Witness Name: Rosemary Dennis
Statement No.: WITN4030001
Exhibits: WITN4030002-WITN4030005
Dated: 26 October 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF ROSEMARY DENNIS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 27 July 2020

I, Dr Rosemary Dennis, will say as follows: -

Section 1: Introduction

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

1) Name: Rosemary Dennis,
Address: GRO-C Edinburgh,
Date of birth: GRO-C 62

Professional qualification: MBBS, DRCOG

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

2) Medical house officer, Royal Free hospital 1/8/84 – 31/1/85

Surgical house officer, Norfolk and Norwich hospital 1/2/85-31/7/85

SHO in pathology, John Radcliffe hospital Oxford 1/8/85 – 30/4/86

SHO in psychiatry, Littlemore hospital Oxford 1/5/86- 31/7/86

SHO in geriatric medicine, Princess Margaret Hospital Swindon 1/8/86- 31/1/87

SHO in obstetrics and gynaecology, Wexham Park Hospital Slough 1/2/87-31/7/87

GP trainee Summertown Health centre, Oxford 1/9/87 - 31/8/88

SHO in A&E High Wycombe 1/9/88 -28/11/88 and 1/5/89 -31/10/89 (7 sessions/week)

SHO in dermatology and ENT 5 sessions/week High Wycombe 1/11/89 – 29/1/90

GP retainer scheme (2 sessions/week) Blackhall medical centre, Edinburgh 1/11/90 – 17/7/92

Part time clinical assistant, Haematology, Royal Infirmary of Edinburgh 20/7/92 – 1/11/93 and 5/10/94 – around 2001

Part time associate specialist in haematology Royal infirmary of Edinburgh around 2001 – April 2017

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) Previous member of UKHCDO from 2000 – 2017. I attended some annual meetings. I have not been on any committees

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

4) I have not provided evidence or been involved in any other inquiries, investigations or litigation as outlined above. I was aware of the Penrose inquiry but was not asked to make a statement.

Section 2: Decisions and actions of the Centre at Edinburgh and your decisions and actions

5. In relation to your work in Edinburgh as Associate Specialist in haematology please:

a. Describe the facilities, organisation, roles, functions and responsibilities of the Edinburgh Centre during the time that you worked there and how they changed over time;

5) To clarify, I initially was appointed as a part time clinical assistant in 1992, later becoming a part time associate specialist. With respect to this question I am referring to 1992 when I started work. In 1992 the haemophilia centre consisted of a small waiting room, treatment room, nursing sister's office, secretarial office containing locked filing cabinets for records, staff office and 2 consulting rooms. It was on the first floor at the Royal Infirmary site in the centre of Edinburgh. There was a lift to the first floor. An additional room used by the centre staff for pentamidine administration was in the adjacent ward corridor. There was a meeting room on the floor above the centre. The centre moved from this site to the new site at Little France around 2003.

6) The new haemophilia and thrombosis centre at the Royal Infirmary site at Little France, provided updated modern accommodation on the ground floor. There were a couple of emergency car parking spaces immediately outside. There was a reception desk with a large waiting area, 2 treatment rooms, one of which was mainly used to treat children, 3 consulting rooms, 3 other offices and a staff room. There was a locked records room. There was also a room for the coagulation factor fridge, allowing treatment to be held in the centre. The haemophilia centre was situated very near to pharmacy and the dental department.

7) Dr (later Prof) Ludlam was the haemophilia centre director when I started in 1992 and Dr (later Prof) A Thomas, paediatric haematologist was a co- director responsible for paediatric care. Around 2011, when Prof Ludlam retired, Prof Thomas became the overall centre director. The centre was staffed during the week from Mon-Friday 830am - 430pm. Out of hours, when the centre was closed, patients initially used to attend one of the wards where they would be seen by one of the haematology on call team. These arrangements changed after some years and patients were asked to attend Accident and Emergency. Children with bleeding disorders attended the haemophilia centre at

the Royal Infirmary during working hours, but out of hours attended the Royal Hospital for Sick Children.

8) There have been several different consultant staff working at the haemophilia centre since 1992, who between them shared the responsibility of patient care. When I started in 1992 there was another clinical assistant, Dr Young already in post. We were both based in the centre, working 5 sessions each. Dr Andrews came to cover my maternity leave in 1993/94 and worked in the centre for a couple of years before taking up a post elsewhere. From memory, Dr Young left sometime in the mid to late 1990s. Several research fellows / senior lecturers, Dr Hanley, Dr Kerr, Dr Zahra, Dr Lynch, Dr Miller and Dr Benson were involved in clinical care at different times, undertaking regular clinics and providing cover for out of hours care and annual leave.

9) The centre was staffed by an experienced nursing team. The haemophilia sister in post when I started in 1992 was Sister Reynolds. She retired around 1997 and Sister Hook was appointed. Over the years the number of nurses working in the centre increased. For many years, I worked closely with Sister Hook, clinical nurse specialist, two deputy charge nurses and two staff nurses. They were assisted at times by a clinical support worker. There were at times between 1 and 3 administrative staff members managing data, hospital and home treatment supplies, maintaining stock levels and accounting for usage of clotting factor products. There was a secretary/receptionist at the reception desk in the centre.

10) There were close links to the coagulation and genetic laboratories at the RIE. The haemophilia centre was responsible for the care of people with bleeding disorders in South East Scotland. This included people with haemophilia, VWD, other clotting factor deficiencies such as FXI, some acquired bleeding disorders and platelet disorders. This responsibility included, but was not limited to, diagnosis, treatment, provision of home treatment, venepuncture education, arranging vaccinations, genetic counselling, providing treatment and plans for surgery and dental work, monitoring for possible side effects of treatment and managing the complications of haemophilia and clotting factor treatment. This included screening for and treating viral infections and inhibitors. Patients were offered regular review appointments where an assessment of any complications of their condition or its treatment could be made.

11) Some people with thrombotic problems were also seen at the centre. For some years the nurses ran a nurse led outpatient DVT service. The nurses provided education to people with a new diagnosis of a bleeding disorder and parents of children with bleeding disorders, to enable them to start or continue with home treatment. They provided venepuncture education and advice about the treatment of bleeding episodes and when to seek help. They sorted out the arrangements for home treatment, arranging home visits when necessary. They also attended schools to educate staff as required if children with bleeding problems were starting school or nursery. The nursing staff took blood and gave the treatment in the centre and most of the treatment on the ward.

12) There were clinics every morning at the centre. Each of the consultants ran a clinic in the centre each week. For many years I worked with Prof Ludlam and Prof Thomas. Dr Horn then joined the centre, I think in around the mid/late 1990s. Some years later, Dr Anderson joined the haematology team and there were then 3 consultant haematologists looking after the adults with bleeding disorders. I would see people at morning clinics and anyone attending the centre with acute problems at other times on the days I worked. Prof Thomas had overall responsibility for the care of the children with bleeding problems. She came to do a clinic once a week at the centre but otherwise was based across town at the Royal Hospital for Sick Children. Children with bleeding disorders could attend the haemophilia centre during the working week for assessment and treatment of acute bleeding episodes. They also came to receive prophylaxis when first starting home treatment until a parent was able to administer treatment at home.

13) From memory, when I started in 1992 some HIV treatment was already being prescribed by the haemophilia centre staff. Dr Brettle, consultant in infectious diseases, provided advice and help with clinical problems. As new treatments became available, management of HIV infection was taken over by the infectious diseases team at the Western General hospital.

14) In the 1990s Geraldine Brown, social worker and Dr Alison Richardson, Consultant clinical psychologist were available to provide help and support to anyone having social, financial or psychological issues. They both met with the haemophilia team on a weekly basis. These meetings were already established when I started in 1992 but stopped after a few years. I think this was before the move to the new RIE site in 2003. Soon after I started work in 1992, a joint clinic with Professor Hayes, consultant hepatologist was set up to see people with bleeding disorders who had become infected with hepatitis C through treatment. Prof Hayes was available to see patients to coincide with

haemophilia review appointments at the centre. This meant that people with a bleeding disorder and Hep C could be seen by the haemophilia team and by Prof Hayes, at the one place on the same day. Over the years, as new treatments became available the hepatology team took over the prescribing and monitoring of hep C treatment for the duration of the treatment.

15) The centre also ran a joint orthopaedic clinic, initially with Mr Macnicol and subsequently with Mr Lawson. I saw patients with bleeding disorders and musculoskeletal problems jointly with Mr Lawson, orthopaedic consultant, in the haemophilia centre. This enabled us to have a joint discussion in clinic with the patient about potential bleeding problems around the time of any planned surgery and how these could be managed.

16) The centre worked closely with the hospital dental team, providing advice and administering treatment prior to any procedures which could cause bleeding. The dental dept was situated very near to the centre in both the old and new RIE sites. People with bleeding disorders could come to the haemophilia centre for treatment on their way to the dental department and return for a period of observation after their dental appointment if for example a tooth had been extracted.

17) The haemophilia centre nurses and doctors also provided genetic counselling. For a while whilst at the new RIE site, one of the genetic nurse counsellors from the genetics department at the Western general hospital came to the centre to counsel people.

b. Describe your role and responsibilities and how they changed over time;

18) Prior to starting work at the centre in 1992, I had been working in general practice, and so I had little specialist knowledge of bleeding disorders or the treatment of HIV and hepatitis C. Prof Ludlam, Dr Horn and Prof Thomas were all experienced clinicians in the management of haemophilia related problems and initially I relied on their guidance and advice. Under their supervision I gained experience in this area and was able to work with less supervision in subsequent years.

19) I worked part time due to family commitments. I was not involved in any inpatient care or out of hours/ weekend work. I did not have any overall clinical responsibility for patients as each patient was under the care of a consultant. I provided clinical care and support to people with bleeding disorders. This included investigation and diagnosis of

bleeding problems. I assessed people presenting with acute bleeding problems and prescribed and monitored treatment, arranging admission when necessary. I saw people with bleeding disorders regularly at clinic to monitoring their condition, including possible side effects of treatment, such as viral infections and inhibitors. I undertook assessment of joint and other musculoskeletal problems and saw people jointly with Mr Lawson, consultant orthopaedic surgeon. I was involved in clinical trials of clotting factor treatments in which Edinburgh patients were participants.

20) As I became more experienced, I saw new referrals for assessment and investigation. I provided genetic counselling for families with bleeding disorders. I liaised closely with Prof Hayes, sometimes seeing patients jointly with him. I regularly saw people with hepatitis C, acquired through previous treatment with blood products. I arranged ultrasound surveillance to look for hepatoma and endoscopy to look for oesophageal varices for anyone with cirrhosis.

21) If someone with a bleeding disorder required elective surgery, my usual practice was to see them pre- operatively to discuss the plans for managing their bleeding disorder. This would have included discussing the treatment plans, gaining their consent for treatment, arranging pre- operative blood tests to check for inhibitors etc. I provided detailed written treatment plans and liaised with the surgical team and anaesthetist pre- operatively to try to make sure that everything went smoothly. I provided advice and treatment plans prior to any invasive dental work. When requested I provided letters of support for people requesting assistance. I completed DLA forms and Skipton fund application forms as requested. I was available to provide telephone advice to patients, GPs, dentists and other teams in the hospital.

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

22) See Q5a and 5b.

23) When I started in 1992, some HIV treatment was already being prescribed by the haemophilia centre staff. I had no experience of managing HIV related problems. I was involved in the out-patient assessment and management of clinical problems, often with guidance from colleagues, mainly Prof Ludlam and Dr Brettle, consultant in infectious diseases. As new treatments became available, management of HIV infection was

provided and monitored by the infectious diseases team at the Western General hospital. The haemophilia centre staff continued to provide care for bleeding problems.

24) Soon after I started in 1992, I noticed that some patients had abnormal liver function tests. I was told that this was most likely due to hepatitis C. As tests had only recently been developed for hep C, I had very little knowledge of it. Around that time, I became aware that stored samples from patients had already been tested for hep C but the patients had not yet been informed of the results. From memory, as people came up to the clinic for review appointments, if a hep C result was available, this was discussed with them and a confirmatory test was done. Those with hep C were offered an appointment to come to see Prof Hayes, consultant hepatologist and Prof Ludlam at a joint clinic which had been set up in the haemophilia centre. I think that some people, who were not due to be seen soon in clinic, were sent a letter inviting them to the joint clinic where they would have been told their hep C results.

25) This was a very difficult time for the patients. Many were understandably very upset and anxious. Some patients were referred for additional psychological support to Dr Richardson, consultant clinical psychologist or to the department of psychological medicine. In the 1990s, I was involved in making arrangements for admission and investigations which had been discussed with the patients at the joint clinic with Prof Hayes and Prof Ludlam. These included ultrasound, laparoscopy +/- liver biopsy and endoscopy.

26) Over the subsequent years, I regularly saw people with hepatitis C at clinic. In addition to monitoring their bleeding disorder treatment, I was also involved in monitoring their liver function and viral status. I was involved in prescribing and monitoring interferon therapy and later interferon and ribavirin in the 1990s. This included monitoring for side effects of treatment and arranging blood tests to assess the response to treatment.

27) It was usual practice that as each new treatment for hep C became available, patients were reviewed by Prof Hayes who was able to discuss the pros and cons of the new treatment options. After a few years, the hepatology team took over prescribing and monitoring of hep C treatment for the duration of any treatment given. Once treatment was completed, patient care returned to the centre, where ongoing monitoring of the possible complications of hepatitis C continued. Prof Hayes continued to be involved in the care of our patients with hepatitis C until they had successful treatment with a sustained virological response.

28) I would arrange for anyone thought to have cirrhosis, to have a liver ultrasound every 6 months, usually on the day of their clinic appointment at the haemophilia centre. This meant that only one hospital visit was required and the result could be discussed at clinic. We monitored blood tests including hyaluronic acid levels and when they became available, arranged fibro scans to try to identify anyone whose liver disease may have progressed to cirrhosis. If someone was thought likely to have cirrhosis, regular endoscopies and AFP blood tests were arranged in addition to the ultrasounds.

29) Prof Hayes arranged referral of anyone with symptoms of a failing liver or evidence of a hepatoma on imaging to the Scottish transplant unit for assessment and consideration of liver transplantation.

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

30) Prof C Ludlam, consultant haematologist, was the haemophilia centre director when I started work in 1992 until he retired in approximately 2011. He directed haemophilia management policies and the running of the haemophilia centre. He was responsible for the overall clinical care of his patients with bleeding disorders. He arranged the purchasing of clotting factors and decided which clotting factor products were to be used for which patients. He was responsible for the out of hours arrangements and staffing of the centre. He had a regular clinic in the centre where he saw new referrals and review patients. When I started work in 1992, he provided HIV treatment to his patients. Later this treatment was provided by the infectious diseases team at the Western General hospital. He set up a joint clinic with Prof Hayes to see people with hepatitis C in the early 1990s and was involved in the investigation and treatment of hepatitis C. He supervised several research fellows/lecturers in haematology. He participated in several clinical trials of clotting factor treatments. He held the role of chairman of the UKHCDO for a few years in the late 1990s. He had joint responsibility for the haematology and coagulation laboratories.

31) Dr L Horn, consultant haematologist, came to work at the haematology department in Edinburgh in the mid/late 1990s but left some years later in approximately 2010/2011. Whilst in Edinburgh she had responsibility for the clinical management of patients with

bleeding disorders under her care, some of whom had hep C and HIV. She also was jointly responsible for the haematology and coagulation laboratories. She undertook regular clinics in the haemophilia centre and provided inpatient and out of hours care for people with bleeding disorders. She was also involved in running the thrombosis service.

32) Both Prof Ludlam and Dr Horn were very knowledgeable and experienced in the laboratory and clinical aspects of adult haemophilia care. They were supportive of junior colleagues, including me, who often relied on them for their expert advice. For some years Dr Horn and Prof Ludlam shared the care of the adult patients until they were joined by Dr J Anderson, Consultant haematologist, who then shared the consultant responsibilities as above.

33) After Prof Ludlam retired and Dr Horn took up a post elsewhere, Dr Anderson was joined by Dr Kanagasabapathy, Consultant haematologist and between them they shared the responsibility for the care of the adult patients. Dr Kanagasabapathy left after approximately 3-4 years and Dr Rodgers, Consultant Haematologist then worked with Dr Anderson and both were in post when I left in 2017.

34) Prof P Hayes, Consultant hepatologist was involved with the management and care of the patients with hepatitis liver disease throughout my time working. He was available to see anyone with liver related problems and provided advice and management plans. He arranged for hepatitis C treatment to be given and monitored by his team in the hepatology department. Several other haematology consultants were involved over the years in a rota providing out of hours care. These included Dr Parker and Dr Johnson. They both worked at the Royal Infirmary during the 1990s. Dr Brettle and Prof Leen, consultants in infectious diseases at the Western General hospital, took over the management of HIV infection, I think in the mid/late 1990s. They also managed and treated hepatitis C infection in some people who were co infected.

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

35) I do not have access to this information and as it is now more than 28 years ago, I regret that I am unable to provide an approximate figure. This information should be available from the UKHCDO records.

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

36) I had no role in the formulation of policies, selection or purchase of blood products. To the best of my knowledge products were chosen on the basis of availability, safety, efficacy and according to UKHCDO guidelines.

8. **Who had responsibility at Edinburgh for the selection and purchase of blood products, and what decisions were taken as to which products to purchase and use? In addressing this issue, please answer the following questions:**

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

37) As far as I am aware since 1992, all decisions regarding selection and purchasing of blood products were made by the haemophilia centre directors, Prof C Ludlam and Prof Thomas, often in consultation with the other Scottish haemophilia centre directors who met regularly. I played no part in treatment selection or purchase.

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

38) See answer to Q3a

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

39) See answer to Q3a

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

40) See answer to Q3a

e. What involvement did you have?

41) None

9. What products were used for treating patients at Edinburgh, over what period of time and for which categories of patients? How were decisions taken, at Edinburgh, as to which products to use for individual patients? What involvement did you have in such decisions?

42) When I started in 1992, virally inactivated plasma derived pooled blood products were being used to treat people with Haemophilia A, B and VWD. Unfortunately, I do not have access to information about exactly which products were used and when. I will try to recall to the best of my memory. I was not involved in any decisions as to which products to use for individual patients.

43) I think that when I started in 1992, people with haemophilia A were being treated with a high purity SNBTS FVIII product, Liberate, in a clinical trial. Those with haemophilia B were treated with an intermediate purity FIX product, DEFIX. DEFIX was associated with a risk of thrombosis. High purity FIX products had less risk of thrombosis. From memory in the mid 1990s, when high purity FIX products, which had a lower risk of thrombosis became available, SNBTS HIPFIX and a commercial Factor IX, possibly Alphanine, patients were offered treatment with these in clinical trials. Prior to licensing of recombinant FVIII and IX some patients received these treatments (Benefix and Refacto) also in clinical trials.

44) Once a licensed recombinant product became available for treating haemophilia A or B this was used in preference to plasma derived products unless there was a contraindication e.g. allergy. From memory licensed recombinant FVIII first became available in approximately late 1990s. Over the years Recombinate, Advate, Kogenate, Helixate, Refacto, Benefix and a long acting recombinant FIX, were all used in Edinburgh.

45) Some plasma derived blood products continued to be used after recombinant products were available for immune tolerance therapy in haemophilia A. FEIBA and rFVIIa treatment were offered to those with inhibitors.

46) Other plasma derived clotting factor concentrates, FXI and FXIII were used to treat patients deficient in factor FXI and factor XIII. Fibrinogen concentrate was offered to those with congenital and acquired fibrinogen deficiency. Some of the fibrinogen concentrate was supplied by SNBTS in a clinical trial.

47) Plasma derived VWF concentrate was used to treat those with VWD who could not be treated with DDAVP. From memory, initially Factor 8Y, then Haemate P and latterly Voncento were used in Edinburgh.

48) As far as I am aware decisions about which products to use were made based on product availability, safety and in accordance with the UKHCDO guidelines. The decision about which product should be offered to which individual, was made by the haemophilia centre directors.

49) If there was an alternative treatment to a clotting factor available, e.g. DDAVP or tranexamic acid these were used when possible. I would have been involved in decisions regarding the use of DDAVP rather than Factor VIII or VWF concentrate on an individual basis when appropriate.

10. What was the relationship between Edinburgh and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?

50) I am unable to comment as I was not involved in any discussions with pharmaceutical companies or decisions around purchasing of blood products.

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

51) I only started to work in the haemophilia centre in 1992 and cannot comment.

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

52) I am unable to comment see answer to Q11.

13. What was the policy and approach at Edinburgh as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?

53) I am unable to comment see answer to Q11.

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

54) I am unable to comment see answer to Q11.

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

55) I am unable to comment see answer to Q11

c. Please consider the enclosed letter [MDUN0000020_193]. What is your recollection of the meeting with Carolyn Leckie? What was discussed? Please provide a copy of the minutes if available. Was a reply to this letter received? What is your recollection of that reply?

56) I remember that I was asked by Prof Ludlam to sit in on his meeting with an MSP. I did not remember the name of the MSP, but I am reminded by the enclosed letter that it was Ms Leckie. I was asked by Prof Ludlam to take some minutes which I did. Unfortunately, I was not very familiar with some of the subject matter and I remember that I had difficulty taking minutes. I am unable to remember details of the discussion that took place. I gave the minutes I had taken to Prof Ludlam and do not have a copy of them. If I later have access to the minutes, they may remind me of the discussion that took place and I may be able to comment further.

57) I am unaware of having seen the enclosed letter before and have not seen a reply.

14. What was the policy and approach at Edinburgh in relation to home treatment? Did the policy and approach change over time and if so how?

58) When I started work in 1992, home treatment was already well established and continued throughout my time at the centre. From memory, most adults and many children with severe haemophilia were receiving home treatment. The nursing staff

provided venepuncture education to patients and parents of children with bleeding disorders starting home treatment. They arranged home visits prior to starting home treatment. Education on how to treat bleeds and when to seek advice was provided on an ongoing basis. The dosage of home treatment was reviewed in clinic and could be adjusted as required.

59) Initially clotting factors for home treatment were collected by the patient or their family from the hospital. Later a home delivery system was set up. Patients recorded their product usage at home and returned this information to the centre. Initially this was in paper form but later some patients provided electronic records.

15. What was the policy and approach at Edinburgh in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

60) I am unable to remember the policy for prophylaxis when I started in 1992. From memory some adults with severe haemophilia were taking regular prophylactic treatment, but I think that many were taking treatment on demand. If someone who was taking on demand treatment had problems e.g. with recurrent bleeding into a target joint or had frequent bleeds, a trial of prophylaxis was usually suggested. I think as time went on increasing numbers of adults with severe haemophilia were taking regularprophylaxis.

61) Children diagnosed with severe haemophilia were offered prophylaxis to prevent joint bleeds. This often started as once weekly treatment, increasing up to 3 times a week treatment as venepuncture became easier. At the time I left the centre in 2017, many of the children who had started prophylaxis when I joined the centre in 1992, had remained on prophylactic treatment into adulthood.

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

62) I can only comment from 1992. Decisions regarding the use and choice of factor concentrate treatment for children were usually made by the paediatric haemophilia consultant Prof Thomas. Factor concentrates were used to treat bleeding episodes as required unless there was an alternative effective treatment available such as DDAVP.

63) Children with severe haemophilia were offered prophylactic treatment with initial infusions being given by the nursing staff until parents were able to administer treatment at home. In 1992 plasma derived clotting factors were used to treat the children and this remained the case until recombinant clotting factors became available. Once a recombinant product was available to treat haemophilia, this was used in preference to a plasma derived blood product.

64) There was no recombinant product available for the treatment of VWD. If possible DDAVP was used, but if this was ineffective a plasma derived VWF concentrate was offered as treatment.

65) Once recombinant clotting factors became available for the treatment of haemophilia some plasma derived clotting factors continued to be used for treatment of bleeding episodes and for immune tolerance in children with anti-FVIII inhibitors.

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

66) I can only comment from 1992. It would have been usual practice for an assessment to have been made regarding the appropriateness of treatment with factor concentrates on an individual basis. The baseline clotting factor levels, reason for needing treatment, e.g. surgery, painful bleed, bleeding due to injury and possible alternative treatments to factor concentrates would have been considered.

67) People with mild, and occasionally moderate haemophilia A and VWD were usually assessed for a response to DDAVP soon after diagnosis, unless there was a contraindication to DDAVP e.g. ischaemic heart disease, hypertension. Clotting factor levels were measured before and at intervals over the following 24 hour period following DDAVP administration. If there was a satisfactory rise in the FVIII level, or VWF levels in VWD, it would then be possible to use DDAVP as an alternative to factor concentrates for some people in some clinical situations.

68) DDAVP is most effective in mild haemophilia A and VWD as it typically produces a 3 to 5-fold increase in clotting factor levels. It often therefore is not effective in people with moderately severe haemophilia where the FVIII level at baseline is low. If there is a

satisfactory response DDAVP can be used for treatment of some minor bleeding episodes and procedures. e.g. dental work, minor surgery often in combination with Tranexamic acid. However, if DDAVP does not produce a significant rise in the FVIII or VWF level treatment with a clotting factor concentrate is usually advised.

69) It is known that the response to treatment with DDAVP declines with repeated administration and it may become ineffective after a couple of doses. This may mean therefore that if it was thought necessary to maintain someone's clotting factor level in the normal range for a prolonged period, e.g. post surgery such as hip replacement or in the event of an intra cranial bleed, that clotting factor concentrates may be required even in mild bleeding disorders. In addition, DDAVP has side effects such as fluid retention which can lead to hyponatraemia particularly if repeated doses are given and this can lead to discontinuation of treatment and the need for factor concentrates.

70) The decision to treat people with mild and moderate bleeding disorders would have been made on an individual basis. If possible DDAVP would be used rather than clotting factor concentrates. However, DDAVP is not effective treatment for everyone with mild or moderate bleeding disorders and may not be deemed appropriate depending on the clinical situation.

71) Unfortunately, DDAVP is ineffective in haemophilia B and therefore if treatment was thought to be advisable to raise the factor IX level to treat a bleeding episode or for surgery, FIX clotting factor concentrate would have been offered as treatment.

18. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at Edinburgh in consequence of the use of blood products. In answering this question, it may be useful to consider the enclosed document [LOTH0000053_073] which summarises the results of an investigation by you into seroconversions in patients at Edinburgh.

72) I am basing my answer to this question on the documents enclosed. According to the documents there was evidence that parvo virus seroconversions occurred in some of the children receiving the high purity solvent/detergent treated product Liberate (SNBTS FVIII). One of the documents gives data of parvo virus results from the SNBTS Liberate study in which Edinburgh patients participated. I was asked by Prof Ludlam to check if the seroconversions were associated with any clinical or laboratory effect. This information is on the handwritten note.

73) Some of the laboratory results are difficult to interpret as 3 out of 6 participants who appeared to have become IgG positive had subsequent tests that were negative. As this was 24 years ago, I was unable to remember if the parvo virus seroconversions were thought to be due to treatment with factor concentrate or alternatively infection acquired in the community, as this is a common infection in young children. However, having read a letter from Dr Prowse, (Thromb Haemost 1998;80;351), I think the conclusion at the time was that the seroconversions in the children more likely represented community acquired infection.

74) I am able to recall a case of parvovirus transmission in an adult, from memory in the early 1990s but I am unsure if there were any other cases.

75) There were concerns in the early 1990s that hep A and parvo virus may be transmitted through products treated using the solvent detergent method of viral inactivation. I am unable to remember any cases of hep A transmission but I am unable to say for certain that there were no cases. However, having read the attached paper by Dr Watson regarding hep A, it suggests that there was no definite evidence of hep A being transmitted through blood products in Edinburgh.

76) See answer to Q75.

Section 3: Knowledge of, and response to, risk

General

19. When you began work as an Associate Specialist in haematology at Edinburgh, 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?

77) When starting as a clinical assistant in 1992, it was widely known that there had been transmission of HIV and hepatitis to people receiving blood and blood products in the 1980s. This had been reported in the media and medical journals. I was informed that with the introduction of adequate heat treatment there had been no further cases of

hepatitis or HIV transmission through pooled blood products. My practice involved the use of pooled blood products and my answer relates to these.

78) In view of viral transmissions in the past through blood product treatment, I was aware that it was possible that there could be a further, as yet unidentified pathogen which may be identified in the future which could potentially be transmitted by blood products. In view of this it was not possible to give 100% guarantee of blood product safety.

79) When I started in 1992, I had no experience of treating people with bleeding disorders or experience of using pooled blood products. I gained knowledge of viral safety steps taken in the manufacturing of blood products, such as heat treatment and solvent detergent treatment from discussions with consultant colleagues and product information.

80) Once recombinant clotting factors became available these were used in preference to plasma derived products when possible, to reduce the risk of infection further.

81) Later, around 1998, I became aware of concerns about the risk of possible transmission of vCJD through pooled plasma derived blood products. See answer to Q 75.

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

82) I am unable to comment before 1992. The haemophilia directors may be able to answer this. As far as I am aware pooled blood products were chosen with consideration given to viral safety, and in accordance with UKHCDO guidelines.

83) If a previously untreated patient or someone with a mild bleeding disorder who rarely had treatment in the past, was thought to require treatment with a blood product, it would have been usual practice to discuss the management of the patient with the consultant in charge of care before making a decision.

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

84) I am only able to comment on products used from 1992. From this time as far as I am aware, both NHS and commercial blood products were no longer thought to be able to transmit HIV, hepatitis B or C. Donor screening, heat treatment, nanofiltration and solvent detergent treatment of products were used to reduce the risk of infection.

Hepatitis

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

85) See answer to Q19. In 1992 it was already known that transmission of hepatitis B and non-A non-B hepatitis had occurred through treatment with blood and blood products. By 1992 viral inactivation steps such as heat treatment in blood product manufacturing were in place to reduce the risks of viral transmission. Increasing amounts of information about hepatitis C became available in the medical literature over the 1990s.

23. What, if any, actions did Edinburgh take to reduce the risk to patients of being infected with hepatitis (of any kind)?

86) From before I started in 1992, blood products used had viral inactivation steps in their manufacturing process and were no longer thought to be able to transmit hepatitis B or C. If there was a suitable alternative to a blood product, such as DDAVP in mild haemophilia A or VWD, this would have been considered if appropriate. Patients who had no immunity to hep A and or hep B on antibody testing were offered vaccination.

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

87) I can only comment from 1992. At that time, liver function tests, including alanine transaminase (ALT) and alkaline phosphatase (Alk phos) were checked when people with bleeding disorders came to review clinics. These tests were performed to look for signs of liver disease.

88) People receiving treatment with plasma derived blood products, those who had received treatment in the past or those who may require treatment in the future were offered virology testing, including hep A, B and C antibody tests. Anyone non- immune to hep A and /or B was offered hep A and /or B vaccine. In the 1990s the virally inactivated pooled blood products were considered safe with regards to transmission of hepatitis B, hepatitis C and HIV. However, it was thought to be good practice to offer regular virology testing to those receiving treatment to monitor product safety and to look for unexpected seroconversions.

89) In people known to have hepatitis C, monitoring was undertaken to look for signs of progression to cirrhosis. Initially, hyaluronic acid levels were used and later additional blood tests looking at AST/ALT ratio and AST/platelet ratio index were used to try to identify those with cirrhosis. Once the fibroscan became available, this was used to assess the degree of liver fibrosis.

90) If the hyaluronic acid level, other blood tests or fibroscan were suggestive of cirrhosis, AFP was then checked every 6 months, in addition to regular 6 monthly liver ultrasounds to screen for hepatoma. Endoscopies were also arranged, sometimes in the form of a capsule endoscopy, to look for varices, usually every 2 years. If varices were identified and were thought to require treatment, patients were offered a beta blocker, latterly this was Carvidelol.

91) For those receiving treatment for hepatitis C, in addition to checking liver function with ALT measurements, Hepatitis C PCR tests were undertaken. Initially in the 1990s the hep C PCR was checked before, during and after treatment to look for a virological response to treatment. Later I do not think that the PCR was checked during treatment but was checked at the end of treatment and 6 months after stopping treatment. See answer to Q 41.

25. 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?

92) I had previously worked as a medical house officer on the liver unit at the Royal Free Hospital in 1984 and had a basic understanding of the different types of hepatitis A, B and non-A non-B and how they were transmitted. When I started in 1992, I had no experience or knowledge of hepatitis C. I rapidly became aware that hep C was

transmitted through blood and blood products and that it could cause chronic infection leading to fibrosis, cirrhosis and hepatocellular carcinoma. Working with Prof Hayes I learnt about the diagnosis and natural history of hep C, how to investigate, monitor and treat it.

Response to risk

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

93) At the time of starting work at the centre in 1992, it was already known that hepatitis had been transmitted through blood products in the past. Pooled blood products being used in the 1990s were thought to be safe with regards to transmission of hep B and C. I am assuming that this question refers to the risk of transmission of hepatitis. See answer to Q5c and Q38.

94) When consenting patients about to receive treatment with a new factor concentrate it would have been usual practice to explain that the new products were thought to be safer than the products used in the 1980s, as a result of donor screening and steps undertaken during the manufacturing process such as heat treatment and solvent detergent treatment. Although the products being used were thought to be the best available at the time, we were unable to give 100% guarantee of their safety as there was always the possibility of transmission of a new unknown infectious agent.

95) In the 1990s patients were offered hep A and or B vaccine if they were found to be non-immune on antibody testing.

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

96) I can only comment from 1992. Pooled blood products used after that date were considered safe with regards to Hep B, C and HIV transmission, as a result of donor screening and viral inactivation steps in the manufacturing process.

97) After 1992, there were concerns about the possible risk of transmission of parvo virus and hep A through products that had been treated with the solvent detergent method of viral inactivation. From memory, I think that once a plasma product with dual viral inactivation methods was available this would have been used in preference to one with only one viral inactivation step, which was an appropriate response. Patients who were found to be non- immune to hep A and or Hep B were offered vaccinations to reduce any risk of infection further.

98) Since 1998, when there was concern about the theoretical transmission of vCJD through UK pooled plasma derived clotting factors, plasma for the manufacture of pooled blood products was sourced from outside the UK. I think that this was an appropriate response to reduce the possible risk of transmission of vCJD.

99) Once recombinant products became available for haemophilia A and B these were used in preference to plasma derived blood products. This was appropriate as the use of recombinant products from around the mid/late 1990s reduced the risk of transmission of an infectious agent. The risk was reduced further by third generation products which were free from human and animal proteins in the manufacturing process and end products.

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

100) I think this question relates to the 1980s and I am unable to comment.

29. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

101) I think this question relates to the 1980s and I am unable to comment.

Section 4: Treatment of patients

Provision of information to patients

30. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at Edinburgh 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.

102) See answer to Q26 and Q38.

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

103) I think this question may relate to the 1980s. See answers to Q26 and Q17.

104) I can only comment from 1992. At that time patients with mild haemophilia A and VWD were offered a trial of DDAVP. If there was a satisfactory response to DDAVP this could be offered in some situations as a possible alternative to FVIII or VWF concentrate. This did not change over time.

NANB Hepatitis/Hepatitis C

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

105) I think this question relates to the 1980s and I am unable to comment on events before 1992.

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

106) Some people had already been tested for hepatitis C, using stored specimens by the time I started work in 1992. Without access to records I am relying on my memory. I think it was soon after I started work in 1992 that people were tested for hepatitis C when they came up to clinic. I was involved in telling people their diagnosis along with colleagues, another clinical assistant Dr Young, Prof Ludlam and Prof Hayes, hepatologist.

107) My recollection is that in 1992/1993 if there was a result from a test that had already been carried out on a stored specimen this was discussed with the patient at the clinic and a confirmatory hepatitis C antibody test was carried out. Patients would then have been given an appointment with Prof Hayes and Prof Ludlam at a joint clinic, where the result of the confirmatory test result would have been discussed.

108) From memory around that time, if a test for HCV was carried out for the first time, the patient would have been given a follow up appointment when the result would have been discussed. If someone asked to be contacted by letter or phone with their result this may have been done and a follow up appointment arranged. All patients with hepatitis C would have been seen again at clinic.

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

109) See answer to Q5.

110) When seen from 1992 onwards, patients with hepatitis C were told that they had been infected through previous treatment with blood products. They were told that it was likely that they had become infected at the time of their first exposure to blood products. Therefore, it was possible that some patients may have been infected for many years.

111) It would have been usual practice to explain that if left untreated hepatitis C could, over some years, cause complications such as liver fibrosis and cirrhosis. For those with cirrhosis there was a risk of developing a hepatoma and oesophageal varices and surveillance screening was recommended. Oesophageal varices could lead to bleeding but if someone was found to have significant varices, treatment with a beta blocker could be given to reduce the risk of bleeding. There were written information leaflets about Hep C available at that time for patients to take away and read.

112) In around 1992/1993 patients were seen by Prof Ludlam and Prof Hayes to discuss investigations to assess if the hepatitis C infection had caused any liver damage. These included ultrasound, laparoscopic liver inspection +/- liver biopsy and endoscopy. It was usual practice to explain the planned procedures, including the potential risk of bleeding associated with the procedures, e.g. laparoscopy and biopsy, and the need for clotting factors to cover these procedures. Using the results of these investigations a decision was made about the need for regular ultrasounds to screen for hepatoma and regular endoscopy to look for varices.

113) I do not currently have any access to any records. As many of these events occurred 28 years ago, I do not have a full recollection of events. I think when patients were seen for the first time to discuss investigation of hepatitis C at the joint clinic, hep C PCR tests were not available. There were results of antibody tests only. Once hep C PCR results became available, patients were advised that those with a negative PCR test were thought to have probably cleared the virus, but those with a positive PCR test were thought to have chronic infection. I think initially that the possibility that those with a negative PCR test could have dormant virus in the liver was discussed. Later as more information about hep C became available, patients who were PCR negative were advised that this was no longer thought to be the case and that they were considered to have cleared the virus.

114) Patients were told that there was a very small risk of sexual transmission and were advised to use barrier methods of contraception. From memory they were given advice not to share toothbrushes, razors etc. It was suggested that partners should arrange to be tested. Advice was given to limit their alcohol consumption.

115) Treatment in the form of interferon was offered in the early/mid 1990s and was prescribed and monitored by the haemophilia centre staff. Interferon and Ribavirin then became available. As each treatment became available, patients were informed and offered an appointment to discuss treatment options.

35. How many patients at Edinburgh were infected with HCV?

116) Information about the total number of patients infected with HCV in Edinburgh should be available at the haemophilia centre or at the UKHCDO. Currently, I do not have access to this information.

117) From memory there were approximately 90 people with hep C who attended the centre during my time working there.

Delay/public health/other information

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

118) I cannot comment on events before 1992. By the time I took up post in 1992 all patients as far as I am aware, had been informed of their HIV results. There was a delay in notifying patients of their hep C results in the early 1990s. There were results of hepatitis C tests, carried out on stored specimens which I became aware of soon after I started work in 1992. I am unsure of the reasons for the delay in informing patients. As far as I can remember, patients were informed of their hepatitis C results in late 1992/1993 as they came up to clinic. Confirmatory hep C tests were carried out and I think it would have been usual practice to inform people of these results at their next clinic appointment unless they asked to be contacted beforehand by phone or letter.

119) My recollection is that later, patients who were having repeat tests, having previously tested negative for HIV and or hep C, would often not want to be contacted with results between appointments unless the result had changed. If someone did want to come back to clinic to discuss results that would have been arranged. Sometimes patients requested a letter to confirm that their virology tests remained negative.

120) From memory, if patients were tested for hepatitis A and or B it was explained that they would be contacted by letter if they were non- immune and would then be offered vaccinations. I think that this would usually have been soon after their clinic visit.

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

121) I do not understand this question. I am unsure what is meant by the public health implications of what treatment to offer patients.

122) When I took up post in 1992, patients with HIV had previously been advised to use barrier contraception in view of the risk of sexual transmission. As far as I am aware they were also advised not to share razors or tooth brushes, to be careful with blood spillages and to use sharps bins for safe disposal of needles and equipment. From memory, the same advice was given to those found to have hepatitis C. It was recommended that partners should arrange to be tested. Patients found to have HIV and /or hepatitis C were offered treatment.

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

123) I cannot comment on events before 1992.

124) I assume that this question is asking about the risks of other infections from treatments. The information given to patients was often on an individual basis and depended on what treatment they were being offered. In the 1990s, it became known that solvent detergent treatments may not be effective in inactivating non-enveloped viruses such as hep A and parvo virus. I can remember discussing parvo virus with some patients, but I cannot remember in relation to which product. As this is now many years ago, I cannot recall with certainty what was said. Patients who were found to be non- immune on antibody testing were offered hep A vaccine to reduce any risk of infection.

125) When discussing new plasma derived concentrate treatments, it would have been my usual practice to explain that we were unable to give 100% guarantee regarding the safety of any treatment in view of the potential risk of an unknown pathogen. My usual practice was to explain that in the past there had been transmission of viruses such as hepatitis B, C and HIV through pooled blood products but that there were now effective viral safety measures in place to reduce this risk and would have discussed these.

126) From 2004, when offering treatment with a plasma derived product, e.g. VWF concentrate or FXI concentrate, it would have been my usual practice to explain that there were concerns about the possible risk of transmission of vCJD through UK pooled blood products. However, since 1998 plasma derived pooled blood products had been made with non UK plasma (plasma from USA or Europe) to reduce this risk. I would have explained what was known at the time about the cases of vCJD that were thought to have been transmitted through blood transfusion as per the 2004 notification. From 2009, it would have been my usual practice to also discuss the information which had been set out in the 2009 notification.

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

127) From memory, to reduce the risk of infecting others, barrier methods of contraception were recommended for those with HIV or hep C, even though the risk of sexual transmission was thought to be low for hep C. It was advised that partners should arrange to be tested. Advice was also given not to share toothbrushes or razors, to wear gloves to clean up blood spillages and to dispose of needles and syringes used for home treatment safely in sharps bins. Patients were advised that they should not donate blood or organs.

128) See answer to Q76g.

40. What actions or decisions were taken at Edinburgh to trace patients who may have been infected through the use of blood or blood products?

129) I can only comment from 1992. We tried to ensure that anyone who may have had treatment with blood or blood products in the past was offered virology testing. This included new patients and patients who reattended after not being seen for some time. If there was any doubt about past treatment virology tests were offered.

130) The UKHCDO undertook a hep C look back exercise, I think in around 2010. From memory, I think centres were notified of all patients who had previously been registered at the centre who could have been at risk of hep C, as a result of previous treatment. We tried to check that all patients on the UKHCDO list had been offered hep C testing or if not that there was clear information that they had never had treatment and were not at risk. Unfortunately, however, there were no records or contact details for some people

on the list and it was not possible to contact them. The information was fed back to the UKHCDO database.

Consent

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

131) As people with various types of bleeding and thrombotic problems were seen at the haemophilia centre, I am confining my answer to the practice relating to people with haemophilia and VWD from 1992. Blood samples were usually taken at each clinic review appointment. For people with severe and moderate bleeding problems this was usually 6 monthly and for those with mild problems annually unless there were other reasons to see individuals more frequently, e.g. bleeding problems, receiving treatment for hep C.

132) When I started in 1992 there was already an established practice in place for blood samples to be taken to monitor the safety of blood product treatments. The tests included full blood count, including haemoglobin, white cell count, platelet count and T cell subsets, renal function tests, liver function tests, inhibitor screen, virology and a sample of serum for storage. It would have been normal practice to ask patients if they were happy for blood to be taken for monitoring tests. If anyone had any questions the tests would have been discussed.

133) The inhibitor assay was undertaken in those people with haemophilia, as one of the complications of treatment with clotting factors is the development of FVIII or IX neutralising antibodies which may make treatment with clotting factors ineffective.

134) It was considered good practice to monitor the viral safety of blood product treatments. Virology tests were undertaken to screen for the presence of antibodies to hepatitis A and B to check if vaccinations were needed. In addition, Hep C and HIV antibody tests were undertaken to check on the viral safety of blood products. Hep C PCR results were used to guide treatment decisions and to monitor the effectiveness of treatment.

135) By the time I started in 1992, many patients had already been tested for HIV. I was advised that if they had given their consent for ongoing regular virology testing that this was indicated on the computer database being used at that time and it was not necessary to seek further consent. However, as I had not been party to the original consenting process my usual practice was to ask for verbal consent prior to virology testing. Unfortunately, I think that documentation in the 1990s was not as good as it could have been, and I am unable to remember what was recorded in the notes.

136) Discussions about virology testing varied on an individual basis. If someone had not been tested before, my usual practice would have been to have a detailed discussion about testing and the implications of the result. If someone had already been frequently tested, I would have asked it they were happy for the tests to be done again. As time went on, if someone was being offered testing for hep C or HIV for the first time in our department, it became my practice to ask them to sign an entry in their case records to record their consent to testing.

137) At various times people were enrolled in clinical trials of FVIII and FIX treatments and blood sampling was carried out according to the study protocols. Participants in the studies had given their written consent to participate and as part of this the blood sampling protocol and follow up schedule would usually have been discussed.

138) When I started in 1992 the established practice in place was for a serum sample to be taken for storage. I understood that the stored samples were to allow retrospective identification of seroconversion should a new pathogen be identified. This may then have made it possible to identify which batch of treatment if any had led to seroconversion. I think this practice had been in place for many years. I do not know what consent was obtained prior to 1992. After this date, verbal consent to take blood would have been obtained but I do not think specific consent for storage of samples was usually obtained in the 1990s. From memory, some years later, I think serum was only stored when someone was changing from one factor concentrate to another and later the practice of storing serum stopped.

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

139) I can only comment on treatments given after 1992. I am not aware of anyone being treated with factor concentrate or other blood products without their consent. If treatment was being given for the first time or if someone was changing from one type of pooled blood product to another, it would have been my usual practice to discuss the pros and cons of the new proposed product. This would have been a verbal discussion but also when possible written information in the form of a patient information leaflet was given. There was usually written information in each box of product. It would have been usual practice to record consent when starting or changing blood products in the case notes. There were no formal consent forms used unless the product was being given in the setting of a clinical trial.

140) If someone was on regular treatment with factor concentrate e.g. prophylaxis, which was often self- administered at home, implied consent to be treated with the same product was assumed if it was being given in the hospital setting.

141) Some plasma derived and recombinant products were given in clinical trials. Informed written consent was obtained and a consent form signed before treatment in the trial started.

142) If someone presented with a bleeding episode for which treatment with a factor concentrate was thought appropriate, the planned treatment would have been discussed, including the dose and frequency of the treatment recommended and the follow up arrangements. Verbal agreement of the treatment plan would have been obtained before administering treatment.

143) If someone required surgery, it would have been usual practice to see them at the haemophilia centre prior to their surgery date when possible, (unless emergency surgery), to discuss the plans for treatment of their bleeding disorder. If they were having treatment with a factor concentrate for the first time, e.g. in factor XI deficiency, we tried to send written information in advance to them so that they had an opportunity to read this before being seen. At the clinic visit the proposed treatment plan including the pros and cons of the product to be used, the amount of treatment, frequency of treatment and likely duration of stay in hospital would have been discussed and verbal consent would have been sought and an entry made in their notes.

43. Were patients under your care tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur?

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

144) See answer to Q41. Some routine tests such as full blood count, kidney or liver function tests were undertaken without express and informed consent. It would have been usual practice to ask patients if they were agreeable to having blood taken for monitoring tests but to discuss all the implications of all the possible results obtained from these tests could have taken some hours. If anyone had any questions about the tests these would have been answered.

145) Stored samples from patients had been tested for hepatitis C prior to July 1992. I think this was when the new hepatitis C test became available. I was not involved in this testing as it was before I took up post. Most patients had already been tested for HIV and knew their results when I started in 1992.

146) If someone was being tested for the first time it would have been usual practice to discuss the pros and cons of having the test and the implications of having a positive result. How the result was to be communicated would have been agreed with the patient and follow up arranged.

147) My usual practice was to seek verbal consent for virology testing. If consent for virology testing had been given in the past, i.e. at previous appointments some patients often did not want to have an in depth discussion before further testing. Therefore, in that situation I may have said something like "would it be possible to take some blood today for the usual tests, such as blood count, kidney and liver function, inhibitor assay and also for virology testing, including hep C and HIV tests?" "Do you have any questions?" I cannot remember if consent was recorded in the case notes in the 1990s. As time went on documentation in case notes improved.

148) Later, if someone was being offered testing for hep C or HIV for the first time in our department, after obtaining consent, it became my practice to ask them to sign an entry in their case records to record their consent to testing.

44. In the enclosed letter dated 24 November 2003 [HCDO0000108_035], Dr Hay wrote to you about the Data Protection Act and National Haemophilia Database. What was the context of this letter? What had you enquired about in relation to the Database? If you retained the letter that you sent to Dr Hay, please provide a copy.

149) The letter from Dr Hay was in response to a letter I had written to Prof Ludlam. A copy of my letter is enclosed [WITN4030002]. I was uncomfortable about information being sent to the UKHCDO without the explicit consent of patients and had written to Prof Ludlam about my concerns. Prof Ludlam had passed on my letter to Dr Hay.

PUPS

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

150) During my time at the Haemophilia centre, from 1992, if a previously untreated patient required treatment for the first time for an episode of bleeding or for surgery, the type of treatment to be given would usually have been the decision of the consultant in charge of their care. It would have been usual practice to seek the advice of the consultant in charge, if considering treatment with factor concentrate for a previously untreated patient.

151) The type of treatment given would have been chosen on the basis of safety and according to UKHCDO guidelines. If an alternative to a clotting factor concentrate was available and thought to be appropriate treatment e.g. DDAVP, this would have been given to avoid exposure to a factor concentrate. If clotting factors were required, where possible recombinant products would have been used for treatment.

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

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

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

152) See Q5. I can only comment on care from 1992 onwards. At the time I started work some people were being treated for HIV at the haemophilia centre. Advice was frequently sought from Dr Brettle who had expertise in managing HIV. As treatment options broadened his team took over the management of HIV infection completely.

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

153) I am unable to comment on treatment given before 1992. From memory, when I started work at the centre treatments included Zidovudine (AZT), Didanosine (DDI) and Dideoxycytidine (ddC). Initially pentamidine inhalations were given as PCP prophylaxis but this changed to oral Septrin. I think that it was around the mid/late 1990s, when the infectious diseases team took over all HIV treatment and management. Information about which HIV treatments were offered should be in case notes and should be available from the infectious diseases unit at the Western general hospital.

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

154) I am unable to comment.

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

155) See answer to Q46a.

156) When I started in 1992, patients with HIV infection were seen regularly in the haemophilia centre for monitoring of their underlying bleeding disorder and viral infections. See answer to Q41. If someone also had hep C this was monitored with blood tests. See answer to Q24. Patients receiving HIV treatment were seen to monitor their general well- being and response to treatment. Blood was sent to check the CD4 count and HIV viral load.

157) After a few years, I think around the mid/late 1990s haemophilia care was provided by the haemophilia centre and HIV care was provided by the specialist infectious diseases unit at the western general hospital. Individual arrangements for follow up of liver related problems were in place. Some liver ultrasound surveillance was carried out at the Western General and some at the Royal infirmary. From memory, some treatment for

hep C infection was prescribed by the haemophilia centre in the mid 1990s, but later hep C treatment was prescribed by the infectious diseases team.

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

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

158) I can only comment from 1992. I am unaware of any new cases of hepatitis B after that date. Anyone with chronic hepatitis B was seen by Prof Hayes, consultant hepatologist, in the haemophilia centre, for assessment, investigation and treatment as appropriate.

b. What treatment options were offered over the years?

159) I am unable to remember.

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

160) I am unable to remember.

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

161) I can only comment from 1992. Regular follow up was at the haemophilia centre 6 monthly. Blood tests were usually taken to monitor liver function, renal function, HBV DNA, hyaluronic acid and FBC. For anyone thought to have cirrhosis surveillance ultrasound and endoscopy were arranged and regular AFP blood test was checked.

48. How was the care and treatment of patients with NANB hepatitis managed at Edinburgh? In particular

162) I think this question relates to the 1980s and I am unable to comment on events before 1992.

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

163) See above

b. What treatment options were offered over the years?

164) See above

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

165) See above

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

166) See above

49. How was the care and treatment of patients with HCV managed at Edinburgh? In particular:

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

167) See Q5 and Q34. Soon after I started in 1992, patients were offered an appointment to see Prof Ludlam and Prof Hayes, consultant hepatologist at a joint clinic held in the haemophilia centre. Prof Hayes was involved in the investigation, follow up management and treatment of patients with hep C.

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

168) I cannot be sure when interferon treatment was first used. I think around 1993. Initially interferon and then interferon + ribavirin treatment were prescribed and monitored by the haemophilia centre staff. Later as more treatment options became available,

treatment was overseen by the hepatology team in their clinic. Details of treatments given are recorded in the case notes to which I currently do not have access. The hepatology team should be able to provide information about the other treatments offered.

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

169) When treating with Interferon and then interferon and ribavirin, it would have been usual practice to discuss the likely response rate to treatment, the treatment schedule, follow up blood tests and potential side effects such as flu like symptoms, low white count, mood changes, anaemia and the possibility of developing a cough.

170) As new treatments became available patients were reviewed by Prof Hayes where treatment options were explained. He would explain the likely response rates and side effects. Once a decision to treat was made, treatment was prescribed and monitored by the hepatology team in their department.

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

171) See Q5a, b, c and Q24

172) Patients not on hep C treatment were seen regularly, every 6 months. Those on hep C treatment were usually seen monthly or more frequently if necessary. At haemophilia centre review appointments in addition to asking about symptoms and general well being, blood samples were taken to assess liver function and possible liver disease progression. Hyaluronic acid levels and fibroscans were used to try to identify development of cirrhosis.

173) If there was concern that cirrhosis may have developed regular liver ultrasounds were arranged to coincide with clinic review appointments. AFP levels were also checked. Regular screening for oesophageal varices was undertaken in those with cirrhosis using endoscopy or capsule endoscopy.

174) Prof Hayes was available to see patients and did so regularly at the haemophilia centre at the time of their haemophilia review appointment if there were any problems or to discuss new treatment options.

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

175) I am unable to comment as I am unaware of any infected children.

51. What, if any, involvement did you and/or colleagues at Edinburgh have with any clinical trials in relation to treatments for HIV and HCV?

176) As far as I can remember, there was a trial of HIV treatment which may already have been underway when I started work in 1992, involving the drugs Didanosine (ddI) and ddC. I am unable to remember the details of this trial.

177) Some of the hepatitis C treatment was given in clinical trials. I think that my haemophilia centre colleagues may have enrolled patients in a hepatitis C treatment trial involving interferon in 1993/1994 when I was on maternity leave. Information should be available in the case notes.

178) Other hep C treatment clinical trials later were run by the hepatology department and I was not involved. Again, information should be in case notes or available in the hepatology department. I do not remember having any personal involvement in hepatitis C treatment trials.

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

179) I can only comment from 1992. In addition to support offered by the haemophilia centre staff, psychological support was provided in the 1990s by Dr Alison Richardson, clinical

psychologist for many years. Social work support was provided by Geraldine Brown also in the 1990s. Some people suffering with anxiety and depression were seen by Dr Masterton and Dr Potts, consultants in the department of psychological medicine at the RIE.

180) In 2016, a clinical psychologist, Dr Grainne O'Brien and Dr Nadine Cossette, consultant psychiatrist joined the haemophilia centre team to provide psychological support.

53. Did Edinburgh receive funding from the government or from any other source to assist with the counselling of patients infected with HIV?

181) I do not know.

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

182) I am unaware of any funding difficulties

Research

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

183) I did not initiate any research myself. A list of any research studies carried out since 1992 involving clotting factor products should be available at the haemophilia centre.

a. Describe the purpose of the research.

184) During my time at the centre there were several SNBTS blood product studies (clinical trials) looking at safety and efficacy of factor VIII, IX and fibrinogen. Further details

should be available through the RIE haemophilia centre or SNBTS. Some of these studies were collecting data prior to licensing.

185) The department also took part in some commercial studies (clinical trials) of factor concentrates which from memory included a high purity FIX product, recombinant FVIII, recombinant FIX and rFVIIa. Some of these were post marketing surveillance studies. Further details should be available at the haemophilia centre.

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

186) All applications for ethical and management approval were undertaken by Prof Ludlam.

c. Explain what your involvement was.

187) For some studies, I was involved in consenting patients, prescribing and monitoring treatment, arranging follow up as per the study protocol, undertaking data collection and reporting adverse events.

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

188) SNBTS and some commercial drug companies

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

189) I am unable to answer this. Any financial arrangement for participation in a study was arranged by Prof Ludlam.

f. State the number of patients involved.

190) There were different numbers of people enrolled in each study. This information should be available in the study records. There was a large variation in number of participants with each study.

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

191) When I started in 1992, it was the usual practice to discuss the clotting factor studies (clinical trials) with individual patients when they attended the haemophilia centre. From memory sometimes letters were written to inform patients about forthcoming trials and to invite them to participate. Later when possible, we tried to send the patient information sheet out in advance of any appointment to discuss the trial.

192) At clinic, the new proposed treatment e.g. FVIII or FIX, would have been discussed. My usual practice would have been to discuss the treatment, possible benefits of the treatment, side effects and risks of treatment and what alternative treatments were available. The trial protocol, including follow up appointment schedule, data to be collected, half- life studies and documentation to be completed would have been discussed. Patients were advised that they were under no obligation to take part and that if they did decide to participate, could withdraw at any time. Each patient participating in a clotting factor trial signed a consent form.

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

193) I was not involved in any publications relating to clinical trials of factor concentrates as far as I am aware.

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

194) I am not aware of being involved in any epidemiological studies

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

195) I cannot comment before 1992. I am unaware of any patients being involved in research studies without their informed consent. For the clotting factor studies mentioned above that I was involved with, informed written consent was obtained.

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

196) See Q58 and Q59.

197) In 1996 several papers were written and published, describing the investigation and treatment of hep C in patients in Edinburgh. The data was anonymised. I am not aware what consent was sought prior to publication. The anonymised results of investigations to assess the severity of liver disease and blood test data collected as part of clinical care was used.

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

198) I can only comment from 1992. At that time identifiable data were being sent to the haemophilia (UKHCDO) database held in Oxford (and later held in Manchester). The haemophilia database had been set up many years before in the 1960s to improve the care of people with bleeding disorders. Many patients with bleeding disorders were already registered on the database in 1992. Details of any treatment given was sent to the database annually. This allowed a central record of treatments received. All the UK haemophilia centres submitted information to the database.

199) Some of the information collected was used to help predict and plan for future factor usage and funding of care. Side effects of treatment, such as allergic reactions and inhibitor development were also notified. Central collection of side effect data meant that clinicians could be alerted if a product was associated with adverse events so that clinical practice could potentially be changed.

200) I was unclear what consent had been given by patients originally for inclusion in the database. Going forward we informed new patients about the database and sought their verbal consent before registering them. Information leaflets were produced by the UKHCDO about the database which were available in the haemophilia centre for patients to read before their appointment so that they could ask questions if wished and confirm if they gave their consent for ongoing inclusion. If anyone did not consent their details could be removed. This allowed information to be given to those attending clinic.

201) I was concerned that those people who no longer attended the centre had not been given the opportunity to consent to ongoing inclusion. I wrote to Prof Ludlam explaining my concerns in 2003 about sending identifiable information without the express consent of patients. Prof Ludlam forwarded my letter to Dr Hay, and his reply is enclosed. I enclose a copy of the letter that I sent to Prof Ludlam, dated 6/11/03 [WITN4030002].

202) Prof Ludlam also wrote to Dr Swainson (Medical director), Dr Muir (Caldicott guardian in ISD) and Dr Keel (Deputy chief medical officer) to gain approval for the database.

203) After a few years, a new information leaflet was produced by the UKHCDO. This was mailed out to registered patients informing them about the database and giving updated details about the information being collected. This meant that those patients who were registered but no longer seen also received the information and had an opportunity to opt out.

204) As time went on the database started to request increasing amounts of information. For example, information on inhibitor development, hep C status and treatment, information about risk status for vCJD. A letter was sent to the local Caldicott guardian, Dr Alison McCallum seeking permission to send this information out with Lothian to the UKHCDO database. Permission was granted. A copy of this correspondence should be available in the haemophilia centre.

205) The UKHCDO is currently required by the department of health to collect data on diagnosis, management and complications of bleeding disorders. The database is currently held within the NHS and is managed by the UKHCDO. The current patient information leaflet explaining about the database is available on the UKHCDO website.

206) See Q59d.

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

a. Your work in 1995 with Dr Watson on Hepatitis A transmission [SBTS0000387_015];

207) I was involved in the clinical management of people with haemophilia from 1992. From memory, at that time hep A antibodies were being checked as part of the SNBTS Liberate trial protocol to look for seroconversions but also as part of clinical care so that hepatitis A vaccine could be offered to anyone that was not immune to hep A. My name was included on this paper as a professional courtesy, as was common practice at the time, as I was involved in seeing patients for review in clinic where I would have requested blood tests.

b. Your two papers in 1996 with Dr Hanley and others on chronic hepatitis C infection in haemophiliacs and Interferon treatment in haemophiliacs;

208) I was working in the haemophilia centre at the time that Dr Hanley was undertaking research. I was involved in the out- patient care of the patients referred to in the papers. I was involved in seeing the patients for follow up in clinic. I was also involved in arranging admission for planned investigations and in prescribing and monitoring treatments such as interferon.

209) My name appears on two of the papers, as they describe the results of some of the investigations and treatment I had been involved in as part of the clinical care of the patients at the time. These are "Investigation of chronic hepatitis C infection in individuals with haemophilia: assessment of invasive and non-invasive methods" and "Interferon treatment for chronic hepatitis C infection in haemophiliacs - influence of virus load, genotype and liver pathology on response".

c. Your work in 1998 with Drs Prowse, Dow and others on Human Parvovirus and Haemophilia; and

210) My name appears, along with 10 other authors on a letter sent by Dr Prowse in response to a publication describing parvovirus seroconversions possibly as a result of contamination of the albumin excipient of a recombinant FVIII product. It was thought more likely that this represented community acquired infection.

211) My name was included in the authorship of this letter as I had previously been involved in looking at parvovirus seroconversions which had been recorded in one of the SNBTS studies in which Edinburgh patients were participants. I had provided Prof Ludlam with anonymised data which he had passed to Dr Prowse. From memory this was my only involvement.

212) See Q18.

d. Your work with Dr Khan assessing Hepatitis C infection and outcomes in the Scottish Haemophilia population [PRSE0003319].

213) I was asked by Prof Ludlam to gather anonymised hep C infection and treatment data on our patients. I gave this in paper form to Prof Ludlam which he then forwarded.

Records

60. What was the policy at Edinburgh as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?

214) I do not know the policy as I was not involved in death certification.

61. What were the retention policies of Edinburgh in relation to medical records during the time you were practising there?

215) As far as I know, the policy was to keep all records of people with inherited bleeding disorders long term. In later years, I am aware that Category C stickers were applied

to paper records which was to indicate that the records were to be kept long term and not destroyed.

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

216) I did not personally maintain any separate files on individual patients.

217) See Q63.

63. Were you aware of any of your colleagues maintaining separate files for some or all patients? If so, which colleagues; why; where were those files located; and where are those files now?

218) When I first started to work at the centre in 1992, there were files held in a filing cabinet in the centre which I was told were related to HIV counselling. My understanding is that in the 1980s these files were held separately and not placed in the main case notes to maintain patient confidentiality. I think that the papers contained in these files were subsequently filed in the patient records.

219) From memory, whilst at the old Royal Infirmary, possibly mid/late 1990s for a brief period there were haemophilia centre case notes made up as patients attended. I think this was so that there were case notes available anytime someone attended if the main RIE notes were not available. As far as I am aware it was not unusual for other departments to have their own notes, e.g. renal unit. However, my recollection is that this practice was stopped after a very short period by medical records and any paper notes which had been made up were filed in the main RIE case records.

220) I am not aware of any other separate files for individual patients.

221) When I started in 1992 there was a folder in the haemophilia centre containing paper copies of hep C antibody results. From memory I think there were also results of some full blood counts. These results were subsequently filed in the individual case notes.

222) There were administrative files in the haemophilia centre containing copies of letters and information sent out to people as part of the vCJD notification processes. These files contain lists of patient names and details of the information they had been sent. The files were referred to if the case notes were not available and it was necessary to check the risk status of a patient e.g. prior to surgery. The files also held a record of some of the treatments received so that it was possible to see how decisions were made with regards to vCJD risk status if this came into question. All the correspondence relating to the treatment of visitors or people who had moved away and the batches of treatment they received was also held in files in the centre. When I left the above files were in a locked filing cabinet in the haemophilia centre and the senior nursing staff had access.

223) There was a file containing a list of names of people with hepatitis C. This list was used to help with patient care, to make sure that no patient was overlooked, for example when a new treatment or investigation for hep C became available. There was a file containing patient information sent by the UKHCDO as part of the hep C lookback.

224) There were files containing copies of genetics results and copies of hyaluronic acid results. These results were referred to if the original result was not available, as it was not possible to access these results electronically on the hospital computer system. The original copies were filed in the case notes. There were also some family genetic counselling files. When I left the above files were in a locked filing cabinet in the haemophilia centre and the senior nursing staff had access.

225) There were administrative files containing patient details that were used to record information relating to treatment. This included the information sent to the UKHCDO, infusion and home treatment records dating back many years.

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

226) No

Section 5: Pharmaceutical companies/medical research/clinical trials

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

227) No

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

228) No

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

229) No

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

230) No

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

231) I have not received any incentives to use any particular products. I was not involved in any decisions relating to the selection for purchase or purchasing of any clotting factor products during my time at the haemophilia centre.

232) I have attended drug company sponsored educational meetings in the past when accommodation and travel expenses were paid.

70. 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.

233) No

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

234) My answer relates to my attendance at drug sponsored educational meetings. I am unable to remember what procedures were in place in the 1990s other than a requirement to request study leave and I think to provide details of any contribution towards expenses. From memory any pharmaceutical company sponsorship was recorded on the study leave form.

235) Later arrangements changed and prior to attending a pharmaceutical sponsored educational meeting, it was necessary to complete a study leave request form and a hospitality form which were sent to management for approval. As far as I am aware, I complied with the requirements at the time.

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

236) The Edinburgh haemophilia centre has over the years enrolled many people with haemophilia, with their informed consent, in several different clinical trials of FVIII and FIX products. Some of these were pharmaceutical post marketing surveillance studies. Some were SNBTS studies.

237) See answer to Q55.

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

238) I have not undertaken any personal research. Results were provided as per answer to Q 72 and Q55.

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

239) I have not undertaken any personal research and have not received any personal funding. Prof Ludlam arranged for clinical trials to be undertaken in Edinburgh. This included gaining ethical approval and making any financial agreements. I am unaware of any funding arrangements.

Section 6: vCJD

75. When and in what circumstances did you first become aware of the risks of transmission of vCJD associated with the use of blood and blood products? How did your knowledge develop over time? In answering this question, it may be useful to refer to the enclosed document [HCDO0000984] which a letter copied to you discussing vCJD implicated blood products.

240) I became aware of a link between cases of vCJD and consumption of beef and beef products in the mid/late 1990s, as cases of people affected by vCJD started to be

reported. I cannot exactly remember when I became aware of the risk of transmission associated with blood and blood products but assume that it was around 1998. There was concern about a theoretical risk of transmission and around this time a decision was made to only use non UK plasma in the manufacture of pooled plasma blood products to reduce any risk of transmission.

241) I think that there was some correspondence about vCJD prior to the 2004 notification process, possibly in 2002/2003, but I am unable to remember details of this.

242) Information became available from the CJD incidents panel, the Health Protection Agency (HPA) and in the medical literature over the next 10 years. In 2004, I was aware of the likely transmission of vCJD through blood transfusion as detailed in the notification letters.

76. Please describe your involvement in decisions as to what information to provide to patients about vCJD. Please address in your answer the 2004 notification process, the 2006 notification process and the 2009 notification process. Please also answer the following questions:

a. What discussions took place within the Centre at Edinburgh?

243) At the time of the 2004 notification process, the haemophilia consultants wrote a covering letter which was sent with the information about vCJD from the HPA to all patients. I was not involved in drafting the letter or in decisions about what information was to be provided to patients.

b. What steps were Centres asked to take?

244) In 2004, centres were asked to identify anyone who had received treatment with UK pooled blood products between 1980 and 2001 and to contact them. Centres were asked to inform them that they were at a potential additional risk of vCJD as a result of their treatment.

245) I was involved in checking treatment records to try to make sure that the correct letters were sent. All patients with haemophilia, VWD, anti thrombin deficiency and some other congenital clotting factor disorders, were sent the information letters from the HPA (see 2004 notification letters [WITN403004]). They were also sent a covering letter. One letter advised patients that we did not have a record of them having received UK pooled blood products between 1980-2001, and the other letter advised that we did have a record of treatment.

246) We were asked to complete a vCJD exposure form which listed the implicated batch numbers for each person. If someone had received vials of an implicated batch this was recorded on the form and placed in the case notes. We also recorded on the form if the patient had wanted to be told if they had received an implicated batch.

247) The centre tried to account for all the vials of the implicated batches which had been issued in Edinburgh.

248) Many people with haemophilia had received treatment in Edinburgh in the past, often as a visitor. Others who had received treatment were no longer registered at the centre and had moved away. At the time of the vCJD notification process we were asked to identify these individuals so that they could be contacted and given the information. I tried to contact the last known haemophilia centre of any patient who had received treatment in Edinburgh but who was no longer seen. I did this by using the information on the UKHCDO database to see where someone was registered. I was then able to notify the centre of the treatment received in Edinburgh, so that they could pass this information onto their patient and provide counselling. I am not certain, but I think that Prof Ludlam may have sent the details of anyone that could not be traced to the HPA.

249) We were requested to notify the infection control team of any surgery that had taken place in the previous year on anyone in the group considered to be at risk of vCJD, so that an assessment regarding the surgical instruments used could be made.

250) We were also asked to inform the patients' GPs so that they knew the information being given to their patients. They would then be able to include the information regarding the at risk status in any referral letters if the patient required surgery or other invasive medical procedure.

251) We were asked to record the information regarding individual at risk status and implicated batches received on the UKHCDO database.

252) From memory in 2006 and 2009 we were asked to send all patients with haemophilia, VWD and anti thrombin deficiency further information (see 2009 notification letters [WITN4030005]). I think that the 2006 notification gave information about a new case of vCJD associated with a blood transfusion. The 2009 notification advised that a person with haemophilia had been found to have evidence of the prion protein that causes vCJD in his spleen at post mortem but had no signs of clinical vCJD.

253) From 2004, if anyone considered at risk of vCJD was having surgery we were asked to inform the surgical team.

254) From memory, some years later, following further information from the CJD incidents panel and the HPA the time period for the use of products considered to be at risk, was reduced from 1980-2001 to 1990 - 2001. We were asked to identify those people who were no longer thought to be at risk and to notify them of the change in advice. Any patients who had only received UK pooled plasma products between 1980 and 1990 were advised that they were no longer considered at risk of vCJD as a result of their previous treatment. We contacted the people affected by this change to explain the revised information.

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

255) See answer to Q76b.

256) All registered patients with haemophilia, VWD and anti-thrombin deficiency were sent the information letters from the HPA about vCJD in 2004, 2006 and 2009. Patients were offered an appointment to come to discuss the information sent.

257) People were given the option of finding out if they had received one of the implicated batches after counselling about the pros and cons of knowing this information. They were advised that an exposure form was being included in their medical records.

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

258) All patients were notified in writing about vCJD in 2004 and were offered appointments.

259) See answer to Q76 a, b, c

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

260) See answer to Q76 a,b,c

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

261) See answer Q76 a,b,c

262) In addition to the written information sent out, people were offered appointments at the haemophilia centre. Anyone who had received UK pooled plasma products within the 1980-2001 timeframe was considered at risk of vCJD for public health purposes and not just those people known to have received an implicated batch of treatment. It was explained that there was currently no test available and no treatment for vCJD. At the time of the original notification process in 2004, there had been no case of vCJD in someone who had received pooled blood products. The information in the notification letters would have been discussed. If after counselling someone wanted to know if they had received an implicated batch they were told.

263) This was understandably a very stressful time for many people and caused considerable anxiety. I tried to provide as much support as I could for our patients. I involved the department of psychological medicine team and also the CJD unit in the care of those requiring additional support.

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

264) The recommended precautions are detailed in the letters from the HPA sent during the notification process in 2004, 2006 and 2009. People considered at risk were asked to follow this advice to reduce the risk of potential spread to other people. This included

not donating blood, organs and tissues. If undergoing any medical or surgical procedures they were asked to tell the person treating them beforehand of their at risk status, so that special arrangements could be taken with any instruments used if necessary, to reduce the risk of spread to others.

77. **Please consider the enclosed letter [LOTH0000057_011] from you to Dr Mackenzie dated 17 April 2008. Please explain the context of this letter, including the correspondence you had with Dr Burns. Why was this letter sent? Did you receive a reply? If so, please provide a copy where possible, or set out your recollection of what was said.**

265) People known to have received UK pooled plasma derived blood products between 1980-2001 had been asked to inform any healthcare professionals treating them that they had been identified as being at increased risk of vCJD if they were undergoing any surgical or medical procedures. This was so that special arrangements could be made for the instruments used in certain procedures to reduce the potential risk of spreading vCJD to others.

266) The information about an individual's risk status was in their case notes but was not always immediately obvious and in time may have been contained in an old volume of records rather than the current one in use. Whilst staff in the haemophilia centre were often aware of individual risk status, colleagues seeing people out of hours and on the ward may not have been. To help identify those people considered at risk we sought management approval to be allowed to place a small sticker inside the cover of the notes giving the risk status. Dr Mackenzie and Dr McCallum (Caldicott guardian) replied to give approval for this. Copies of letters from Dr Burns, Dr Mackenzie and Dr McCallum are enclosed [WITN4030003].

Section 7: The financial support schemes

78. **What, if any, involvement did you have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund) which were set up to provide financial support to people who had been infected?**

267) I had no direct involvement with the trusts other than to complete application forms and provide supporting letters for patients when requested.

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

268) I can only comment from 1992. The haemophilia centre staff were involved in informing patients about the Skipton fund and changes to payments when these arose.

269) I think people had already registered with the Macfarlane trust before I started in 1992. I had no dealings with the Eileen trust.

80. Did Edinburgh have any policy or guidance for staff members in relation to the referral of patients to the trusts and funds for support? If so, please provide details.

270) I can only comment from 1992. Staff were encouraged to make sure that people knew about the Skipton fund and how to access it. I am unaware of any policy in relation to referrals to other trusts or funds.

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

271) I completed Skipton fund application forms and provided the information requested on the form. When it was not straightforward to complete the form, I sent a covering letter to explain individual circumstances and results. Without access to records, I cannot remember what information was sent in support letters to other trusts.

82. What kind of support or assistance was provided by you and/or Edinburgh to patients making applications for financial assistance?

272) I completed the Skipton application forms as requested. I provided letters of support to the trusts when requested. Prof Hayes completed the forms for anyone applying for stage 2 payments from the Skipton fund.

273) I wrote letters of support to other trusts such as the Macfarlane trust when requested. I completed DLA forms as requested.

274) In the 1990s Geraldine Brown, social worker was available to help people applying for financial assistance.

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

275) I mainly had experience of completing Skipton fund application forms and my answer relates to these. Staff tried to complete application forms promptly. Sometimes it was not always possible to answer yes or no to the questions asked and if necessary, it was my usual practice to send a covering letter to explain the individual situation. The fund would then determine if someone was eligible to receive payments. Occasionally a situation could arise when it was not possible to complete a form for someone e.g. if someone had only received treatment out with the UK prior to 1991, with no record of UK treatment.

276) If someone requested a support letter to send to one of the other trusts, e.g. the Macfarlane trust this would have been provided.

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

277) I am not aware of any involvement

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

278) I am aware of a case when no records could be found for a deceased patient. I am afraid that I do not know what happened to the application being made by the family. As far as I am aware this was not a widespread problem.

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

279) I mainly had dealings with the Skipton fund and my answer relates to this fund. I am not aware of any significant problems experienced by applicants to the fund. I am aware of one application which was refused but later approved following internal review.

280) I cannot comment on the other trusts or funds.

Section 8: Other Issues

87. 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.

281) I am unaware of any complaints.

88. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues

282) Medical practice has changed considerably over my working life. Many standards of practice that were accepted in the 1980s and 1990s would not be considered best practice today. Improvements in the process of gaining consent, information giving and record keeping evolved during my time at work.

283) I would just like to say how sorry I am that our patients and their families have suffered as a result of treatment given to them for their bleeding disorders. I went into the medical profession to provide care and to improve the lives of those with health problems. It is a tragedy that the treatment given to help people has had such terrible consequences for so many.

284) I was deeply saddened listening to the evidence given so far by our patients. Over the 25 years that I spent working at the haemophilia centre, I always tried to do my best for every patient that I saw and to keep them well informed about their condition, accepting that our understanding of hep C and vCJD evolved over some years. I am very sorry if anyone feels that the care or support that I gave them fell short of their expectations.

Statement of Truth

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

Signed GRO-C

Dated 26 October 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
6 November 2003	Letter to Dr Ludlam from Dr Dennis	WITN4030002
April & May 2008	Letters to Dr Dennis from Dr Burns, Dr MacKenzie and Dr McCallum	WITN4030003
September 2004	Template vCJD notification patient letter, patient vCJD information sheet and patient reply sheet.	WITN4030004
February 2009	Template vCJD notification patient letter	WITN4030005