusiastic and dedicated team, who strive to achieve the highest professional standards. This excellent quality of comprehensive care is clearly appreciated by the majority of patients".

12.4.3.9. The unit was noted to participate in clinical governance activities, audit, teaching, continuing professional development and clinical trials.

12.4.3.10. There is evidence from these 2006/7 audit reports that the haematology laboratory at this time had full Clinical Pathology Accreditation, with a laboratory that was adequately staffed,

and with adequate laboratory space and facilities. The laboratory participated in a national quality assurance scheme and had a full repertoire of specialist tests; coagulation factor assays were always available 24 hours/day and a regional diagnostic genetic laboratory service was provided on site.

12.4.3.11. For children, dedicated paediatric in-patient facilities were based at the Royal Hospital for Sick Children (RHSC), and out of hours treatment facilities were centred at the RHSC. A play therapist was only available at the RHSC, and a growth and development assessment programme was overseen by Dr Thomas. The specialist nurse liaised with health visitors, schools and school nurses, and nurseries.

12.4.3.12. According to the audit of 2007 (**WITN4027011**), the Edinburgh Centre had a total number of 384 patients registered with the national database led by the UK Haemophilia Centre Doctors Organisation (UKHCDO). There were 120 patients treated in total during 2006. The total number of patients with severe haemophilia A and B and type 3 von Willebrand was recorded as 46, and there were 6 patients recorded as having active inhibitors.

12.4.4. *Roles, function and responsibilities*

12.4.4.1. The roles, function and responsibilities of the Edinburgh Centre were unchanged from previously.

12.5. ***2008* to 2019:**

12.5.1. I was appointed as a Consultant Haematologist in the Department of Haematology, Royal Infirmary of Edinburgh on April 1, 2008.

12.5.2. The following consultants have taken responsibility as Haemophilia Centre Director:

12.5.2.1. Director: 2008 - Jan 2012: Professor C Ludlam, Co-director, Dr A Thomas

12.5.2.2. Director: 2012 - 2016: Professor A Thomas

12.5.2.3. Director: 2016-2019: Dr Ryan Rodgers

12.5.2.4. Director: 2019 to date: Dr Andrew Page

12.5.3. Since 2008, other consultant medical staff that have been involved with people with inherited bleeding disorders are: Dr Lishel Horn (1999 - 2010); Dr Pamala Kanagasabapathy (2012 - 2014); Dr Nicole Priddee (2012 - Jan 2020); Dr Susan Baird (Paediatric Haematology) (2011 to date); Dr Matt-Howard Jones (2018 to date).

12.5.4. Associate Specialist Dr Rosie Dennis WTE 0.8 (acting in this role from 2001 - 2017).

12.5.5. There have been two rotating specialist registrars from the NHS Lothian Haematology Training Scheme, based within the Department of Haematology, who attend to see patients at clinics, as well as walk-in referrals. The registrars take part in an on- call 1:10 out-of-hours rota, but may cover the whole city at night for on call queries, and back up support is offered from the on-call Consultant if the registrar is busy at another hospital site.

12.5.6. Nursing staff included a full time specialist nurse (Band 7 WTE : 1.0), a further specialist nurse (Band 6 WTE : 1.0), 2 staff nurses (Band 5 WTE: 1.0), and a clinical support worker (Band 2 WTE 1.0). In 2010, the UKHCDO triennial audit also notes a Band 6 Research Nurse, who was in post for a one year period, before taking up the role of specialist nurse in thrombosis.

12.5.7. The Edinburgh Centre remains in the same location in Outpatient Department 1 at the Royal Infirmary of Edinburgh, and there have been no changes to the rooms or the layout of the Centre materially. A vacuum system has been in place since 2003 for the

transportation of laboratory specimens to the laboratories that are located in level 2 of the hospital.

12.5.8. The 2010 UKHCDO audit report (**WITN4027013**) conducted by medical, nursing and patient auditors, describes the centre as “a high quality purpose built unit with all required facilities in a bright and open environment”, with a "welcoming" and "homely" atmosphere despite being within a very large hospital. There was evidence of rigorous stock procedures, and a list of audits, teaching activities and clinical trials.

12.5.9. In this audit report, there was comment made about having only a single paediatric haematologist, although there was a plan to appoint a second consultant shortly after the audit visit. The appointment of Dr Susan Baird as Consultant Paediatric Haematologist in 2011 addressed this issue. The Centre continues to have paediatric haematology clinics weekly on Friday mornings, with the development of transition clinics for young people with inherited bleeding disorders since around 2016.

12.5.10. The 2013 UKHCDO audit (**WITN4027014**), conducted by medical, nursing and patient auditors in addition to a scientific auditor for the genetics network, took place when Professor Angela Thomas was the Director of the Edinburgh Centre. At this time the Edinburgh Centre had three adult consultants, two paediatric consultants and one associate specialist providing service, with the same level of nursing support previously described, and there was the same range of comprehensive care services.

12.5.11. It was noted that fibroscan investigation was available, and directed by the hepatology service.

12.5.12. Home delivery had been in place for many years when I took up position as Consultant Haematologist in 2008, and the 2013 UKHCDO audit report notes this to be under a national (Scottish) contract.

12.5.13. It was noted that at this time there were no clinical trials ongoing at the Centre, but much evidence of teaching to a wide multidisciplinary team and audit.

12.5.14. Patient feedback was noted to be positive and the auditors felt that "The care of patients with haemophilia and HIV and / or HCV appeared to be excellent"

12.5.15. Some comments from this audit include: "Clear evidence of an extremely high quality, patient focused service of which the staff should feel justifiably proud" "The Centre was welcoming, light and spacious"; "the case notes were exemplary and a model for other centres"; "Stock management is impressive and we found no areas of concern" (although the auditors were keen to point out that a stock manager should be appointed; "feedback from regional haemophilia centres was very positive and there were no areas of concern". Staffing pressures within the specialist coagulation laboratory were also highlighted.

12.5.16. Roles, function and responsibilities

12.5.16.1. The roles, function and responsibilities of the Edinburgh Centre were unchanged from 1994.

12.6. **2019 to date**:

12.6.1. I continue to work as a Consultant Haematologist and am one of two adult full-time consultant haematologists and two paediatric consultant haematologists working at the Edinburgh Centre. The third consultant haematologist appointed to primarily have a role in general haematology and haemoglobinopathy currently plays no role in the Edinburgh Centre. The Centre was audited as part of the Quintennial UKHCDO Audit in January 2019 by the West Midlands Quality Review Service (WMQRS) (outlined in IABD Edinburgh Final Report [EXPG0000029]), and Dr Ryan Rodgers was the Director of the Edinburgh Centre at the time of the audit.

12.6.2. *Organisation:*

12.6.2.1. The Edinburgh Centre remains in Outpatient Department 1, Royal Infirmary of Edinburgh and has not materially changed.

12.6.2.2. The current director is Dr Andrew Page, Consultant Haematologist, who was appointed in 2019, and there has been an expansion of the regional haemophilia genetics service, which is also overseen by Dr Page.

12.6.2.3. There have been changes to nurse staffing recently, and there is currently a Band 7 Charge Nurse, Bindu Abraham and a Band 6 Specialist nurse, Angela Davanna, with two band 5 nurses, and a clinical support worker, as before. There are two factor coordinators, who deal with data entry to local and national databases, and who manage home delivery, stock control and the supply of factor concentrate to other haemophilia centres. There is a full time receptionist, Mrs Yvonne Watt, who also supports the factor coordinators. Administrative work is now done with the support of the administrative team based within the Department of Haematology, located on the second floor of the Royal Infirmary building. The administrative team provides robust support to the Centre and consists of a Team Lead, Mrs Hannah MacLean, and two other full time medical secretaries, and two full time clerical officers, one part-time secretary and one part time clerical officer.

12.6.2.4. There are two Consultant Paediatric Haematologists, who are based in the newly renamed Royal Hospital for Children and Young People and see emergency referrals at the Accident and Emergency Department based at this hospital. There is a continuing paediatric clinic each week on Friday mornings at the Edinburgh Centre, with a transition clinic for young people due to be transferred over to the adult service. The children's hospital is due to relocate to a new build at the Little France site in late March 2021. The paediatric haematology laboratory

has been incorporated into the main haematology laboratory based on the second floor of the Royal Infirmary in advance of this move. The paediatric team have a designated physiotherapist joining their team who is currently undergoing specialist training.

12.6.2.5. The wide range of comprehensive care services remain in place as before, with a quarterly orthopaedic clinic continuing to be held within the Centre, under the supervision of Mr Graham Lawson, Consultant Orthopaedic Surgeon; weekly haematology-obstetric, and haemophilia/gynaecology clinics are available at Simpsons Centre for Reproductive Health and at the Edinburgh Centre, overseen by myself, Dr Anne Armstrong, Consultant Obstetrician, Dr Hanan Mustafa, Consultant Obstetrician, and Professor Hilary Critchley, Consultant Gynaecologist.

12.6.2.6. The previous support offered by Mrs Jenny Forsyth and colleagues in the physiotherapy department has changed, with provision of physiotherapy support by appointment and availability of physiotherapy for in-patients. This was prominently noted in the 2019 UKHCDO audit and is being actively addressed.

12.6.2.7. The Centre is linked to the Regional Genetics Service, which relocated to the Genetics Laboratory based at the Western General Hospital in October 2020 to take advantage of the necessary infrastructure, including appropriate staffing and equipment, required for next generation sequencing and modern sequencing technologies. The senior Clinical Scientist in Haemophilia Genetics is Dr Vicky Cloke.

12.6.2.8. Since 2016, a psychologist (0.8 WTE), Dr Grainne O'Brien, has been supported by a liaison psychiatrist, initially Dr Nadine Cossette, and now Dr Sarah Kennedy, Consultant Psychiatrist, and are embedded into the Edinburgh Centre team. The psychologist works between both paediatric and adult

services. Her role has expanded since appointment, and the service now extends to the Glasgow Centre for one day each week, and there is provision of both virtual and telephone-based support for patients and families at other locations in Scotland.

12.6.2.9. The specialist coagulation laboratory provides the same comprehensive repertoire of specialist coagulation tests with no concerns about access to factor VIII, factor IX or VW testing 24 hours a day.

12.6.3. *Roles, function and responsibilities*

12.6.3.1. The Edinburgh Centre remains a Comprehensive Care Haemophilia Centre, with a role to provide coordination of the delivery of factor concentrate to the other East Coast Centres (Dundee, Aberdeen and Inverness), and the provision of a regional service to Edinburgh and the Lothians, the Borders, Fife and Forth Valley.

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

13.1. Professor Christopher Ludlam – Centre Director, Consultant Haematologist: 1994 - end Jan 2012

13.2. Professor Angela Thomas, Consultant Paediatric Haematologist, and Centre Co-Director, 1994-2012, Centre Director 2012-2018

13.3. Dr Ryan Rodgers, Consultant Haematologist, 2016-2019; Centre Director 2018-2019

13.4. Dr Andrew Page, Consultant Haematologist, 2019 to date; Centre Director: 2019 to date

13.5. Dr Rosie Dennis, Staff Grade and then Associate Specialist, 1994 – 2017

14. Please describe your role and responsibilities at the Edinburgh Centre and how those have changed over the years.

14.1. As a trainee in haematology I worked at the Edinburgh Centre for six months in 1994 and for seven months in 1999. As a haematology registrar, I would review and assess any emergency referrals when on-call out-of-hours in the Accident and Emergency Department, or in ward 25 of the old Royal Infirmary. I would conduct a daily ward round, if I was working for the coagulation team (which was only 25% of the time during my attachment to the Royal Infirmary Department of Haematology in 1994) and then discuss with the Consultant about the management of each patient. In 1999, the registrars had responsibility for an occasional clinic each Friday at the Edinburgh Centre, and I would see patients with mild forms of inherited bleeding disorders, under the supervision of the Consultant, approximately once every 3 to 4 weeks.

14.2. In 2008, I was appointed as a Consultant Haematologist at the Royal Infirmary of Edinburgh. I had one dedicated consultant session at the Edinburgh Centre, and I built up a clinic for patients with both haemostasis and thrombosis disorders on a Friday morning. For those patients, I provided care around the time of surgery with the provision of a written management plan. In September 2012 (after returning from maternity leave), I managed 50% of those adult patients previously under the care of Professor Ludlam, who had by then retired, alongside Dr Pamala Kanagasabapathy, Consultant Haematologist and Dr Nicole Priddee, Consultant Haematologist, who both had haemophilia sessions in their job plans, supported by Dr Rosie Dennis, Associate Specialist. At this time Professor Thomas was the Centre Director.

14.3. In 2017 I required a six-month period of sick leave, and with a reconfiguration of clinics due to the retirement of Dr Rosie Dennis around this time, and the change of Director to Dr Ryan Rodgers, although continuing to see patients with inherited bleeding disorders, my clinics changed to enable more work with women with bleeding conditions, especially the further development of the haematology-obstetric clinic, and the development of a clinic for women with inherited bleeding disorders and gynaecological conditions. Currently at the Centre, patients with inherited bleeding disorders are seen mainly by Dr Andrew Page, on Wednesday and Friday mornings, and by a Specialty

Doctor, Dr Alasdair Gray. I continue to support peri-operative management for patients with inherited bleeding disorders and on-call review.

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

15.1. According to the audit of 2007:

15.1.1. Total number of patients registered with UKHCDO: 384

15.1.2. Total number of treated patients during 2006: 120

15.1.3. Total number of patients with severe haemophilia A and B and type 3 von Willebrand: 46

15.1.4. Total number of patients with active inhibitors: 6.

15.1.5. This audit does not have a breakdown of adults and children.

15.2. Currently (September 2020), the Edinburgh Centre has:

15.2.1. Total number of patients registered with UKHCDO: 422

15.2.2. Total number of treated patients during 2019: 163

15.2.3. Total number of patients with severe haemophilia A and B and type 3 von Willebrand: 59

15.2.4. Total number of patients with active inhibitors: 7

15.2.5. Approximately 85% adults, 15% children

16. Over the years that you have worked at the Edinburgh Centre:

a. **What products have predominantly been used for the treatment of patients with bleeding disorders?**

b. **Who has been responsible for the selection and purchase of those products?**

c. **How and on what basis have decisions been made about the selection and purchase of the products?**

d. **What, if any, role have financial and/or commercial considerations played?**

e. **What has been the relationship between the Centre and pharmaceutical companies manufacturing/supplying the products, and what, if any, influence has that relationship had on decisions regarding the selection and purchase of products?**

16.1. **a.** This is also covered in section 98.

16.2. In 1994, as far as I can recall, there were no recombinant products available, so plasma-derived products were in use. I recall being taught about the use of intravenous desmopressin in 1994 by my consultant to manage patients with mild haemophilia A who require a transient rise in factor VIII, as well as for patients with type 1 von Willebrands, and platelet function disorders. I also recall using tranexamic acid for people with inherited bleeding disorders to try to reduce the overall amount of factor replacement needed, or as a sole therapy.

16.3. In 1999, I recall that at this time, the Centre was using recombinant factor products for as many patients as possible, and this included patients with factor VIII and factor IX deficiency, as well as those with inhibitors, when the use of recombinant factor VIIa was commencing.

16.4. When I left the Edinburgh Centre in November 1999, I recall that the majority of the patients I met with haemophilia A and B were taking recombinant factor concentrate.

16.5. Since my return to the Edinburgh Centre in 2008, there has always been a range of haemostatic treatments offered and these vary according to the individual's condition. Factor and blood product sparing treatments including DDAVP and tranexamic acid are offered to patients with haemophilia A, von Willebrand disease, unidentified bleeding disorders, congenital thrombocytopenia and platelet function disorders where applicable.

16.6. Recombinant factor concentrates are favoured over plasma-derived products where available. Currently, all patients requiring factor replacement therapy for haemophilia A, or haemophilia B, receive recombinant products (including a mixture of standard and extended half-life products). Please refer to section 98.

16.7. Extended half-life products were offered from 2016 onwards.

16.8. From 2018, all patients with haemophilia A with active inhibitors receive prophylaxis with the bispecific monoclonal antibody, Emicizumab. This is currently being used in a small number of patients with severe haemophilia A without inhibitors. Breakthrough bleeding and surgery is managed with recombinant factor VIIa where necessary.

16.9. Patients with von Willebrand disease requiring treatment with factor concentrate (where desmopressin (DDAVP) and / or tranexamic acid are not sufficient) are treated with plasma-derived von Willebrand factor concentrate, although change to recombinant von Willebrand factor is imminent.

16.10. Patients with rare inherited factor deficiencies are treated with plasma-derived concentrates where these are available and tranexamic acid is not sufficient. Where no plasma-derived concentrate is available, or where it is unsuitable for use, as in some patients with factor XI deficiency who have already received tranexamic acid, fresh frozen plasma would be used (with virally inactivated Octaplas being used as a preference provided this does not unduly delay emergency treatment).

16.11. Patients with platelet function defects and heritable thrombocytopenia are treated with HLA-matched platelet transfusions, obtained by apheresis from a

single donor, when tranexamic acid and / or desmopressin (DDAVP) are insufficient or not appropriate.

16.12. Patients with acquired haemophilia are treated with a combination of haemostatic agents depending on the clinical situation. Agents used include tranexamic acid, recombinant human factor VIII, recombinant porcine factor VIII, recombinant factor VIIa and (plasma- derived) FEIBA. I also recall the use of porcine-derived factor VIII in one person who developed factor VIII allo-antibodies in 1999.

16.13. **b.** I was not involved directly or in any way with the selection and purchase of products used for the treatment of bleeding disorders at the Edinburgh Centre between 1994 – 2008.

16.14. Since I returned to work at the Edinburgh Centre in 2008, the selection and purchase of products has been made by a collaboration between National Procurement (NP) and National Services Scotland (NSS), in consultation with the Scottish Haemophilia Directors Group. Six-monthly and annual reports are written by the Comprehensive Care Centre Directors based in Edinburgh and Glasgow to reflect usage and costs.

16.15. Since circa 2008, as far as I can recollect, the selection of products in Scotland has been based on national guidance from UKHCDO, and contractual arrangements have tied in with those agreed for NHS England through national commissioning routes to offer highly competitive costs (sometimes based on a matrix-pricing arrangement, whereby an award is made to a company based on amount of product offered and cost over a given period of time: the higher the volume, often the lower the price offered) with significant savings for the NHS.

16.16. This has meant that when a contract is nearing completion, it is possible that patients might be asked to switch to a different product. When this has happened, there is consultation with local patient groups such as Haemophilia Scotland to explain the rationale for the switch in product, and to promote education about new products and their reconstitution and vial size.

16.17. **c.** I am only able to comment since my appointment as Consultant Haematologist in 2008 at the Royal Infirmary of Edinburgh.

16.18. Since 2008, decisions depend on whether there is a recombinant product available, as this would be chosen over and above a plasma-derived product for a given bleeding disorder.

16.19. If there is more than one equally efficacious recombinant product in the marketplace, criteria for choice of product include, for example: method of manufacture including the presence of human or animal proteins within the product constituents, viral inactivation steps and the source of the plasma (country that has no record of new variant CJD, voluntary donations), unitage and vial size offered by the manufacturer to avoid product wastage; product packaging to avoid reconstitution errors in the workplace, as well as safety features to ensure aseptic reconstitution, filters to avoid drawing up particulate matter prior to administration and avoidance of needlestick injuries; and, ease of reconstitution. If there are several products available, a scoring system has been used in some procurement exercises in the past.

16.20. It may be favourable to have more than one supplier to avoid critical supply shortages in the event of a manufacturing issue.

16.21. There is a tender process, overseen by National Procurement, NHS Scotland that involves assessment of volume of product required by NHS Scotland, a bidding process for given volumes with cost, and then an award as a contract for a given period. This is a legally binding process with transparency throughout the entire process and is the same process for all medicines in NHS Scotland. During the tendering process, advice is sought from the Scottish Haemophilia Directors' Group regarding commercial supplier's bids and preference for a given product should there be more than one product in the marketplace, based on clinical grounds. If there is the need to choose between one product over another, a formal multidisciplinary group has been appointed in the past who have scored the product on the basis of a set of standards to enable objectivity and clarity about product choice. More recently, National Procurement has joined NHS England commissioning to obtain the optimal contractual arrangements for NHS Scotland.

16.22. **d.** I have attended meetings of the Scottish Haemophilia Directors Group, National Procurement and National Services Scotland to discuss product tenders, should discussion be necessary.

16.23. Financial considerations play a role if products are viewed to be equally efficacious, but the procurement process importantly also takes product safety, packaging, vial size and details of reconstitution into account. Commissioning often takes place using a matrix pricing system based on the volume being commissioned, so that NHS Scotland can treat as many patients with maximal cost-efficiency.

16.24. I do not know what is meant by the term "commercial considerations". There is a strict code of conduct for staff at the Edinburgh Centre in relation to engaging with pharmaceutical representatives, and this code of conduct is endorsed through the Pharmacy Department.

16.25. e. I am not able to comment on any individual colleague's relationship between the Edinburgh Centre and pharmaceutical companies manufacturing/supplying the products from 1994 to date.

16.26. Since 2009, I personally do not meet with pharmaceutical companies that manufacture or supply factor products, nor their representatives.

16.27. Since 2008, some Centre Directors, but not all, have chosen to meet representatives of pharmaceutical companies to discuss new products, and emerging data on existing products, which would be important to further the management of patients. From 2008 until circa 2017, pharmaceutical companies' representatives would attend the Centre to meet the Charge Nurse to discuss products in relation to packaging and educational materials.

16.28. From 2019 onwards, representatives from pharmaceutical companies attend the Edinburgh Centre by appointment with the Director only, usually to update Centre staff about new products, new developments to currently used concentrates, such as changes in packaging and reconstitution. There is a strict code of conduct in place for the relationship between Centre staff and pharmaceutical companies, and appointments to attend the Edinburgh Centre must be made with the current Director.

16.29. As the final contracts for NHS Scotland are awarded through an independent commissioning process via National Procurement with complete transparency, any relationship that an individual company has with an individual member of Centre staff, such as, for example, sponsorship for an individual to attend an educational event, will not influence the overall decision to select or purchase a given product.

16.30. Patient and staff education is an expected part of any contract with a pharmaceutical company, and often enables staff to attend conferences and educational seminars that would be out with the normal study budget for a given department.

17. **Were any viruses or infections, other than HIV, HCV and HBV, transmitted to patients at the Edinburgh Centre in consequence of the use of blood products during the time that you have worked there, and if so what? As far as you are aware (from your current knowledge of the patients that you have treated at the Centre over the years), were any viruses or infections, other than HIV, HCV and HBV, transmitted to patients at the Edinburgh Centre in consequence of the use of blood products prior to the time you joined the Centre, and if so what?**

17.1. During the time I have worked at the Edinburgh Centre I am not aware of any viruses or infections transmitted to patients in consequence of the use of blood products.

17.2. I am aware that a patient developed parvovirus infection in circa 1997 as a consequence of the use of factor concentrate, that led to a transient pancytopenia (a reduction in all the cells produced by the person's bone marrow) that fully recovered.

Section 3: Knowledge of, and response to, risk

18. **When you first began to work with patients with bleeding disorders, 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?**

18.1. I first started to work with patients with bleeding disorders in 1994.

18.2. Hepatitis: I had been taught as an undergraduate student in 1986 that hepatitis B and an entity described as "hepatitis non-A/non-B" were transmissible by blood-borne routes and that people who received treatment with plasma-derived therapies may be at risk of infection. I was also aware that there was a vaccine available to prevent hepatitis B infection.

18.2.1. In 1989, when I was a Senior House Officer in Medicine, I was at a journal club in my place of employment when the first report of the identification of hepatitis C using molecular techniques was presented.

18.3. HIV: I had been taught as an undergraduate student in 1986 that HTLVIII infection, later renamed as HIV, was transmissible by blood-borne routes and that people who received treatment with plasma-derived therapies may be at risk of infection. I was also aware that an antiviral drug, azidothymidine or "AZT", was being used to treat HIV infection.

18.4. Other pathogens: As an undergraduate student I was also aware of the transmission of bacterial and parasitic infections, such as malaria, through the use of blood products.

18.5. In 1994, during my rotational attachment at the Department of Haematology, Royal Infirmary of Edinburgh, as part of training in haematology, I gained a limited knowledge of some of the viral inactivation steps involved during plasma fractionation, and continued to gain further knowledge during my further attachment in 1999. I also gained knowledge of the risk of unknown pathogens and their potential transmission through the blood-borne route, and was taught about the use of local haemostatic agents, as well as antifibrinolytic agents and desmopressin (DDAVP) as means to reduce exposure to factor concentrate, but also as sole adjunctive therapies if appropriate.

18.6. I was taught during my rotational attachments in 1995 and in 1999, at the Scottish National Blood Transfusion Service, as part of training in

haematology, that constant vigilance is required to counter the risk from established and newly emergent pathogens.

18.7. I was taught that with modern donor selection and testing, hepatitis B, hepatitis C and HIV transmission are now very rare in the UK blood supply. Nonetheless, as a philosophy, I was taught to have an emphasis on blood conservation, avoidance of the use of blood products and plasma-derived therapies if possible, and appropriate use of plasma-derived blood products, with monitoring of levels (for example), should no recombinant product available, when striving to restore haemostasis.

18.8. Use of local haemostatic agents, as well as antifibrinolytic agents and desmopressin (DDAVP) to avoid the need for exposure to plasma-derived treatments, or to minimise the amount of product given, were also emphasised. During these attachments, I also gained some limited knowledge about plasma fractionation and viral inactivation steps.

18.9. I also gained knowledge of the risks of viral transmission through use of blood products and the steps taken to minimise this risk (such as donor selection, use of regular donors, testing for known viruses on donations, and the use of viral inactivation techniques during the manufacture of blood products).

What were the sources of your knowledge?

18.10. I had been taught as an undergraduate medical student at Edinburgh University about hepatitis B and non-A and B viral infection, and about HTLVIIII, now known as HIV, in 1986.

18.11. Once I qualified, I gained further knowledge of the risks of infections associated with blood and/or blood products through local postgraduate teaching programmes, such as departmental educational meetings, educational sessions for clinicians working within the hospital (known as "Grand Rounds"), and bedside teaching from senior colleagues, that were in place during my training, prior to taking up training in haematology.

18.12. As I studied for the examination to become a Member of the Royal College of Physicians over the period 1991 to 1993, prior to entering higher specialist

training in haematology, I gained knowledge from self-directed learning from journal articles and knowledge from courses in general medicine.

18.13. During my training rotation in haematology in Edinburgh, I gained knowledge from teaching sessions, educational courses and self-directed learning on the different rotational attachments, and especially during my attachments at the Edinburgh Centre, located at the Royal Infirmary of Edinburgh, and at Scottish National Blood Transfusion Service.

How did your knowledge and understanding change over time?

18.14. HIV: From an initial knowledge of the acute and chronic complications of HIV infection, learned during microbiology classes and training in infectious diseases as an undergraduate, I gained knowledge of the consequences of HIV infection from continuing medical education; knowledge of the available antiviral therapy from 1987 (azidothymidine or "AZT"), and had personal experience of managing individuals infected with the HIV virus during my training in general medicine and haematology from 1988 to 1999.

18.14.1. Since 1994, I became very aware of the need for specialist input and the extensive multidisciplinary team required for an individual person's management.

18.14.2. From 1995, a new class of antiretroviral drug had been developed (saquinavir, an anti-HIV antiretroviral drug protease inhibitor) that worked differently to AZT, and in 1996, a further class of anti-HIV drug known as NNRTI (non-nucleoside reverse transcriptase) was approved for use, enabling these drugs to be used in combination, and heralding the introduction of highly active antiretroviral therapy (HAART) in 1996.

18.14.3. From 1996 to 2004, I gained a basic knowledge of these combination anti-retroviral therapies, and some of the complications of therapies, because I helped to manage some patients with underlying haematological malignancy, which may be a complication of HIV infection, as well as through the management of people with bleeding disorders who became infected through

plasma donations contaminated with HIV. I became aware of the lengthened lifespan of people infected with HIV and the effect of HAART treatment on disease course. I also became aware of the need for good compliance with the medications, the complexity of taking multiple medications at different times and the impact of this on the individual, and the need for vigilance with monitoring of HIV infection and attendance at specialist clinics. I also became aware of the complex psychological needs of patients and their families.

18.15. Hepatitis B:

18.15.1. From an initial knowledge of the acute and chronic complications of hepatitis B infection, learned during microbiology classes and training in infectious diseases as an undergraduate, I gained further knowledge of the consequences of hepatitis B infection from continuing medical education, and through the management of an occasional patient who had been infected with hepatitis B through routes other than blood product administration.

18.15.2. During training at the Scottish Blood Transfusion Service in 1995, I gained more knowledge of the protective role of hepatitis B immunoglobulin G, used for exposures such as needlestick injuries.

18.15.3. I was also aware, through continuing medical education, as a postgraduate, of the limited treatment options of interferon-alpha, prior to the introduction of lamivudine and other anti-viral drugs in the mid 1990's.

18.16. Non-A non-B Hepatitis and Hepatitis C:

18.16.1. To the best of my recollection, I was taught during microbiology classes in virology and during my training in infectious diseases as an undergraduate that post-transfusion hepatitis was frequently negative for hepatitis B serology and also hepatitis A serology, and related to unidentified pathogens, known as "non-A non-B hepatitis". It was unclear at that time if this was more than one virus. During a virology lecture on viral hepatitis in 1985 I have some

recollection of the teaching. Non-A non-B hepatitis was covered briefly but I do not recollect being taught in any strong way about chronic sequelae or risk of hepatocellular carcinoma. Unfortunately I discarded my lecture notes in 2014 and no longer have them to refer to. With reference to a medical textbook, "Clinical Medicine" (Kumar and Clark 1987) published in 1987 by Baillière Tindall (**WITN4027015**) and commonly used by medical students and junior doctors preparing for the Membership of Royal College examinations, including myself, I learnt at that time that non-A non-B hepatitis was transmitted by blood and blood products and was therefore seen in intravenous drug users and patients who had received multiple transfusions. A chronic carrier state was noted to follow infection and chronic disease may develop, and there was a query about whether hepatocellular carcinoma could occur. By 1990, the second edition of this textbook (Kumar and Clark 1990) was updated to include sections on hepatitis C and I note that there was, at this time, no longer a query over the potential complication of hepatocellular carcinoma. (**WITN4027016**)

18.16.2. In 1989, hepatitis C was identified through advances in molecular diagnostics, and I recall a presentation relating to a leading journal article describing this advance, and given by one of my colleagues at a departmental lunchtime educational meeting when I was a Senior House Officer at Falkirk and District Royal Infirmary (to the best of my recollection the presentation was in the spring of 1990) that made me realise that this could pose a major health problem.

18.16.3. Since 1989, my knowledge of hepatitis C infection has developed over the years, through continuing medical education and particularly from knowledge of outcomes collected from epidemiological and observational studies conducted by groups in the United Kingdom, such as the UKHCDO, and the Scottish Haemophilia Directors' Group, who have published observational studies in 2007 and 2013, respectively, in peer-reviewed journals. (**PRSE0001620** and **GRAM0000025**) I have also gained knowledge from my personal experience of caring for people who have been infected with, and affected by, hepatitis C infection.

18.16.4. In particular, through talking to patients who have been infected with the hepatitis C virus I became aware that many had chronic health issues, including many non-specific symptoms of fatigue and general malaise that led to a chronic debilitating illness. I also became very aware of the risks of ongoing hepatitis, liver cirrhosis and of hepatocellular cancer, and the need for surveillance and monitoring of the liver for these complications.

18.16.5. When I worked at the Edinburgh Centre in 1999, I can recall meeting a patient who was experiencing side effects from the treatment combination of ribavirin and interferon-alpha, and I gained knowledge of the monitoring required for this combination treatment and also the significant side effects of these treatments, as well as the limited potential success of viral eradication. This made me realise how difficult this must be for patients and their families to go through and comply with treatment.

18.16.6. From 2000, pegylated forms of interferon became available providing a new breakthrough at the time with a higher chance of a sustained virological response. I was fully aware of this advance in treatment, and also aware of the approval by NICE in NHS England for use. I tried to get access to these therapies for patients at the Belfast Centre who had been infected with the hepatitis C virus as a consequence of infected blood products at the Belfast Centre, should they wish, during my time as Director, from November 2000 to August 2004. (**WITN4027017** - 12 January 2001 by K Pappenheim; **WITN4027008** - Agenda for RMSC Project team; **WITN4027018** and **WITN4027019** - Meeting of the issues arising from the contamination of blood products Tuesday 6 Feb 2001)

18.16.7. A hepatitis C workshop had been set up for the region and held on 5 December 2001 at a local hotel to accommodate a wide multidisciplinary group, and involved 5 plenary sessions and discussion about strategies for managing an emerging hepatitis C public health crisis. (**WITN4027020** - Hep C workshop group 1;

WITN4027021 - Hepatitis C workshop group 4; **WITN4027022** - Hepatitis C Workshop, Ramada Hotel)

18.16.8. From 2014 onwards, new antiviral drugs, simeprevir, sofosbuvir and daclafasvir have been developed, proven successful in clinical trials and reached the marketplace, and are well tolerated. I have gained some knowledge of these new drugs from educational symposia, but also from reviewing patients at the Edinburgh Centre, who have now completed treatment through the local hepatology service.

18.16.9. I have witnessed the success of these new treatments, offering a cure in terms of absent detection of hepatitis C by a laboratory test using the RNA polymerase chain reaction. However, I have also noted the psychological consequences of going through a further treatment, having often been through a treatment, or treatments that were unsuccessful and fraught with unpleasant side effects and complications. I am also aware that the risk of developing hepatocellular cancer remains despite eradication of the hepatitis C virus and requires ongoing monitoring and surveillance that can be distressing for the patient.

19. By the time you began work at the Belfast Centre, what was your knowledge and understanding of the risks of the transmission of hepatitis, including HBV and HCV, from blood and/or blood products? What were the sources of your knowledge?

19.1. I started to work at the Belfast Centre in November 2000. At that time, my knowledge and understanding of the risks of the transmission of hepatitis, including HBV and HCV from blood and /or blood products was that due to donor selection and screening; the use of repeat (previously tested) donors; and advances in viral testing on donated samples, that the risk of transmission of hepatitis B and C transmission through the UK blood supply was, and remains, rare.

19.2. Regarding pooled plasma therapies, the risk of the transmission of hepatitis, including HBV and HCV was also very low, due to screening of plasma

donors, the use of repeat donors; and advances in viral testing on donated samples.

19.3. The sources of my knowledge were from the postgraduate teaching I received whilst training in general medicine for the Membership of the Royal College of Physicians, and whilst training in haematology on the Lothian Haematology Training Scheme from 1993 to 1999, as well as from the Scottish National Blood Transfusion Service during my training in 1995 and 1999, as outlined in my response to section 18.

20. How has that knowledge and understanding developed over time since then?

20.1. Since then, my knowledge and understanding has continued to develop, with an awareness of the need for ongoing vigilance for unknown pathogens. Despite the awareness of the continuing low risk of transmission of hepatitis B and C within the UK blood supply, there is a need for ongoing vigilance through the Serious Hazards of Transfusion reporting scheme.

20.2. From teaching students and keeping up to date with transfusion medicine through continuing professional education, I am aware that hepatitis C remains highly prevalent worldwide, and the initial infection is often symptomless. Around 80% of patients develop a carrier state with long-term risk of cirrhosis, liver failure and hepatocellular carcinoma. The risk of transmission by blood transfusion has fallen dramatically since the introduction of antibody screening in 1991 and progressively more sensitive tests for hepatitis C antigen and RNA since 1999.

21. 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?

21.1. Hepatitis B:

21.1.1. From an initial knowledge of the acute and chronic complications of hepatitis B infection, learned during microbiology classes and training in infectious diseases as an undergraduate medical student from 1986 - 1988, I have gained further knowledge of the consequences of hepatitis B infection from continuing medical

education, and through the management of an occasional patient who had been infected with hepatitis B through routes other than blood product administration.

21.1.2. I was aware, and was taught as a medical student that hepatitis B can cause serious long-term health complications including liver cirrhosis and liver cancer.

21.1.3. During training at the Scottish Blood Transfusion Service in 1999, I gained more knowledge of the protective role of hepatitis B immunoglobulin G, used for exposures such as needlestick injuries.

21.1.4. I was also aware, through continuing medical education, as a postgraduate, of the limited treatment options of interferon-alpha, prior to the introduction of lamivudine and other anti-viral drugs in the mid 1990's.

21.2. Non-A non-B Hepatitis and Hepatitis C:

21.2.1. To the best of my recollection, I was taught during microbiology classes and training in infectious diseases as a medical student undergraduate that post-transfusion hepatitis was frequently negative for hepatitis B serology and also hepatitis A serology, and related to unidentified pathogens, known at the time as "non-A non-B hepatitis".

21.2.2. In 1989, hepatitis C was identified through advances in molecular diagnostics, and I recall a presentation when I was a Senior House Officer that made me realise that this viral infection could pose a major health problem.

21.2.3. Since 1989, my knowledge of hepatitis C infection has developed over the years, through continuing medical education and particularly from knowledge of outcomes collected from epidemiological and observational studies conducted by groups in the United Kingdom, such as the UKHCDO, and the Scottish Haemophilia Directors' Group, who have published observational

studies in 2007 and 2013, respectively, in peer-reviewed journals ((**PRSE0001620** AND **GRAM0000025**). I have also gained knowledge from my personal experience of caring for people who have been infected with, and affected by, hepatitis C infection.

21.2.4. In particular, through talking to patients who have been infected with the hepatitis C virus I became aware that many had chronic health issues, including many non-specific symptoms of fatigue, arthralgia (joint aches and pains) and general malaise and constitutional problems that led to a chronic debilitating illness that I feel was previously unrecognised at medical teaching sessions. I also became very aware of the risks of ongoing hepatitis and inflammation of the liver, the risks of developing liver cirrhosis and of hepatocellular cancer, and the need for surveillance and monitoring of the liver for these complications.

21.2.5. When I worked at the Edinburgh Centre in 1999, I can recall meeting a patient who was experiencing side effects from the treatment combination of ribavirin and interferon-alpha, and I gained knowledge of the monitoring required for this combination treatment and also the significant side effects of these treatments, as well as the limited potential success of viral eradication. This made me realise how difficult this must be for patients and their families to go through and comply with treatment.

21.2.6. From 2000, pegylated forms of interferon became available providing a new breakthrough at the time with a higher chance of a sustained virological response. I was fully aware of this advance in treatment and actively tried to get access to these therapies for patients who had been infected with the hepatitis C virus as a consequence of infected blood products at the Belfast Centre, should they wish, during my time as Director, from November 2000 to August 2004. My knowledge of the side-effects of the combination of ribavirin and interferon, made me very sympathetic to those patients who declined in advance any form of interferon, when I discussed such matters at clinic reviews.

21.2.7. From 2014 onwards, new antiviral drugs, simeprevir, sofosbuvir and daclafasvir have been developed, proven successful in clinical trials and reached the marketplace, and are well tolerated. I have gained some knowledge of these new drugs from educational symposia, but also from reviewing patients at the Edinburgh Centre, who are being offered, or undergoing treatment through the local hepatology service. I have noted the success of these new treatments, offering a cure in terms of absent detection of hepatitis C by a laboratory test using the RNA polymerase chain reaction. However, I have also noted the psychological consequences of going through a further treatment, having often been through a treatment, or treatments that were unsuccessful and fraught with unpleasant side effects and complications. I am aware that patients often request repeat PCR tests, due to the ongoing anxiety that the virus infection will recur, showing me the psychological consequences of the infection and the effect this has had on the patient. I am also aware that the risk of developing hepatocellular cancer remains and requires ongoing monitoring, despite these new treatments.

22. By the time you began work at the Belfast Centre, what was your knowledge and understanding of HIV and AIDS and in particular of the risks of transmission from blood and blood products? What were the sources of your knowledge?

22.1. I started to work at the Belfast Centre in November 2000.

22.2. By the time I started work at the Belfast Centre, I had knowledge and understanding of HIV infection and how it is transmitted, its clinical presentation and features, its diagnosis, and the complexity of the management of HIV infection with HAART drugs and the monitoring of the infection and response to treatment, as outlined in question 18.

22.3. At that time, my knowledge and understanding of the risks of the transmission of HIV from blood and /or blood products was that due to donor selection and screening; the use of repeat donors; and advances in viral testing on donated samples, that the risk of transmission of HIV through the UK blood supply was, and remains, rare.

22.4. Regarding pooled plasma therapies, the risk of the transmission of HIV was also very low, due to screening of plasma donors, the use of repeat donors, advances in viral testing on donated samples, as well as viral inactivation techniques during manufacture.

22.5. The sources of my knowledge were from the postgraduate teaching I received whilst training in general medicine for the Membership of the Royal College of Physicians, and whilst training in haematology on the Lothian Haematology Training Scheme from 1993 to 1999, as well as from the Scottish National Blood Transfusion Service during my training in 1995 and 1999, as outlined in my response to section 18.

22.6. I had knowledge that HIV could be transmitted through blood and blood products. This compelled me to switch as many patients as possible who were not already on recombinant products at the Belfast Centre over to recombinant products as soon as I was able, if available.

23. How has that knowledge and understanding developed over time since then?

23.1. Since then, my knowledge and understanding has continued to develop, with an awareness of the need for ongoing vigilance for unknown pathogens. Despite the awareness of the continuing low risk of transmission of hepatitis B, C and HIV infection within the UK blood supply, there is a need for ongoing vigilance, and this is achieved through the haemovigilance reporting schemes of Serious Hazards of Transfusion (SHOT) and Serious Adverse Blood Reactions and Events (SABRE).

24. What, if any, actions were taken at (a) any centre at which you worked prior to Belfast (b) the Belfast Centre and (c) the Edinburgh Centre to consider and/or assess the risks of infection associated with the use of blood and/or blood products and/or to reduce the risk to patients of being infected?

24.1. a) any centre at which you worked prior to Belfast:

24.1.1. I worked as a haematology registrar at the Edinburgh Centre for rotational attachments in 1994 and 1999. I do not recall being involved in considering or assessing the risk of infection associated

with the use of blood and/or blood products at those times. The management of a patient in relation to the choice of factor concentrate used would be decided by the responsible consultant, even for out of hours management decisions.

24.1.2. To reduce the risk of patients being infected at this time, patients were given recombinant products if available, and efforts were made to incorporate desmopressin (DDAVP) and tranexamic acid into haemostatic management plans to reduce the need for further factor therapy. Where appropriate, desmopressin and antifibrinolytic inhibitors such as tranexamic acid were administered as sole therapy if appropriate for an individual.

24.2. b) at the Belfast Centre, I re-developed review clinics for patients with inherited bleeding disorders. I tried to review all registered patients, and, to the best of my recollection, I met a very small number of patients who had not attended the Centre for several years, sometimes decades, often with mild bleeding disorders. All patients were offered testing for hepatitis B, C, and HIV if they had not previously been tested.

24.2.1. To reduce the risk of being affected, I sought to try to introduce, at the earliest opportunity, recombinant factor products over plasma-derived products where appropriate. I also incorporated the use of desmopressin (DDAVP) and antifibrinolytic inhibitors such as tranexamic acid into haemostatic management plans to reduce the need for further factor therapy. Where appropriate, I used tranexamic acid and desmopressin (DDAVP) as sole therapy for an individual.

24.2.2. When using pooled plasma-derived products, I considered the source of the plasma, the type of plasma donations (voluntary donations from repeat donors being acceptable), the viral screening tests used, and the viral inactivation steps employed by the manufacturer, as well as the risks of inhibitor development.

24.3. c) since 2008 at the Edinburgh Centre, my colleagues Dr Dennis and Dr Rodgers were involved with a retrospective hepatitis C surveillance exercise

to monitor the clinical outcomes of patients infected with hepatitis C registered at Scottish haemophilia centres, and a similar exercise has been conducted for UKHCDO.

24.3.1. Since 2008, if new patients were assessed at the Edinburgh Centre, who have been treated previously with plasma-derived factor concentrate and do not know, or have not had their hepatitis B, hepatitis C or HIV status checked, or do not know their status, we have advised this is checked, and offered to do this, with the necessary counselling in place in the event of a positive test result. This would be the case, for example, for people with inherited bleeding disorders who have now relocated to the United Kingdom having been treated in another country.

24.3.2. In terms of reducing the risk to patients of being affected, if no recombinant product is available, and if alternative haemostatic approaches are not felt sufficient to effect haemostasis, a pooled plasma-derived product may need to be considered. If using a pooled plasma product, I consider the source and country of origin of the plasma, the type of plasma donations (voluntary donations from repeat donors being acceptable), the viral screening tests used, and the viral inactivation steps employed by the manufacturer, as well as the risks of inhibitor formation.

Section 4: Treatment of patients

Provision of information to patients

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

25.1. When I began work at the Belfast Centre in November 2000, I, and others at the Belfast Centre, provided as much information as possible about a new blood product or new factor concentrate prior to treatment commencing.

25.2. I counselled patients about the origin and source of the plasma used for the concentrate, or the blood product; the manufacturer and the type of plasma donation, the viral screening tests used prior to plasma fractionation, and the viral inactivation steps used by the manufacturer, as well as the risks of inhibitor formation. I used the most simple language possible without medical jargon, and took as much time as needed for each patient, as understanding can vary from one patient to another.

25.3. This is the case, for example, in relation to a new diagnosis of type II or III von Willebrands, factor X deficiency (as no alternative recombinant products were available), or a new diagnosis of acquired haemophilia with bleeding issues where recombinant factor VIIa was either not enabling haemostasis, or its pharmacokinetic properties were not felt likely to lead to effective haemostasis.

25.4. Even if switching patients over to recombinant products, I advised about the buffers used in the manufacture of the product, for example if albumin had been used, in addition to the way the recombinant product had been manufactured, as well as the risk of inhibitor formation and allergic reactions.

25.5. For any new product, I provided written educational material from the manufacturer as an aide memoire. I ensured that any written material provided could be easily understood and written in lay terms that was understandable and informative.

25.6. My staff also had a role in explaining such information in depth. Often one member of the multidisciplinary team spoke to a patient at a review clinic, and then another staff member might also speak later in the visit to the centre, just in case the patient related to different staff members differently, and also to make sure there were no questions.

25.7. Alternatively, discussions may have taken place at a review clinic, and then I invited the patient on a separate occasion for a full and open discussion about

the treatment, and welcomed any family members that the patient might wish to accompany them. I did this to ensure that the patient and their family were fully informed of any risks and side effects from the treatment.

25.8. I set up dedicated clinics to switch patients from plasma-derived to recombinant factor VIII that enabled counselling to take place ahead of the switch as well as blood to be drawn for baseline inhibitor assessment and future surveillance post switch.

25.9. Over the four years I worked at the Belfast Centre, this practice did not change and we always communicated to patients about the products they received by face-to-face consultation, and provided written material to act as an aide-memoire.

25.10. We provided direct dial numbers and contact numbers for the Centre to enable patients to contact us easily should they have any queries or questions.

25.11. We took time to ensure clear and adequate written documentation of any counselling session in the medical case notes.

26. Please detail the information provided to patients at the Edinburgh Centre about the risks of infection in consequence of treatment with blood products, and whether and if so how this has changed over time.

26.1. During my time at the Edinburgh Centre in 1994 and 1999, I was not involved in providing information about the risks of infection in consequence of treatment with blood products as it was not my role to do so as a trainee registrar. I do not recollect any time I had to personally do this, but I do recall my consultant counselling a patient with an inhibitor, who was bleeding, about the type of plasma-derived product he was advised to receive that might stem his bleeding, and to ensure the patient had no questions, and ensure that there was adequate documentation made in the patient's case notes.

26.2. From 2008 to date there have been several switches of recombinant products due to changes to factor contracts, and counselling had been given about the

manufacture and production of such products by the Director and senior nursing staff. This involved a face to face consultation, sufficient time for the patient or carer to ask questions, and sufficient time to show the patient and/or carer how to reconstitute the product.

26.3. On occasion, I have had patients with acquired haemophilia, type II and III Von Willebrand and rare bleeding disorders who have required plasma-derived concentrates in the absence of a recombinant product. On such occasions, I have discussed the treatment options with the patient; the pros and cons of treating the patient with the product versus not treating; the source of origin of the plasma and the viral tests used prior to plasma fractionation; its manufacture in depth including the use of any human or animal proteins, and the viral inactivation steps; and I have provided written materials if available, or provided the manufacturer's package insert.

26.4. My practice has not changed and my approach is the same as outlined in question 25.

27. To the best of your knowledge, how many of the Belfast Centre's patients, overall, were infected with HIV in consequence of their treatment with blood products? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

27.1. I have read a published journal article describing HIV infection in Northern Ireland from 1981-1989 that describes the identification of 16 patients with haemophilia as infected with HIV in 1985 when HIV antibody testing became

available. **(WITN3082020 – Mayne et al HIV infection in Northern Ireland 1980-1989)**

27.2. I do not have any knowledge of the answers to the questions a to f.

27.3. During my period of time at the Belfast Centre, from November 2000 to August 2004, no patients infected with HIV at another centre were referred or came to live in the region.

27.4. When I became Director at the Belfast Centre there were 4 adult patients who had been infected with HIV either in consequence of their treatment with blood products, or in consequence of their spouse's treatment with blood products.

27.5. **a.** See the introductory paragraph above.

27.6. **b.** See the introductory paragraph above.

27.7. **c**. See the introductory paragraph above.

27.8. **d**. See the introductory paragraph above.

27.9. **e**. See the introductory paragraph above.

27.10. **f**. During my period of time at the Belfast Centre there were no children who had been infected with HIV in consequence of their treatment with blood products.

28. To the best of your knowledge, was work undertaken at the Belfast Centre to establish the time period during which patients seroconverted? If so, please describe (to the extent that you are able to) what work was done and what if any conclusions were reached.

28.1. I do not know the answer to this question.

29. To the best of your knowledge, how many of the Edinburgh Centre's patients, overall, were infected with HIV in consequence of their treatment with blood products? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

29.1. To the best of my knowledge, 20 patients were infected with HIV at the Edinburgh Centre in 1984, 1 patient was infected in 1986, 1 patient was infected in 1981 and 1 patient was infected in 1983 in consequence of their treatment with blood products. The source of my knowledge is from reading a published report written by Professor Ludlam and colleagues and published in the Lancet journal in 1985 **(HSOC0002656)** and also from table 3.16 presented at the Penrose Inquiry **(PRSE0007002).**

29.2. I do not the answer to questions a to f.

29.3. **a.** See the introductory paragraph above.

29.4. **b.** See the introductory paragraph above.

29.5. **c.** See the introductory paragraph above.

29.6. **d.** See the introductory paragraph above.

29.7. **e.** See the introductory paragraph above.

30. To the best of your knowledge, was work undertaken at the Edinburgh Centre to establish the time period during which patients seroconverted? If so, please describe (to the extent that you are able to) what work was done and what if any conclusions were reached.

30.1. Yes, I believe that work was undertaken at the Edinburgh Centre to evaluate the presence of human T-lymphotrophic virus type III (HTLV-III) infection in seronegative haemophiliacs after transfusion of factor VIII. This work was published in the Lancet on 3 August 1985. This is an extremely detailed report. The conclusions of this body of work are given in the summary statement at the start of the publication [**PRSE0004177**].

Hepatitis B

31. To the best of your knowledge, how many of the Belfast Centre's patients, overall, were infected with HBV in consequence of their treatment with blood products?

31.1. To the best of my knowledge I cannot recall any patients I met that had been infected with Hepatitis B virus in consequence of their treatment with blood products.

32. To the best of your knowledge, how many of the Edinburgh Centre's patients, overall, were infected with HBV in consequence of their treatment with blood products?

32.1. To the best of my knowledge I am aware of one patient who had been infected with Hepatitis B virus in consequence of their treatment with blood products.

Hepatitis C

33. When, to the best of your knowledge, did the Belfast Centre begin testing patients for HCV? Over what period of time was testing for HCV carried out after a test became available? How and when were patients told of their diagnosis of HCV? Were they told in person, by letter or by phone?

33.1. I do not know when the Belfast Centre began to test patients for HCV.

33.2. I do not know over what period of time HCV testing was carried out after a test became available.

33.3. I do not know when individual patients were informed of their diagnosis of hepatitis C in relation to being tested, nor the exact way in which they were informed.

34. What information was provided to patients infected with HCV about the infection, its significance, prognosis, treatment options and management during the time that you worked at the Belfast Centre?

34.1. During the time that I worked at the Belfast Centre, from November 2000 to August 2004, I tried to update my patients on the status of their hepatitis C infection from liver function tests, ultrasound scan appearance, and assessment of alpha-fetoprotein measurements.

34.2. Very few patients had received the input of a specialist hepatologist and I voiced concern to the relevant line managers and the Medical Directors of the Royal Victoria Hospital (where the Belfast Centre was originally located), and the Belfast City Hospital (where the Belfast Centre relocated in 2001) within weeks of my appointment (see question 56). Efforts were made to train in-house a registrar to fill this niche for Northern Ireland during my time in post.

34.3. I was able to ask a Consultant Virologist, Professor Peter Coyle about queries over liver function tests and hepatitis C test results in relation to diagnosis. If a patient appeared to have developed liver cirrhosis, either from clinical examination, or from imaging results, or both, I was able to seek further expert advice from a part-time Consultant Hepatologist, Dr Michael Callender, who was based at the Royal Victoria Hospital.

34.4. I referred each patient at the time of review formally to Dr Callender so that there was a formal referral in place in case the situation regarding Consultant Hepatologist availability became rectified.

34.5. My team and I endeavoured to provide my patients with as much information about the hepatitis C infection, its prognosis and the available treatment options to the best of our ability.

34.6. Regarding management, I was aware that the combination of pegylated interferon and ribavirin became available as an approved treatment option, and was advised by NICE in NHS England to be a standard of care. Although this combination treatment held the possibility of many side effects it led to the possibility of a higher chance of sustained viral response compared to other previously offered treatments. As far as I am aware, the combination of ribavirin and pegylated interferon was not made available in Northern Ireland, until June 2004 when the combined hepatology/haemophilia clinic commenced.

34.7. A trainee in gastroenterology and hepatology, Dr MacDougall, completed specialist training, and this would have taken around 3 years of time. In June 2004, he started a joint haemophilia/hepatology clinic in June 2004 with myself and Dr Orla McNulty. The Belfast City Hospital pharmacy department supported the prescription and counselling of patients on combined antiviral treatment.

35. To the best of your knowledge, how many of the Belfast Centre's patients, overall, were infected with HCV in consequence of their treatment with blood products?

35.1. Dr McNulty, Staff grade assistant, Dr Peter Coyle, Consultant Virologist and myself conducted an audit of patients infected with hepatitis C in early 2002. We found 75 patients with inherited bleeding disorders were infected with hepatitis C prior to 1991. **(WITN4027023 - letter to Mr Dorian DHSS 10 September 2003 re hepatitis C issues including data on number of cases)**

35.2. This audit was presented at a hepatitis C meeting on 6 February 2003 in Edinburgh at a meeting of the Scottish and Northern Ireland Haemophilia Directors Group **(WITN4027024, WITN4027025 and WITN4027026).**

36. What information has been provided to patients infected with HCV about the infection, its significance, prognosis, treatment options and management during the time that you have worked at the Edinburgh Centre?

36.1. To the best of my knowledge, on return to the Edinburgh Centre in 2008, all patients who had received plasma-derived concentrates in the past had been tested for hepatitis C by the Centre Director, and I assume had been told of the prognosis and treatment options by Centre Director and the Consultant Hepatologist, and their multidisciplinary teams, who came to the Centre to assess patients.

Since 2008, I have ensured that any questions asked by my patients relating to hepatitis C have been communicated to the hepatologist linked to the Centre, and also ensured that patients had access to the fibroscanner. This was available in the Department of Hepatology from 2010.

36.2. The main antiviral therapies available since 2014 are stated below. The main combinations in use have been: Sofosbuvir/ ledipasvir (+/- ribavirin)(2014); Sofosbuvir / velpatasvir (+/- ribavirin)(2016) and Sofosbuvir/velpatasvir/voxilaprevir (2017).

36.3.

36.3.1. 2014 Sofosbuvir, Pegylated Interferon and ribavirin

36.3.2. 2014 Simeprevir, pegylated interferon and ribavirin

36.3.3. 2014 Simeprevir + sofosbuvir

36.3.4. 2014 Sofosbuvir/ ledipasvir (+/- ribavirin)

36.3.5. 2014 Sofosbuvir + daclatasvir (+/- ribavirin)

36.3.6. 2015 Ombitasvir/ritonavir/paritaprevir +/- dasabuvir (+/- ribavirin)

36.3.7. 2016 Elbasvir/ grazoprevir (+/- ribavirin)

36.3.8. 2016 Sofosbuvir / velpatasvir (+/- ribavirin)

36.3.9. 2017 Glecaprevir / pibrentasvir

36.3.10. 2017 Sofosbuvir/velpatasvir/voxilaprevir

36.4. Treatment is based on national guidelines: https://hpspubsrepo.blob.core.windows.net/hps-website/nss/1862/documents/1_national-clinical-guidelines-treatment-hepatitis-c-in-adults-june-2018.pdf

36.5. All patients (17 in total since 2013) have been offered treatment, with, as far as I am aware, a universally successful outcome in terms of sustained viral eradication. This aspect of patient management has been led by the Department of Hepatology and has involved a hepatology nurse practitioner, Sister Kim Macbeth who discusses the treatment, its side effects, and the monitoring blood tests.

36.6. A few patients who were co-infected with HIV and hepatitis C, have had their hepatitis C treatment given and monitored at the Regional Infectious Diseases Unit (RIDU), based at the Western General Hospital in Edinburgh.

36.7. Since 2015, medicines have been prescribed by the secondary care specialist treatment centres (Hepatology Unit at the Royal Infirmary of Edinburgh and RIDU at Western General Hospital) but dispensed in community pharmacies. Prior to that they were prescribed and dispensed by secondary care treatment centres.

37. To the best of your knowledge, how many of the Edinburgh Centre's patients, overall, were infected with HCV in consequence of their treatment with blood products?

37.1. I do not know the exact number of patients attending the Edinburgh Centre that were infected with hepatitis C in consequence of their treatment with blood products.

37.2. My colleagues, Dr Rosie Dennis and Dr Ryan Rodgers conducted a hepatitis C look back exercise for UKHCDO, but I was not involved in its collation, and have not been able to access the report.

37.3. Please see my response to 103 b.

37.4. Data from the hepatology service at the Royal Infirmary of Edinburgh confirms a total of 54 patients referred to the Department of Hepatology with hepatitis C from the Edinburgh Centre to date.

37.5. Currently there are 32 patients at the Edinburgh Centre who were infected with hepatitis C through blood products. All patients have now been treated with antiviral treatments and are in sustained viral remission. 17 patients have been treated with new antiviral treatments since 2013, and 11 patients were treated in Edinburgh with older combination therapies; 2 patients self-cleared the virus, and 2 patients have been treated at other centres and have a sustained viral response. 11 patients are no longer alive.

Consent

38. When you began work at the Belfast Centre, how often were blood samples taken from patients attending the Belfast Centre and for what purpose(s)? What information was given to patients about the purposes for which blood samples were taken? Were samples stored for prolonged periods and if so why? Did the Belfast Centre obtain patients' informed consent to the storage and use of those samples? Was their consent recorded and if so how and when? Please detail whether and if so how this changed over time.

38.1. When I began work at the Belfast Centre, blood samples were taken when patients attended for their routine clinic reviews in accordance with standard recommendations. The purpose was to (a) ensure diagnostic accuracy about the classification of type of bleeding disorder due to changes in the classification of severity of haemophilia, as well as changes in reagents and analysers over the years; (b) to ensure a general check of health by taking a full blood count to ensure no evidence of anaemia, check platelet count and baseline coagulation status if there had been exposure to plasma-derived products, and check for inhibitor status, and tests of renal and liver function.

38.2. When I advised for blood tests to be taken from a patient, I explained the purpose for testing the blood, the expected time-frame for results, and that I will advise the patient of any abnormal results, and the implications of abnormal test results. I always record the blood tests I am taking in the

medical notes and the details of the discussion. I never take blood tests without the express permission of the patient.

38.3. No samples were stored for prolonged periods, with the exception of storage of samples taken for DNA analysis for genetic testing. At the time I was Director there was guidance from UKHCDO in place about the need for written consent for the extraction of DNA for testing, and for long-term storage. Consent was recorded in the case notes, and to the best of my knowledge, there was also a separate photocopy of the consent form in the genetics laboratory.

38.4. Over time, this changed in that a second confirmation sample was drawn on a different date to confirm the findings of the first sample prior to the results being issued.

39. During the time that you worked at the Belfast Centre, were patients under its care ever tested for HIV or for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing? Was their consent recorded and if so how and where? Please detail whether and if so how the Belfast Centre's approach has changed over time.

39.1. During the time that I worked at the Belfast Centre, patients were always asked if they were in agreement to being tested for HIV or hepatitis B or C. A written note would be made in the case notes to record that the patient's verbal consent had been sought, as well as a typed letter to the patient's general practitioner. Permission was asked to ensure that the consultation details could be sent to the general practitioner. The implications of a positive test result were discussed. The blood sample would be taken, and the patient would be informed of his or her result in person at a follow up clinic. During my time at the Belfast Centre, this approach did not change. My staff followed this approach.

40. When you began work at the Edinburgh Centre, how often were blood samples taken from patients attending the Edinburgh Centre and for what purpose(s)? What information was given to patients about the purposes for which blood samples were taken? Were samples stored for prolonged periods and if so why?

Did the Edinburgh Centre obtain patients' informed consent to the storage and use of those samples? Was their consent recorded and if so how and where? Please detail whether and if so how this has changed over time.

40.1. In 1994, when I began work at the Edinburgh Centre I did not frequently attend the outpatient haemophilia review clinics, so I cannot comment on how often blood samples were taken, nor for what purpose.

40.2. In 1999, as a trainee, I helped alongside my fellow trainees to do a small clinic each Friday morning for review patients, usually with mild bleeding disorders. Blood samples were taken as and when required, for the purposes of monitoring the patient's blood condition, but were not stored. I was also asked on occasion to take plasma for storing on the direction of the Consultant, and I would always have told the patient that the plasma was to be stored. I assumed this might be for the purposes of any look-back exercise in the event of the finding of an unknown pathogen.

40.3. On return in 2008, when I had my own clinic at the Edinburgh Centre, I have only taken blood samples for the purpose of defining the patient's current health and underlying haematological diagnosis. No samples have been stored, with the exception of samples being stored indefinitely for the purposes of DNA extraction for genetic testing.

40.4. For this situation, the patient is counselled and provided with written information about the test. I make sure the patient is given adequate information in lay terms and has plenty of time to ask any questions. I make sure ahead of the consultation that there is no language or communication barrier.

40.5. After a full and open discussion, if the patient is in agreement to go ahead with the testing of DNA for a specific condition, that patient is also requested to provide written consent, a copy of which is kept in the case records, and since 2017 is also now scanned into the patient's electronic record. A copy of the consent form is also stored in the genetics laboratory.

40.6. The genetics laboratory only store DNA. Blood is discarded after the DNA has been successfully extracted.

DNA samples are stored indefinitely unless a patient specially requests for a sample to be discarded after testing is completed. This is in keeping with the Royal College of Pathologists guidance on "The retention and storage of pathological records and specimens", 2015. https://www.rcpath.org/uploads/assets/049ea966-df5c-4a9f-9353ba24a69bb808/The-retention-and-storage-of-pathological-records-and-specimens-5th-edition.pdf

41. During the time that you have worked at the Edinburgh Centre, have patients under its care ever been tested for HIV or for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur??

41.1. During the times that I worked at the Edinburgh Centre, in 1994, 1999 and from 2008 to date, I have never been aware of patients being tested for HIV or hepatitis without their express and informed consent.

What was the approach to obtaining consent for testing? Was their consent recorded and if so how and where?

41.2. In 1994, and in 1999, I had limited involvement with the Edinburgh Centre outpatient clinics and was mostly involved with the care of patients on the ward. I do not recall being involved in obtaining consent for the testing of HIV or hepatitis for patients with inherited bleeding disorders at these times when I was a registrar.

41.3. I am not able to comment on the approach taken by others at the Edinburgh Centre in relation to obtaining consent for testing.

Please detail whether and if so how the Centre's approach has changed over time.

41.4. The approach to obtaining consent for testing has changed over time. HIV testing in 1994 had implications for insurance and involved a discussion with the patient ahead of the test(s) being carried out about that. Earlier than that, even the process of testing for HIV might have led to insurance implications. Effective treatments were not available at this time, and would have changed

the discussion and counselling with the patient prior to obtaining consent to test.

41.5. HIV is now treatable, with the majority of patients remaining fit and well on active retroviral treatment (ART). Hepatitis C is also treatable. Staff at the Edinburgh Centre will obtain informed consent in the same way as for any medical investigation, in accordance with GMC principles, and a written record is made in the case notes that verbal consent was obtained. Testing is voluntary and confidential. There is a discussion about how the test is performed, and how the result will be managed, turnaround time for the test, and a follow up consultation to receive test results.

41.6. The amount of counselling depends on the clinical setting, and how information is delivered is very much adapted to individual circumstances. Basic information is provided on the advantages of testing (for example, avoidance of late complications of disease if left undetected), the likelihood of false positive and false negative results, and the availability and effectiveness of treatment and prevention.

41.7. In terms of recording decisions, an accurate record is made in the clinical notes of any discussions leading to the decision to proceed to testing. Currently there is an electronic record made at the time of a consultation, and a letter is written for the patient's general practitioner, and a copy sent to the patient.

PUPS

42. 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).

42.1. In recent times "previously untreated patients" (PUPs) studies and clinical trials usually refer to studies of previously untreated children with severe haemophilia who are being exposed to a new product. There has been much focus in relation to recombinant products and inhibitor development. However, in those patients with non-severe bleeding disorders, a "PUP" could equally be an adult.

42.2. Historically, however, a "PUP" would be any previously untreated child, or adult, with an inherited bleeding disorder, and in that context prior to the advent of recombinant products it would mean they were plasma naïve, and had never been exposed to plasma products.

42.3. To qualify this, I interpret question 42 to ask about previously untreated children and adults with an inherited bleeding disorder who are plasma naïve – that is, they have never been exposed to plasma products.

42.4. When I was working at the Belfast Centre, I had a small number of adult patients diagnosed with a non-severe bleeding disorder who were "plasma naïve". If the patient required an operation or procedure with high bleeding risk, or had encountered a situation where the patient required several days of treatment to prevent bleeding, I avoided the use of plasma-derived products if at all possible, and used recombinant products if available.

42.5. If there was no available recombinant product, as, for example, has been the case for patients with Von Willebrands until recently, or for patients with inherited deficiencies or dysfunction of fibrinogen, then there would be a relatively limited choice in terms of avoiding plasma products. In such instances, I chose what was deemed the safest product in terms of viral inactivation steps, source of plasma, and ensure the plasma had been donated voluntarily. I considered the use of alternative haemostatic measures such as the use of DDAVP for mild haemophilia A, some subtypes of von Willebrands and patients with congenital thrombocytopenia. I also considered the use of antifibrinolytic inhibitors such as tranexamic acid, as well as monitoring factor assays to guide dosing, and the use of local haemostatic measures if appropriate. All these techniques may avoid, or reduce the amount of, plasma-derived therapy used.

42.6. If a patient requires a therapy and I am in a position that I am only able to administer a plasma-derived therapy, then I counsel the patient about the product, its manufacture, the source of origin of the donor plasma, the viral inactivation techniques used in the product's manufacture and I provide a copy of the manufacturer's product information leaflet, and any other patient information leaflets.

42.7. At the Edinburgh Centre, I am not responsible for the management or care of children, and have not been involved with haemophilia A or B "PUPs".

42.8. I have a small number of adult patients with rare or mild bleeding disorders who are plasma naïve. I try to avoid the use of plasma-derived products if at all possible, and use recombinant products if available. If not available I will consider alternative means to effect haemostasis if undergoing surgery, such as the use of tranexamic acid, desmopressin (DDAVP) and local haemostatic agents. Similar to my previous practice in Belfast, if a patient requires a therapy and I am only able to administer a plasma-derived therapy, then I counsel the patient about the product, its manufacture, its source of origin of the donor plasma, the viral inactivation techniques used in its manufacture and provide a copy of the manufacturers product information leaflet, and any other patient information leaflets. I counsel the patient regarding the consequences of not receiving the plasma-derived product.

Recombinant

43. During the 4th meeting of the UKHCDO Advisory Committee held on 15 May 2001 [BART0000936_002] you were noted as saying that a very minimum (1 week) stock of rVIII was held in Belfast, only children got rVIII and many children previously treated with pdVII had been taken off rVIII. Was the low availability of recombinant treatment more scarce in Northern Ireland at this time than in England, Wales or Scotland? If so, did the low availability of recombinant products result in treatment of children with plasma derived products? Were any patients (children or adults) treated with plasma derived products for the first time due to lack of availability of recombinant products?

43.1. The minutes of this meeting record a discussion about the effect across the United Kingdom of an acute shortage of Kogenate, one of three available recombinant factor VIII products at the time.

43.2. Kogenate was made by Bayer pharmaceuticals, and due to a manufacturing issue, there was an acute shortage of the product in the marketplace, that immediately caused pressures for the other companies manufacturing recombinant factor VIII (namely (Baxter plc, and Wyeth) to fill. Each company

had only one manufacturing plant at that time, leading to an acute global supply problem.

43.3. During the UKHCDO Advisory meeting held on 15 May 2001, chaired by Professor Frank Hill, each Centre Director was asked to state how the shortage was affecting their centre. The purpose of this discussion was to ensure a coordinated approach to the sharing of recombinant products across the UK, and to try to ensure that as few plasma-naïve patients were exposed to plasma-derived products as a result of the acute shortage.

43.4. At the time, in 2001, to the best of my knowledge, which was gained from speaking to a number of Haemophilia Comprehensive Care Centre Directors across England, Wales, Scotland and Ireland, only Wales had switched all patients uniformly over to recombinant products (for those indications where a recombinant product was available), although Ireland, at the time, had switched their haemophilia A patients over to Recombinate, and I think that Canada also had uniformly switched over as well. Additionally at this time, it is my recollection that there were insufficient supplies of recombinant factor VIII to meet the demands of the UK.

43.5. Since taking up appointment as the Belfast Centre Director in November 2000, I had been actively working with the Department of Public Health in Northern Ireland to audit the use of factor concentrate to estimate the cost of switching any remaining adult patients over to recombinant products, and the anticipated time-frame to do so **(HCDO0000264_125 - letter dated 13 May 2002 to Dr F Hill re: Profile of Coagulation Factor Usage in Northern Ireland; HCDO0000264_125 - "A Profile of Haemophilia patients in Northern Ireland and their use of clotting factors, dated July 2001)**

43.6. The situation in Northern Ireland when I first arrived in November 2000, was that all children received recombinant factor VIII and, specifically, were receiving the product Kogenate. The total number of children receiving recombinant factor products was 48. Their management was under the guidance of my colleague, Dr Sid Dempsey, Consultant Paediatric Haematologist.

43.7. One adult patient, who had participated in a clinical trial with Wyeth, was taking Refacto, a B-domain deleted recombinant factor VIII. A few adults had just been switched by myself from plasma-derived factor VIII to Recombinate, a recombinant factor VIII product.

43.8. 54 adult patients with mild to moderate haemophilia A, and any previously unexposed patients (PUPS) requiring treatment, were treated with Recombinate.

43.9. 31 adult patients with severe haemophilia A were receiving plasma-derived factor VIII (Liberate (SNBTS) and Replenate (BPL).

43.10. All patients with severe factor IX deficiency were receiving Benefix, the only available recombinant factor IX concentrate, when I started to work at the Belfast Centre. For all children and adults with mild haemophilia B, procedures and operations were covered with recombinant factor IX.

43.11. Patients with inhibitors to haemophilia A had also been offered treatment with recombinant factor VIIa.

43.12. This information is captured in a brief I wrote to inform the Minister of Health, Ms de Brún ahead of questions taken at the Northern Irish Assembly on 7th May 2001 and on 11 May 2001. **(WITN4027027, WITN4027028 and WITN4027029)**

43.13. I do not believe that this pattern of recombinant factor usage was different to the majority of other English comprehensive care centres at the time, and it may have been superior to many centres, but fell a little behind the Welsh and Scottish centres who were a little ahead with the transition of all severe haemophilia A patients to recombinant products.

43.14. The stock control for factor concentrates was maintained at the Royal Victoria Hospital Blood Bank, and to the best of my knowledge, there was a small stock supply of Kogenate held in the Blood Bank that was dispensed to the Royal Hospital for Sick Children, that was on the same hospital site. Top up

supplies were received monthly, to the best of my recollection, by ferry, and occasionally did not arrive at the anticipated time.

43.15. The acute shortage had not been realised by Blood Bank staff, who were very vigilant about stock supplies, as we were used to stores being replenished at frequent intervals; but also I recall that the company had not informed the Belfast Centre of the global shortage.

43.16. An acute shortage of recombinant factor VIII followed, with the result that Dr Dempsey and his team had to discuss with the parents and carers of children about reducing the level of prophylaxis, and in some children stopping altogether and treating "on demand" for a period of time, until the supplies of Kogenate and other recombinant factor VIII products once again became available. This explains my comment that some children had been "taken off recombinant factor VIII".

43.17. Thanks to the relocation of supplies urgently from two centres in the UK– from the Glasgow Adult Haemophilia Centre, who sent a supply of Refacto overnight by ferry (acknowledging the support and help from Professor Campbell Tait), and from the Manchester Haemophilia Centre (acknowledging the efforts of Professor Charles Hay) who relocated supplies of recombinant factor VIII to Belfast, in addition to some extra supplies from Wyeth, and Baxter plc, I can recall clearly that no children were treated with plasma-derived factor VIII at this time, and we managed to get through this period of acute shortage.

43.18. Specifically, in relation to the question about availability of recombinant factor VIII in Northern Ireland compared to other regions of the UK, my recollection is that Scotland and Wales at this time had largely moved their patients with haemophilia A over to recombinant factor VIII, as had the rest of Ireland. However my recollection is that the majority of English centres continued to use plasma-derived factor concentrate for adult patients with severe haemophilia A, due to the lack of availability of recombinant products from the three suppliers.

43.19. Following the 2001 crisis, the three suppliers opened second manufacturing plants and were in a position to offer Northern Ireland guaranteed supplies of

recombinant factor VIII with sufficient stock to enable the switch of adult patients with severe haemophilia A to recombinant products.

43.20. No patients (neither adults nor children) who were plasma-naïve, were treated with plasma-derived products due to the lack of availability of recombinant products at this time, nor at any time during my tenure as Director of the Belfast Centre.

43.21. This acute global shortage of factor VIII influenced the rationale to have more than one manufacturer at any given time to supply products to a region in the event of a further supply problem from one manufacturer. It followed that children and PUPs received Kogenate (Bayer), the majority of adult patients who had been on SNBTS and BPL- plasma-derived factor VIII were switched to Recombinate (Baxter plc) and a smaller number of patients were switched to Refacto (Wyeth). The choice of recombinant product was largely dictated by the initial volumes of product that each manufacturer could provide, and to a lesser extent the need for a different factor assay to measure factor VIII levels in the laboratory, making the Wyeth product a little more difficult to introduce at the time.

Research

44. Please list any research studies that you have been involved with that could be relevant to the Inquiry's Terms of Reference and please:

a. describe the purpose of the research;

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

c. explain what your involvement was;

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

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

f. state the number of patients involved;

g. provide details of the steps taken to inform patients of their involvement and seek their informed consent; and

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

44.1. LIST OF RESEARCH STUDIES

44.1.1. A prospective registry of European patients receiving BeneFIX for usual use (26th November 2001).

44.1.2. A prospective registry of European Haemophilia B patients receiving BeneFIX (Nonacog Alfa, Recombinant Human Factor IX) for usual use (amendment 1: 22nd January 2002)

44.1.2.1. **a.** This was an open-label multi-centre Registry in patients with haemophilia B receiving BeneFIX. All patients who commenced treatment with BeneFIX in European Union countries were eligible for participation. Patient demographics were collected at baseline for all patients. A baseline FIX activity and Bethesda assay for inhibitor based on historical data was recorded if available. Adverse events, as defined in a protocol, were to be reported on the appropriate forms. Data was to be collected from patients on an ongoing basis to ensure that information was being captured for each patient being treated with BeneFIX.

44.1.2.2. **b.** The research was approved by the Research Ethics Committee, Royal Group of Hospitals, Belfast. (Application No 270/02 MREC/02/7/24)

44.1.2.3. c. My involvement was as a local investigator.

44.1.2.4. d. This was a pharmaceutical company funded project, and Bayer plc was the manufacturer of BeneFIX. No other organisations were involved.

44.1.2.5. e. The registry was funded by Bayer plc. No funds were received for recruitment of patients nor for participation in the study.

44.1.2.6. f. I cannot recall any patients being approached or involved during my time in Belfast, and I do recall only one patient at the Belfast centre who received BeneFIX regularly who would be eligible. It is likely that I obtained ethical approval but did not move forwards with the research due to time constraints. The Belfast Centre is not listed as a participating centre in the final publication of this work.

44.1.2.7. g. There were patient information leaflets and written consent forms that were fully approved locally in Northern Ireland by the Research Ethics Committee of the Royal Group of Hospitals. Although I requested approval to move ahead with the research project from the Ethics Committee, and approval was granted, it seems Belfast was not a recruiting centre.

44.1.2.8. h. There are no details of any publications relating to the research. As far as I can recall, no patients were recruited.

44.1.3. 2. 5-year surveillance study of new variant CJD in patients with haemophilia.

44.1.3.1. a. The purpose of the research was a 5-year surveillance study of new variant CJD in patients with haemophilia.

44.1.3.2. The aims of this study were to determine the extent of exposure of individual patients with inherited bleeding disorders to implicated batches of clotting factor concentrate; to analyse tissue biopsies and autopsy material for vCJD and to notify possible and confirmed clinical cases of vCJD in the UK haemophilia population. It was requested that consideration was given to all patients with haemophilia or inherited bleeding disorders undergoing surgical procedures involving the central nervous system or lymphoid tissue such

as lymph node biopsy, splenectomy or tonsillectomy to consent to participate in the study. The control group comprised haemophilic patients who had not received known implicated batches of factor concentrate.

44.1.3.3. It was hoped that in addition to facilitating the appropriate monitoring and long-term follow up of patients, the findings from this study would inform future assessments of the risk of vCJD transmission by plasma products.

44.1.3.4. b. The research had been granted ethical approval by the London Multi-Centre Ethics Committee, MREC/01/2/11. The research was fully approved locally in Northern Ireland by the Research Ethics Committee of the Royal Group of Hospitals. The Chairman of the Research Ethics Committee, Dr T J McMurray spoke with Dr Millar ahead of granting full approval for this study (**WITN4027030** - MREC/01/1/11 vCJD study).

44.1.3.5. c. My involvement was as a local investigator.

44.1.3.6. d. Other organisations or bodies involved in the research: the UKHCDO was the organisational body that coordinated this research project, and Dr Carolyn Millar was the principal investigator, under the direction of Professor Christine Lee, Royal Free Hospital, London.

44.1.3.7. e. The research was commissioned and funded by the UK Department of Health, and coordinated by UKHCDO.

44.1.3.8. No research funds were received.

44.1.3.9. f. One patient was recruited to this study from the Belfast Centre.

44.1.3.10. g. I met with the patient ahead of an operation to discuss the arrangements for haemostatic cover. During that clinical consultation, I explained the nature of the study and discussed

the need for verbal and written informed consent, if the patient wished to enter the study. The patient was under no obligation to enter the study. The patient willingly accepted entry to the study and was keen to know of any results. The patient was able to withdraw from the study at any time. I met with the patient after the operation, and updated the patient of the results that had been given to myself directly from the CJD surveillance team in Edinburgh.

44.1.3.11. h. The publication by Zaman et al. from 2011 details, in general, the results of the UKHCDO variant Creutzfeldt Jakob Disease surveillance study to date: The risk of variant Creutzfeldt-Jakob disease among UK patients with bleeding disorders, known to have received potentially contaminated plasma products. (**WITN0644101**)

45. Please provide the same details in relation to any epidemiological or similar studies which you undertook or in which you were involved (insofar as they are relevant to the Terms of Reference).

45.1. Apart from the UKHCDO led 5-year surveillance study of new variant CJD, outlined in section 44, I have not been involved in any other epidemiological or similar studies.

46. Please include details of the Belfast Centre's participation in a UKHCDO study on surveillance of vCJD.

46.1. The details of the Belfast Centre's participation in a UKHCDO study on surveillance of vCJD are given in my response to question 44.

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

47.1. I understand that the following ethical principles, as taught in the Edinburgh Clinical Research Facility course "Good Clinical Practice", that I attend annually, and by which I abide, should guide research:

47.1.1. To conduct research as capably as the researcher's knowledge permits.

47.1.2. To protect the dignity and preserve the wellbeing of human research participants.

47.2. To meet these obligations requires:

47.2.1. Respect for free and informed consent from research participants.

47.2.2. Respect for privacy and confidentiality of research participants, from the identification of research participants through analysis of data and dissemination of results.

47.2.3. Minimising the impact and possible risks of research, whether the impact is on an individual, a community, or an environment.

47.2.4. The protection of data to comply with UK regulations and agreed procedures regarding storage, archiving, and in some cases, destruction of data.

47.2.5. Conducting research based on a protocol that has been passed by an ethics committee.

47.2.6. Operating with honesty and integrity at all times.

47.2.7. A full declaration of any conflicts of interest.

47.3. I fully applied these principles to the research studies referred to in question 44.

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

48.1. No. Patients were only involved in research studies after free and full informed verbal and written consent.

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

49.1. No. Patient data was not used in any way (anonymised, de-identified or otherwise) for the purpose of research or for any other purpose without their express consent.

50. Was patient data (anonymised, de-identified or otherwise) shared with third parties (e.g. to UKHCDO)? If so how and why did this occur and what information was provided and to whom?

50.1. I have not undertaken research where patient data was shared with third parties.

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

51.1. I presented an abstract "Seroconversion to Parvovirus B19 following a course of treatment with plasma-derived factor VIII" at the XXIV International Congress of the World Federation of Hemophilia, 16-21 2000. **(WITN4027031)**

51.2. Permission and consent was obtained from the patient prior to the presentation of the abstract.

Treatment of patients who were infected with HIV and/or hepatitis

52. How was the care and treatment of patients with HIV/AIDS managed at the Belfast 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?

52.1. I only have knowledge of the care and treatment of patients with HIV/AIDS managed at the Belfast Centre relating to when I was Consultant there from November 2000 – July 2004.

52.2. At that time, to the best of my recollection, there were four patients with HIV infection as a consequence of treatment with contaminated blood products, or as a consequence of treatment of a spouse who had been infected through contaminated blood products.

52.3. All patients were co-managed by a specialist in infectious diseases, Dr Michael McBride, Consultant in Infectious Diseases initially, and later (from September 2001 onwards) by Dr Say Quah, Consultant in Infectious Diseases.

52.4. This clinic was primarily based at the Royal Victoria Hospital, Belfast and had access to specialist pharmacists, counsellors and used highly active anti-retroviral medication, and provided a state-of-the-art clinical service to the patients.

52.5. Following the Centre's relocation to the Belfast City Hospital site, Dr Say Quah continued a joint HIV/haemophilia clinic at the Centre with myself and Dr Orla McNulty, Staff Grade/Associate Specialist. During my time in Belfast, I did not perceive any issues with the care that had been given, or was being given, to those patients who were infected with HIV.

52.6. **a.** All patients had been referred to the relevant specialist prior to my taking up post as Consultant and were being seen and followed by the specialist unit. There was excellent written communication between the clinics so that the Belfast Centre team was kept up to date with specialist reports.

52.7. **b.** When I was at the Belfast Centre, from 2000 – 2004, all patients were regularly reviewed and had been offered, and were taking a combination of highly active anti-retroviral drugs. I am not able to comment on the treatments available prior to my taking up post.

52.8. **c.** When I met these patients at the Belfast Centre, they had already received full counselling about the risks and benefits of specific medications and about side effects and complications by Dr McBride and Dr Quah.

52.9. **d.** The follow up and ongoing monitoring of patients infected with HIV initially involved follow up at the Infectious Diseases Clinic as well as at the Haemophilia Centre. Along with Dr McBride, I set up a joint HIV/haemophilia at the Royal Victoria Hospital, and this joint clinic continued when the service relocated to the Belfast City Hospital site in 2001, and was led by Dr Say Quah. Counselling and pharmacy support was available through this clinic, and the clinic was conducted within the Belfast Centre.

53. How has the care and treatment of patients with HIV/AIDS been managed during the time you have worked at the Edinburgh Centre? In particular:

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

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

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

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

53.1. I am only able to comment on the care and treatment of patients with HIV at the Edinburgh Centre from 2008 onwards.

53.2. I have read, from the audit reports from 1994 through to 2019, that Dr Ray Brettle, from the Regional Infectious Diseases unit, was the specialist who provided input prior to Professor Christopher Leen.

53.3. In 2008, patients were already referred to the Regional Infectious Diseases Unit (RIDU), based at the Western General Hospital in Edinburgh. Specialist care was provided by Professor Clifford Leen until his retirement, and is currently provided by Dr Rebecca Sutherland, Consultant in Infectious Diseases and also an Associate Specialist, Dr Hazel Rae, with access to a specialist pharmacist and counsellors.

53.4. Blood tests are usually taken for the RIDU team when the patient attends the Edinburgh Centre in a coordinated way to avoid the need for two venepunctures. We try to coordinate the visits and there has always been good written and verbal communication between the teams, with the receipt of timely clinic correspondence.

53.5. **b.** Since starting work at the Edinburgh Centre in 2008, patients had been offered anti-retroviral drugs, with counselling and advice, and a full discussion about the side-effects by the RIDU team.

53.6. **c.** Patients seem well-informed about the risks and benefits of specific treatments and about side-effects of therapies. The RIDU has specialist pharmacists who have expertise in the various drug regimens and potential for drug resistance, as well as knowledge of drug-interactions with other medications and help with counselling of patients.

53.7. **d.** The follow up involves attendance at the RIDU and the Edinburgh Centre, where blood tests are taken at the request of RIDU to save multiple venepunctures. Sometimes our nursing team have attended a patient's home to take blood tests if RIDU need blood taken and there are practical difficulties getting to the Edinburgh Centre.

54. How was the care and treatment of patients with HBV managed at the Belfast Centre? In particular:

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

b. **What treatment options were offered over the years?**

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

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

54.1. I am not aware of any patient with HBV infection when I was at the Belfast Centre, nor the care and treatment of patients with HBV managed at the Belfast Centre prior to 2000. I am not aware of the treatment options over the years, nor the information provided to patients about the risks and benefits of specific treatments and about side effects.

54.2. During my time at the Belfast Centre, I did not meet any patient with active hepatitis B infection, nor with chronic hepatitis B infection, and so I was not in the position that I needed to seek this type of specialist input.

55. **How has the care and treatment of patients with HBV been managed during the time that you have worked at the Edinburgh Centre? In particular:**

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

b. **What treatment options have been offered over the years?**

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

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

55.1. In 1994 and 1998 I did not assess or review any patients with acute hepatitis B infection or chronic hepatitis B infection at the Edinburgh Centre.

55.2. Since 2008, I have not assessed or reviewed any patients with acute hepatitis B infection or chronic hepatitis B infection at the Edinburgh Centre. In the event that advice might be required, our colleagues in the Department of Hepatology, or from the Regional Infectious Diseases Unit (RIDU) can be contacted.

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

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

b. What treatment options were offered over the years?

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

d. What if any advice was given with respect to lifestyle, including but not limited to the consumption of alcohol and different kinds of food?

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

56.1. To the best of my knowledge prior to taking up my post in Belfast, the care and treatment of patients at the Belfast Centre in relation to hepatitis C management rested solely with the Haemophilia Centre Director as there was a lack of access to specialist care locally in Northern Ireland.

56.2. In 2000, there was a part-time hepatologist based at the Royal Victoria Hospital for the region of Northern Ireland. This doctor's workload was such that, to the best of my knowledge, only a small number of patients who had been infected with hepatitis C (as a consequence of the receipt of plasma products infected with hepatitis) had been assessed on the basis of the severity of liver disease and the development of clinical complications such as liver cirrhosis.

56.3. My role in highlighting this service deficiency and resolving the issue is described in my responses to questions 57 to 60.

56.4. **a.** I am not able to comment on the steps that were taken to refer patients for specialist care prior to November 6 2000, when I started my position as Centre Director.

56.5. From the time of my appointment until the end of June 2004, Dr McNulty and I formally referred patients who had been infected with hepatitis C in consequence of blood product transmission, to a part-time hepatologist, Dr Callender, Consultant Physician, who was based at the Royal Victoria Hospital. This was done at the time of their haemophilia clinic review appointment by letter.

56.6. I systematically attempted to review each patient registered at the adult Belfast Centre through the establishment of haemophilia review clinics. These review clinics included patients with all types and severities of inherited bleeding disorders across the region of Northern Ireland. As my colleagues and I reviewed each patient, we made a formal referral to the hepatology service, and a written record was made in the clinical notes and the referral letter was filed.

56.7. It is stated in the UKHCDO 2003 audit "Summary of Audit Findings and Recommendations"-

56.7.1. "Despite referrals from Dr Anderson, patients with haemophilia are not being evaluated (for complications of hepatitis C) systematically or in a timely manner".

56.8. To the best of my recollection, only a very small number of patients were seen, usually those patients who had developed late complications of hepatitis such as advanced liver cirrhosis complicated by portal hypertension.

56.9. My efforts in relation to addressing the deficiency in this aspect of service provision are detailed in questions 57 to 60.

56.10. To the best of my recollection, during my tenure as Belfast Centre Director, two patients developed hepatocellular carcinoma. The patients were referred to the Department of Oncology, and the hepatobiliary surgeon with an interest in liver disorders, for opinion and advice.

56.11. **b.** To the best of my knowledge, prior to my tenure in Belfast as Centre Director, some patients had gained access to antiviral treatment options through entry into clinical trials.

56.12. From 2000, the treatment options available to treat hepatitis C, to the best of my knowledge, were ribavirin and interferon in combination, and from 2001, with pegylated interferon. Despite my best efforts to highlight both a lack of specialist service as well as the need to fund these antiviral drugs for patients who had been infected with hepatitis C as a consequence of contaminated plasma products, the combination treatment of ribavirin/ pegylated interferon alpha was not available until June 2004, around the time that the combined hepatology/haemophilia clinic was established.

56.13. The report prepared for the Northern Ireland Regional Medical Services Consortium by Dr Callender, dated 13 May 2003, highlights the available treatment options for patients with hepatitis C in Northern Ireland (**RHSC0000275_001 - Proposal for the Treatment of Hepatitis C 2003 – 200**6). This report was based on information from a hepatitis C database and the projected number of new cases, and indicated a "backlog" of 48 patients who, in the opinion of the author of the report, merited treatment for hepatitis C.

56.14. As per conclusion point 10, this number of patients did not include the cohort of patients with inherited bleeding disorders who had been infected with hepatitis C as a consequence of contaminated plasma products.

56.15. Conclusion points 11.6 to 11.8 highlight that, in 2003, pegylated interferon alpha was not funded in Northern Ireland. The author of the report makes the case to fund pegylated interferon on the basis that a sustained viral clearance is more likely with a combination of ribavirin/pegylated interferon compared to ribavirin/interferon.

56.16. Commenting on liver transplantation, no patients in Northern Ireland were referred for liver transplantation when I was Centre Director from November 2000 to June 2004.

56.17. **c.** During my tenure as Director of Haemophilia at the Belfast Centre, from November 2000 to July 2004, no patients at the Belfast Centre were offered antiviral treatments for hepatitis C. However, available treatments and their main side-effects were discussed at clinic review appointments by myself as far as I was able.

56.18. **d.** General advice regarding the consumption of alcohol and avoidance of hepatotoxic medications was provided at haemophilia review clinics.

56.19. **e.** The follow-up and ongoing monitoring of the status of hepatic function was provided, as best as my team and I were able, at the Haemophilia Centre review clinics.

56.20. This included: regular checks of liver function on a three or six monthly basis; full blood count analysis to monitor the haemoglobin; white blood count and platelet count; a coagulation screen; and, a measurement of the alpha fetoprotein level to monitor for hepatocellular cancer. Patients also underwent liver ultrasound examination. A very helpful consultant virologist, Professor Peter Coyle, assisted with the interpretation of virology results and their significance, and I recall he met with some patients on occasion at the Belfast Centre to explain their results to them.

56.21. In the event that clinical signs and symptoms, and/or trends in blood results required further opinion I would re-contact the part-time hepatologist, Dr Callender, to seek advice, usually in respect of initiating endoscopic surveillance of varices and treatment for chronic complications of hepatitis C such as portal hypertension and cirrhosis.

56.22. In the UKHCDO 2003 audit, the medical auditor, in the section: "Summary of Audit Findings and Recommendations" writes-

56.22.1. "Whilst Dr Anderson and her colleagues are monitoring liver function tests and are requesting ultrasound examinations in an attempt to monitor disease progression, this approach is no longer considered sufficient. The standard of care expected by UKHCDO is that every patient has access to a hepatologist. It is not acceptable to expect a haematologist to manage the complexities of liver disease in patients with haemophilia."

56.23. This audit finding was noted by the Medical Director of Belfast City Hospital, Dr Fullerton in a letter dated 17 October 2003 **(WITN4027032)** and the response was "I understand that those (findings) relating to a hepatology service are shortly to be resolved by the appointment of an additional consultant at the Royal Hospital Trust".

56.24. This was indeed the case. By the end of June 2004, a consultant hepatologist had been trained to completion of specialist training from within the specialist registrar rotation in gastroenterology and liver disease in Northern Ireland, enabling a consultant-led joint hepatology/haemophilia clinic to be established. As soon as the joint clinic was established, there was immediate access to combination pegylated interferon and ribavirin therapies, and support from the Belfast City Hospital Pharmacy with respect to counselling about side effects of treatments alongside the Belfast Centre nursing and medical staff.

56.25. Unfortunately I was only able to attend a few of the combined haemophilia/hepatology clinics before I left the Belfast Centre in August 2004.

57. In a fax you wrote to Dr Frank Hill, the Chairman of the UKHCDO dated 10 January 2002 [HCDO0000264_131] you referred to a "major problem with provision of care for patients with hepatology problems" at the Belfast Centre. What was the nature of this problem? What if any steps were taken to resolve it?

What was the nature of this problem?

57.1. Seventy-five patients registered at the Belfast Centre with congenital bleeding disorders were infected with hepatitis C prior to 1991. Of these patients, twenty-five had been treated with either monotherapy with either ribavirin or

interferon, or dual therapy, and often on two separate occasions, but only five had a sustained viral response. Twenty-seven patients were untreated. Patients that were co-infected with HIV infection had hepatitis C managed by the infectious diseases team **(SEE WITN4027023 - letter to Mr Dorian DHSS 10 September 2003)**

57.2. The nature of the problem, at the time of my appointment, and during my tenure as Centre Director at the Belfast Centre, from November 2000 to August 2004, was two-fold:

57.2.1. The adult patients at the Belfast Centre had lack of access to specialist hepatology opinion due to a lack of available service provision within Northern Ireland. There was only one part-time hepatologist for the whole region.

57.2.2. A lack of funding for the combination treatment of ribavirin and pegylated interferon during the time-frame that I was in tenure, from Nov 6 2000 to June 2004 (SEE **RHSC0000275_001**- Proposal for the treatment of hepatitis C, 2003 to 2006).

What, if any, steps were taken to resolve it?

57.3. The steps I took, the discussions held with colleagues, and the level of discussions are catalogued by the following references and diary extracts, and culminated in the development of a combined hepatology/haemophilia clinic at the Belfast Centre that commenced on 28 June 2004.

57.3.1. Letter to Head of Department of Haematology, Royal Victoria Hospital, Belfast, Dr F Jones prior to accepting appointment as Director of the Haemophilia Centre, outlining the need to ensure provision of hepatology support to correct the deficit demonstrated in 2000 UKHCDO Audit (**WITN4027033**)

57.3.2. Post appointment discussion with Medical Director, and prior to taking up post, dated 18 August 2000 (**WITN4027034)**

57.3.3. Meeting with Medical Director, 15 December 2000 (**WITN4027035**, **WITN4027036** and **WITN4027037**) and the actions taken by the Medical Director to address issues raised (raising discussions with Chief Medical Officer).

57.3.4. Service Planning Group meeting regarding hepatitis C, Medical Director, RVH, Dr I Carson: 3 January 2001. (**WITN4027038**)

57.3.5. Attendance at a meeting of the Regional Medical Consortium, County Hall, Ballymena: 18 January 2001 where the service deficit and other issues relating to hepatitis C were highlighted (see **WITN4027008**). Minutes from this meeting advise that issues were taken to the deputy CMO regarding service pressures.

57.3.6. Planned meeting with Dr Jane Collins (Oxford), Dr P Coyle (Virology), Dr Callender, Consultant Hepatologist and the medical directorate service manager regarding hepatitis C issues: 21 February 2001. At this stage it was hoped that a service might be available from the Oxford hepatology service, but to the best of my recollection, pre-meeting discussions led to a decision that this arrangement was not feasible (**WITN4027039**)

57.3.7. Meeting with directorate service manager, Valerie Jackson, Service Manager, Royal Victoria Hospital regarding hepatitis C issues, 25 April 2001 (**WITN4027040**)

57.3.8. Hepatitis C Audit meeting, 21 August 2001 (**WITN4027041**)

57.3.9. Representing the Belfast Centre at a Regional Hepatitis C Workshop, 5 December 2001 (SEE **WITN4027020, WITN4027021 AND WITN4027022**)

57.3.10. Meeting with Dr McNulty, Dr P Coyle and Dr C McCaughey regarding Hepatitis C in Northern Ireland, 29 March 2002 (**WITN4027042**)

57.3.11. Meeting with Dr Mock, Department of Health, Castle Buildings, Stormont, to discuss issues relating to hepatitis C, 2 October 2002. (**WITN40270423**)

57.3.12. Meeting with Dr Coyle, Regional Virology Lab regarding a hepatitis C audit, 2003) (**WITN4027044)**

57.3.13. Dr Callender meeting re hepatitis C, 4 Feb 2003 (**WITN4027045**)

57.3.14. Belfast Centre represented by myself and Dr Orla McNulty at the Scottish and Northern Ireland Haemophilia Directors' Hepatitis C Audit meeting, Edinburgh, 6 Feb 2003 (SEE **WITN4027026**)

57.3.15. Letter to Medical Director, Belfast City Hospital regarding perceived regional variation in care dated 19 March 2003 (**RHSC0000275_002**)

57.3.16. 22 Sept 2003 – telephone discussion with Dr J Little, Director of Public Health regarding hepatitis C – and I have a note that I discussed: "the hep C audit, extracontractual referrals to Scotland, compensation; as well as recombinant products roll out, time taken, and the need for a second haemostasis post. Apparently a hep C strategy to be circulated 'soon' ". (**WITN4027046**)

57.3.17. 23 September 2003 - letter received from Dr Callender regarding the appointment of a Consultant Hepatologist (**WITN4027047**)

57.3.18. 14 January 2004 – follow up letter to Dr Fullerton regarding the date of appointment of the new consultant hepatologist (**WITN4027048**)

57.3.19. 6 May 2004: Dr McDougall appointed and discussions surrounding a joint haemophilia/hepatitis C clinic starts, with pharmacy support for combination therapy (**WITN4027049**, **WITN4027050** and **WITN4027051**)

57.3.20. Date of the first hepatology/haemophilia clinic : 28 June 2004 x 5 patients seen. (**WITN4027005**)

58. In a letter you wrote to Dr Ken Fullerton, Medical Director at Belfast City Hospital, dated 19 March 2003 [RHSC0000275_002] you wrote that strategies for the management of hepatitis C were well implemented throughout Scotland, but you were not in a position to provide a similar strategy (and in particular, pegylated interferon) for patients at the Belfast Centre. What were the reasons for the difference you perceived in the standard of care provided in Scotland and Northern Ireland? What steps if any were taken following your letter to improve the treatment available?

What were the reasons for the difference you perceived in the standard of care provided in Scotland and Northern Ireland?

58.1. The differences in the standard of care related to (i) access to antiviral therapies, and (ii) access to a designated (named) hepatologist.

58.2. I noticed a difference in the standard of care provided between the two regions having attended a meeting in Edinburgh, convened by the Chairs of the Scottish/Northern Ireland Haemophilia Directors' Group, on 6 February 2003. At this meeting, the access to services at all the represented centres in Scotland and Northern Ireland was discussed. **(SEE WITN4027024, WITN4027025 and WITN4027026**)

58.3. As I outlined in my letter to Dr Fullerton, there was access to a named hepatologist at each haemophilia centre in Scotland, and Scottish patients had received access to pegylated interferon for some years.

58.4. I had also communicated with colleagues in two large comprehensive care haemophilia centres in England (Manchester and Birmingham), and I had communicated with my colleague in Dublin: from these personal communications I was able to inform my Medical Director that there was access to pegylated interferon at all these centres in different regions of the UK.

58.5. The standards of care at this time were available, and were referenced in my letter to the Medical Director **(HCDO0000264_001 - National Service Specification for Haemophilia and other IBD 2001 AND WITN3761021 -**

UKHCDO 2001 Guidelines on hepatitis management). I was anxious to alert our management that failure to meet the expected standards of care could jeopardise the comprehensive care status of the centre. Importantly I was concerned that my patients were not receiving access to the most optimal therapies for hepatitis C at this time.

58.6. On reflection, as the combination of pegylated interferon and ribavirin therapies became available at the time of the joint hepatology/haemophilia clinic in June 2004, the lack of access to therapies might in retrospect have been due to the lack of specialist hepatology opinion, but I cannot be sure. The report written by Dr Callender **(RHSC0000275_001)** prepared for the Northern Ireland Regional Medical Services Consortium, and dated 13 May 2003, highlights the situation regarding the available treatment options for patients with hepatitis C in Northern Ireland from 2001 onwards.

58.7. The various options for service provision were, I believe, discussed at a regional level, although not with myself. The options including sending patients to another country, or to a hepatology unit in England or Scotland posed logistical and practical problems and was not felt ideal. Telemedicine was not an option at that time, and certainly was not explored as far as I am aware.

58.8. I do not know which English or Scottish Trusts were approached to determine if a hepatologist could attend Belfast regularly to provide a service for the patients at the Belfast Centre. However, this model of remote care would have created challenges when monitoring patients on antiviral combination therapies.

58.9. I understand that it was felt most appropriate to train a registrar within the Northern Ireland gastroenterology/hepatology service to gain expertise in hepatology. However this process of training can take at least three years.

What steps if any were taken following your letter to improve the treatment available?

58.10. As I had kept Dr Fullerton well appraised of the situation, and he was most engaged with the adult Belfast Centre since its relocation to the Belfast City Hospital site in 2001, especially with matters relating to transfusion-

transmitted infection, I believe that he further discussed with colleagues in the Department of Health.

58.11. I suspect at this time the strategy to support patients with hepatitis C registered at the Belfast Centre centred on training a specialist in hepatology to take on the various aspects of service, and to appoint a new colleague who could be allocated to the Belfast Centre to enable a quality service for the management of patients with hepatitis C as a consequence of contaminated plasma products.

58.12. Towards the end of 2003, I received a letter from Dr Callender that a designated hepatologist would be appointed for the Belfast Centre **(SEE WITN4027047)**

58.13. However, treatments remained unavailable despite my best efforts until June 2004. At that time, a joint hepatology/haemophilia clinic was established at the Bridgewater Suite, Belfast Haemophilia Centre. Pegylated interferon and ribavirin combination therapy was available from that date onwards, and counselling was also available from the pharmacy.

59. How has the care and treatment of patients with HCV been managed during the time you have worked at the Edinburgh Centre? In particular:

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

b. What treatment options have been offered over the years?

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

d. What if any advice has been given with respect to lifestyle, including but not limited to the consumption of alcohol and different kinds of food?

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

59.1. **a.** When I worked at the Edinburgh Centre in 1994 and in 1999 as a haematology registrar, I was not involved in referring patients for specialist care regarding the treatment of hepatitis C virus, as it was not my role in the Edinburgh Centre to do so, and I am therefore unable to comment further on the arrangements. However, I recall clearly the ready availability of hepatology opinion from the Department of Hepatology, and the involvement of Professor Hayes as the lead of the hepatology/haemophilia liaison service at the Edinburgh Centre.

59.2. From 2008 onwards, the care and treatment of patients with hepatitis C virus was managed as an integral part of the Centre as part of a joint service, led by Professor Ludlam and Professor Hayes. Instructions for the arrangement of ultrasound scans, if needed, and any specialist monitoring was given by Professor Hayes, usually directly to the Associate Specialist, Dr Dennis, who knew the patients very well.

59.3. If I reviewed a patient, and there were any questions in relation to imaging, test results of any sort or anything else, I just needed to contact Professor Hayes, and he would come to review the patient at the centre in a timely manner.

59.4. **b.** I can recall patients being treated with combination ribavirin and interferon when I worked as a registrar in 1999, because I remember having to assess patients at the Edinburgh Centre who felt they were no longer able to tolerate the antiviral treatment, and also to monitor their blood counts.

59.5. I did not work at the Edinburgh Centre from late 1999 until April 2008.

59.6. In 2010 the Department of Haematology at the Royal Infirmary of Edinburgh started using the fibroscanner to assess the liver for fibrosis, that is an indicator of cirrhosis and more advanced liver disease.

59.7. The main antiviral therapies since 2014 are:

59.7.1. 2014 Sofosbuvir, Pegylated Interferon and ribavirin

59.7.2. 2014 Simeprevir, pegylated interferon and ribavirin

59.7.3. 2014 Simeprevir + sofosbuvir

59.7.4. 2014 Sofosbuvir/ ledipasvir (+/- ribavirin)

59.7.5. 2014 Sofosbuvir + daclatasvir (+/- ribavirin)

59.7.6. 2015 Ombitasvir/ritonavir/paritaprevir +/- dasabuvir (+/- ribavirin)

59.7.7. 2016 Elbasvir/ grazoprevir (+/- ribavirin)

59.7.8. 2016 Sofosbuvir / velpatasvir (+/- ribavirin)

59.7.9. 2017 Glecaprevir / pibrentasvir

59.7.10. 2017 Sofosbuvir/velpatasvir/voxilaprevir

59.8. The main combinations in use have been: Sofosbuvir/ ledipasvir (+/- ribavirin)(2014); Sofosbuvir / velpatasvir (+/- ribavirin)(2016) and Sofosbuvir/velpatasvir/voxilaprevir (2017).

59.9. The Royal Infirmary of Edinburgh is also a regional liver transplant centre, and since 2008 there have been, to the best of my recollection, 5 liver transplants for the region of NHS Scotland, and 2 of those patients have been registered at the Edinburgh Centre.

59.10. **c.** I am not able to comment on the information provided to patients about the risks and benefits of specific treatments and about side effects in 1999 as it was not my role or responsibility to initiate the treatments for hepatitis C.

59.11. From 2008 onwards, the treatment of hepatitis C has been led by the hepatology service under the guidance of Professor Hayes. Professor Hayes and his team counselled patients about the risks and benefits of specific treatments and side effects.

59.12. Currently, antiviral treatment is discussed and monitored by a hepatology nurse practitioner, and treatment is based on national clinical guidelines from Healthcare Improvement Scotland.

59.13. **d.** At general clinic reviews, patients were reminded of the need to moderate alcohol consumption, and provided with advice regarding diet and lifestyle.

59.14. **e.** Since 2008, there is ongoing follow up of patients, as part of their ongoing haemophilia review, either six monthly or annually, and this includes a review of their liver function and liver status.

59.15. Since 2013, all hepatitis C PCR positive patients at the Edinburgh Centre have been offered new antiviral treatments based on national guidance from Healthcare Improvement Scotland and all the patients have sustained viral clearance.

59.16. There is ongoing surveillance for hepatocellular carcinoma at the Edinburgh Centre with input from Professor Hayes regarding imaging and interpretation of blood test results.

60. Reviewing the time that you worked at the Belfast Centre, do you consider that the care and treatment available for patients with HCV has been more limited than for patients in other parts of the United Kingdom? If so, please explain your understanding of the reasons for the difference; how it has changed over time; and what if anything you/the Belfast Centre/Belfast Health and Social Care Trust did in response.

60.1. My knowledge of the care and treatment available for patients with hepatitis C in different regions of the United Kingdom, between November 2000 and August 2004 arrives from several sources: (i) acting as auditor for the Scottish and Northern Ireland Doctors Group, I audited a Scottish Centre in 2001 and was asked to comment on the hepatology service and treatments available in relation to UKHCDO standards; (ii) acting as auditor for the Leicester Comprehensive Care Haemophilia Centre in 2001, I was asked to comment on the hepatology service and treatments available in relation to the UKHCDO standards; (iii) informal discussion with other comprehensive care

haemophilia centre directors in England, Wales, Scotland and Ireland; (iv) my haematology training in Edinburgh, that enabled comparison of the care and treatment available for patients in the South East of Scotland with that in Northern Ireland; (v) draft report of the triennial UKHCDO audit **(WITN4027071- Triennial CCC Audit summary draft report August 2002)** that highlighted service deficits across the UK – there were 3 haemophilia centres who lacked a designated hepatologist, but it is unclear if there was access issues to a hepatology team in general, or if there were access issues to a named hepatologist.

60.2. Using this knowledge, I state that the care and treatment available for patients with hepatitis C was more limited than for patients living in other parts of Scotland and England over the specific time-frame, November 2000 to June 2004. The virology testing, and diagnostic testing was, however, of a similar standard to other parts of the United Kingdom and was well led.

60.3. The reasons upon which I confirm this are:

60.3.1. Lack of a formal hepatology /haemophilia service: the standards of care in place, as stipulated by UKHCDO, were that a specialist hepatology opinion was necessary for patients infected with hepatitis C. However, over the period of time, November 2000 until June 2004 there was no formal haemophilia/hepatology service or clinic that I was able to refer patients to. The monitoring of liver function tests and ultrasound imaging, and results interpretation was primarily managed by myself and my Associate Specialist, Dr McNulty.

60.3.2. I formally referred patients to Dr Callender, part-time and the only available consultant hepatologist for the region of Northern Ireland. To the best of my recollection, only a few of those patients were seen, and I would stress that there was a very good relationship between the departments with frequent telephone consultations between the departments for other matters. A local trainee that had undergone specialist training to be a hepatologist, was subsequently appointed in 2004 as Consultant Hepatologist, and it

was in late June 2004 that a combined haemophilia/hepatology clinic was established.

60.3.3. Lack of regional funding for antiviral therapies for hepatitis C for those infected in consequence of contaminated blood products.

60.3.4. Please refer to my response to question 58 for further details.

If so, please explain your understanding of the reasons for the difference; how it has changed over time; and what if anything you/the Belfast Centre/Belfast Health and Social Care Trust did in response.

60.4. I have provided evidence in question that I escalated my concerns in writing to the Medical Director of the Royal Victoria Hospital about this service deficit in August 2000 prior to taking up my consultant position, and this concern led to a series of meetings with the Medical Director for the Royal Victoria Hospitals in December 2000 and January 2001.

60.5. I believe that my sincere efforts to raise concerns were taken very seriously by the senior management to whom I spoke, including several detailed discussions with Dr Ian Carson, Medical Director for the Royal Victoria Hospital, and I will provide evidence to this Inquiry that my concerns were escalated to the deputy Chief Medical Officer, and the Directors of Public Health for the four health boards in Northern Ireland. I had several dialogues with the Director of Public Health for the Eastern and Social Services Board, Dr Janet Little.

60.6. The Department of Health and the Health Boards convened a meeting, attended by both healthcare professionals and members of the public at Templepatrick on 5 December 2001 to discuss a Hepatitis C strategy for Northern Ireland, to which I was invited and attended.

60.7. I believe this strategic meeting was required to enable discussion about how to address the emerging need for a regional hepatology service, at a time when there was only a part-time hepatologist for the region, based in Belfast. If I recollect, there was an increasing workload and an exponential rise in new

referrals in Northern Ireland of patients infected with hepatitis C from all sources.

60.8. The Belfast Centre relocated to a different Hospital Trust in 2001, so I also discussed the service deficit with the Medical Director, Dr Ken Fullerton, and with Mr Quentin Coey, Chief Executive. Again, I am sure that my concerns were taken very seriously, and were escalated to the Department of Health. From 2003, I have notes in my work diary detailing meetings with Dr Glenda Mock, from the Northern Ireland Department of Health in relation to matters relating to hepatitis C.

60.9. I can recollect one discussion at some stage alluding to possible solutions for the cohort of haemophilia patients infected with hepatitis C in consequence of contaminated blood products as being: to invite a hepatologist to review patients at intervals in Belfast; to arrange a service agreement with one of the Scottish or English Trusts so that patients could obtain an opinion; or, to train a local trainee to become a specialist. I think, in retrospect, this last option was chosen as the most likely to have long-term benefits for the patients. However, I was not updated regarding the strategy so it was hard to keep the patients and the relevant patient groups updated.

60.10. I believe that my concerns were raised at the highest possible level, and at the earliest time I was able, during my time as Haemophilia Centre Director, and I continued to give this service deficit as high a profile as possible during my tenure. I believe that the Eastern Healthcare and Social Services Board (EHSSB) responded to my requests to improve service delivery by training a specialist in hepatology to serve the region, and this training period would have taken around 3 years.

60.11. I am unable to comment as to why the combination antiviral treatments were unfunded, nor when funding might have been approved, although I am aware that from June 2004, when the first hepatology/haemophilia clinics commenced, these therapies were available with appropriate pharmacy support and counselling.

60.12. When I first started to work at the Belfast Centre, I requested psychological support for the haemophilia patients and families infected with, and affected

by hepatitis C, but my request was declined by the Psychology departmental lead at the Royal Victoria Hospital, which was disappointing at the time - although realistically a business case was required.

60.13. Following relocation of the adult centre to the Belfast City Hospital site in May 2001, I had great support from the service manager, Dr Brian Armstrong, and I liaised with Professor Robin Davidson, Consultant Clinical Psychologist who was also most supportive. Although there was no specific funding allocated for service provision, and although there was no possibility of embedding a psychologist within the centre for support of patients and staff, I was able to introduce an ad hoc service that enabled medical staff to refer patients for psychological support, including patients who were requiring psychological support as a consequence of being infected with, and affected by infections as a consequence of contaminated plasma-derived products.

60.14. I was also able to put in place an aromatherapy service, funded in part by the Belfast Centre endowments and in part by a pharmaceutical company, Bayer, to enable support to patients and families infected through, and affected by contaminated blood products, including hepatitis C and HIV. The aromatherapy service also provided support to haemophilia patients in general.

61. What if any involvement have you and/or colleagues at (a) the Belfast Centre and (b) the Edinburgh Centre had with any clinical trials in relation to treatments for HIV and HCV? Please provide details.

61.1. (a) I had no involvement with any clinical trials in relation to treatments for HIV and HCV at the Belfast Centre during my time as Centre Director from November 2000 to August 2004.

61.2. I am aware that the Belfast Centre was involved with clinical trials in relation to treatments for HCV, only in so far as this was a route to obtain access to the hepatitis treatments of interferon and ribavirin, but I have no specific knowledge of the trials. I believe that Dr McNulty and Dr Mayne may be able to provide more information.

61.3. (b) Since 2008, to the best of my knowledge, the Edinburgh Centre has not been involved with any clinical trials in relation to treatments for HIV and HCV.

62. What if any arrangements have been made at or through (a) the Belfast Centre and (b) the Edinburgh Centre to provide patients infected through blood products with counselling, psychological support, social work support and/or other support during the time that you have worked there?

62.1. (a) At the Belfast Centre, regarding social work support, it is detailed in the 2000 UKHCDO report that there was designated social work support of up to 18 hours per week when the adult Centre was based at the Royal Victoria Hospital. The paediatric Centre at the Royal Hospital for Sick Children also had designated social work support. Following relocation to the Belfast City Hospital site in May 2001, there was social work support available for all patients using the Bridgewater suite on request, and I do not recall any issues in relation to the provision of social work support if this was required.

62.2. Regarding psychological support: when I first started to work at the Belfast Centre, I requested support for the haemophilia patients and families infected with hepatitis C, and affected by hepatitis C, but my request was declined by the departmental lead at the Royal Victoria Hospital, which was disappointing although somewhat expected as a business case for the workload was required. At the time the service was due to relocate to another Trust so a business case was put on hold temporarily.

62.3. Following relocation of the adult centre to the Belfast City Hospital site in May 2001, I had great support from the service manager, Dr Brian Armstrong, who put me in touch with Professor Robin Davidson. Although there was no specific funding allocated for service provision, and although there was no possibility of embedding a psychologist within the centre for support of patients and staff, a psychological support service was provided with the goodwill from the consultants that enabled medical and nursing staff to refer patients for expert counselling and psychological support therapies. Psychological support and counselling was provided at the Belfast Centre, as well as the Gerard Lynch Centre, Belvoir Park Hospital, Belfast.

62.4. I was also able to develop an aromatherapy service, funded in part by the Centre Endowments and in part by a pharmaceutical company, Bayer, for support to patients and families with inherited bleeding disorders. I was pleased to see the supportive effect of this service, particularly for patients and family members infected with, and affected by plasma products contaminated with hepatitis C and HIV.

62.5. (b) At the Edinburgh Centre, regarding social work support, I am unable to comment specifically in relation to the period 1994, and 1999, except that audit reports for these periods indicate that social work was available on request. From 2008 onwards, the haemophilia centre is located adjacent to the Social Work department, and support is available if required, but there is no designated social worker allocated to the centre.

62.6. Regarding psychological support, it is detailed in the 1994 UKHCDO audit report that there was a psychologist available, Dr Alison Richardson, who worked with patients and families infected with HIV. There was also access to a liaison psychiatry service at the Royal Infirmary of Edinburgh, led by Dr George Masterton, with counselling services available.

62.7. From 2008 onwards, on my return to the Edinburgh Centre, there was continuing access to counsellors and liaison psychiatric support from the Department of Liaison Psychiatry. This department is located along the main corridor of the hospital, not far from the Edinburgh Centre in its current location.

62.8. From 2016 there has been a service part-funded from Scottish Government, and part-funded from National Services Scotland, designed to embed a psychologist within the Edinburgh Centre, as well as funding for sessions from a liaison psychiatrist, who assesses patients within the Centre. After scoping the extent of service need, the psychologist has extended this service to the rest of Scotland, and there are now clinics at the Glasgow Centre. Even prior to the Covid-19 pandemic, the service was extended using virtual techniques such as Skype and NearMe technologies for patients in Inverness, Dundee, Aberdeen and other regions of Scotland. Please see my response to question 105.

63. During the time that you have worked there, was (a) the Belfast Centre and (b) the Edinburgh Centre allocated, whether by government or another source, any funding to help with counselling of patients infected with HIV or HBV or HCV? If so please provide details.

63.1. a. During the time that I worked at the Belfast Centre there was no funding from any source made available to help with counselling of patients infected with HIV, or hepatitis B infection, or hepatitis C infection.

63.2. b. The Edinburgh Centre was allocated funding in 2016, in part from Scottish Government, and in part from National Services, Scotland to support a pilot project evaluating psychological support services for patients and families with haemophilia and inherited bleeding disorders.

63.3. The funding was initially made available from Scottish Government to support and help with counselling of patients infected with HIV, and hepatitis B and C, but after discussion with Haemophilia Scotland and patient representatives, it was felt more appropriate for the funding of a psychological support service in general. Currently well over 50% of the workload supports those infected with, and affected by infection with HIV, hepatitis B and hepatitis C. Please refer to my response to question 105 for further details.

64. What kind of counselling if any has been made available to patients during the time that you have worked at (a) the Belfast Centre and (b) the Edinburgh Centre?

64.1. a. Please refer to my response in section 62 (a).

64.2. b. Please refer to my response in section 62 (b).

65. What (if any) difficulties have you whilst at (a) the Belfast Centre and (b) the Edinburgh Centre encountered in obtaining sufficient funding for the treatment of people who have been infected with HIV and/or HCV?

65.1. I interpret this question as "What (if any) difficulties have you had whilst at (a) the Belfast Centre, and (b) the Edinburgh Centre in relation to the funding of treatment or people infected with HIV and/or HCV" to mean "What, if any,

difficulties have you had whilst at Belfast, or Edinburgh…. in relation to the funding of antiviral therapies and the overall management of patients infected with HIV and/or HCV.

65.2. a. In Belfast, from November 6 2000 to 31 August 2004 there were no problems with the funding of services to support people infected with HIV, and there were no problems with the funding of the highly active retroviral therapies. Additionally the HIV clinic offered counselling, and there was also counselling from the psychology service made available at the Belfast Centre from September 2001 onwards. The aromatherapy service was funded by the adult Centre endowments and in part by a pharmaceutical company, Bayer plc.

65.3. However, as summarised in sections 56-58 of this witness statement, there were issues with the funding of antiviral therapies for hepatitis C from 2000 to 2004, and I believe pre-dating this.

65.4. Also, until June 2004 there was no designated hepatology service for patients with haemophilia who had been infected with hepatitis on consequence of receiving contaminated plasma products.

65.5. b. From 2008, when I returned to the Edinburgh Centre, I am not aware of any difficulties in funding either anti-retroviral therapy, nor any aspect pertaining to the HIV service.

65.6. I am not aware of any issues pertaining to the provision of antiviral therapies to treat hepatitis C, that have since been rolled out across Scotland irrespective of postcode since circa 2013.

Records

66. What was the policy and practice at (a) the Belfast Centre and (b) the Edinburgh Centre', during the time that you have worked at each, as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?

66.1. a) From November 2000 to August 2004 to the best of my recollection there was no requirement to complete a death certificate in the Belfast Centre. In accordance with policy and practice at the time full details were always completed on death certificates.

66.2. b) In 1994, when I worked within the Department of Haematology at the Royal Infirmary of Edinburgh and worked with colleagues within the Edinburgh Centre, I cannot recall the policy and practice as regards recording information on death certificates when a patient had been infected with HIV or hepatitis.

66.3. In 1999, when I worked within the Department of Haematology at the Royal Infirmary of Edinburgh and worked with colleagues within the Edinburgh Centre, I do not recollect any problems about recording information on death certificates when a patient had been infected with HIV or hepatitis.

66.4. From 2008 to date, the policy and practice is to fill out a death certificate as fully as possible, as for any other patient, giving full information about primary and secondary causes of death, and stating infection with HIV or hepatitis if relevant.

67. What were the retention policies, as regards medical records, of (a) the Belfast Centre and (b) the Edinburgh Centre during the time that you have worked at each?

67.1. (a) At the Belfast Centre, I moved all the patient archived records, and all relevant blood bank records, from the Department of Haematology, Royal Victoria Hospital to the Haemophilia and Thrombosis Centre, Bridgewater Suite, Belfast City Hospital at the time of the Centre's relocation in September 2001. The records were kept in a locked room within the Haemophilia Centre in the Bridgewater Suite. Old records were kept, to the best of my recollection, at Musgrave Park Hospital Records Department and there were strict instructions that old records must never be discarded owing to the likelihood of patients wishing to review their case records in the years to come.

67.2. I do not know the individual retention policies of the Royal Victoria Hospital, Belfast, nor the Belfast City Hospital Trust, but the Belfast Centre records

were kept unique and separate within these aforementioned areas when I was Director of the Centre.

67.3. b. At the Edinburgh Centre, all volumes of records were kept and maintained within the centre until issues with space in 2016, when old volumes were sent to a storage facility known as "Iron Mountain". Paper records relating to current notes are still kept in the Edinburgh Centre in a locked room, and the Centre has now moved to electronic records since 2018. Documents written at the time of a hospital admission, or an outpatient appointment are scanned in to the electronic record.

67.4. The individual retention policy for NHS Lothian is 10 years, but this is not relevant for patients registered at the Centre.

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

68.1. I did not, and do not, maintain separate files for any patients.

69. Did you (or do 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 relevant Centre? If so, why, what information and where is that information held now?

69.1. No, I do not, and did not, keep records or information for any reason whatsoever about any of my patients at my home, or anywhere other than the relevant Centre.

Section 5: UKHCDO

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

70.1. I became a member of the UKHCDO, and a member of the Advisory Group in December 2000, following my appointment as Director of the Belfast Centre. I

remained a member of UKHCDO and the Advisory Panel until August 2004, when I relocated to Canada.

70.2. On return to the UK in 2008, I again became a member of UKHCDO. I was invited to be a Chair of the Dental Task Force in 2009, and was invited to attend Advisory Group meetings in this capacity. I have also attended Advisory Committee meetings on an ad hoc basis since 2008 to represent Edinburgh on behalf of the Centre Director if she/he was unable to attend.

70.3. In 2017, I was appointed to the position of UKHCDO representative on the British Society of Haematology Haemostasis and Thrombosis Task Force, and I oversee the update and development of guidelines for UKHCDO. I am in my second term of this position, and am invited to attend Advisory Committee meetings in this capacity.

70.4. I was a member of the Peer Review Working Party from 2016 to 2018.

70.5. I have been invited to Chair the newly re-formed Dental Task Force (February 2021) to address updating the guidance on dental care.

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

a. the purpose, functions and responsibilities of UKHCDO, as you have understood them;

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

c. the relationships between UKHCDO and pharmaceutical companies;

d. how decisions have been taken by UKHCDO;

e. how information or advice has been disseminated by UKHCDO and to whom;

f. any policies, guidance, actions or decisions of UKHCDO in which you have been involved and which relate to:

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

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

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

iv. vCJD exposure; and

v. treatments for HIV and hepatitis C.

71.1. **a.** The United Kingdom Haemophilia Centre Doctors' Organisation (UKHCDO) is an association of clinicians who work within the haemophilia centres across the United Kingdom.

71.2. I believe the purpose, functions and responsibilities of UKHCDO are, as stated on its internet site, (ukhcdo.org):

71.2.1. (i) to preserve, protect and relieve persons suffering from haemophilia and other inherited bleeding disorders.

71.2.2. (ii) to advance the education of the medical profession, the nursing profession, professions allied to medicine and the general public in the knowledge of haemophilia and other inherited bleeding disorders and their treatment.

71.2.3. (iii) to promote or assist in the promotion of audit and research into the causes, prevention, alleviation and management of haemophilia and other inherited bleeding disorders and to disseminate the useful results of such research.

71.3. **b.** The structure, composition and role of the UKHCDO's various committees or working groups is also set out on the UKHCDO website.

71.4. An Executive Committee made up of elected officers, consisting of Chair, Vice-Chair, Secretary and Treasurer directs UKHCDO and is advised by a 34-person committee.

71.5. The Executive Committee meets monthly via conference call, and interacts directly with the Department of Health on a regular basis, as required.

71.6. The Advisory Committee meets with the Executive Committee three times a year in a central location in London, and during the Covid-19 pandemic by virtual meetings.

71.7. Specific clinical and research areas are dealt with by relevant Working Parties. These produce published clinical guidelines, conduct surveys, and enable discussion and facilitation of research projects. There are currently 12 working parties: Data Management Working Party, Co-morbidities Working Party, Data Analysis Group, Genetics Working Party, Gynaecology Task Force, Laboratory Working Party, Peer Review Working Party, Prophylaxis Task Force, Inhibitor Working Party, Paediatric Working Party, Musculoskeletal Working Party, and the Von Willebrand Working Party. Two Task Forces have just been announced – a group that will look at providing guidance for care in the Emergency Department, and a Dental Task Force.

71.8. The Data Management Working Party oversees the National Haemophilia Database, which is currently located in Manchester.

71.9. An Annual General Meeting is held in November of each year, and the place of the meeting rotates around the UK. Two representatives of the Haemophilia Society are invited, one representative of the Haemophilia Nurses' Association, one representative of the Haemophilia Chartered Physiotherapists' Association, and one haemophilia commissioner are invited.

71.10. **c.** The UKHCDO has a relationship with pharmaceutical companies that enables sponsorship of its Annual General Meeting alongside an Education Event for the purpose of education of its members. This usually involves a dinner event to enable networking in a relaxed environment away from the pressures of daily work. To the best of my knowledge, pharmaceutical

companies offer sponsorship, and UKHCDO will use all companies offering funding so there is no question of bias. The funding and support is open and transparent, and a Treasurer is responsible for the accounts and finances, and has a duty to provide a report at each Advisory Panel meeting.

71.11. **d.** Decisions are taken within the structure of the organisation by the Executive Committee, and by the Advisory Committee. Meetings must be quorate, and there is open discussion, and decisions are made following a group consensus on best practice or issues of concern.

71.12. **e.** How has information been disseminated by UKHCDO:

71.13. Information or advice is disseminated widely by UKHCDO by many routes and formats; these include (i) dissemination of information at the Annual General Meeting to key representatives that are involved in the care of people with haemophilia and inherited bleeding disorders; (ii) information on the UKHCDO website; (iii) through the UKHCDO Annual Report; (iv) publication of guidance and best practice guides in peer-reviewed journals; (v) through the presentation of work at national and international meetings in written and oral abstract forms.

71.14. To whom has information or advice been disseminated: Information or advice is disseminated to other doctors with an interest in haemostasis and thrombosis, trainees in haematology, nurses, physiotherapists, dentists, psychologists and members of the wider multidisciplinary team who hold an interest in inherited bleeding disorders; and to patients, carers and parents of children with inherited bleeding disorders, as well as patient organisations.

71.15. **f.**

71.15.1. (i) I have not been involved in any policies, guidance, actions or decisions of UKHCDO in relation to the risks of infection associated with the use of blood products.

71.15.2. (ii) I have not been involved in any policies, guidance, actions or decisions of UKHCDO in relation to the risks of infection associated with the use of blood products, excepting for discussions held from

2001 to 2004 relating to notification of patients of their risk of vCJD if treated with UK-sourced plasma products between 1980 and 2001.

71.15.3. (iii) I have not been involved in any policies, guidance, actions or decisions of UKHCDO in relation to obtaining consent from patients for the testing and storage of their blood for treatment and for research.

71.15.4. (iv) I was involved with discussions at the Advisory Panel about the notification exercises pertaining to vCJD from 2000 to August 2004.

71.15.5. (v) I have not been involved in any policies, guidance, actions or decisions of UKHCDO in relation to treatments for HIV or hepatitis C infection.

72. Please describe your involvement with the Scotland and Northern Ireland Haemophilia Directors' Group.

72.1. As Director of the Belfast Centre, I became a member of the Scottish and Northern Ireland Haemophilia Directors Group from November 2000 – August 2004. This was a well-established group when I joined, and involved all the Centre Directors for the Scottish Centres of Edinburgh, Glasgow, Dundee, Aberdeen and Inverness, as well as Belfast. The Group met every quarter in either Edinburgh or Glasgow. The Group also met with the Scottish and Northern Ireland Coagulation Working Party, which was an interface group with the Scottish National Blood Transfusion Service (SNBTS), known as "the Coagulation Working Party", to discuss plasma-derived products manufactured in Scotland and their supply to Scotland and Northern Ireland. I was a member from 2000 – 2004.

72.2. The Scotland and Northern Ireland Haemophilia Director's Group discussed issues relating to haemophilia care within Scotland and, through my representation, within Northern Ireland. The group set up a triennial audit which continues to this day. The group also chaired an annual meeting with patients and representatives of local patient groups within Scotland.

72.3. On return to Edinburgh in 2008, the Scottish Directors were continuing to meet face to face every 3 months, rotating between Glasgow and Edinburgh. At this time, representation from Northern Ireland was no longer continuing, and may have ceased when I left my position as Centre Director in August 2004.

72.4. With the start of a managed clinical network, the Scottish Inherited Bleeding Disorders Network, (SIBDN), in 2016, the Scottish Haemophilia Directors Group continue to meet every eight weeks for Peer Review meetings in the presence of National Services Scotland (NSS) to ensure regional agreement about use of factor products, and also continue to have business meetings to discuss issues that are then taken to SIBDN Steering Committee meetings.

72.5. On starting as a single-handed and inexperienced director in Belfast, I was reliant on the experience, advice and steer from the Scottish and Northern Ireland Haemophilia Directors' Group and its senior consultant members to help guide my decision-making for the Centre in Belfast, for example in relation to the vCJD notification exercises. Decisions inevitably had to be different to the Scottish Centres as the supply of plasma at the Belfast Centre had been from both Scottish and English plasma donations in the past, but the discussions were nonetheless helpful and important when decisions about SNBTS-derived plasma products were required.

72.6. I tried to attend every meeting in person, and contribute to group discussions, and then disseminate information and advice for best practice to the Belfast Centre haemophilia team on return, as well as to service managers within Belfast City Hospital Trust, and others such as Directors of Public Health and the Northern Ireland Department of Health, and the Chief Medical Officer for Northern Ireland.

Section 6: Pharmaceutical companies/medical research/clinical trials

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

73.1. No, I have never provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products.

73.2. I attended a Haemophilia Advisory Board Forum on 15th May 2008 for Wyeth Pharmaceuticals to explore the issues and advances in haemophilia treatment such as treatment efficacy, inhibitor development, B-domain deletion, innovation and compliance support for recombinant factor VIII. I received an honorarium for my involvement that was gifted to NHS Lothian endowments after being taxed.

73.3. I acted as a tutor for a day in October 2008 to help teach on a course sponsored by Baxter Healthcare ltd. for newly qualified haematology consultants involved in haemophilia care about the ins and outs of being a haemophilia director. I received an honorarium for my involvement that was gifted to NHS Lothian endowments after being taxed.

73.4. I have taught on the clinical day on a Haemophilia Academy sponsored by NovoNordisk that educates annually around 30 young doctors from countries around the world in 2010, 2011, 2012, and 2013 and possibly 2014. I received an honorarium in 2010, 2012 and 2013, and all have been gifted to NHS Lothian endowments after being taxed.

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

74.1. No, I have never received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products.

74.2. Regarding other pharmaceutical companies, please see (a).

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

75.1. No, I have never sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products.

75.2. Please see (a) above in relation to an advisory board role for the Wyeth company in relation to recombinant factor VIII.

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

76.1. No, I have never received any financial incentives from pharmaceutical companies to use certain blood products, nor recombinant factor products.

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

77.1. No, I have never received any non-financial incentives from pharmaceutical companies to use certain blood products.

77.2. I have received support from several pharmaceutical companies for travel, accommodation or registration fees for attendance at national and international conferences from 2001 to 2004, and then from 2008 to 2009, that would otherwise not have been possible to attend from my NHS study leave budget. From 2009 to date I have not received sponsorship from pharmaceutical companies to attend meetings and have self-funded my travel, with the exception of receiving funding for an overnight stay to enable attendance at a meeting in January 2017.

77.3. These details have been kept as part of my record of continuing professional development, and are as follows:

Date of meeting	Title of meeting	Sponsors
14-21 August 1999	XVII Congress of the International Society on Thrombosis and Haemostasis,	Travel, registration and accommodation funded by Wyeth Genetics Institute

	Washington DC	
2 Nov 1999	Joint meeting of the Section of Pathology of the RSM and the Haemostasis &Thrombosis Task Force of the BSH; Barnes Hall, Royal Society of Medicine (*see footnote at the end of this section)	Meeting sponsored by: Organon Technika Ltd; Grifols (UK) Ltd; Biostat Ltd; Sysmex (UK) Ltd; Instrumental Laboratory (UK) Ltd; 4S-Dawn Clinical Software Travel costs were paid by myself
5-8 May 2000	16th International Congress on Thrombosis, Porto	Travel and registration funded by Bayer
16-21 July 2000	XXIV International Congress of the World Federation of Hemophilia, Montreal, Canada	Travel, registration, accommodation funded by Wyeth Genetics Institute
28 Sept 2000	UKHCDO Annual Scientific Meeting, Royal College of Physicians and Surgeons, Glasgow (*see footnote at the end of this section)	Meeting sponsored by Aventis, Baxter, Bayer, Grifols, Novo Nordisk, Wyeth
Sept 19- Dec 12 2001	Haemostasis meetings at Belfast City Hospital Trust	Lunch (sandwiches/ fruit juice) sponsored by Bayer Pharmaceuticals
6-12 July 2001	International Society on Thrombosis and Haemostasis, Paris, France	Details of sponsorship not available in my records
8-11 October 2001	British Society for Haemostasis and Thrombosis/ UKHCDO Annual Scientific Meeting, Bath (*see footnote at the end of this section)	Self-funded registration and travel; Sponsorship of this meeting: Bayer PLC, Wyeth laboratories, Leo Pharmaceuticals, Baxter Hyland Immuno, Aventis Behring and Aventis Pharma, Astrazeneca UK Ltd, Grifols

		UK Ltd
19-21 October 2001	Haematology Association of Ireland, Kilkenny Ormonde Hotel (*see footnote at the end of this section)	Self-funded travel and accommodation, meeting sponsors: Technopharm, Amgen
3-4 March 2002	Update on Venous Thromboembolism: Translating Research into Practice 3-4 March 2002, Barcelona, Spain	Meeting supported by an unrestricted educational grant from Aventis (including travel and accommodation)
18-24 May 2002	World Federation of Haemophilia, Seville, Spain	Details of funding not available in my records
19 September 2002	Belfast Links Laboratory Coagulation Workshop	Meeting funded by Fannin Healthcare, Stago Diagnostica, NovoNordisk, Bayer PLC
6-11 December 2002	American Society of Hematology, Philadelphia	Details of sponsorship not available in my records
1 May 2003	Meeting on heparin-induced thrombocytopenia, Birmingham	Meeting and accommodation funded by Pharmion
8-9 May 2003	7th NovoNordisk Symposium on Haemostasis Management, Copenhagen	Meeting and travel/ accommodation - funded by NovoNordisk
12-18 July 2003	XII International Society on Thrombosis and Haemostasis, Birmingham, UK	Bayer covered the flight costs of Belfast to Birmingham; otherwise registration and accommodation self-funded
25-31 Oct 2003	IXth ETRO advanced Teaching Course on Thrombosis, Blankenberge, Belgium	Meeting programme sponsored by NovoNordisk, AstraZeneca, Baxter
6 February 2004	Educational meeting for Haemophilia Consultants, London	Sponsored by Wyeth Biotechnology
March 2004	Meeting on use of recombinant	Meeting, travel costs and

	factor VIIa, Copenhagen, Denmark	accommodation sponsored by NovoNordisk
6-9 December 2008	American Society of Hematology, San Francisco, USA	Travel, accommodation and registration for this meeting funded by Baxter Healthcare Ltd.
11-12 July 2009	55th Annual SSC Meeting for International Society on Thrombosis and Haemostasis, Boston, USA	Details of sponsorship not available in my records
January 2017	Expert Clotters Meeting, Birmingham	Overnight accommodation sponsored by Bayer PLC

77.4. *I have also regularly attended the UKHCDO Annual General Meeting, and the British Society for Haematology Annual Scientific Meeting, and these meetings are funded with the support from several pharmaceutical companies.

78. 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.

78.1. No, I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company.

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

79.1. Since I became a consultant in 2000 to date, declaratory procedures have been necessary annually as a member of UKHCDO, as well as local Drugs and Therapeutics Committees, Regional Medicines Consortia and prior to presentations and talks to any local, national or international audience. I follow declaratory procedures for any involvement with SIGN, NICE and the

Scottish Medicines Consortium, as well as the British Society for Haematology, the American Society of Hematology and the International Society on Thrombosis and Haemostasis.

79.2. I have always complied fully with any regulations, requirements and guidelines and filled out Declarations of Interest when, and as, requested.

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

80.1. No, I have never undertaken medical research for, or on behalf of, or in association with, a pharmaceutical company involved in the manufacture or sale of blood products.

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

81.1. See comment to 80.

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

82.1. I have not received funding from pharmaceutical companies for medical research.

Section 7: vCJD

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

83.1. I interpret this question as: When, and in what circumstances, did you become aware of the possible risks of transmission of vCJD associated with the use of blood and blood products?

83.2. I became aware of the theoretical risks of transmission of vCJD associated with the use of blood and blood products during my training in haematology in Edinburgh in 1998 and 1999 prior to completing my specialist training in haematology.

83.3. I also gained knowledge after taking up my consultant post from continuing medical education, and specifically from talks given, for example, in 2001 at the Royal Society of Medicine in London; and a talk by Joan O'Riordan from the Irish Blood Transfusion Service entitled "vCJD and blood: an update" on October 19 2001 at the Haematology Association of Ireland (HAI) meeting in Kilkenny, Ireland; in addition to talks and seminars at meetings of the British Society of Haematology, the International Society on Haemostasis and Thrombosis, and the World Federation of Hemophilia.

83.4. At the time I was working at the Belfast Centre, from November 2000 to August 2004, I was aware that there was no evidence of transmission of the agent responsible for sporadic/classic CJD by blood or blood products.

83.5. I was aware of the identification of vCJD in 1996 by the CJD Surveillance Unit in Edinburgh, and that this was clinically and histologically distinct from sporadic CJD.

83.6. I was aware that there was evidence supporting the finding that vCJD and bovine spongiform encephalopathy (BSE) are caused by the same infectious agent.

83.7. I was aware that vCJD in man probably arose from the ingestion of bovine products containing the agent responsible for BSE in cattle.

83.8. I was aware of the finding of abnormal prion-related proteins in the tonsils and spleen of patients with vCJD raising the possibility that circulating lymphocytes in the blood of symptom-free individuals could transmit the agent responsible for vCJD. I was aware that this led in 1998 to the recommendation for universal leucodepletion of all blood products to a white cell concentration of less than $10^6 L^{-1}$ at the time of donation, and was implemented in 1999.

83.9. I was aware that these findings also reinforced the recommendation made earlier in 1996 by UKHCDO to use recombinant coagulation factors free of bovine protein or albumin to treat haemophilia A and B in place of plasma-derived coagulation factors.

83.10. I was also aware that a recommendation was made in 1998 by the Committee on the Safety of Medicines, and implemented in 1999, to use non-UK donors for plasma product fractionation, and donor plasma should be collected from countries such as the USA where there were no recorded cases of vCJD or BSE.

83.11. I was also aware of the measures taken in the UK to minimise the risk of vCJD transmission including the Department of Health's "Better Blood Transfusion Initiative" in 1998, and also 2002.

83.12. I was also aware of an article published in the Lancet in September 2000 from the Institute of Animal Health regarding the transmission of BSE in sheep with preclinical BSE to healthy animals via whole blood transfusion. This article heightened concerns about the possibility of vCJD transmission by blood and blood products.

83.13. At the time of its publication, a Department of Health statement read as follows –

83.14. "The report shows that BSE can be transmitted via whole blood transfusion from sheep with preclinical BSE to healthy animals. However there remains no evidence that CJD or vCJD has ever been transmitted to humans through blood transfusion or blood products. The research also points out that whole blood is not used for human blood transfusions in the UK. White cells are now removed from blood for transfusion (leucodepletion) and all blood products used in the UK are made from plasma imported from countries where there is no evidence of vCJD.

83.15. The Government introduced these precautionary measures following expert advice of SEAC (Spongiform Encephalopathy Advisory Committee) to minimise any theoretical risk to patients on the basis that transmission of vCJD through blood might take place before symptoms occur. This risk

remains theoretical. Government will continue to seek and act on recommendations from SEAC as more is known about the disease".

83.16. I was also aware of the following statement from the National Blood Service regarding the article published in the Lancet in September 2000 from the Institute of Animal Health regarding the transmission of BSE in sheep with preclinical BSE to healthy animals via whole blood transfusion –

83.17. "The National Blood Service welcomes this interesting piece of research. The preliminary results certainly inform the discussion but differences between species must not be ignored in evaluating this research.

83.18. The National Blood Service has closely monitored the development in the science of vCJD ever since it was acknowledged that the cause of the disease was most likely to be from exposure to BSE. As a precaution against potential vCJD transmission, taking the advice of experts, all blood for transfusion has been leucodepleted since 1999. Similarly the use of UK donated plasma in the production of blood products has ceased. They are now made from imported plasma from countries where there is a very low incidence of BSE and no vCJD.

83.19. Systems for reporting are robust and it remains the case that there is no direct evidence of blood transmission of the equivalent natural human disease, CJD.

83.20. Blood is required to save lives or prevent serious disability. The NBS actively promotes through carefully researched guidance, an approach to the use of blood which minimises any associated risks. Programmes, both research and operational, aimed at improving blood safety, are given the highest priority by the NBS. Research into vCJD is collaborative across the UK Blood Services and with organisations such as The Institute for Animal Health."

83.21. (These statements were sent to myself by fax on 21 December 2000 by Professor Brian McClelland, Director of SNBTS **(WITN4027052),** in response to my request for advice about the handling of the notification process following receipt of a letter from BPL informing the Blood Bank at the Royal

Victoria Hospital of the receipt of implicated batches of BPL factor concentrates in 1996 and 1997)

83.22. In April 2004, I was aware of a publication of a case of vCJD transmission by blood transfusion in the Lancet.

83.23. I am also aware of several other risk reduction measures being introduced in 2004 and thereafter, including the importation of fresh frozen plasma for children and certain groups (recipients born on or after 1st January 1996 in 2004 and those suffering from thrombotic thrombocytopenic purpura in 2006); excluding recipients of blood components and products since 1980 from donating (2004); and the use of apheresis platelets in recipients born on or after 1st January 1996 (2005).

83.24. In 2009, I was aware of the finding of prion proteins in the spleen of a patient with haemophilia, in the post-mortem arm of the UKHCDO vCJD surveillance study, who had no evidence of any neurological disorder whilst alive, and had been known to have been treated with at least one implicated batch of BPL product. I was aware that this finding led to the HPA and UKHCDO providing an update to patients at the time in the form of an information letter sent as soon as possible by post, even though the investigation of the case was ongoing.

83.25. In 2012, there was a revision of guidance surrounding the "at risk" period for vCJD, with a change in the "at-risk period" from 1980 – 2001 to 1990 - 2001, following a reassessment of the risk for vCJD transmission through blood **(GGCL0000190 - Minute AGM Patient Nurses Directors 22 November 2013)**

84. How and by whom were decisions taken (either nationally or locally or both) as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?

84.1. The Belfast Centre - at <u>national level:</u>

84.1.1. The first notification involving BPL products was in January 2001. The suggested approaches were circulated by the Chair of UKHCDO, Professor Frank Hill, after discussion at the UKHCDO Advisory Committee meeting on 15 January 2001. **(GGCL0000090_002 – UKHCDO NEWSLETTER NO. 5)**

84.1.2. At this meeting there was a consensus view that the patients had a right to be informed of receipt of an implicated batch of product, and that Centre Directors should proceed to inform patients at the earliest opportunity of receipt of an implicated batch; or, alternatively, to counsel all patients to ask them whether they wish to be told. Some Centre Directors had already written to inform patients who received the implicated batches. Others, such as myself, had been waiting to discuss the matter further at the above-mentioned UKHCDO Advisory Committee meeting and then further discuss with local leads.

84.1.3. As far as I am aware, the decision made by UKHCDO to move to this type of notification exercise was made after liaison with the UK Haemophilia Society (who circulated a letter to its members on 16 January 2001 regarding the incident). This decision differed from the view taken by the CJD Panel regarding information to be given to patients who had received a plasma product fractionated from a person who had developed vCJD. (as per fax from Dr B McClelland, SNBTS (**WITN4027053**) and from Professor Banner's undated draft letter (**DHSC0014927_021**)

84.1.4. A draft letter was circulated by UKHCDO that could be personalised and sent out from the Centre, if this was the approach to be adopted, along with a reply sheet and a fact sheet on vCJD. (**WITN4027054**)

84.1.5. It was also felt essential to document in the notes if a patient had been exposed to an implicated batch, and this information passed on to other Centres if the patient had moved.

84.1.6. For the second notification, that involved SNBTS products in November 2002, advice on handling the notification exercise was given by the Scottish and Northern Ireland Haemophilia Directors' Group, the Scottish/Northern Ireland Coagulation Working Party, the Chief Medical Officer for Scotland and deputy Chief Medical Officers, and SNBTS (**WITN4027055** - Minutes of CFWP 7 Feb 2002; **LOTH0000082_019** -minutes of CFWP (3/6/03), with local discussion in Northern Ireland as set out in the section below entitled "How were decisions taken at a local level as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?"

84.1.7. There was a further notification process in September 2004. However, I left my position as Director of Haemophilia at the Belfast Centre in the first week of August 2004. There was discussion about this notification exercise between HPA, the UK Departments of Health, and UKHCDO. (**BART0000929** – Minutes of UKHCDO Advisory Committee Meeting 10 May 2004; **WITN4027056** - email from dCMO from HPA re vCJD)

84.2. The Belfast Centre - at <u>local level:</u>

84.2.1. First notification exercise:

84.2.1.1. In Northern Ireland, for the first notification exercise, that involved implicated batches of BPL product in January 2001, to the best of my recollection, I had initiated local discussion regarding the process of notification between the Medical Director, Dr Ian Carson and the Chief Executive of the Royal Hospitals Trust; the Department of Public Health, Dr Janet Little; the Director of NI BTS, Dr M McClelland; and the paediatric haemophilia consultant, Dr Sid Dempsey; and with the Departmental Head of the Department of Haematology, Dr Frank Jones, who was also lead of the Blood Bank, both before and after the UK Advisory Meeting on the 15th January 2001. I believe that the Chief Executive, Mr William McKee,

had notified the deputy Chief Medical Officer for Northern Ireland.

84.2.1.2. An urgent meeting was convened by the Northern Ireland Advisory Committee on Blood Safety on Tuesday 6th February 2001 at Castle Buildings, Department of Health and Social Services, Belfast, to discuss the implicated batches. **(SEE 18,5)**

84.2.2. Second notification exercise:

84.2.2.1. In Northern Ireland, a second notification exercise was necessary that involved implicated batches of SNBTS product. To the best of my recollection, I initiated local discussion between the Medical Director, Dr Ken Fullerton, and the Chief Executive of the Belfast City Hospitals Trust, Mr Quentin Coey; the Department of Public Health, Dr Janet Little, and the Director of NI BTS, Dr M McClelland paediatric haemophilia consultant, Dr Sid Dempsey and Dr Henrietta Campbell, Chief Medical Officer. I believe that the Medical Director liaised with the Northern Ireland Department of Health about the notification process, and I have stated this in a letter summarising the notification exercise to Professor Frank Hill, dated 28 November 2002. **(HCDO0000266_051)**

84.2.3. There had also been discussion at the Scottish and Northern Ireland Haemophilia Doctors' Group, that indicates ongoing discussion between the Scottish directors and the CJD Panel, and the delays that occurred (see IBI Tranche, minutes of meetings held on 14 June and 23 September) **(GGCL0000194 and GGCL0000195)**

84.2.4. In the minutes of the Scottish and Northern Ireland Haemophilia Director's Group, item 3, page 1 of 4: Professor Lowe and Professor Ludlam summarised discussions with the Chief Medical Officer for Scotland, Dr Harry Burns and his deputies, including Dr

Aileen Keel, and a detailed discussion about the proposed notification process.

84.2.5. As the second notification involved SNBTS product and affected patients in Scotland and Northern Ireland, it was felt appropriate to inform patients through a notification process in the same manner in both regions and at exactly the same time, with the same letter albeit with minor local modifications to reflect the prior notification exercise in Belfast (see question 93).

84.2.6. In 2004, there were discussions about the notification procedure in Northern Ireland involving Health Protection Agency and the Department of Health.

84.2.7. The HPA and the Northern Ireland Department of Health, represented by Dr Miriam McCarthy and Dr Glenda Mock became involved in discussions about the decision-making for this notification exercise from June 2004 onwards. As per entries in my diary, there was a meeting held on Tuesday 8 June 2004 at Belfast City Hospital with Dr Glenda Mock; Dr Miriam McCarthy, deputy Chief Medical Officer; Dr Anne Loughrey, Infection Control team and myself along with the Medical Director. A further meeting was held on Tuesday June 15th 2004 involving representatives from the Department of Health, myself representing the Belfast Centre, Dr Frank Jones, Consultant Haematologist, the Medical Director, Dr Fullerton, Dr Kieran Morris (NIBTS), Dr Edgar, Consultant Immunologist and Dr S Dempsey, Consultant Paediatric Haematologist, and to which the infection control team was also invited but were unable to attend.

84.2.8. However, I was not involved in any final decisions about the exact nature of the notification exercise in 2004 as I left my post in early August 2004.

84.2.9. From my diary I note that I had a meeting on Monday 26 July with Dr Frank Jones, and I handed over details regarding the files on

vCJD held at the Belfast Centre and an update on the forthcoming notification. (**WITN4027057**)

How and by whom were decisions taken (either nationally or locally or both) as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?

84.3. The Edinburgh Centre - at national level:

84.3.1. From 2000 to 2004, I was not working at the Edinburgh Centre and am unable to comment on the information that was provided to patients about vCJD and the steps taken in relation to patients and their care and treatment.

84.3.2. From 2008 onwards, decisions have been taken at a national level by UKHCDO alongside advice from the HPA in relation to information updates provided to patients about vCJD.

84.4. The Edinburgh Centre - at local level:

84.4.1. From 2000 to 2004, I was not working at the Edinburgh Centre and am not able to comment in any detail.

84.4.2. As I was a member of the Scottish/Northern Ireland Haemophilia Doctors' group, and a member of the Scottish/Northern Ireland Coagulation Working Party Group, I recall discussions at the meetings regarding the notification exercises, and details were recorded in the minutes of these meetings.

84.4.3. From 2008 to 2010, any decisions taken at a national level by UKHCDO or other bodies in relation to the information provided to patients about vCJD were discussed at the Scottish Haemophilia Doctors' Group and locally led by Professor Christopher Ludlam, who was the Director at the Edinburgh Centre along with Professor Angela Thomas, Co-director, and after discussion with myself and Dr Lishel Horn, Consultant Haematologist. From 2010 until 2016, Professor Thomas would have been responsible for such decisions

as Centre Director, and thereafter, Dr Ryan Rodgers from 2016 to 2019.

85. What was the process at (a) the Belfast Centre and (b) the Edinburgh Centre for informing patients about possible exposure to vCJD?

85.1. **(a) Belfast Centre**

85.1.1. Background: In total, between December 2000 to August 2004, the Belfast Centre received three separate notifications of implicated batches of factor concentrates prepared from individual donors who later developed vCJD; this resulted in two notification exercises in January 2001 and November 2002, and a further notification exercise that was being discussed at the time of my leaving post in August 2004.

85.1.2. Notification regarding Bio Products Laboratory (BPL) implicated batch, January 2001.

85.1.3. Replenine FJM 4596; (plasma from the donor supplied to BPL in 1996 and 1997).

85.1.4. I refer to the letter dated 19 January 2001 regarding the BPL notification exercise December 2000. (**WITN4027059**)

85.1.5. To the best of my recollection, the first notification of implicated BPL batches of factor IX involved the following process that I have listed as best able, and to the best of my recollection, as follows:

85.1.5.1. (i) Letter received by the Royal Victoria Hospital Blood Bank dated Dec 14 2000 from BPL giving details of batch numbers. (At this time I had only been in post for 5 weeks, so I was not directly notified. I contacted BPL and requested that I was notified directly, and BPL sent myself the same letter re-dated 19 January 2001).

85.1.5.2. (ii) Request to Ms Audrey Savage, Chief, Blood Bank, Royal Victoria Hospital to establish recipients of the implicated batches.

85.1.5.3. (iii) Case notes review and review of the Belfast Centre Annual returns to ensure implicated batches had been administered

85.1.5.4. (iv) An entry was made in all notes if the patient had received an implicated batch.

85.1.5.5. (v) There was a check made to ensure the patient had not moved to another haemophilia centre.

85.1.5.6. (vi) Initial discussions locally from 15 December 2000 – 22 December 2000 with Dr S Dempsey, Consultant Paediatric Haematologist, Royal Belfast Hospital for Sick Children and Paediatric Lead in Haemophilia; Dr I Carson, Medical Director who liaised with Dr J Little, Director of Public Health; Dr M McClelland, Director NIBTS, and colleagues in the Department of Haematology at Royal Victoria Hospital including Dr Frank Jones, Consultant Haematologist, as well as informal discussion with peers, including the SNBTS Director, Dr B McClelland; and Professor Peter Collins, Cardiff University Hospital, Cardiff. Professor Collins helpfully suggested waiting for further discussions at the UKHCDO Advisory Committee meeting on 15 January 2001.

85.1.5.7. (vii) I attended the UKHCDO Advisory Committee meeting in London on 15 January, made notes about possible strategies to inform patients, and then discussed further with colleagues on return, from 15-19 January 2001.

85.1.6. At the UKHCDO Advisory meeting on 15 January 2001 it became apparent that different strategies were being considered to inform patients, and some Centre Directors had already directly written to patients who had received implicated batches of product. However there was a deeply held view that patients had a right to be

informed of receipt of an implicated batch of product, should they wish, and to withhold this information if this was not acceptable. **(SEE GGCL0000090_002 – UKHCDO NEWSLETTER NO 5)**

85.1.7. On 17 January 2001, a template letter to patients was circulated by fax to the Belfast Centre by Professor Frank Hill for comments by Thursday 18 January 2001 so that the letters could be sent out to all UK Centre Directors on 19 January 2001. (SEE **WITN4027054**)

85.1.8. Along with the template letter to patients that could be adapted for local use, there was a reply sheet for patients, and a fact sheet about vCJD. There was also a copy of the letter sent by the Chief Executive of the UK Haemophilia Society, Karin Pappenheim, to all its members on 16 January 2001 that specified the affected products (8Y, Replenate and Replenine) and the period of time the donated plasma would have been in use (in 1996 and 1997). (**WITN2336005**)

85.1.8.1. (i) A letter was adapted from the UKHCDO template for use in Northern Ireland and sent in the post (to the best of my recollection on 22 January 2001) to all adult patients who had received plasma-derived products, including cryoprecipitate and fresh frozen plasma from 1980 -2001, identified from case records and the centre registry. This letter provided some background information, and advised the patient clearly that they had not received any of the implicated batches, but that in the future should a similar event arise, the patient was asked to kindly inform myself if they wished to know or not. **(WITN4027058)**

85.1.8.2. (ii) In the given time-frame available, haemophilia centre staff came in on a Saturday morning (to the best of my recollection on 20 January 2001) to help with the administrative tasks involved, and letters were sent out on Monday morning, 22 January 2001, via the local post office to avoid any delays from the hospital mail room.

85.1.8.3. (iii) Patients and parents / carers of children who had received the implicated batch, to the best of my recollection, were invited to the Centre by letter, or seen at the time of a clinic appointment, and informed and counselled personally by myself and Dr Dempsey, with support from the paediatric social worker, and the haemophilia staff.

85.1.8.4. (iv) As there was media interest, a regional helpline was set up, and Dr Maurice McClelland appeared on the regional evening television news on the day the letter was received to answer questions about vCJD and the safety of blood products.

85.1.8.5. (v) Counselling and support to patients and families: I recall very few telephone calls to the Centre, and I can recall that no patients requested counselling following the letter being sent out. However, at clinic visits, patients did seek more information about the situation in general, and this enabled a general discussion to take place and any queries to be answered. We tried to build up a picture of who might wish to be informed in the future in the event of a future notification.

85.1.8.6. (vi) I found, in general, that the majority of my patients did not wish to be informed of an implicated batch in the future. We recorded the patient's wishes in the case notes.

85.1.9. **Notification regarding Bio Products Laboratory (BPL) implicated batch, January 2001.**

85.1.10. **Antithrombin III ATA 4535; (plasma from the donor supplied to BPL in 1996 and 1997).**

85.1.11. The UKHCDO Advisory Panel had not discussed the situation regarding informing patients who had received an implicated batch of antithrombin. To the best of my recollection, the process I followed on receipt of this information was as follows:

85.1.11.1. (i) Letter received by the Royal Victoria Hospital Blood Bank on Dec 14 2000 giving details of batch numbers. (At this time I had only been in post for 5 weeks, so I was not directly notified. I contacted BPL and requested that I was notified directly, and BPL sent myself the same letter on 19 January 2001. **(WITN4027059 - BPL Notification Dec 2000).**

85.1.11.2. (ii) Request to Ms Audrey Savage, Chief, Blood Bank, Royal Victoria Hospital to establish recipients of the implicated batches.

85.1.11.3. (iii) Case notes review of patients who had received the implicated batch of concentrate to ensure implicated batches had been administered.

85.1.11.4. (iv) An entry was made in all notes if the patient had received an implicated batch.

85.1.11.5. (v) There was a check made to ensure the patient had not moved to another locality

85.1.11.6. (vi) Due to a different pattern of use of antithrombin concentrate in Northern Ireland compared with the rest of the UK, the strategy to inform the entire patient group treated between 1996 and 1997 about an implicated batch by letter was not desirable (see point viii). This meant there was the option of either informing patients on a case-by-case basis as felt appropriate by the clinician in charge of the patient, or waiting for further advice from the vCJD Panel about the risk of infectivity of the implicated batches. I chose to inform patients on a case-by-case basis. To the best of my recollection, one patient who had received the implicated batch of antithrombin during treatment at a hospital in another Health Board, was counselled by the relevant haematologist in that Trust.

85.1.11.7. (vii) To the best of my recollection, the other patients were asked if they wished to be informed if they had received an

implicated batch, or if they were to receive an implicated batch in the future, on a case by case basis. I ensured careful documentation in the case notes regarding any discussions.

85.1.11.8. (viii) I raised the issue of the high use of antithrombin concentrate in Northern Ireland at a meeting of the Regional Medical Consortium on 18 January 2001, attended by the 4 Directors of Public Health for each Health Board in Northern Ireland. This meeting prompted an urgent meeting to be convened on 6 February 2001 by the Northern Ireland Advisory Committee on Blood Safety at Castle Buildings, Stormont, and chaired by Dr MPJ Kilbane, Chief Executive. The matter was escalated to Dr H Campbell, Chief Medical Officer. Antithrombin was in use for acquired situations including heparin resistance during cardiac bypass surgery and to ensure haemofiltration devices did not develop thrombosis. The use of antithrombin concentrate in Northern Ireland significantly declined thereafter. (**WITN4027060** – LETTER FROM DR KILBANE TO MR WILLIAM MCKEE 24 JANUARY 2001; **WITN4027061** – AUDIT OF ANTITHROMBIN USAGE IN NORTHERN IRELAND)

85.2. **Notification regarding SNBTS implicated batch: Z8 030170320, November 2002**

85.2.1. (i) Local review of blood bank records from RVH blood bank to identify recipients of implicated batch.

85.2.2. (ii) Check with annual returns regarding matching of blood bank issues and with receipt of administration, and ensuring that these records matched those held at the UKHCDO database held in Oxford.

85.2.3. (iii) Ensuring the entire batch of implicated product was accounted for.

85.2.4. (iv) Attendance at Scottish and Northern Ireland Coagulation Working Party meetings to understand how Scottish Directors were approaching issue, alongside SNBTS and Department of Health, Scotland.

85.2.5. (v) Liaison with Dr Ken Fullerton, Medical Director of Belfast City Hospital about process, who in turn liaised with Northern Ireland Department of Health about the decision to send letters to a specific group of haemophilia A patients who had received SNBTS factor VIII concentrate issued between 1987 and 1989 giving the opportunity to know, or not know, of their possible exposure.

85.2.6. (vi) Using the wording of the letter to be sent to patients in Scotland and then making changes in two paragraphs to better reflect the situation for patients in Northern Ireland, taking into account that all patients in Northern Ireland had been updated about the BPL vCJD notification in general in January 2001, and had been asked to inform the centre if they wished to know, or decline to know, about future notifications.

85.2.7. (vii) Sending out the letters at exactly the same date and time as Scottish patients (evening post on November 26 2002), making sure that no letters were sent to patients who had not received implicated product, and who had already expressed in writing a wish to not know of future notifications.

85.2.8. (viii) Providing a regional helpline for patients and families, and support for patients through the Belfast Centre.

85.2.9. (ix) Liaison with the UK Haemophilia Society about the entire process to ensure appropriate support for patients and families.

85.3. **Notification regarding third implicated batch in Northern Ireland:**

85.3.1. I cannot recollect details of when I was informed of a further implicated batch of product. To the best of my knowledge this was around May 2004.

85.3.2. The process followed would have been the same as previously:

85.3.2.1. Local review of blood bank records from RVH blood bank to identify recipients of implicated batch(es).

85.3.2.2. Case notes review and review of the Belfast Centre Annual returns to ensure implicated batches had been administered to the patient, and ensuring that these records matched those held at the UKHCDO database held in Oxford.

85.3.2.3. Ensuring the entire batch of implicated product was accounted for.

85.3.2.4. An entry was made in all notes if the patient had received an implicated batch.

85.3.2.5. There was a check made to ensure the patient had not moved to another haemophilia centre.

85.3.2.6. The HPA and the Northern Ireland Department of Health, represented by Dr Miriam McCarthy and Dr Glenda Mock became involved in discussions about the decision-making for this notification exercise from June 2004 onwards. On this occasion, the notification exercise took into account the individual's risk of vCJD.

85.3.3. A meeting was held on Tuesday 8 June 2004 at Belfast City Hospital with Dr Glenda Mock; Dr Miriam McCarthy, Deputy Chief Medical Officer; Dr Anne Loughrey, Infection Control team and myself along with the Medical Director. A further meeting was held on Tuesday June 15th 2004 involving, to the best of my recollection, representatives from the Department of Health, myself representing the Belfast Centre, Dr Robert Cuthbert, Consultant Haematologist, Dr Ken Fullerton, Medical Director, Dr Kieran Morris, Consultant Haematologist, (NIBTS), Dr David Edgar, Consultant Immunologist and Dr Sid Dempsey, Consultant Paediatric Haematologist, and to

which the infection control team was also invited but were unable to attend.

85.3.4. However, I was not involved in any final decisions about the notification exercise in 2004 as I left my post in the first week of August 2004.

85.3.5. From my diary I note that I had a meeting on Monday 26 July with Dr Frank Jones, and I handed over details regarding the files on vCJD held at the Belfast Centre and an update on the forthcoming notification exercise.

85.4. (b) Edinburgh Centre

85.4.1. I returned to work at the Edinburgh Centre in 2008, and was not involved with any of the vCJD notification exercises that affected the Edinburgh Centre from 2000 to 2008.

85.4.2. As I attended the Scottish/Northern Ireland Haemophilia Directors' Group and the Coagulation Factor Working Group from 2000 to August 2004 I was aware of the strategy to inform patients about possible exposure to vCJD in November 2002 as the process undertaken was exactly the same as the process undertaken at the Belfast Centre.

86. How and when were patients told of possible exposure to vCJD at (a) the Belfast Centre and (b) the Edinburgh Centre?

86.1. Belfast

86.1.1. Please see my response in section 85 regarding the notification exercises conducted at the Belfast Centre when I was Director, from November 2000 to August 2004.

86.2. January 2001:

86.2.1. The Royal Victoria Hospital Blood Bank was informed on 15 December 2000 about the implicated batches from BPL that affected different patient groups.

86.2.2. There were GRO-A patients with haemophilia who had received the implicated batch involving a combination of children and adults. The patients and parents/carers of the children were informed at the earliest opportunity following the UKHCDO Advisory Panel meeting on 15 January 2001, between 24 hours and 2 weeks from this date, as some patients and parents/carers were contacted initially by letter by Dr Dempsey. Support was provided from the social worker attached to the paediatric haemophilia team. I informed one adult patient, and kept in regular contact with the patient to ensure the patient's wellbeing. This is detailed in the information provided in a brief for the Minister of Health of the Northern Irish Assembly. (**WITN4027027**, **WITN4027028** AND **WITN4027029**)

86.2.3. A letter was sent at this time to all other adult patients, to inform patients of the notification exercise and to inform patients that they were not exposed to any of the implicated batches. The letter invited patients to inform the centre if they did or did not wish to be informed of future notification exercises. I do not recall the exact date in January 2001 (and I have searched my 2001 diary to no avail) when letters were sent out to support the first notification exercise, but I do clearly recall that myself, Dr Orla McNulty and Sister Colette McAfee came in "out of hours" on one Saturday morning (I think it was 20 January 2001) to identify patients from the Centre registry (there was no local database at that time), go through all the adult records in the Day Hospital unit to (a) record sending out the letter (by placing a copy of the letter in the clinical notes), and (b) placing the letter into an envelope with a stamped addressed envelope for replies to the question about whether they wished to know of future notification exercises, placing a stamp on the envelope and addressing the envelope ourselves. The letters were then sent out on the following Monday morning (I think it was the 22 January 2001) to avoid weekend post, and to avoid franking delays by the hospital mail service, the letters were taken to a local

post office by my administrative assistant. I recall that we went to such efforts to make sure that the letters were sent out on the same date as letters around the rest of the UK, as a similar process was taking place at other centres throughout the UK, and because a letter had been sent out by the UK Haemophilia Society on 16 January 2001.

86.2.4. To the best of my recollection, a small number of patients with antithrombin deficiency had received the implicated batch.

86.2.5. Patients were asked in person if they wished to be informed if they had received an implicated batch, or if they received an implicated batch in the future, on a case by case basis. I ensured careful documentation in the case notes regarding any discussions. GRO-A

GRO-A

86.2.6. For the second notification exercise relating to the SNBTS product, the process has been set out in question 85. I was informed by SNBTS of the implicated batch at the February meeting of the Coagulation Factor Working Party. (SEE **WITN4027055**)

86.2.7. The Inquiry has already provided the letter that I sent to Professor Frank Hill, Chair of UKHCDO, dated 21 February 2002 (**HCDO0000264_132**), requesting a search of the Oxford database to confirm those patients who had received SNBTS factor VIII or factor IX between June 1987 and 31 January 1989, to whom a notification letter should be sent.

86.2.8. The Scottish and Northern Ireland Coagulation Factor Working Party minutes detail the lengthy discussions that ensued with the CJD Panel, and on reading through these minutes I think this led to the delays in sending out the notification letter.

86.2.9. To avoid regional variation in care, the strategy in Northern Ireland required to be similar, if not the same, as the strategy undertaken by the Scottish Haemophilia Directors. The Scottish Directors

finalised the letter to be sent to Scottish patients after the meeting held on November 2nd 2002.

86.2.10. The notification letter was dated 25 November 2002, and was sent out on the evening of November 25 2002, and would have been received by patients on, or after 26 November 2002.

86.2.11. The number of patients requesting counselling is stated in my letter to Frank Hill, 20 Dec 2002. (**HCDO0000266_001**) None of these patients had received the implicated batches. I can only recall one patient who received one of the implicated batches asking for more information several months later when he attended for routine review, and the patient was counselled by myself in person, and I was in regular contact with the patient to ensure his well-being.

86.2.12. Regarding the implicated batches of product in 2004, I am not able to recall the date the Belfast Centre was informed. To the best of my recollection, the number of patients affected with this notification were a small number, and of those still alive, there had been indications made in writing to the Centre that these patients had not wished to be informed of any future notifications.

86.2.13. Although I was involved with discussions at the level of the Medical Director for my Trust and the Northern Ireland Department of Health, I was not involved with the notification exercise in September 2004 as I had left my post as Director of Haemophilia in early August 2004.

86.3. (b) Edinburgh

86.3.1. As I was not working at the Edinburgh Centre until 2008, I am unable to comment on how and when patients were told of possible exposure to vCJD from 2000 to 2004.

87. In the meeting of Scotland & Northern Ireland Haemophilia Directors Group held on 14 June 2002 [GGCL000194] you highlighted clinical problems which were

arising because of prior vCJD exposure and the need for urgent advice from the CJD Incidents Panel. In the meeting of Scotland & Northern Ireland Haemophilia Directors Group held on 4 November 2002 [GGCL000196_001], you were noted as saying that you were awaiting clarification as to whether a vCJD exposure notification letter should be sent to patients in Northern Ireland. Was this clarification provided, and what steps were taken as a result? What if any clinical problems arose because of the delay and what if anything was done to address the situation?

In the meeting of Scotland & Northern Ireland Haemophilia Directors Group held on 14 June 2002 [GGCL000194] you highlighted clinical problems which were arising because of prior vCJD exposure and the need for urgent advice from the CJD Incidents Panel.

87.1. A summary of some of the clinical problems are highlighted in the undated draft response from the CJD Incidents Panel Secretariat, Health Protection Agency, London to myself.. – **(SEE DHSC0014927_021)**

In the meeting of Scotland & Northern Ireland Haemophilia Directors Group held on 4 November 2002 [GGCL000196_001], you were noted as saying that you were awaiting clarification as to whether a vCJD exposure notification letter should be sent to patients in Northern Ireland. Was this clarification provided, and what steps were taken as a result? What if any clinical problems arose because of the delay and what if anything was done to address the situation?

87.2. The events surrounding the decision to send a vCJD exposure notification letter to recipients of SNBTS products from 1987 to 1989 are recorded in summarised fashion in my letter to Professor Frank Hill dated 28 November 2002. **(SEE HCDO0000266_051).** In this letter, on page 2, I clearly state "the Medical Director of the Belfast City Hospital Trust (Dr Ken Fullerton), following discussion with the Northern Ireland Department of Health, decided to write to all patients who received factor VIII coagulation factor concentrate from SNBTS between 1987 and 1989 giving the opportunity to know, or not know, of their possible exposure." A fact sheet on vCJD was also included compiled from a SNBTS position statement that had been recently compiled.

87.3. The letters were sent out in the evening post on 26th November 2002.

87.4. Therefore, clarification to send out the letter was provided through discussion with Dr Fullerton, the Medical Director for the Belfast City Hospital Trust, and would have involved my liaison with Dr Fullerton, and the Northern Ireland Department of Health, following each meeting of the Scottish and Northern Ireland Director's Group that I attended. The steps taken at the Belfast City Hospital and adult Belfast Centre have been outlined in Question 84.

87.5. There was no delay to the letter being sent to patients in Northern Ireland, and the notification exercise was conducted simultaneously across the two regions of the UK.

88. What information was provided to patients about the risks of vCJD at (a) the Belfast Centre and (b) the Edinburgh Centre?

88.1. Belfast Centre

88.1.1. The notification exercise in 2001 involved both the paediatric and adult centres.

88.1.2. Face-to-face counselling was offered by myself and Dr Dempsey, Consultant Paediatric Haematologist. Dr Dempsey was also supported by the social worker attached to the paediatric centre.

88.1.3. An information fact sheet was available, and had been collated by the UKHCDO Advisory Panel (SEE **WITN4027054**)

88.1.3.1. vCJD is a newly recognised condition, with cases mainly in the UK and a small number in France;

88.1.3.2. vCJD is considered to be the human form of BSE, a condition caused in cattle by a prion;

88.1.3.3. vCJD has been transmitted to humans by eating beef from cows with BSE;

88.1.3.4. Anyone who has eaten contaminated beef may be at risk of developing vCJD;

88.1.3.5. There is no reported case of vCJD transmitted by blood or blood products – the risk therefore at this time remains theoretical;

88.1.3.6. There is no test for vCJD that can be used to test blood donors or to identify people with vCJD before they become unwell;

88.1.3.7. All plasma products now made by BPL are made with plasma from USA donors, as there have been no cases of vCJD in the USA;

88.1.3.8. There may be further notifications in the future if other patients with vCJD have been blood donors;

88.1.3.9. Some plasma products are made with American and non-UK European plasma.

88.1.3.10. The use of European plasma may be reconsidered in the future as BSE is being identified in an increasing number of European countries.

88.1.3.11. In the notification exercise in November 2002, an up to date fact sheet was sent out with the notification letters (**NIBS0000569**) and its source was the UK Blood Services Position Statement, October 2002.

88.2. (b) Edinburgh Centre

88.2.1. I returned to the Edinburgh Centre in 2008.

88.2.2. I was not involved in any vCJD notification exercises in Edinburgh, although I am aware that the same notification exercise took place as in Belfast in November 2002.

88.2.3. There was a letter sent to "at risk" patients in 2009, and signed by myself, alongside Dr Horn and Professor Ludlam advising of the finding of prion proteins in the spleen of a patient with haemophilia, in the post-mortem arm of the UKHCDO vCJD surveillance study, who had no evidence of any neurological disorder whilst alive, and had been known to have been treated with at least one implicated batch of BPL product.

88.2.4. There was a denotification exercise in 2012, when the "at risk period" of 1980 to 2001 was revised to 1990 to 2001, and where relevant patients were informed by the Edinburgh Centre. I was not involved in this exercise and I was on leave at the time. Professor Angela Thomas was director of the Edinburgh Centre at this time.

89. What counselling, support and/or advice was offered to patients who were informed that they might have been exposed to vCJD at (a) the Belfast Centre and (b) the Edinburgh Centre?

89.1. Belfast Centre

89.1.1. At the time of both notification exercises in 2001 and 2002 there were helplines made available during the day and overnight after any media coverage on the television or radio. At the adult centre, counselling was offered, and was available, through face-to-face sessions with myself and our Associate Specialist should patients wish this. Patients were also given counselling and support, and updates at review clinics. In 2001, at the paediatric centre, counselling was provided by Dr Dempsey through face to face sessions with support from a social worker, if needed.

89.2. (b) Edinburgh Centre

89.2.1. As I was not working at the Edinburgh Centre until 2008, I do not know what counselling, support and/or advice was offered to

patients who were informed that they might have been exposed to vCJD.

90. In the meeting of Scotland & Northern Ireland Haemophilia Directors Group held on 4 November 2002 [GGCL000196_001], it was noted that " With regard to patient counselling it was agreed that Haemophilia Directors would undertake this role unless the numbers became very large ". Did this counselling of patients who had been notified of potential vCJD exposure fall within your remit as Centre Director? If so, how was this responsibility discharged?

90.1. Yes, the responsibility of counselling patients who had wished to know of potential vCJD exposure fell within my remit as Centre Director. To the best of my recollection, for the 2001 notification exercise, only a few patients requested to meet myself to find out more information. Many patients chose to discuss the subject at their clinic appointments, and we counselled patients at clinic to ensure they had up to date information.

90.2. Similarly, for the 2002 notification exercise, only a small number of patients attended the Centre to discuss the situation. They were provided with an appointment, usually on the day of calling, or the next convenient date for the patient and family. I would then discuss the notification exercise, current information available at the time regarding vCJD, and anything else relevant, leaving open the possibility of further counselling sessions if needed. Sister McAfee and Dr McNulty were also most supportive in terms of counselling and speaking to patients with up to date knowledge at the time of clinic reviews from 2001 through to the first week of August 2004, when I left the Centre.

91. What measures were put in place regarding vCJD at (a) the Belfast Centre and (b) the Edinburgh Centre, from a public health perspective, in relation to the care and treatment of patients?

91.1. (a) Belfast Centre

91.1.1. In January 2001, to the best of my recollection, there was no advice available regarding the public health measures required in relation

to the care and treatment of patients who had received factor concentrate from a donor who had subsequently been diagnosed with vCJD. I raised this issue with the Director of Public Health, Eastern Health and Social Services Board at the earliest opportunity on 20 December 2000 and at subsequent meetings in January and February 2001. (**WITN4027062**)

91.1.2. This was problematic. For example, I recall one instance when the Dental School at the Royal Hospitals site required to shut for decontamination of surgical instruments overnight in early 2001.

91.1.3. Initially, all surgical instruments and ventilators were quarantined for patients who had received implicated batches of products, many of whom had not wished to be informed of their exposure.

91.1.4. Patients were not able to undergo endoscopy and colonoscopy as the public health risk had not been clearly defined, leading to waiting lists for procedures and delays to diagnosis. From discussion with other Centre Directors at the time, this was a common situation around the UK, and not unique to the Belfast Centre. This issue is also highlighted in the publication by Millar et al. (**DHSC0014927_022**)

91.1.5. Revised TSE Guidance in 2003 provided advice regarding the decontamination of surgical instruments, if the patients were assumed to be in an "at risk" group, with the need to quarantine surgical instruments if the operation had involved exposure to fixed lymphoid tissue. Such operations included, for example, tonsillectomy, splenectomy, and lymph node biopsy. Endoscopy with biopsy of tissue was also viewed to be a high risk procedure, so endoscopes were quarantined and were re-used for single patients.

91.1.6. With such practical difficulties for the multidisciplinary team in terms of knowing which patients had wished to be informed, and those who wished not to be informed, to the best of my recollection around 2003 I think we took a pragmatic approach at the Belfast

Centre to apply the same infection control measures to all the patients. As this involved quarantine of only some surgical instruments this was relatively straightforward. Operating theatre staff would be informed of the need for disposable instruments, and it seemed that these were becoming more common place in use.

91.1.7. By 2004, advice from the Health Protection Agency was forthcoming, and, to the best of my recollection, a general approach was being considered to advise infection control measures for all patients who had received UK-derived plasma within the time-frame of 1980 to 2001, including factor VIII, factor IX and antithrombin concentrates, when undergoing certain types of surgery. At this time, the Belfast Centre was already following this principle.

91.1.8. There was a notification exercise under way and implementation of universal public health measures for all patients who had received UK-derived plasma factor concentrates in 2004, but the final details of the exercise had not been developed by the time of my departure from my position as Director of the Belfast Centre in the first week of August 2004. As a result, I was not involved in the execution of the 2004 vCJD notification exercise.

91.2. (b) Edinburgh Centre: I am not aware of the public health measures that were put in place regarding vCJD at the Edinburgh Centre until my return to Edinburgh in 2008.

91.2.1. In 2008, there was clear advice from the HPA about the measures to take for various surgical procedures and the decontamination of surgical instruments, and this advice was followed at the Edinburgh Centre.

91.2.2. If a patient had received UK-derived plasma within the time-frame of 1980 to 2001, and deemed "at risk" of vCJD for the purposes of public health, and was going for an operation or a procedure, then the Infection Control team would be informed, and the surgical consultant, and the theatre team would be made aware of the necessary measures to take, such as use

of disposable instruments, and the need to quarantine an endoscope, for example.

91.2.3. It was also evident from the case notes at the Edinburgh Centre that all recipients of UK-sourced plasma products from 1980 to 2001 had been identified and were considered "at risk" of vCJD for public health purposes.

91.2.4. As written management plans are made for every patient undergoing surgical procedures, the vCJD risk is made clear within any plan ahead of elective surgery within the background details section relating to the patient's management.

91.2.5. When I started working at the Edinburgh Centre in 2008, all patients requiring regular endoscopy had their own endoscope.

92. Please see enclosed an undated draft letter from Professor Banner of the CJD Incidents Panel [DHSC0014927_021 and DHSC0014927_022], which refers to your request for advice concerning patients who had been treated with antithrombin III that was prepared from plasma pools including plasma from a donor who later developed vCJD. What advice did the Panel provide in relation to this concern? What steps were taken as a result? Was advice sought from the Panel in relation to any other patients or batches of product? Please provide details if so.

92.1. I recollect requesting advice from the CJD Incidents Panel concerning patients who had been treated with antithrombin III that was prepared from plasma pools including plasma from a donor who later developed variant CJD (batch ATA 4535)**.(Minutes of meeting S NI HDG 230902- see point 3, final sentence – GGCL0000195).**

92.2. My recollection is that I did not receive the letter **(DHSC0014927_021 - Letter from CJD Incidents Panel incident reference** GRO-A as it currently reads, and I think it is likely that it had been further amended. Whilst there was something

of a delay in receiving the letter, the solutions to many of the situations that I had sought advice for had already been resolved through pragmatic decision making locally.

92.3. I note that the letter was also copied to my colleagues in Infection Control at the Belfast City Hospital Trust, as well as Dr Mock and Dr Jecock in the Northern Ireland Department of Health.

What advice did the Panel provide in relation to this concern?

92.4. The advice clearly states in its introduction that the Risk Assessment on CJD and plasma products was incomplete and that meant that it was not possible to differentiate between the exposed patients and their risk, and that when the Risk Assessment had been completed, there could be a full assessment of the risk of individual patients.

92.5. It is likely that my letter sought clarification of the public health measures and infection control measures required for those patients who required, or had already undergone the procedures.

92.6. The letter advised firstly on general issues. The CJD Panel advised that until the risk was calculated, and until appropriate support systems had been put in place, that individuals were not informed of their exposure.

92.7. The Panel advised that a precautionary approach to infection control issues was taken such that this group of patients be considered "at risk" as described in the Revised TSE Guidance issued by the Joint Working group. The letter provided a website for reference to this guidance. Yet, the letter also states "The panel is keen to ensure that infection control measures do not adversely affect patient care. This is especially important for this group of patients as their exposure risk is so uncertain".

92.8. The letter referenced the relevant section of the revised TSE Guidance that described "the actions to be taken regarding non-disposable instruments used on patients with or at risk of CJD".

92.9. In particular, there was advice about dentistry, explaining that the risk of transmission of infection from dental instruments was felt to be very low providing optimal standards of infection control and decontamination were maintained. The letter also emphasised the Revised TSE Guidance that stated: "There is no reason why (these patients) should be refused routine dental treatment".

92.10. The letter then advised on specific details in relation to each patient. Specifically in relation to surgical instruments used in a number of different surgical procedures, the letter advised that provided the instruments did not come into contact with fixed lymphoid tissue, or any other high or medium risk tissue then they could be decontaminated and returned to use.

What steps were taken as a result?

92.11. Firstly, the Infection Control team were better placed to advise on specific situations for the Belfast Centre by referencing the revised TSE Guidance and this proved very supportive to the haemophilia multidisciplinary team.

92.12. Secondly, it was assumed that this group of patients were to be considered "at risk" from an infection control perspective until viewed otherwise at the time of the completed Risk Assessment. This was also helpful to know.

92.13. Other groups of patients who had received factor VIII and factor IX from plasma pools including plasma donated by a donor later diagnosed with vCJD were also considered "at risk". Irrespective of whether those patients had requested to know, or not know, of their risk, all were managed from a public health perspective and an infection control perspective in the same way at the Belfast Centre.

92.14. Thirdly, a meeting was convened on Tuesday 4 February 2003 at the Department of Health, Social Services and Public Safety, Castle Buildings, Stormont to further discuss decontamination, CJD and dentistry, that was attended by a representative for the Chief Dental Officer for Northern Ireland, the Medical Director for the Royal Victoria Hospital and representatives from the Department of Health **(WITN4027063)** GRO-A

GRO-A

GRO-A

GRO-A this resulted in the Royal Dental School being closed temporarily until all dental instruments were decontaminated, and led to subsequent issues with access to dental care for patients receiving plasma-derived products.

92.15. Following this meeting, to the best of my recollection, as the risk of transmission of infection from dental instruments was felt to be very low providing that optimal standards of infection control and decontamination were maintained, it was felt appropriate that all patients who had received plasma-derived products, irrespective of those who had received an implicated batch, would be considered for the same infection control measures. I understand this became general advice from September 2004 onwards.

92.16. Fourthly, it was not possible to contact the National Disease Surveillance Centre in Dublin, as the whereabouts of the individual (patient number not supplied) was unclear, having left no contact details. GRO-A GRO-A GRO-A I was therefore unable to contact the haematologist responsible for the patient's medical care or the relevant hospital infection control doctor.

Was advice sought from the Panel in relation to any other patients or batches of product? Please provide details if so.

92.17. To the best of my recollection, I did not write to the vCJD Panel in relation to any other patients or batches of product.

92.18. Irene Thompson, Senior Infection Control Nurse, Belfast City Hospital Trust wrote to the CJD incidents Panel **(DHSC0014927_022 - Incident reference** GRO-A **patient** GRO-A I can recall this incident in August 2003. Irene Thompson had written following discussion with myself and my colleague in Infection Control, Dr Anne Loughrey, Consultant Microbiologist.

92.19. Advice was sought in relation to the management of a patient during an admission involving GRO-A

GRO-A

92.20. The advice provided in the letter was followed up by the Infection Control team at Belfast City Hospital.

93. Please see enclosed a letter you wrote to Professor Frank Hill, Chairman, UKHCDO, dated 28 November 2002 [HCDO0000266_051], having traced the recipients of a batch of implicated SNBTS products. The letter mentions that you had chosen to use a similar strategy to the Scottish haemophilia directors but to tailor it to the local situation in Northern Ireland. What were the local differences, and how was your strategy adapted to meet them?

93.1. In November 2002, this was the second notification exercise in Northern Ireland, the first being in January 2001, that involved implicated batches of BPL products.

93.2. The first letter (sent in January 2001) was sent to all patients at the Belfast Centre who had received plasma-derived therapies in the past explaining that further vCJD notification exercises were anticipated in the future, and to ask patients to inform the Centre if they did, or did not, wish to be notified. In doing so, and also when reviewing patients face-to-face at the clinic, we built up a record of who wished to be informed, and who did not wish to be informed further.

93.3. In November 2002, the proposed letter written by the Scottish Haemophilia Directors to the Scottish patients had specific particular wording in its introductory paragraph as it was the first notification exercise in Scotland, and so the letter to the patients in Northern Ireland had to differ in its introduction.

93.4. Specifically, this second notification letter was not sent to all patients who had received plasma-derived therapies, but intended only for all patients who had received the SNBTS factor product over a given time-period, namely 1987 to 1989.

93.5. After discussion with the Medical Director, Belfast City Hospital, Dr Ken Fullerton, who helped guide me with process and support in general, and who, in turn, discussed with colleagues in the Northern Ireland Department of Health, it was felt important that the same process was followed in the two regions. This second notification letter was sent out, with some slight amendments to the wording, to ensure that there was no regional variation between Northern Ireland and Scotland in relation to how patients were notified about the implicated product.

93.6. The letter was sent out by post at exactly the same time in Scotland and Northern Ireland on 26 November 2002. It was anticipated that patients in Northern Ireland would receive their post one day later, so it was anticipated there would be media interest 12 to 24 hours later to that in Scotland, enabling support to be put in place to counsel patients about vCJD if necessary in a timely manner. This was indeed the case, with the media interest taking place on the morning after the letters were sent in Scotland, and later into the evening in Northern Ireland and the next day.

93.7. Dr Fullerton represented the Belfast Centre and spoke on the regional evening news and on the radio, on the 27 November 2002, along with provision of a regional helpline to support patients and families. The Trust communications department supported the Belfast Centre staff at this time. As Centre Director, I was available each day for counselling and to support patients.

93.8. I recall there were relatively few patient enquiries. If I recall correctly, I think patients preferred to just discuss the situation when at the clinic and talk freely about it.

93.9. Regarding the exact wording of the letter (**NIBS0000569**), the first and third paragraphs are (i) tailored to the local situation in Northern Ireland and acknowledge the previous letter sent to all patients regarding the previous notification in 2001, and (ii) state the regional bodies that made the decision to inform the patient that they might have received implicated product, and to let myself know if further information was wished.

93.10. The strategy was adapted as follows:

93.10.1. local review of blood bank records from RVH blood bank to identify recipients of implicated batch

93.10.2. check with annual returns regarding matching of blood bank issues and with receipt of administration

93.10.3. accounting for the entire batch of implicated product

93.10.4. attendance at CWP meetings regarding how Scottish Directors were approaching issue, alongside SNBTS and Department of Health, Scotland.

93.10.5. Liaison with Medical Director of Belfast City Hospital about process, who in turn liaised with Northern Ireland Department of Health.

93.10.6. Using the wording of the letter to be sent to patients in Scotland and then making changes in two paragraphs to better reflect the situation for patients in Northern Ireland who would receive the letter, taking into account that all patients in Northern Ireland had been updated about vCJD notifications in general in January 2001, and had been asked to inform the centre if they wished to know about future notifications.

93.10.7. Sending out the letters at exactly the same date and time as Scottish patients (evening post on November 26 2002), and gauging local media response.

93.10.8. Providing a regional helpline for patients and families, and support for patients through the Belfast Centre.

93.10.9. Liaison with the UK Haemophilia Society about the entire process to ensure patients and families were supported.

Section 8: Involvement with the financial support schemes

94. What if any involvement have you had with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund, the Scottish Infected Blood Support Scheme) which were set up to provide financial support to people who had been infected?

94.1. At the Belfast Centre, I had some involvement just prior to leaving over the summer of 2004, with assistance to patients and families for the completion of applications to the Skipton Fund; to the best of my recollection the application form had two parts to complete. However, I was aware that many patients and families of deceased patients had not been aware of the existence of the fund. The Belfast Centre endeavoured to contact as many patients and families as we could to ensure of their awareness of the Skipton Fund, and to ensure leaflets and flyers were made available in our waiting area at the centre located in the Bridgewater Suite, Belfast City Hospital.

94.2. I have not been involved with the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation nor the Scottish Infected Blood Support Scheme.

95. To the extent that you had any involvement with the trusts or funds or with the applications made by patients for assistance, please answer the following questions in respect of the time that you have worked at (a) the Belfast Centre and (b) the Edinburgh Centre:

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

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

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

d. Did the Centre, or any of its staff (including you), act as a gateway for determining whether a particular patient met the eligibility criteria for the

receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

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

95.1. Belfast Centre

95.1.1. a. In respect of the time that I worked at the Belfast Centre, I tried to inform as many of the patients as possible of the existence of the Skipton Fund, as did all the Centre staff, when patients attended the clinics. At the time 2001 to 2004, there were a number of local patient groups, as well as a local Northern Ireland branch of the UK Haemophilia Society. I recollect we tried to contact the leads of the various groups to enable the dissemination of information about the existence of the Skipton Fund, and our Charge Nurse/Sister would have contacted relatives of deceased patients that I would otherwise have been unaware of.

95.1.2. I was aware that the Belfast Centre had helped patients and families previously with applications to the Macfarlane Trust and the Caxton Foundation, from discussions I had with patients at their review clinics.

95.1.3. b. We had no policy or formal staff guidance in relation to referring patients to the trusts and funds. In respect of the time that I worked at the Belfast Centre, there was only the Skipton Fund that comes to light as being a new fund from which assistance could be sought.

95.1.4. If a patient was seeking assistance from the trusts and funds, then Centre staff tried to help, and would act as a link to the relevant trust if required.

95.1.5. c. When I was at the Belfast Centre, my staff grade physician, Dr McNulty and I were asked to fill out the first and second parts of the Skipton Fund application forms. Criteria for eligibility were set by the

Fund, so when setting out the application we had to provide detail of any signs and symptoms, blood test results and a clinical interpretation of the test results, such as presence of abnormal liver function tests and/or the presence of cirrhosis.

95.1.6. d. To the best of my recollection, the eligibility criteria for the receipt of a certain level of financial assistance from the Skipton Fund was the clinical finding of liver cirrhosis. As we did not have a hepatologist regularly reviewing the patients this required considerable input from myself and my Staff Grade assistant, but in many cases the clinical diagnosis was very much evident from clinical examination and imaging, so I had no concerns with completing all the forms required to the best of my ability.

95.1.7. e. For the Skipton Fund, the Belfast Centre was not involved in determining applications made by patients for assistance from the trusts or funds.

95.2. b) Edinburgh Centre

95.2.1. In 1994 and 1999 I was not involved in making patients aware of any Trusts or funds.

95.2.2. a. From 2008 onwards, the Associate Specialist, Dr Rosie Dennis, was a key member of the multidisciplinary team at the Edinburgh Centre, and helped to complete any forms for individual Trust or Fund applications, alongside the Director.

95.2.3. From 2017 onwards, I have been asked to support a few applications for personal independence claims (PIP), and have been involved in writing letters of support, although my colleague, Dr Rodgers, was more involved with this than myself in his capacity as Centre Director.

95.2.4. b. I noted flyers and leaflets to advertise the various Trusts and funds in the waiting room at the Centre, but am not aware of any

formal policy or any guidance for staff members in relation to referring patients to the trusts and funds for support.

95.2.5. c. I have no knowledge of this at the Edinburgh Centre.

95.2.6. d. I have no knowledge of this at the Edinburgh Centre.

95.2.7. e: For the Skipton Fund, the Edinburgh Centre was not involved in determining applications made by patients for assistance from the trusts or funds.

96. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of the Centre's patients in relation to the trusts or funds, do you consider that the trusts and funds were (or in the case of the current schemes, are) well run? Do you consider that they achieved (or in the case of the current schemes, are achieving) their purposes? Were (or in the case of the current schemes, are) there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

96.1. I only have experience of the Skipton Fund.

96.2. I am not able to comment on how well this Fund is, or was, run. I recall helping to fill out individual applications for this Fund when I was in Belfast, but as I left my position in 2004, I never knew if those applications were successful, nor how long the process took for funding to be made available. As a result, I am not able to state if this fund achieved its purpose in terms of providing financial support.

96.3. Regarding difficulties or shortcomings in the way in which the Skipton Fund operated or in their dealings with beneficiaries and applicants for assistance, my impression was that many patients, carers and families of bereaved patients might not have been informed of the fund's existence and it seemed that if a patient was not in a local Society, or for any reason missed clinic or Centre appointments, could miss the opportunity to seek assistance.

96.4. Regarding shortcomings in the way in which the Skipton Fund is that the completion of the application form takes a not inconsiderable amount of time, and Centre staff, whilst very much committed to helping patients and families, usually do not have the allocated time necessary to help in a timely way.

96.5. A more formal process for contacting all patients via their Centre would seem sensible for any future awards or funds, with the necessary funding of personnel and staff to ensure this is carried out in a timely way, and with assistance for patients and families to fill out forms, (which are often complex, and may be distressing to complete).

Section 9: Current haemophilia care and treatment

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

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

b. your current roles and responsibilities at the Edinburgh Centre.

97.1. Please also refer to section 12, subsections headed 2008 – 2019; and 2019 to date.

97.2. The Edinburgh Centre is a Comprehensive Care Haemophilia Centre, with a role to provide coordination of the delivery of factor concentrate to the other East Coast Centres (Dundee, Aberdeen and Inverness), and provides a regional service to Edinburgh and the Lothians, the Borders, Fife and Forth Valley, as well as some of the islands around Scotland including Orkney and Shetland.

97.3. The current Centre Director is Dr Andrew Page, Consultant Haematologist, who was appointed in 2019, and who also leads the Regional Haemophilia Genetics Service.

97.4. Following the retirement of Dr Rosie Jones, our Associate Specialist for many years, the role of Specialty Doctor has been filled by Dr Alasdair Gray, who is embedded in the centre in Outpatient Department 1, works for 6 sessions per week designated for haemophilia care, and is available in a flexible capacity for 3 other sessions per week to help with haemophilia matters if this level of clinical service is required.

97.5. There have been changes to nurse staffing since late 2017, and there is currently a Band 7 Charge Nurse and two Band 6 specialist adult nurses, a Band 6 specialist paediatric nurse (based at the Department of Paediatric Haematology) and a band 5 nurse. A clinical support worker has also been appointed.

97.6. There are two factor coordinators, who deal with data entry to local and national databases, and who manage home delivery, stock control and the supply of factor concentrate to other centres.

97.7. There is a full time receptionist, who supports the work of the factor coordinators, and administrative work is done with the support of the administrative team based within the Department of Haematology under the direction of Hannah MacLean, the administrative team lead. Including Ms MacLean, there are currently 2 full time secretaries, 1 part-time secretary, 1 full-time clerical assistant and 2 part-time clerical assistants.

97.8. There are two consultant paediatric haematologists, with Dr Matt Howard-Jones taking the lead in haemostasis and thrombosis conditions. There is a continuing paediatric clinic each week, incorporating a transition clinic for young people due to be transferred over to the adult team.

97.9. The children's hospital has been renamed as the Hospital for Children and Young People, and is due to relocate to a new build at the Little France site in March 2021. The paediatric haematology laboratory has been incorporated into the main haematology laboratory based on the second floor of the Royal Infirmary. The paediatric team have a designated physiotherapist joining their team who is currently undergoing specialist training that is being funded from endowments to the Centre.

97.10. The wide range of comprehensive care services remain in place and are unchanged from my previous description in question 12. There is a quarterly orthopaedic clinic held within the Centre under the supervision of Mr Graham Lawson, Consultant Orthopaedic Surgeon.

97.11. There is a weekly haematology-obstetric clinic, and a haemostasis/gynaecology clinic, available at Simpsons Centre for Reproductive Health, overseen by myself, Dr Anne Armstrong, Consultant Obstetrician, Dr Hanan Mustafa, Consultant Obstetrician, and Professor Hilary Critchley, Consultant Gynaecologist.

97.12. Dr Matt-Howard Jones, Consultant Paediatric Haematologist provides neonatal expertise for the newborn with haemophilia and other bleeding disorders.

97.13. Professor Peter Hayes, Consultant Hepatologist, provides advice on matters relating to hepatology, and visits the Centre to see patients when required, and there is a specialist nurse, Sister Kim Macbeth who has overseen new antiviral therapies for hepatitis C. Fibroscan is available.

97.14. Dr Rebecca Sutherland, Consultant in Infectious Diseases provides advice on matters relating to HIV infection, and oversees the management of haemophilia patients at the Regional Infectious Diseases Unit, Western General Hospital, alongside an associate specialist.

97.15. The Centre is adjacent to the hospital dental department, and there is good communication regarding dental hygiene and routine and conservative dentistry, with links to the oral surgery department based at St John's Hospital if required.

97.16. The Centre is linked with the Regional Genetics Service, which relocated to the Genetics Laboratory based at the Western General Hospital in October 2020 to take advantage of the apparatus and staffing required for next genome sequencing. The senior Clinical Scientist in Haemophilia Genetics is Dr Vicky Cloke.

97.17. A pre-implantation genetics service is available from the Edinburgh Fertility and Reproductive Endocrinology Centre if requested (led by Dr Joo Thong, Consultant Gynaecologist), and there is an antenatal diagnostic service available with expertise from the foeto-maternal team led by Dr Shona Cowan, Consultant Obstetrician.

97.18. Since 2016, a psychologist (0.8 WTE), Dr Grainne O'Brien, is supported by a liaison consultant psychiatrist, initially Dr Nadine Cossette and now replaced by Dr Sarah Kennedy, Consultant Psychiatrist, and are embedded into the Edinburgh Centre team. Our psychologist works between paediatric and adult services and additionally works at the Glasgow Centre for one day each week, as well as providing virtual and telephone based support for patients and families at other locations in Scotland.

97.19. Staffing pressures continue within the specialist coagulation laboratory, but the same excellent repertoire of tests is available, and there are no concerns regarding access to factor VIII, factor IX or VW testing 24-hours a day. A member of the laboratory team attends the team handover every Monday morning for liaison purposes. The laboratory is inspected by the UK Accreditation Service (UKAS) and is fully accredited.

97.20. A business case for a physiotherapist has been made and is a key outstanding member of the multidisciplinary team that is required.

97.21. The configuration of clinics has changed slightly, with consultant-led haemophilia clinics available on Wednesday, Thursday and Friday mornings, and specialty doctor led review on Monday and Tuesday mornings. Each day has a slightly different emphasis, with Wednesdays focussing on new patient referrals, and review of patients with bleeding disorders; on Thursdays, my clinic focusses on bleeding disorders affecting women, pre-pregnancy counselling and liaison with the gynaecology team, as well as new referrals; and on Fridays, the clinic focusses on transition, young people with haemophilia, and links with the paediatric clinic.

97.22. The Centre holds a multidisciplinary meeting each Monday morning to guide and inform staff about forthcoming procedures and consultations. There is also a monthly psychosocial meeting.

97.23. There is currently a monthly meeting with the service manager and nurse manager to address any service requirements, as well as a monthly Business Meeting, that incorporates other issues from the Department of Haematology and is attended by the Clinical Director for Haematology, the Nurse Manager, the Laboratory Service Manager and the Assistant Service Manager and departmental administrative and team leads. Meetings have continued virtually during the Covid-19 pandemic.

97.24. The Centre remains committed to the teaching and training of all staff, including undergraduate and postgraduate medical staff, nursing staff, and all members of the multidisciplinary team. There is a track record of teaching and training, locally, nationally and internationally. In 2018, the Centre hosted a 6–month attachment for a haematologist from Delhi, India to train in haemostasis and thrombosis, funded by NovoNordisk, and the Centre has been chosen to host a haematologist from Pakistan for 6 months, funded by a Reach-the-World training award from the International Society on Thrombosis and Haemostasis (ISTH) Education Committee. The Centre annually hosts the clinical day of the International Haemophilia Academy.

97.25. There is also active interest in audit and research.

97.26. The Edinburgh Centre acts as a comprehensive haemophilia centre, and links to other centres along the east coast of Scotland. Owing to the seniority and expertise of the consultants that direct these centres, only a few patients require referral to Edinburgh for review, and surgery, including orthopaedic surgery and surgery on patients with known factor inhibitors is possible in these centres.

97.27. The haematology consultants, myself and Dr Page, join an 8-weekly meeting, now held virtually, of the Scottish Haemophilia Directors' Group. This meeting starts with a Peer Review meeting of any patient requiring high levels of factor replacement, or a new inhibitor, and includes discussion of any patients with acquired haemophilia. This is conducted to ensure there are no outliers in terms of factor usage or therapy, and ensure treatment of rare and complex cases is consensus-based within the region.

97.28. The Scottish Directors Group links to the managed clinical network (MCN), known as the Scottish Inherited Bleeding Disorders Network (SIBDN). SIBDN was initiated as an MCN in 2014, and the first clinical lead was Professor Campbell Tait. In late 2017, I was appointed as clinical lead until February 2021.

97.29. SIBDN is currently undergoing a review process to further define its role and future direction, and also to determine if the funding mechanisms for bleeding disorders products is still fit for purpose. The review will also make recommendations as to how the 14 territorial boards in Scotland should finance the clinical service for bleeding disorders.

97.30. **b**. I am currently a Consultant Haematologist at the Edinburgh Centre. My role has developed into evaluation of patients with minor bleeding conditions, the management of patients with acquired haemophilia, and rare bleeding disorders. I have also taken a particular interest in women with bleeding disorders, especially the gynaecological management of women with bleeding conditions, and link with Professor Critchley's gynaecology team on Thursday mornings. With the support from my colleague in general haematology, Dr Alice Klauser, I also provide a weekly haematology-obstetric clinic that jointly manages the care of women with bleeding disorders and carriers during pregnancy, and we offer pre-pregnancy counselling and support.

97.31. I join in multidisciplinary team discussions and assist in the provision of the on call consultant service.

97.32. I have a role to teach the multidisciplinary team about the investigation and management of bleeding disorders, and continue to do audit projects to reflect quality of service provision.

97.33. I am the Project Manager for the Edinburgh Psychology Life Support Project.

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

98.1. I interpret this question to outline the haemostatic treatments currently provided to patients with bleeding disorders at the Edinburgh Centre.

98.2. A range of haemostatic treatments are offered and these vary by condition. Factor and blood product sparing treatments including desmopressin (DDAVP) and tranexamic acid are offered to patients with haemophilia A, von Willebrand disease, unidentified bleeding disorders, congenital thrombocytopenia and platelet function disorders where applicable.

98.3. Recombinant factor concentrates are favoured over plasma-derived products where available. Currently, all patients requiring factor replacement therapy for haemophilia A or B receive recombinant products (including a mixture of standard and extended half-life products).

98.4. All patients with haemophilia A with active inhibitors receive prophylaxis with the bispecific monoclonal antibody, Emicizumab. This is also being used in a small number of patients with severe haemophilia A without inhibitors. Breakthrough bleeding and surgery is managed with recombinant factor VIIa where necessary.

98.5. Patients with von Willebrand disease requiring treatment with factor concentrate (where desmopressin (DDAVP) and / or tranexamic acid are not sufficient) are treated with plasma-derived von Willebrand factor concentrate, although a recombinant von Willebrand factor product will be available shortly.

98.6. Patients with rare inherited factor deficiencies are treated with plasma-derived concentrates where these are available and tranexamic acid is not sufficient. Where no plasma-derived concentrate is available, or where it is unsuitable for use, as in some patients with factor XI deficiency who have already received tranexamic acid, fresh frozen plasma would be used (with virally inactivated Octaplas being used as a preference provided this does not unduly delay emergency treatment).

98.7. Patients with platelet function defects and heritable thrombocytopenia would be treated with HLA-matched platelet transfusions (obtained from a single donor by apheresis) when tranexamic acid and / or desmopressin (DDAVP) are insufficient or not appropriate.

98.8. We treat patients with acquired haemophilia with a combination of haemostatic agents depending on the clinical situation. Agents used include tranexamic acid, recombinant human factor VIII, recombinant porcine factor VIII, recombinant factor VIIa and (plasma-derived) FEIBA, as well as the monoclonal antibody, Rituximab.

99. Please describe how you typically obtain your patients' consent to treatment. In particular:

a. What information do you give patients about the risks of the treatment?
b. What information do you give patients about the side-effects of the treatment?
c. What information do you give patients about the risks of not having the treatment?
d. What information do you give patients about the benefits of having the treatment?

99.1. My approach to obtaining consent to treatment often involves a series of face-to-face discussions, if time permits. This enables the introduction of discussion about a therapy, and then further time to discuss later any questions that arise, after the patient has had an opportunity to read through any written material provided, and after discussion with his or her family. Depending on the type of treatment, this layered discussion might involve other members of the multidisciplinary team, including our specialist nurses and our psychologist.

99.2. My approach is to initially involve the patient and/or carer in a general discussion about the patient's diagnosis or condition; provide counselling about the short-term and long-term side-effects and /or risks of a given treatment; the acute and long-term risks of not proceeding with treatment; a discussion about any monitoring that is required, for example, with blood testing (types of tests, frequency of testing and provision of results) and imaging; how to contact the out-of-hours service should any complications arise as a result of the therapy; the provision of written information where possible from the manufacturer of the treatment, and written in lay terms.

99.3. If there is a language-barrier, there must be open access to a translator, present at the time of the consultation, or available via telephone (as has been the case during COVID-19 pandemic). There also needs to be translation of any written material into lay terms in the patient's language.

99.4. If the treatment is part of a peri-procedural plan, I aim to provide this information well in advance of a given procedure, with further time for ongoing discussion if needed, about whether the patient wishes to proceed to have the treatment.

99.5. If relevant (if the patient is advised to receive a plasma-derived product, for example), I counsel the patient about the types of transfusion-transmitted infections that can occur, particularly emphasising the potential of unknown pathogens in the future; the origin and source of the plasma used for the concentrate, or the blood product; the manufacturer and the type of plasma donation (voluntary), the viral screening tests used prior to plasma fractionation, and the viral inactivation steps used by the manufacturer, as well as the risks of inhibitor formation.

99.6. Currently, this would most likely be in relation to a new diagnosis of type II or III von Willebrands although a recombinant product will soon be available, factor XI deficiency, or dysfibrinogenaemia, or a new diagnosis of acquired haemophilia with bleeding issues where recombinant factor VIIa is either not enabling haemostasis, or its pharmacokinetic properties are not felt likely to lead to effective haemostasis.

99.7. Even if I switch patients between recombinant products, I advise about the buffers and cell lines used in the manufacture of the product, for example if albumin had been used, in addition to the way the recombinant product had been manufactured, as well as the risk of inhibitor formation. I also counsel about the risks of allergic reaction and anaphylaxis with certain recombinant products.

99.8. New treatments are now available, such as Emicizumab, and there is guidance from UKHCDO about specific issues to discuss with patients prior to its prescription that reflect the complexity of its mode of action. This includes how to manage a bleed, when to seek advice from the Centre and the

avoidance of certain treatments, such as FEIBA, for example. (Collins P W, Liesner R, Makris M et al. Treatment of bleeding episodes in haemophilia A complicated by a factor VIII inhibitor in patients receiving Emicizumab. Interim guidance from UKHCDO Inhibitor Working Party and Executive Committee). **(WITN4027064)**

99.9. Other treatments may become available, and will require tailored counselling, to enable informed consent.

99.10. There is a record kept of each discussion in the patient records; currently we use electronic records, so this is legible and easy to record and find for future reference. After each patient consultation, I write a letter to the general practitioner to outline any discussions, and will provide a copy of the letter to the patient as a record, and also to act as an aide-memoire, and in the event the patient may have any other questions, when they are welcome to contact me.

99.11. The patient is given written information about how to contact the Centre in the event of any queries or questions, and we have a direct dial telephone number and an email contact address to make communication as easy as possible, and ensure an ongoing discussion and dialogue with the patient.

99.12. **a.** The information provided to a patient depends on the type of treatment being advised.

99.13. From my response in section 98, there are a variety of treatments offered at the Edinburgh Centre.

99.14. For those receiving plasma-derived factor concentrate, I counsel the patient about the types of transfusion-transmitted infections that can occur, particularly emphasising the potential of unknown pathogens in the future; the origin and source of the plasma used for the concentrate, or the blood product; the manufacturer and the type of plasma donation (voluntary), the viral screening tests used prior to plasma fractionation, and the viral inactivation steps used by the manufacturer, as well as the risks of inhibitor formation.

99.15. For those being commenced on recombinant products, I advise about the buffers and cell lines used in the manufacture of the product, for example if albumin had been used, in addition to the way the recombinant product had been manufactured, as well as the risk of inhibitor formation. I also discuss the issues relating to transfusion-transmitted infections in the past. I also advise about the potential for allergic reactions, and for recombinant factor IX products, the risk of anaphylaxis.

99.16. For other novel therapies there may be specific side effects or risks linked to a given therapy, and these would be discussed in detail. For example, when commencing a patient on Emicizumab I would discuss the risk of thrombotic microangiopathy if there is concurrent administration of FEIBA, and that all supplies of FEIBA should be returned to the centre to avoid inadvertent administration. I would also counsel the patient about what to do if a bleed occurs when taking Emicizumab.

99.17. For all types of treatment there is a verbal discussion, as well as the provision of written information.

99.18. **b.** As outlined in my introduction to this section and in section (a) I discuss any known common side-effects of a treatment with the patient and allow plenty of time for questions within the time-frame of the consultation. I also discuss rare side effects as well, and place them into context in terms of frequency of occurrence. I will refer to the British National Formulary, or the manufacturer's summary of product characteristics, during the discussion.

99.19. **c.** I outline the risks of not having a given treatment in as much detail as possible, and as relevant to the patient's condition as possible, and place the risks into a realistic context as far as I am able.

99.20. **d.** I outline the benefits of receiving a treatment in as much detail as possible, and as relevant to the patient's condition as possible.

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

100.1. Please also see question 102 b. After detailed discussion with the patient, and any family members that the patient wishes to be present, I record my

patients' consent to treatment in writing in the medical records. Currently all medical records at the Edinburgh Centre are electronic. There is a clinical note section that is dated and the time of the entry is automatically recorded, along with my name. I also dictate a letter to the patient's general practitioner to outline any discussions, and I send a copy of the letter to the patient for information to serve as a record of the discussion, and ensure the patient has the up-to-date departmental and centre contact telephone numbers and email address.

101. Do you routinely take blood samples from patients attending the Edinburgh Centre? If so, what information do you provide to patients about the purposes for which the samples are being taken? Do you obtain patients' consent to the storage and use of the samples and if so how and is that recorded?

101.1. I request blood samples to be taken from patients attending the Edinburgh Centre for the purposes of making a diagnosis of a bleeding disorder, and for monitoring that bleeding disorder.

101.2. As has always been my practice, I inform the patient prior to testing exactly which tests I am undertaking, providing an opportunity to make sure they are in full agreement with proceeding (please see my response to question 102).

101.3. The only samples that are stored are samples taken for DNA extraction for the purposes of genetic mutational analysis. The blood is discarded after the DNA has been successfully extracted and the DNA samples are stored indefinitely unless a patient specially requests for a sample to be discarded after testing is completed. This is in keeping with the Royal College of Pathologists guidance on "The retention and storage of pathological records and specimens". **(RLIT0001474.1)**

101.4. Written consent is obtained for the storage and use of these samples specific to a given test, and a copy of the written consent is kept in a file in the Edinburgh Centre, and a copy is scanned into the patient's electronic record. A copy is also retained in the haemophilia genetics laboratory.

101.5. Blood samples taken for diagnostic studies may be frozen at minus 70 degrees Celsius for the purposes of testing in the laboratory, or further testing

assays to follow a diagnostic algorithm. These samples are destroyed after a 12-week period as per the standard operating procedures within the laboratory, in accordance with the United Kingdom Accreditation Service (UKAS) standards of accreditation.

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

102.1. The process of informed consent is relevant to all clinical decisions I make for a patient, and includes decisions about investigations and tests of any kind, onward referrals and clinical examination.

102.2. The way I gain consent depends on what I know of the patient's situation, and in turn, what the patient knows of their condition and the possible options for treatment and management. It will involve a discussion with the patient that might lead to follow up discussions and an ongoing dialogue, to enable an understanding of the key features of importance to an individual patient. Through doing so, and by listening to the patient and encouraging the asking of questions, I try to clarify what information a patient will need to make their own fully informed decision.

102.3. The nature of the discussion may be influenced by such factors as the complexity of the decision, the options available to the patient to treat or manage a condition - as well as the option to take no action; the risks of harm and the benefits and likelihood of success of each option, and the level of certainty of the risks and benefits. The time limit to make a decision may be important, and what the implications may be of delaying a decision. I try to check that the patient has understood the information I have provided and find out if more advice or discussion is needed before making a decision.

102.4. In some situations, written consent is necessary, for example when undergoing an invasive procedure or when undergoing complex procedures that might have risks. For the majority of healthcare decisions, I use verbal consent, on the basis that the patient has had the opportunity to consider any relevant information and has made a clear decision to go ahead. I like to ensure that it is the patient's decision, and not that of another person who might have influence on the patient.

102.5. I take into account any issues with communication such as language barrier or disability ahead of a consultation, and address communication issues with the help of an interpreter or translation services. I also try to take as much time as the patient requires, and provide follow up opportunities to go over information or ask questions, if decisions are complex. I ensure discussions are held in a private area that is quiet and comfortable. If a patient wishes to record a discussion, that is no problem, and I encourage a partner, relative, friend or carer to be involved in discussions if the patient wishes.

102.6. I try to make sure that the information I provide is objective, and provided in lay terms avoiding medical jargon. I try to provide clear and up to date information, based on the best available evidence from the literature or national guidance. Where possible, I provide written information to reinforce any main points of a discussion, with the time and opportunity to consider the written material before and after making a decision.

102.7. I discuss expected common side effects and harms, and what action to take should these occur.

102.8. Should a patient have had a previous discussion about a test or a treatment, I still review the available options in case the patient has changed their mind, or in case the available options have changed. There should also be an opportunity to review decisions, for example if the decision was made some time previously, or if the patient's condition has changed, or if any aspect of the chosen treatment or testing has changed.

102.9. I provide contact details in writing in case of any further questions or concerns, and provide the names and roles of key staff members who may be involved with their care.

102.10. I try to answer questions as honestly and accurately as I am able, try to be polite and considerate in my approach, and point out the limits of my knowledge and experience.

102.11. I may involve other members of the multidisciplinary team to ensure the patient is fully informed, and to aid communication and understanding, as

different team members may relate to the patient in different ways. I am aware of my responsibilities when involved with informed decision making, and the need to ensure any colleagues involved with decision making are suitably trained, competent and qualified.

102.12. I try to always treat patients fairly, respect their views and beliefs, and not discriminate in any way.

102.13. (b) After detailed discussion with the patient, and any family members that the patient wishes to be present at the time of the discussion, I record my patients' consent to testing (of any kind) in writing in the medical records. I record a summary of the discussion with the patient about their future care and any decisions made to inform future decisions, and to serve as a record for the future to justify actions agreed and decisions made.

102.14. Currently all medical records at the Edinburgh Centre are electronic. There is a clinical note section that is dated and the time of the entry is recorded, with my name. I also dictate a letter to the patient's general practitioner to outline any discussions, and I send a copy of the letter to the patient for information to act as a record of the discussion.

103. How many current patients at the Edinburgh Centre (a) were infected with HIV through blood products; (b) were infected with HCV through blood products; (c) were infected with HBV through blood products; (d) were co-infected with HIV and HCV through blood products?

103.1. (a) Currently there are 6 patients attending who were infected with HIV through blood products. All 6 patients were co-infected with hepatitis C virus.

103.2. (b) Currently there are 32 patients at the Edinburgh Centre who were infected with hepatitis C through blood products. All patients have now been treated with antiviral treatments and are in sustained viral remission. 17 patients have been treated with new antiviral treatments since 2013, and 11 patients were treated in Edinburgh with older combination therapies; 2 patients self-cleared the virus, and 2 patients have been treated at other centres and have a sustained viral response.

103.3. (c) Currently there are no patients attending who were infected with hepatitis B virus through blood products

103.4. (d) see (a)

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

104.1. Hepatitis:

104.1.1. The Edinburgh Centre has referred all patients with hepatitis C virus and/or hepatitis B virus to the hepatology service led by Professor Peter Hayes, who now works alongside a hepatology clinical nurse specialist, Kim Macbeth.

104.1.2. All patients with hepatitis C virus, if PCR positive, have been offered treatment with modern antiviral therapies with successful outcome and sustained clearance of the virus. Since 2013, seventeen patients have been successfully treated with new antiviral therapies with all have had a sustained viral response. The therapies offered have been in line with national (Scottish) guidance from Healthcare Improvement Scotland (HIS).

104.1.3. Ongoing surveillance for hepatic complications such as cirrhosis and hepatocellular carcinoma continues to take place at the Centre's haemophilia review clinics, in close liaison with the hepatology team. The Centre connects the haemophilia and hepatology services alongside the psychology service, providing an individualised management plan for each patient.

104.1.4. This arrangement is multidisciplinary, with the consultant hepatologist attending the Edinburgh Centre, as and when needed, to consult alongside the Director of Haemophilia, so a set joint clinic is not felt to be required.

104.2. HIV:

104.2.1. The HIV service is based at the Regional Infectious Diseases Unit (RIDU), and this unit is based at the Western General Hospital. I have experienced excellent liaison between the Edinburgh Centre and RIDU, and patients attend for review by their HIV physician and the wider team of nurses, pharmacists and counsellors at RIDU. The current lead clinician for the haemophilia patients is Dr Rebecca Sutherland, Consultant in Infectious Diseases, Western General Hospital. Blood tests are either taken at the HIV consultation, or are taken on behalf of the HIV team by the haemophilia team when attending for review at the Centre, or at the time of a home visit by the haemophilia nurse. The service is multidisciplinary, with counsellors and pharmacists, and benefits from being at the RIDU site for the multidisciplinary team input. If needed, a member of the Edinburgh Centre can travel to RIDU to provide joint consultation, but this has historically rarely been needed.

105. What if any psychological services are available at the Edinburgh Centre? Do you have a psychologist as part of the staff team? Is there psychological support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

105.1. Since 2016 there has been a lifespan psychological support service embedded into the Edinburgh Centre, and I will provide detail about its inception and progress in my response below.

Do you have a psychologist as part of the staff team?

105.2. Yes, there is a lifespan psychological support services embedded into the Edinburgh Centre, and I will provide detail about its inception and progress in my response below.

Is there psychological support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

105.3. Yes, there is a psychological support service embedded into the Edinburgh Centre that supports those infected with HIV and /or hepatitis in consequence of infected blood products and their families, and this service has now been rolled out across Scotland.

105.4. In addition, the Scottish Government has recently agreed (January 2021) to fund 1.0 whole time equivalent applied psychologist to work with those who received contaminated blood in Scotland. This will be a national service which will be based in NHS Lothian and travel to other health boards. This will be primarily focused on those who received contaminated blood rather than blood products but our patients could access this new service if they prefer or want to be seen for psychology support outside of the haemophilia team. The post job description has been agreed by NHS Lothian and has been advertised.

The Inquiry notes that in the minutes of Annual Meeting of the Scottish Haemophilia Patients, Nurses and Directors held on 22 November 2013 [GGCL000190] and in the minutes of the Scottish Haemophilia Directors Group Meeting held on14 November 2014 [TAYS0000137] there are references to your plan for setting up psychological support services in Edinburgh.

105.5. I will provide a detailed account of the lifespan psychological support service for inherited bleeding disorders in Edinburgh, and how this has been further developed as a wider service within Scotland.

105.6. I represented the Scottish Haemophilia Directors at a meeting of the Haemophilia Alliance in London on 19 November 2012. Towards the conclusion of the meeting, the haemophilia psychology service provided in Wales was highlighted for discussion by Welsh representatives. At the end of this meeting, my colleagues, Nancy Brodie (representing data managers for UK), Susan Warren (representing Haemophilia Scotland), and I discussed with Robert Girvan, then Policy Manager, Blood Policy, Scottish Government, the possibility of seeking funding from Scottish Government to support the establishment of a psychological service within Scotland.

105.7. I will go on to describe proceedings that have led to the Lifespan Psychological Support Service as it currently exists.

105.8. It followed that I was invited to a meeting "Contaminated Blood and Haemophilia: Psychological Support Services" at St Andrew's House, Edinburgh on 24 July 2013 chaired by Robert Girvan, with Scottish Government representatives, and colleagues from Haemophilia Centres around Scotland, and representatives from the Scottish Infected Blood Forum and Haemophilia Scotland. The background to the meeting is noted in point 2 of the minutes **(WITN4027065)** and an outline of psychology services in Scotland (December 2011) is given in point 15. At the meeting it was suggested that an option would be to select one area as a pilot project (point 29) in order to scope the need for psychology services.

105.9. After the meeting, I informally approached my colleague, Dr Robby Steel, Consultant Psychiatrist, Department of Liaison Psychiatry, Royal Infirmary of Edinburgh, who had the forward vision of embedding a psychologist within the Edinburgh Centre, alongside a liaison psychiatrist, and we enthusiastically discussed a potential model.

105.10. I also liaised with Dr Anna Brazier, Consultant Clinical Psychologist and colleagues at the Haemophilia Centre in Cardiff, and the psychology team there, who forwarded details of their service and liaised by telephone in early January 2014.

105.11. I was invited to represent the Scottish Haemophilia Directors' Group alongside Professor Campbell Tait, Co-director of West of Scotland Comprehensive Care Haemophilia Centre at a meeting convened by the Scottish Government Health Directorate, held on 20 January 2014 at St Andrews House, Edinburgh: Infected blood: HCV support scoping exercise: Project Reference Group **(WITN4027066)** It was immediately following this meeting that I was informed by Robert Girvan that financial support would be made available to develop a psychological therapy support pilot project in NHS Lothian funded by Scottish Government.

105.12. On 28 January 2015, I attended a further meeting at St Andrew's House along with colleagues, Dr Belinda Hacking, Consultant Clinical Psychologist, Dr

Robby Steel, Consultant Psychiatrist, and Dr Angela Thomas, Director of the Edinburgh Centre and Consultant Paediatric Haematologist to discuss the preferred pilot model of a whole time equivalent clinical psychologist embedded in the haemophilia services at the Royal Infirmary of Edinburgh and the Royal Hospital for Sick Children, Edinburgh as two half-time posts. **(WITN4027067)**

105.13. It was envisaged that the post would have oversight and support from the psychological services based at the Royal Infirmary of Edinburgh, and would include the support of a liaison psychiatrist, as an additional haemophilia session in an existing consultant job plan.

105.14. This model was based largely on the psychology service in Wales. It was anticipated that a pilot would run for 2 years, leading to an evaluation report. It was anticipated that the proposed model would increase patient confidence in clinicians and NHS services, enable positive patient engagement and improve quality of life, with secondary benefits to staff. A key aim would be to assess feasibility and potential benefits of a national service.

105.15. Following discussion with colleagues in charitable organisations including Haemophilia Scotland, it was agreed that the psychology service was for all aspects of care relating to people with inherited bleeding disorders, one facet of which was dealing with the consequences of transfusion-transmitted infections.

105.16. A total cost of £152,716 was estimated for 2 years, covering a 1.0 Band 8A Clinical Psychologist, 0.1 wte Consultant Liaison Psychiatrist based at the Royal Infirmary of Edinburgh, and band 3 administrative support, and it was hoped that if the project was successful there was the potential for further Government funding.

105.17. I interviewed for the position of clinical psychologist alongside the senior Clinical Psychologist, Belinda Hacking on 11 September 2015.

105.18. In September 2015, Dr Nadine Cossette, Consultant Psychiatrist started providing a session per week for the Edinburgh Centre, and joined the weekly Monday morning handover meetings. In January 2016, Dr Grainne O'Brien,

Consultant Psychologist, started her post within the Edinburgh Haemophilia Centre, and is now embedded within both paediatric and adult haemophilia services, with paediatric cases accounting for just over 20% of referrals to the service and more time spent in the adult services.

105.19. A Steering Group was established with regular meetings to guide the newly appointed team. Project Leads are Belinda Hacking and Robby Steel, and I hold position as Strategic Manager. Our Project Board is the Scottish Haemophilia Centre Directors Group, and subsequently the Scottish Inherited Bleeding Disorders Managed Clinical Network (SIBDN).

105.20. Pilot Project outcomes 2016-2018:

105.20.1. In the first year, a key objective was the advertisement of the service to people with inherited bleeding disorders and their families, and letters and information leaflets about the service were sent to all people including adults, young people and families with an inherited bleeding disorder linked to the Edinburgh Centre.

105.20.2. Close working relationships were established between the service and Haemophilia Scotland, and the team attended the Haemophilia Scotland Annual General Meeting to give information about the service and describe the referral criteria. An article was published about the service in "The Wire", Haemophilia Scotland's magazine.

105.20.3. At this time, links were made with other teams across the UK and Ireland to establish outcome measures, including a questionnaire set to include anxiety, depression, quality of life and self-efficacy measures.

105.20.4. Initial referrals were made by clinicians and nurses within the Edinburgh Centre, and a smaller proportion self-referred to the service. A detailed analysis has been recorded of the number of sessions required by individuals, with some individuals requiring more than seven sessions and for some, sessions are ongoing.

105.20.5. The psychology team have worked directly with adults, young people and children with inherited bleeding disorders, their parents and siblings, and the families of those who have lost a family member due to the receipt of contaminated blood products.

105.20.6. Appointments take place in both out-patient and in-patient settings, and at the patient's home. Referral issues have included anxiety related to treatment (e.g. needle phobia) or hospitals, depression, anger, non-adherence to prescribed treatments, adjustment difficulties, body image difficulties, pain management, grief and bereavement, neuropsychological assessments related to receipt of contaminated blood products and medication review.

105.20.7. Psychological input has also proven relevant and beneficial for young people during the transition from paediatric care to adult haemophilia services. The team are taking a leading role in developing a Transition Policy for the Scottish services and ran an information gathering day in March 2017 to establish the views of patients and their families on the strengths and weaknesses of the current Transition Process. In turn, this has helped inform the new redesigned National Transition Policy, in collaboration with Haemophilia Scotland.

105.20.8. A psychology presence is invaluable and has brought great insight at the regular adult psychosocial meetings held in the Edinburgh Centre, and our psychologist now sits as a member of the Scottish Inherited Bleeding Disorders Network Steering Committee, and is Vice-Chairperson of the Haemophilia Psychology Association (HPA) UK & Ireland. This group contributed to the standards of care for psychological services in the recent UKHCDO Peer Review Working Group and recent national audit.

105.21. 2018 to 2020 and onwards:

105.21.1. In late 2018, once the need for psychological support had been scoped, the service was widened to support patients and families in

Glasgow (West Coast clinic : three adult, and one paediatric clinic per month).

105.21.2. There was also discussion about how to support individuals in other geographical locations in Scotland through satellite clinics supplemented with telemedicine such as Skype and NearMe technologies (e.g. Grampian, Highland and Tayside).

105.21.3. The West Coast clinic has been referred 58 adults and 17 paediatric patients with inherited bleeding disorders. The Edinburgh service has been referred 50 adults and 14 paediatric cases with inherited bleeding disorders. Six people (4 in Edinburgh, 2 in Glasgow) have been seen by both the clinical psychologist and Consultant Psychiatrist. A breakdown of the services provided to Dundee, Aberdeen and Inverness is summarised on page three of Haemophilia PSS Business Extension 2020-2022 (**WITN4027068**)

105.21.4. 57% of adult patients referred to the Scottish Psychology Service have been affected by the complex impact of blood-borne infection (including HIV and hepatitis C infections) on mental health problems, including the distress associated with the stigma relating to blood-borne infection that has played a toll on personal relationships and life opportunities.

105.21.5. Haemophilia treaters also completed a recent training audit to scope their preferred psychological training programmes and highlighted communication skills, basic anxiety and mood management skills and recognition of one's own resilience. A national training programme is to be implemented in 2020-2021.

105.21.6. The psychology project was initially a two year pilot. Its success is palpable, with the demonstration that the delivery of psychological treatments within haemophilia services is acceptable to patients and staff, and leads to clear, statistically significant improvements in mental health parameters and quality of life. Through audit, it has been shown that psychological intervention with the psychological support service has led to statistically significant improvements in

anxiety, depression, psychological distress, and quality of life. Equally, healthcare professionals have reported, through a series of qualitative interviews, that the psychological support service was a needed additional support for people with inherited bleeding disorders. This work has provided insight to the benefits of the programme for those accessing the service and the wider multidisciplinary team.

105.21.7. Extension funding has been successfully secured each year from Scottish Government alongside National Services Scotland:

105.21.7.1. Extension Funding £101,756 (Jan 2018 - April 2019)

105.21.7.2. Extension Funding £92,247 (April 2019 - 31 March 2020)

105.21.8. A further 2 years of ongoing funding has been requested (see Haemophilia PSS Business Extension 2020-2022 **(WITN4027068)** There are three possible permanent funding sources for specialist psychology input in haemophilia in Scotland: (i) national commissioning of the whole haemophilia service which would incorporate psychology as part of the risk-share agreement with National Services, Scotland; (ii) national commissioning of the psychology service by National Services alone; (iii) each health board to separately fund psychology input to haemophilia.

105.21.9. There is an ongoing review evaluating the SIBDN managed clinical network and the risk share agreement: outcome pending and likely to be announced in March 2021.

105.21.10. Meanwhile, the Comprehensive Care Centres in Edinburgh and Glasgow were audited by UKHCDO/WMQRS in 2019 [EXPG0000029]. Within the audit reports, the psychology service was highlighted as an "achievement" but equally "an area of concern" due to the permanent lack of funding.

105.21.11. In January 2021, the Scottish Government has agreed to fund a 1.0 wte applied psychologist to work with those who received

contaminated blood in Scotland. This will be a national service which will be based in NHS Lothian and travel to other health boards. Although there is a focus with this post for those who received contaminated blood rather than plasma-derived products, our patients could access this new service if they prefer or want to be seen for psychology support outside of the haemophilia team. The post job description has been agreed by NHS Lothian and has been advertised.

106. What if any other support services are available at the Edinburgh Centre?

106.1. There are no other support services available at the Edinburgh Centre, but we would refer to social services when necessary (social service office is adjacent to the Centre), or give information on support groups and patient charities (such as Haemophilia Scotland) as appropriate. Referral to a specialist genetic counselling service is also available.

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

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

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

107.1. **a.** *Impact of HIV and hepatitis infection on physical health*

107.2. In 1994, as a trainee in haematology, I helped to care for three patients with AIDS, and witnessed the devastating consequences for the families.

107.3. Since 2008, I have looked after patients who have developed hepatocellular cancer as a complication of hepatitis C virus.

107.4. In addition, a range of complications have occurred including – for hepatitis C - ongoing hepatitis and liver inflammation, and the development of liver cirrhosis, and for HIV infection, the development of lymphoma, other solid

tumours and neurological disorders (such as progressive multifocal leukoencephalopathy (PML), and seizures) and retinopathy.

107.5. Patients experienced a series of side effects from previous treatments. In 1999, as a trainee in haematology I witnessed the side-effects some patients were experiencing from combination treatments (ribavirin and interferon-alpha) including reduction in blood counts (anaemia, leucopaenia and thrombocytopaenia), as well as influenza-type chills and fevers often of such severity as led to the discontinuation of the therapy.

107.6. I have also managed patients who have developed complications such as osteoporosis and facial dystrophy secondary to antiretroviral medication taken to control HIV.

107.7. Whilst all of the Edinburgh Centre patients have been successfully treated for HCV with modern antiviral therapies, those with cirrhosis require ongoing ultrasound surveillance for hepatocellular carcinoma on a 6-monthly basis.

107.8. Since 2008, two patients from the Edinburgh Centre have required liver transplantation in view of complications of hepatitis C.

Impact of HIV and hepatitis infections on mental health:

107.9. I am also very aware of the effects of HIV and hepatitis infection, as a consequence of blood product transfusion, on mental health difficulties. This includes the distress associated with the stigma associated with blood-borne infection that has played a toll on personal relationships and life opportunities for our patients and their families over many years. It includes issues relating to anxiety, depression, frustration and anger. It has affected the patient and their family and loved ones in a profound way over the years.

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

Ways in which decisions about treatment and care are taken:

107.10. As a result of the transfusion of HIV and hepatitis B and C viruses in the past, decisions about treatment and care are taken very carefully at the Edinburgh Centre, and there is an emphasis on good communication. The privacy and comfort of the patient when making decisions about their management and care is of paramount importance. The time taken at consultation enables the doctor or treater to understand what is important to each individual, and what may be the factors that will influence decision making. Interpreter services are used if there are language barriers, and communication difficulties anticipated ahead of consultation to ensure the patient and accompanying family members can understand discussions clearly.

107.11. The need to take time to discuss options for care is important, the side-effects of treatment and any anxieties the patient might have, with the need to re-visit discussions if there is any uncertainty, is also immensely important, to ensure all questions are covered. Written material is provided if possible to support discussions. The provision of contact details, a direct dial number, and an open policy for walk-in appointments enables an ongoing dialogue with the patient if this is necessary.

Ways in which decisions about treatment and care are provided:

107.12. Blood product sparing treatments including desmopressin (DDAVP) and tranexamic acid are offered to patients with haemophilia A, von Willebrand disease, unidentified bleeding disorders, congenital thrombocytopenia and platelet function disorders where applicable.

107.13. Recombinant factor concentrates are favoured over plasma-derived products where available. Currently, all patients requiring factor replacement therapy for haemophilia A or B receive recombinant products (including a mixture of standard and extended half-life products).

107.14. All patients with haemophilia A with active inhibitors receive prophylaxis with the bispecific monoclonal antibody, Emicizumab. This is also being used in a small number of patients with severe haemophilia A without inhibitors. Breakthrough bleeding and surgery is managed with recombinant factor VIIa where necessary.

107.15. Aside from the actual treatment itself, there is recognition that hospital visits, and in particular, hospital admissions may be difficult for many patients based on their past experiences of healthcare. The emphasis on management of bleeding disorders at home is partly due to this, and our specialist nurses have managed patients at their homes on the occasion that this has been needed.

107.16. Psychological support has been built into the service provided at the Edinburgh Centre to try to support individuals when admitted to our ward at the hospital. The psychological service has also helped teach and train staff members how to better manage approach patients who have been affected with HIV and/or hepatitis through blood products.

107.17. Decisions about treatment and care are made by consultants qualified as specialists in the field, and follow national and international guidance for treatment recommendations. A Peer Review group meets every 8 weeks, under the auspices of the Scottish Haemophilia Director's Group to discuss any unusual presentation, or high use of factor, to ensure there are no outliers in factor prescribing; that is, there is a consensus among peers about patient management, and an individual's practice is subject to scrutiny by peers.

107.18. At a local level, management decisions are discussed within the setting of a multidisciplinary team, and involve the views of all team members, for the optimal benefit of the patient.

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

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

b. Changed or influenced the practice and approach of your colleagues and if so how?

c. Changed or influenced the way in which haemophilia care is now provided and if so how?

108.1. **a.** The infection of patients with HIV and/or HBV and/or HCV through blood products has changed, and has deeply influenced, my professional practice and approach.

108.2. I favour the use of non-factor concentrate products where possible, and I try to use recombinant products where available to treat patients. I try to counsel patients about anticipated side effects of any given treatments, and to provide clear written information to help guide an individual to a decision about accepting treatment with a given product. Please see my response to question 107 b.

108.3. I try to teach members of the wider multidisciplinary team at all levels, both undergraduate and postgraduate, about transfusion-transmitted infections, and the concern about emerging pathogens, and the need for ongoing haemovigilance when prescribing blood products. I explain to new members of our team and to junior doctors and nurse trainees about the impact that transfusion transmitted infections have had on patients and how families have also been affected. As a senior examiner for the Royal College of Pathologists, I have introduced examination questions on blood product safety, and consent to ensure the ongoing teaching and knowledge of this area for future qualifying consultants.

108.4. It is important that we engage in clinical trials to evaluate novel therapies that avoid plasma-derived therapies, and encourage novel approaches to manage patients, such as gene therapy, and to introduce these therapies, such as the monoclonal antibody, Emicizumab, once available and approved by the medicines and health regulatory bodies. It is also important to respect the wishes of patients in terms of trial recruitment and engagement in research.

108.5. I am also aware of the enormous impact that these infections have had, not only on the patient, but also on the families of those infected with HIV, HBV and/or HCV, in terms of stress, anxiety and impact on personal and family relationships.

108.6. This made me determined to improve access to psychological support at our centre, in addition to widen access and support to this service within Scotland, for the benefit of those patients and families affected.

108.7. **b**. I believe that the infection of patients with HIV and/or HBV and/or HCV through blood products has definitely changed, and has influenced, the practice and approach of my colleagues locally and throughout the United Kingdom.

108.8. It is now standard practice to use non-factor products where possible, and to use recombinant products where available to treat patients.

108.9. We teach our students and trainees about these first principles, and emphasise the effect and toll these infections have had from a physical and mental health perspective on patients, families and loved ones.

108.10. The changing peer review system at UKHCDO has introduced the concept of assessment and evaluation of a centre based on a wider multidisciplinary team than previously, including representatives from social work and psychology backgrounds as auditors. This should emphasise these key services as being essential components of the multidisciplinary team within a centre caring for patients with inherited bleeding disorders, and especially for those patients who have been infected as a consequence of blood products.

108.11. It is of note that already one English haemophilia managed clinical network has been in contact with myself this year to ask about our model of psychology service, with the hope of setting up a similar service in their locality.

108.12. Many colleagues have also commendably nurtured areas of research that have led to the development of novel therapies such as Emicizumab, longer-acting recombinant factor therapies, as well as pharmacokinetic approaches to gauge the optimal dose of factor replacement, and gene therapy - all approaches to avoid the use of plasma-derived products in the future and to avoid the potential for the transmission of an unknown, or undetected pathogen.

108.13. **c.** The transmission of blood borne infections has changed, and influenced the way in which haemophilia care is now provided. For example:

108.13.1. There is a changing emphasis on the necessity for the embedding of psychological support and the availability of good quality social services support for those affected by, and infected with HIV and/or HBV and /or HCV.

108.13.2. The way in which factor concentrates are purchased from manufacturing companies involve clear routes of commissioning, and legal transparency and are not reliant on individual persons making decisions.

108.13.3. The peer review process is being updated to include a much heavier reliance on multidisciplinary assessment and patient involvement in the process of audit.

108.13.4. Patients and patient groups are represented on local managed clinical networks and have influence on the service that is shaped to provide care. Patient education forums and patient engagement form an essential component of the role of a managed clinical network.

108.13.5. Patients are provided with counselling and written information about new factor products including product safety, manufacturing steps, and are welcomed to ask questions about therapies, and in turn have explanations in a manner they can easily understand.

108.13.6. Working today in the practice of medicine, there is an emphasis on openness and honesty, avoidance of paternalism and a duty of candour in any situations of adverse outcome, and the need for informed consent when helping patients to make decisions.

109. The Inquiry notes you were part of the UKHCDO Working Party that contributed to quality standards on the 'Care of People with Inherited and Acquired Haemophilia and Other Bleeding Disorders' [EXPG0000029]. Do these standards represent professional consensus? Are they widely applied?

109.1. I interpret the first part of this question as: do I believe that the quality standards proposed and used in the recent UKHCDO Peer Review of Haemophilia Centres in the United Kingdom reached a consensus for acceptance by all stakeholders as a standard on which one would base a centre's quality of care for people with congenital and acquired haemophilia, and other bleeding disorders.

109.2. I was a member of the UKHCDO Peer Review Working Party although I was unable to join the initial meetings from December 2016 until May 2017 due to ill health.

109.3. The aim of the Peer Review process is stated in point 3 of the introductory section of the paper entitled "Peer Review of Services for People with Haemophilia" [**(WITN4027074)** *"This peer review programme aims to evolve the historical audit process using contemporary methodology and also aims to address some of the problems which have been grappled with over the years. The aim is to carry out a complete peer review of haemophilia services in the UK using agreed standards to be developed by the UKHCDO Peer Review Working Party, in collaboration with WMQRS. The aspiration is that the peer review process will cover the entire UK and will publish open and transparent reports which are available to all stakeholders including patients and commissioners"*

109.4. Alongside my working party colleagues and colleagues from the West Midlands Quality Review Service (WMQRS), I contributed to the development of Quality Standards on the "Care of People with Inherited and Acquired Haemophilia and Other Bleeding Disorders" [**EXPG0000029**].

109.5. I believe that these standards do represent professional consensus. I base this statement on the following:

109.5.1. (i) The final standards were developed meticulously from several sources, involving many relevant stakeholders at an early stage in their development.

109.5.2. With reference to meeting notes of the Peer Review Working Party, May 19 2017 (**WITN4027069**) that outline the sources used to develop the initial working draft, specifically (point 2):

109.5.2.1. *"Development of Peer Review standard proforma*

109.5.2.2. *JE outlined the process of developing the peer review standards. WMQRS will use available information from multiple sources including:*

109.5.2.3. *Previous UKHCDO audit proforma; update proforma worked on by David Perry*note 1; existing Guidelines (tapping into Julia's recent guideline review work*note 2); Physio standards; Nursing competencies; Clinical psychology/social work standards; previous service specifications both for haemophilia and generic standards for care of children – and any other literature /useful documents. All this info will be distilled into the WMQRS standard format and form a "first draft" for discussion, further modification and wide consultation before being finalised. It will take 6-8 weeks to produce the first draft".*

109.5.3. Additionally I refer to the document "IABD Quality Standards and Peer review process", **(WITN4027070)** Key Point 1, where it is stated*: "….The Standards build on the proforma used by the UKHCDO for its previous audit programme and are consistent with the NHS England Service Specification B05/S/a for Haemophilia (All ages) which also includes a full list of conditions and their ICD 10 codes".*

109.5.4. I draw attention also to the efforts to have inclusion of all stakeholders at an early stage of the development of the Quality Standards. (see point 4, Peer review WP meeting notes, May 19 2017**(WITN4027069)**

109.5.4.1. ***"Involvement of other stakeholders in development of peer review standards***

109.5.4.2. *Agreed need to involve others in the working party at early stage as part of the standards development process:*

109.5.4.2.1. Patient/Carer representatives LCa/CH to recruit

109.5.4.2.2. Commissioner JH to email Will Horsley

109.5.4.2.3. Trust ManagerJH to email UKHCDO membership

109.5.4.2.4. Social WorkerJH to invite social worker rep

109.5.4.2.5. Clinical Psychologist JH to invite psychologist rep

109.5.4.2.6. Laboratory issues....."

109.5.5. (ii) The working draft of the Quality Standards was circulated widely for consultation to all stakeholders for comment. Please refer to IABD QS and Peer review WP cover letter to UKHCDO, **(WITN4027070)** point 2 : *"The draft standards were circulated, for consultation, in early December (2017). A number of people took the opportunity to comment which was encouraging and overall feedback was positive. Following consultation, the Working Party met on the 14th December 2017 to review the comments received. The agreed amendments are included in the final draft of the standards which are included with this paper. Feedback will be provided to those who submitted comments following the final approval of the Quality Standards".*

109.5.6. This references the UKHCDO Peer Review Working Party meeting alongside WMQRS, on December 14 2017, at the Haemophilia Society Headquarters in London. I chaired this meeting, in the absence of the working party chair, Dr John Hanley, during which the working group systematically evaluated every part of each standard, assessing any comments relating to the standards, and making amendments where necessary. I can therefore confirm that there was full consensus within the working group on the quality standards.

109.5.7. A peer review programme process paper was also circulated for comment, although no comments were received; this paper outlined the process to be followed for the reviews and the reporting timetable.

109.5.8. The amended "final" Quality Standards and associated documents were sent to the UKHCDO Chair for discussion at the UKHCDO Advisory Meeting on 19 January 2018 and were subsequently approved. Feedback was given to all those who had provided comments by WMQRS once the Quality Standards were approved by the UKHCDO Advisory Board.

109.5.9. A few extra comments were returned to the Chair of the Peer Review Working Party following the Scottish Inherited Bleeding Disorders Network All Network Committee Meeting on 22 February 2018, and were incorporated into the final version of the Quality Standards.

109.5.10. In conclusion, the Quality Standards were developed by a multidisciplinary UK-wide team in collaboration with WMQRS, and there was a wide consultation process inclusive of all stakeholders, leading to a unique set of agreed standards on which to base a complete peer review of haemophilia services covering the UK.

109.5.11. The aspiration is that open and transparent reports will be available to all stakeholders including patients and commissioners, and in so doing, improve the quality of care for patients with haemophilia and other bleeding disorders using a consistent and supportive process.

109.5.12. Throughout the process of developing the Quality Standards it was recognised that the standards will require honing and further revision following the first audit cycle, after feedback and reflection on the overall audit experience.

109.5.13. I interpret the second part of this question: "Are they widely applied?" as: have the Quality Standards been used in a consistent fashion during the Peer Review process?

109.5.14. The answer is "yes". At least 33 services were reviewed as outlined in the document "Peer review of services for people with haemophilia", point 6, [(**WITN4027074**) including 28 English Comprehensive Care Centres and other large haemophilia services; 2 centres in Wales; 1 in Northern Ireland; 2 Comprehensive Care Centres in Scotland; and the care of both children and adults were to be reviewed in each location".

109.5.15. Prior to the start of the audit process, every reviewer was trained by WMQRS regarding the application of the quality standards. A chief auditor attended all 33 visits to ensure that the audit was conducted in a consistent fashion, ensuring the same application of standards at each audit visit, and thereby allowing a degree of comparison between centres.

109.5.16. I reviewed the Comprehensive Care Centre in Newcastle as part of the audit process, and can state that the auditors, drawn from various multidisciplinary backgrounds including a patient or carer representative, checked the centre against every standard and then advised the lead auditor as to whether a standard had been met along with any comments.

109.5.17. I can therefore state that the Quality Standards were widely applied during the recent Peer Review process.

109.5.18. note 1: David Perry was the lead auditor for UKHCDO Audit circa 2012 – 2016.

109.5.19. note 2: refers to my work for the British Society for Haemostasis and Thrombosis Task Force to collate UKHCDO guidelines to highlight areas for update, a copy of which can be provided on request.

Section 10: Other issues

110. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

110.1. I have had no complaints made about me to my employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

111. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry.

111.1. If I may, I would like to make this statement:

111.2. Over the past 27 years, I feel very privileged as a doctor with an interest in bleeding and thrombotic disorders to have been able to care for patients and their families with inherited bleeding disorders. I was warmly welcomed to Belfast by the patients and their families, and treasure the many gifts when I got married, and the good wishes when I subsequently left for pastures new in 2004, bound for a more academic spell of time in Canada. In turn, the stories I learned, and the sadness and grief experienced through the loss of loved ones noted by myself when I was the Belfast director touched me greatly.

111.3. As a junior doctor, I helped to care for patients dying from AIDS, and, as a consultant in both Belfast and Edinburgh, I have cared for patients dying from the late consequences of hepatitis C. I am now involved in helping the daughters of those infected with, and affected by contaminated blood products, to make decisions about future pregnancies, and feel honoured to be in a multidisciplinary team that enables the safe delivery of a baby with a bleeding disorder into this world – hopefully a world with recombinant therapies, novel therapies and the possibility of gene therapies that hold a different and very optimistic outlook for patients with haemophilia and bleeding disorders. Looking back at these years of clinical service, I recognise the unique position I have had, and continue to hold.

111.4. Working with local patient groups in Northern Ireland for the short time I was there, senior patient representatives and more recently with my remarkable colleagues at Haemophilia Scotland, I have noted their commitment and dedication given to improve the care of patients with heritable bleeding disorders, working alongside government bodies and local network teams, and I wish to acknowledge the campaigns led by some who are sadly no longer with us, that have contributed and led to the request for an independent Inquiry.

111.5. The team that I led at the Belfast Centre from 2000 to 2004, and the team I currently work within at the Edinburgh Centre, were, and are, highly aware of the suffering caused to patients and their families caused through treatment with infected blood products. In particular, it has been important for me to be integral to the psychology support project at our Centre, now being rolled out to the rest of Scotland, that is demonstrating ways we may be better able to support patients and families who continue to face the psychosocial consequences and wider ramifications of receiving contaminated blood products.

111.6. I am so very sorry that the many patients and their families that I have had the honour and privilege to care for, and who have shown me great warmth, kindness and support, have had to deal with such silent suffering and pain over the years.

Statement of Truth

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

Signed GRO-C

Dated 19/03/21

Date	Notes/Description	Exhibit number
1-2 June 2000	Report of audit visit to the Belfast Comprehensive care haemophilia Centre	WITN4027002
14 June 2003	Northern Ireland Haemophilia Society Annual General Meeting	WITN4027003
20 October 2003	UKHCDO CCC Audit 2003	WITN4027004
28 June 2004	Diary extract - First hepatology haemophilia clinic	WITN4027005
18 September 2003	Letter from Dr TCM Morris, Consultant Haematologist to Dr Miriam McCarthy, Deputy CMO	WITN4027006
January 2003	Report by Dr RJG Cuthbert 'Consultant Haematologist with a Specialist Interest in Haemostasis and Thrombosis - Bid for a second post'	WITN4027007
July 2001	Draft report 'A profile of Haemophilia patients in Northern Ireland and their use of clotting factors'	HCDO0000264_125
18 January 2001	Agenda for RMSC project team	WITN4027008
17 June 1994	Letter from Christopher Ludlam to Dr Mayne RE Haemophilia Centre Audit Report 1994	WITN4027009
1 Sep 2000	UKHCDO Audit of CCCs 2000	WITN4027010
22 Nov 2007	WITN402700 - SCOTLAND & NORTHERN IRELAND HC AUDIT 2007 - Edinburgh Royal Infirmary	WITN4027011
5-6 Feb 2007	UKHCDO Audit of CCCs 2006. Audit report	WITN4027012
24 May 2010	UKHCDO HC audit 2009-2010 Royal Infirmary Edinburgh	WITN4027013
9 May 2013	UKHCDO CCC audit Royal Infirmary Edinburgh	WITN4027014
1987	Kumar and Clark Clinical Medicine 1st Edn, 1987	WITN4027015
1990	extracts from Kumar and Clark 2nd ed 1990 hepatitis C.	WITN4027016

1 Aug 2007	Sarah Darby et al 'Mortality rates, life expectancy, and causes of death in people with haemophilia A or B in the United Kingdom who were not infected with HIV'	PRSE0001620
	M M Khan et al 'Hepatitis C infection and outcomes in the Scottish haemophilia population'	GRAM0000025
12 Jan 2001	Email from Karin Pappenheim to Julia Anderson re Haemophilia Alliance	WITN4027017
6 Feb 2001	Meeting of the issues arising from contamination of blood products	WITN4027018
29 Jan 2001	Letter from Northern Ireland Advisory Committee on Blood Safety to members of the Northern Ireland Advisory Committee on blood safety	WITN4027019
	Hepatitis C Workshop group 1 attendance sheet	WITN4027020
	Hepatitis C workshop Group 4 record of attendance	WITN4027021
5 Dec 2001	Programme for the Hepatitis C workshop at the Ramada Hotel	WITN4027022
22 Feb 1991	Mayne et al 'Human immunodeficiency virus infection in Northern Ireland 1980-1989'	WITN3082020
3 Aug 1985	Ludlam et al 'Human T-Lymphotropic virus Type III (HTLV-III) infection in seronegative haemophiliacs after transfusion of factor VIII' The Lancet	HSOC0002656
	Table 3.16 from the Penrose Final Report - Royal Infirmary of Edinburgh HIV infections	PRSE0007002
10 Sep 2003	Letter from Dr Anderson to Mr Gerry Dorian	WITN4027023
6 Feb 2003	Minutes of meeting - haemophilia hepatitis C project in Scotland and Northern Ireland	WITN4027024
6 Feb 2003	Minutes of meeting - haemophilia hepatitis C project in Scotland and Northern Ireland - Appendices to meeting	WITN4027025
6 Feb 2003	Agenda - haemophilia hepatitis C project in	WITN4027026

	Scotland and Northern Ireland	
13 May 2003	Letter from Julia A.M Anderson to Frank Hill attaching a Draft paper: "A Profile of Haemophilia patients in Northern Ireland and their use of clotting factors" by Dr Tracey Owen (Public Health Medicine, EHSSB)	HCDO0000264_125
17 May 2001	Email from Desiree Bradshaw to Dr Anderson (Marie George) attaching excerpts from Northern Ireland Assembly questions on Haemophilia	WITN4027027
30 April 2001	Fax from Mary Graham to Dr Anderson RE Assembly questions	WITN4027028
2001	Letter from Dr Anderson to 'Mary' RE brief for health minister	WITN4027029
16 Aug 2002	Letter from Dr TJ McMurray to Dr Anderson re nvCJD	WITN4027030
17 Jan 2011	Zaman et al 'The Risk of variant Creutzfeldt-Jakob disease among UK patients with bleeding disorders, known to have received potentially contaminated plasma products' Haemophilia Jan 2011	WITN0644101
26 March 2000	Letter from Scientific Programme Department, Haemophilia 2000 World Congress to Dr Julia Anderson RE abstract on seroconversion to parvovirus B19 following pd-factor VIII	WITN4027031
13 May 2003	Royal Victoria Hospital Belfast proposal for the treatment of Hepatitis C 2003 - 2006 by Dr Michael E Callender.	RHSC0000275_001
17 Oct 2003	Letter from Dr KJ Fullerton to Dr J Anderson	WITN4027032
19 June 2000	Letter from Dr Anderson to Dr FGC Jones	WITN4027033
18 Aug 2000	notes made on meeting with Dr I Carson Friday 18 August 2000	WITN4027034
23 Nov 2000	Letter from Secretary to Dr Anderson, to Mrs Arlene Pentland	WITN4027035

23 Nov 2000	Letter from Secretary to Dr Anderson, to Mrs Arlene Pentland attaching agenda for a meeting with Dr I Carson Friday 15 Dec 2000	WITN4027036
20 Dec 2000	memo from Dr IW Caron to Dr Anderson re outcomes of meeting with Dr Carson Dec 2000	WITN4027037
3 Jan 2001	Diary extract - Service planning group meeting	WITN4027038
21 Feb 2001	Diary extract - meeting with VJ MC and Oxford hepatologist	WITN4027039
25 April 2001	Diary extract - meeting with V Jackson service manager re hepatology service	WITN4027040
21 Aug 2001	Diary extract - Hepatitis C audit meeting	WITN4027041
29 March 2002	Diary extract - meeting re hepatitis C audit McNulty Coyle McCaughey	WITN4027042
2 Oct 2002	Diary extract - meeting with Dr Mock	WITN4027043
7 Jan 2003	Diary extract - meeting with Dr Coyle regional virology service re hepatitis C audit	WITN4027044
4 Feb 2003	Diary extract - meeting with Dr Callender	WITN4027045
19 Mar 2003	Letter to Dr Ken Fullerton from J A M Anderson re management of Hepatitis C in patients with haemorrhagic diathesis.	RHSC0000275_002
22 Sep 2003	Diary extract - telephone discussion with PH director re hepatology service Sept 22 2003	WITN4027046
23 Sep 2003	Letter from Dr Michael Callender to Dr Julia Anderson	WITN4027047
14 Jan 2004	Letter from Dr Julia Anderson to Dr KJ Fullerton	WITN4027048
7 April 2004	Diary extract - meeting to plan hepatology haemophilia	WITN4027049
24 May 2004	Diary extract - meeting with MC re hepatology service	WITN4027050
7 June 2004	Diary extract - meeting with MC to plan haematology hepatology service	WITN4027051
2001	The Haemophilia Alliance 'A national	HCDO0000264_001

	service specification for haemophilia and related conditions' 1st Edition 2001 first half	
2001	The Haemophilia Alliance 'A national service specification for haemophilia and related conditions' 1st Edition 2001 first second	HCDO0000264_001
2001	Makris et al 'Guidelines on the diagnosis, management and prevention of hepatitis in haemophilia'	WITN3761021
Aug 2002	UKHCDO Triennial CCC Audit summary draft report August 2002	WITN4027071
21 Dec 2000	Bundle of faxed documents - communication from Prof B McClelland SNBTS	WITN4027052
22 Nov 2013	Minutes of AGM of the Scottish Haemophilia patient, nurses and directors	GGCL0000190
15 Jan 2001	UKHCDO newsletter number 5 Advisory Committee Meeting on 15th Jan 2001	GGCL0000090_002
21 Dec 2000	Bundle of faxed documents - communication from Prof B McClelland SNBTS	WITN4027053
	Draft letter from Prof Michael Banner to Dr Anderson RE Incident reference GRO-A	DHSC0014927_021
16 Jan 2001	Letter from Dr FGH Hill to all members of the UKHCDO Advisory committee	WITN4027054
7 Feb 2002	Minutes of meeting of the coagulation factor working party	WITN4027055
3 June 2003	Minutes of the AGM of the Scotland and Northern Ireland haemophilia directors, SNBTS director and Scottish Executive health department	LOTH0000082_019
10 May 2004	Minutes of the 14th meeting of the UKHCDO Advisory Committee	BART0000929
7 June 2004	Email from Glenda Mock to Julia Ander son RE Current timing - vCJD plasma products patient notification	WITN4027056

28 Nov 2002	Letter from JAM Anderson to Professor Frank Hill re Creutzfeldt Jacob disease notification strategy. One "implicated" batch of Factor VIII Z8 030170320 was sent to Northern Island Haemophilia Centre from SNBTS on 1 June 1987. Sets out numbers of patients who may have received the infected product. Refers to a previous time potentially infected people were notified and encloses letter that was sent to them.	HCDO0000266_051
14 June 2002	Minutes of meeting of Scotland & Northern Ireland Haemophilia Directors Group chaired by Professor C A Ludlam	GGCL0000194
23 Sep 2002	Minutes of meeting of Scotland & Northern Ireland Haemophilia Directors Group 23rd September 2002	GGCL0000195
26 July 2004	Handwritten Agenda for meeting with FJ 26 July 2004	WITN4027057
Jan 2001	Letter from Karin Pappenheim to Haemophilia Society members	WITN2336005
Jan 2001	Draft of proposed letter to all adult patients re vCJD Jan 2001	WITN4027058
Dec 2000	Bundle of letters relating to BPL vCJD notification	WITN4027059
24 Jan 2001	Letter from Dr MPJ Kilbane to Mr William McKee	WITN4027060
	Audit on antithrombin usage in Northern Ireland	WITN4027061
21 Feb 2002	Letter from Julia Anderson, Consultant Haematologist at the Northern Ireland Haemophilia Comprehensive Care Centre, to Dr Frank Hill, Chairman of the United Kingdom Haemophilia Centre Doctors' Organisation (UKHCDO) requesting that the UKHCDO database be searched for the names of patients registered at the Northern	HCDO0000264_132

	Ireland Haemophilia Centre who may have received SNBTS Factor VII or Factor IX products between 1 June 1987 and 31 January 1989.	
20 Dec 2002	Letter from Julia A M Anderson, Consultant Haematologist to Professor Frank Hill, Chairman, UKHCDO regarding funding of treatment for haemophiliac in Northern Ireland	HCDO0000266_001
25 Nov 2002	Factsheet on vCJD	NIBS0000569
21 Dec 2000	Letter from Dr Anderson to Dr Janet Little	WITN4027062
20 Jan 2010	CM Millar et al 'Risk reduction strategies for variant Creutzfeldt-Jakob disease transmission by UK plasma products and their impact on patients with inherited bleeding disorders' Haemophilia	HSOC0016641
22 Jan 2003	Letter from Secretary to Glenda Mock to Dr Anderson et al	WITN4027063
	Letter from Prof Michael Banner to Irene Thompson, Senior Infection control nurse RE Incident reference GRO-A	DHSC0014927_022
	WITN402700 - Collins et al. - Emicizumab article	WITN4027064
	The retention and storage of pathological records and specimens 5th edition	RLIT0001474
24 Jul 2013	Minutes of meeting - Contaminated Blood and Haemophilia: Psychological Support Services	WITN4027065
20 Jan 2014	Scottish Government Health Directorates - Infected blood: HCV support scoping exercise: Project Reference Group	WITN4027066
28 Jan 2015	Minutes of meeting - Scottish Government Health Directorate - Psychological Support Services For Patients with Haemophilia	WITN4027067
	Lifespan Psychological Support Service for Inherited Bleeding Disorders in Scotland -	WITN4027068

	Business case for Extension (April 2020 – 31st March 2022)	
19 May 2017	West Midlands Quality Review Service - Peer review of services for people with haemophilia	WITN4027074
19 May 2017	Meeting Notes - UKHCDO Peer Review Working Party	WITN4027069
Jan 2018	West Midlands Quality Review Service - IABD Quality standards and peer review process	WITN4027070