Witness Name: Dr John Hanley
Statement No.: WITN5572001
Exhibits: WITN5572002 - WITN5572003
Dated: 19/4/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR JOHN HANLEY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 15 February 2021.

I, Dr John Hanley, will say as follows: -

Section 1: Introduction

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

1.1. Name: John Patrick Hanley
Date of Birth: GRO-C 63
Address: Department of Haematology
Newcastle Hospitals NHS Trust
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP

1.2. Qualifications

1.2.1. 1987 MB ChB (Leicester University)

1.2.2. 1991 MRCP (UK)

1.2.3. 1998 MD (Leicester University)
"The clinical and laboratory evaluation of chronic liver disease in haemophilia"

1.2.4. 1999 MRCPath

1.2.5. 2000 FRCP

1.2.6. 2006 Certificate in Clinical Education (University of Newcastle upon Tyne)

1.2.7. 2007 FRCPath

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

2.1. Aug 1987 – Jan 1988: House Officer, General Surgery Pilgrim Hospital, Boston, Lincolnshire

2.2. Feb 1988 – July 1988: House Officer, Cardiology / General Medicine, Groby Road and Glenfield Hospitals, Leicester

2.3. Aug 1988 – July 1989: Senior House Officer, General Medicine, Shotley Bridge Hospital, Co. Durham

2.4. August 1989 – July 1991: Senior House Officer Medical Rotation, Lincoln Hospitals

2.5. Aug 1991 – July 1994: Specialist Registrar in Haematology, Nottingham and Derby Hospitals

2.6. Aug 1994 – July 1997: Lecturer in Haematology, University of Edinburgh

2.7. Aug 1997 – Nov 1997: Specialist Registrar in Haematology, Western General Hospital, Edinburgh

2.8. Nov 1997 – Dec 1998: Specialist Registrar/Locum Consultant Haematologist, Christchurch Hospital, New Zealand

2.9. Jan 1999 – June 1999: Specialist Registrar in Paediatric Haematology, Royal Hospital for Sick Children, Edinburgh

2.10. July 1999 – Dec 2000: Consultant Haematologist, Ninewells Hospital, Dundee

2.11. Jan 2001 – **present**: Consultant Haematologist and Co-Director of Newcastle Haemophilia Comprehensive Care Centre, Royal Victoria Infirmary, Newcastle Hospitals NHS Trust

2.12. Sept 2005 – August 2010: Clinical Director, Specialist Haematology Directorate, Newcastle Hospitals NHS Trust

2.13. July 2008-March 2011: Clinical Tutor, Newcastle Hospitals NHS Trust

2.14. August 2010-April 2013: Clinical Director, Directorate of Cancer Services and Clinical Haematology, Newcastle Hospitals NHS Trust

2.15. December 2013-April 2019: Director of Medical Education, Newcastle Hospitals NHS Trust

2.16. April 2019 – **present:** Chair, Specialised Blood Disorders, Clinical Reference Group

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. If applicable, please ensure your answer addresses your involvement with the UKHCDO.

3.1. Member - British Society for Haematology (ongoing)
Member - International Society of Thrombosis and Haemostasis (ongoing)
Member - UK Haemophilia Centre Doctor's Organisation (ongoing)

3.2. UKHCDO Committees:
Paediatric Working Party (Previous member)
Emergency Care Taskforce (Previous Chair)
Musculoskeletal Working Party (Previous Chair; current member)
Peer Review Working Party (Chair 2017 - present)

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

4.1. I have not provided evidence, or been involved in to any previous inquiries, investigations, criminal or civil litigation in relation to HIV, HBV, HCV or CJD.

Section 2: Decisions and actions of the Nottingham & Edinburgh Haemophilia Centres

The dates in the Rule 9 letter are incorrect. I was appointed as a Haematology Registrar in Nottingham from August 1991. This was a 3-year training post in Haematology which spent 2 years in Nottingham and a year in Derby on a planned programme of training (the first year at the Queens Medical Centre; the following year at City Hospital Nottingham and the final year I rotated to Derby Royal Infirmary).

5. **Insofar as relevant to the Terms of Reference, please:**
   a. **describe the roles, functions and responsibilities of i) Nottingham and ii) Edinburgh during the time that you have worked there.**
   b. **outline the facilities and staffing arrangements for the care of patients with bleeding disorders at i) Nottingham and ii) Edinburgh;**
   c. **identify senior colleagues at i) Nottingham and ii) Edinburgh and their roles and responsibilities during the time that you worked there, insofar as they were involved with the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**

5.1. a i) Nottingham: I worked as a Haematology Registrar in Nottingham for 2 years. The first year was based at Queens Medical Centre. The role included all aspects of clinical and laboratory haematology. I saw patients with bleeding disorders – both children and adults, when they presented with acute bleeding problems.

5.2. a ii) Edinburgh: I was a Lecturer in Haematology in Edinburgh for 3 years. I was employed by Edinburgh University but I was based in the Haematology Department at the Royal Infirmary. My duties were split roughly 50:50 between clinical work and

research. I was also involved with teaching. I covered the Haemophilia Centre in the afternoons and also covered clinics when other colleagues were on leave. I was involved with the on-call rota (working at Registrar level) covering haematology inpatients and I would review any patients with bleeding disorders who presented out of hours.

5.3. b i) Nottingham: When I started working at Queen's Medical Centre in Nottingham in August 1991, there was no dedicated haemophilia centre as such. Children with acute bleeding problems would be reviewed in the children's emergency department. Adults would be reviewed on the haematology ward. Follow-up of patients was ad-hoc I do not recall any patients being seen in outpatient clinics which I attended. With the arrival of Dr Gerry Dolan, as a new consultant haematologist and Director of the haemophilia service, he rapidly established outpatient review clinics and lobbied for some dedicated space to accommodate the haemophilia centre. When I worked in Nottingham there were no dedicated haemophilia staff, but I understand subsequently the staffing infrastructure was developed by Dr Dolan

5.4. b ii) Edinburgh: I moved to Edinburgh in August 1994 as a lecturer in haematology. There was a well-established Haemophilia centre at the Royal infirmary. This was led by Dr (now Professor) Christopher Ludlam and staffed by a haemophilia sister, haemophilia staff nurse and two Clinical assistants (Doctors who worked at the haemophilia centre and had developed an expertise in the field of bleeding disorders). The haematology registrar also attended clinics and provided cover for the haemophilia centre as part of their training. There was also some dedicated time for physiotherapy and a social worker. Patients had open access to the haemophilia centre Monday to Friday during normal working hours and often presented with acute bleeding problems. Out of hours adults were assessed on the haematology ward at the Royal infirmary and children went to the Haematology ward at the Royal Hospital for Sick children. Dr Angela Thomas, Consultant Paediatric haematologist, did a regular paediatric clinic at the haemophilia centre. There was very close working between all members of the haemophilia centre team with a weekly team meeting.

5.5. c i) Nottingham: When I arrived in Nottingham the Consultant Haematologist at Queen's Medical Centre was Dr Ted Bletcher. A Consultant Haematologist called Dr Eric French had just retired and I did not meet him. I am not sure if Dr Bletcher or Dr French had been the lead for the haemophilia service previously. After I had been in Nottingham for a few months Dr Gerry Dolan arrived as a new consultant and he was

also in charge of the haemophilia service Until the arrival of Dr Dolan, I do not think there was much involvement in the care of patients with HIV from the haematology team. In addition I do not think many, if any, patients had been tested for hepatitis C (see below)

5.6. c ii) Edinburgh: Dr Ludlam was the consultant in charge of the haemophilia centre. He had established a very close working relationship with Dr Peter Hayes (Consultant Hepatologist) and both were actively involved in reviewing patients with hepatitis C at the haemophilia centre. There were also close with working relationships with the HIV experts based in the infectious diseases department in Edinburgh.

6. Please describe:

a. your role and responsibilities at i) Nottingham and ii) Edinburgh and how, if applicable, this changed over time;

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

6.1. i) Nottingham: As a new haematology registrar in Nottingham I was right at the start of my training in haematology. I always worked under the supervision of the Senior Registrar and Consultants. When Dr Dolan arrived, he initiated a much more organised approach to the review and follow-up of patients with haemophilia and other bleeding disorders. At that time very few patients had been offered testing for hepatitis C. I was charged with the responsibility of organising hepatitis C testing for as many patients as possible. When patients with haemophilia or other bleeding disorders attended with acute bleeds, I would review the records and discuss hepatitis C testing with them. At that time the usual approach to performing blood tests was not to take written consent. I explained that hepatitis C testing was now available and both serological anti-HCV tests and HCV RNA tests by PCR were performed. Many patients were aware that chronic hepatitis referred to as Non-A Non-B hepatitis was recognised in patients who had received plasma concentrates previously. I would explain the state of knowledge at that time including that some patients might have evidence of progressive liver disease. At the same time, I would review the liver function tests and document the results in the medical notes. The results were generally communicated to patients at subsequent clinic appointments but if I happened to see any patients prior to the clinic visit I would often explain the results

and do my best to answer any questions. At this time there was still a lot of uncertainty about the natural history of hepatitis C and whether treatment would benefit patients.

6.2. ii) In Edinburgh my role was as a lecturer in haematology under the supervision of Dr Christopher Ludlam. Over the 3 years of the lectureship, I took the lead for a number of projects in relation to hepatitis C infection in patients with bleeding disorders. By the time I started in Edinburgh all patients had already been tested for hepatitis C and many had undergone detailed evaluation to assess the severity of the liver disease. This was done in conjunction with the hepatology team. The Edinburgh hepatologists were skilled in the procedure of laparoscopic liver inspection and biopsy. A protocol to fully assess the stage of hepatitis C related liver disease had been developed. This involved an upper GI endoscopy to look for evidence of varices and portal hypertension as well as a laparoscopic inspection of the liver and/or liver biopsy. Part of my role was to collate the information about the approach to the investigation of chronic liver disease which had been developed in Edinburgh. This was subsequently published (See answer to Q57 h) and also contributed to my MD thesis. By this time, patients with evidence of chronic hepatitis C infection were being offered treatment with interferon, which had been shown to clear the virus in some patients. I was responsible for collating the information of response to treatment and subsequently the experience of treatment in 31 patients with haemophilia was published. I was also involved in the Clinical review of patients receiving interferon at this time.

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

7.1. I can't remember exactly how many patients with bleeding disorders were in Nottingham. The exact numbers should be available from the Nottingham haemophilia centre team or the UKHCDO annual reports. In Edinburgh there were 87 anti HCV positive patients of which 74 had evidence of chronic HCV infection.

8. **To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by i) Nottingham and ii) Edinburgh regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:**
   a. **How, and on what basis, and by whom were decisions made about the selection and purchase of blood products?**
   b. **What (if any) other bodies or organisations or individuals (e.g. other centres in the same region, or the Regional Health Authority) were involved in the arrangements for the selection, purchase or use of blood products?**
   c. **What were the reasons or considerations that led to the choice of one product over another?**
   d. **What role did commercial and/or financial considerations play?**
   e. **What, if any, involvement did you have?**
   f. **What products or treatments were generally used for treating (i) patients with severe haemophilia A; (ii) patients with moderate haemophilia A; (iii) patients with mild haemophilia A; (iv) patients with haemophilia B; (v) patients with von Willebrand's disease? Who had responsibility for the selection and purchase of blood products?**

8.1. By the time I worked in both Nottingham and Edinburgh, plasma derived factor concentrates were in use which had to been subject to viruses activation. I had no involvement in the selection of products for use.

9. **What was the relationship between i) Nottingham and ii) Edinburgh and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on i) Nottingham and ii) Edinburgh's decisions and actions? In answering this question, please describe the kinds of interactions and communications (such as visits from sales representatives) you had with pharmaceutical companies which supplied factor concentrates.**

9.1. I am not aware of any influence of pharmaceutical companies in relation to the decisions about use of particular concentrates either in Nottingham or Edinburgh. As a haematology registrar in Nottingham and lecturer in Edinburgh I would meet representatives from pharmaceutical companies most often at educational events. I applied for and received some financial support to attend research and educational

meetings. This type of support was extremely common at the time. I did not see any evidence that this influenced decision making about the use of particular concentrates.

10. If the responsibility for the selection and purchase of blood products lay with an organisation other than i) Nottingham and ii) Edinburgh, please specify which organisation and provide as much information as you can about its decision-making. If you have any information relevant to this question relating to Newcastle, please include this in your answer.

10.1. I have no knowledge of the involvement of other organisations in the selection purchase of blood products in Nottingham or Edinburgh.

10.2. I started work in Newcastle in January 2000. Looking back at the records in Newcastle in 2000 adult patients with haemophilia were treated with plasma derived concentrates (Beriate, Replanate, Fandhi, DEFIX, Repelnine). Children were already receiving recombinant products (Helixate, Recombinate, Kogenate, Refacto, Benefix). Patients with inhibitors received recombinant VIIa (novoseven) or FEIBA.

10.3. Subsequently, in 2004, recombinant concentrates were approved for adults and patients were switched as soon as possible (this was phased in over a period of 3 years as mandated by the Department of Health). The approach taken in Newcastle was to try to use all the available products as it was thought to be prudent in case of supply disruption. This proved to be wise as there was a temporary disruption to the supply of Kogenate which was easier to cope with as we had access to other recombinant factor VIII concentrates. This approach continued until the start of national contracting which initially mandated use of certain products. This did involve switching some patients to different products. This was always done with involvement of the patient in the discussion.

10.4. The decision about how to use concentrates in Newcastle was always clinically-driven. There was oversight within the hospital via pharmacy and the Drugs and Therapeutics Committee. For many years there as an Adult Haematology Specialist Services Commissioning Group which was chaired by a local commissioner and was a forum to discuss all aspects of the haemophilia service. More recently there has been an excellent channel of communication with the local commissioners as newer products for haemophilia such as Emicizumab have become available.

11. What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders at i) Nottingham and ii) Edinburgh? What were, in your view, the advantages and disadvantages of those alternative treatments? What use did i) Nottingham and ii) Edinburgh make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

11.1. I cannot comment in detail about what treatments were available in 1970s and 1980s in either Nottingham or Edinburgh. As part of by MD thesis I studied the medical literature from this era and over the years I have spoken to many patients about their experiences. Up until the 1960s the only treatment available for haemophilia was whole blood or fresh frozen plasma. As you will have heard from many witnesses to the Inquiry, the natural history of severe haemophilia was of progressive joint damage due to recurrent bleeding and often premature death, mainly due to intracranial bleeding. Cryo precipitate was developed in 1960s and improved treatment for haemophilia A, but had to be administered in hospital and in many situations did not stop bleeding completely. In the 1970s factor VIII and IX concentrates became available. Talking to patients who lived through this era and doctors and other healthcare professionals who were involved in the care of patients with haemophilia at this time, I think it is fair to say that the availability of concentrates led to a massive improvement in the quality of life for patients with haemophilia and their families.

11.2. Factor concentrates transformed the lives of many patients with haemophilia and heralded in the era of home therapy. From an early stage of their use, reports started to appear in the literature of abnormal liver function tests. It was ultimately shown that any patients who received factor concentrate from any plasma source were exposed to non-A non-B hepatitis. It was not until 1989 that hepatitis C was identified as the causative virus. In the 1970s and into the 1980s the immediate and obvious benefits of concentrates, outweighed the concern about abnormal liver function tests and the possible long term risk of liver disease. It was only over a period of 10-15 years of longitudinal studies that it emerged that progressive liver disease was a major clinical problem. In retrospect, how this issue was discussed with patients and parents at this time almost certainly was not done in a way that reflected the uncertainty of the situation and may have been falsely reassuring. It is difficult to know if a different approach at this time would have led to a different course of action. Nowadays we practice medicine in a different way, with much more sharing of uncertainty with patients. If I try to put myself in the shoes of a haemophilia doctor in say, 1975, with

the information available at the time, would I have advised my patients against the use of factor concentrates? To be honest, I don't think I would, in the sense that the immediate benefits seemed to outweigh any longer term uncertain risks.

11.3. DDAVP became available in the late 1970s for the treatment of mild haemophilia A and von Willebrand disease. I do not know exactly when DDAVP was first used in Nottingham and Edinburgh, but I do recall seeing patients who had been treated with DDAVP in both centres.

11.4. In retrospect, the only other strategy to reduce the risk of virus infection would have been to use cryoprecipitate instead of concentrates to reduce the "donor exposure". I have no knowledge about how this was approached in Nottingham or Edinburgh in the 1970s and 1980s.

12. At i) Nottingham and ii) Edinburgh, what was policy and approach as regards:

a. the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and if so how?

b. home treatment? When was home treatment introduced?

c. prophylactic treatment? To what extent and when was treatment provided on a prophylactic basis?

12.1. a) By the time I worked in both Nottingham and Edinburgh, cryoprecipitate was not in use for the treatment of patients with bleeding disorders.

12.2. b) By the time I started in Nottingham and Edinburgh, patients will already on home treatment. I do not know the exact dates when the Home Treatment was introduced.

12.3. c) Prophylactic treatment became more common in the late 1980s and early 1990s.

13. What was the policy and approach of i) Nottingham and ii) Edinburgh in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?

13.1. By the time I had worked in Nottingham and Edinburgh, children were treated with factor concentrates which had been subjected to virus inactivation procedures. As soon as recombinant treatment was available, children were switched on to this.

14. What viruses or infections, other than HIV, HCV and HBV, were or have been transmitted to patients at i) Nottingham and ii) Edinburgh in consequence of the use of blood products?

14.1. I do not recall other viruses being transmitted in either Nottingham or Edinburgh. There was residual concern about the risk of hepatitis A and parvovirus.

Section 3: Knowledge of, and response to, risk

15. When you began work at i) Nottingham and ii) 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?

15.1. Prior to starting work in Nottingham I had learnt about the risks of infection associated with blood transfusion and blood products at medical school and during the first few years of my postgraduate medical training. I was aware of the risk of HIV transmission, hepatitis B transmission and non-A non-B hepatitis. My knowledge and understanding developed considerably during my haematology registrar training in Nottingham. This was partly due to the availability of tests for hepatitis C and specific training I received particularly on attachment at the Sheffield transfusion centre. The sources of my knowledge included being taught by more senior haematologists and blood transfusion specialists as well as reading haematology text books and journals.

15.2. In Edinburgh, I was involved in both clinical activity and research in the field of hepatitis C and chronic liver disease. During this time I read all the available literature from the 1970s onwards, so I developed an understanding of the way the understanding of the natural history of chronic hepatitis C infection had evolved.

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

16.1. I am not aware of any specific advisory or decision-making structures having been put in place in either Nottingham or Edinburgh over and above the individual patient discussion on ward rounds or outpatient clinic visits. The entire approach to issues such as clinical governance, patient consent, shared decision making and the

oversight of clinical practice through multi-disciplinary team working, which is at the heart of the way haemophilia care and medicine is practiced these days, did not really started evolving until the 1990s. So back in the 1970s and 1980s I do not think any hospitals in the UK had advisory or decision-making structures as such. These only evolved subsequently.

17. What was your understanding of the relative risks of infection from commercially supplied factor concentrates and NHS factor concentrates?

17.1. By the time I started working in Nottingham only concentrates which would be subjected to a virus in activation procedures were in use, so my understanding on the relative risks of infection was in the light of knowledge which had accumulated in the medical literature that time.

18. How did you keep up-to-date with relevant scientific and medical developments in knowledge? What journals did you regularly read?

18.1. In Nottingham I used to read medical journals to keep up-to-date including the Lancet and the New England Journal of Medicine. I also read haematology journals include the British Journal of Haematology and Blood.

19. When you began work as a senior registrar at i) Nottingham and ii) Edinburgh, what was your knowledge and understanding of:

a. the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products?

b. the nature and severity of the different forms of blood borne viral hepatitis?

19.1. a) see answer to question 15

19.2. b) During my time in Nottingham and Edinburgh there was a rapid increase in the understanding of the natural history of hepatitis C infection. This was mainly due to the availability of serological tests for hepatitis C and the ability to identify HCV RNA by PCR testing. This approach confirmed that the majority of patients had evidence of ongoing virus replication.

20. What were the sources of your knowledge? How did that knowledge and understanding develop over time?

20.1. The sources of my knowledge were medical journals. In addition I had the opportunity to attend educational events and conferences. When I was working in Edinburgh main focus of the research aspect of my post was hepatitis C and liver disease so I had the opportunity to meet and discuss this area in detail with many experts in the field. In Edinburgh my research in the molecular virology laboratory was supervised by an experienced postdoctoral researcher called Dr Lisa Jarvis. She was expert in all aspects of hepatitis-C laboratory work including PCR testing and genotyping. The research group was led by Dr (now Professor) Peter Simmonds. He was a leading international expert on both molecular biology of HIV and HCV. His research group developed the analysis of HCV sequence variation which under-pins the identification of different genotypes of HCV which then led to understanding of the differences between the genotypes in relation to severity of liver disease and response to treatment.

21. What, if any, actions were taken by you and/or i) Nottingham and ii) Edinburgh to reduce the risk to patients of being infected with hepatitis (of any kind)?

21.1. As I mentioned in answers to earlier questions by the time I arrived in Nottingham only concentrates which had been subjected virus inactivation were in use.

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

22.1. I was at medical school between 1982 in 1987. This coincided with the emergence of AIDS and as understanding increased about mode of transmission, we learnt about this at medical school.

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

23.1. By the time I started working in Nottingham, as part of my haematology training in blood transfusion, I learned about the risks of HIV transmission from blood and blood

products. This was from reading medical journals and specific training in blood transfusion at the Regional transfusion centre in Sheffield. I spent some time in the microbiology lab which by this time was heavily involved in screening blood donors for HIV. The risk of HIV transmission from blood transfusion had been reduced to a very low level by this time. There was still the possibility of "window period" donations. Also by this time factor concentrates were successfully inactivated to eliminate the risk of HIV transmission.

24. What, if any, actions were taken by you and/or i) Nottingham and ii) Edinburgh to reduce the risk to your patients of being infected with HIV?

24.1. Blood donor screening advice and virus-activation of concentrates were already in use the time I started working in Nottingham.

25. Did you or i) Nottingham and ii) Edinburgh continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?

25.1. I have no knowledge of the decision making about the use of Factor concentrates prior to working in Nottingham or Edinburgh.

26. Were steps taken by you and/or i) Nottingham and ii) Edinburgh to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

26.1. Question 26-30 relate to a period of time in the late 1970s and early 1980s in Nottingham and Edinburgh. I have no knowledge of the specific actions taken as it is well before the time I worked in either place.

27. Did you or your colleagues at i) Nottingham and ii) Edinburgh revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, when and how was it determined which patients would be offered a return to cryoprecipitate?

27.1. Question 26-30 relate to a period of time in the late 1970s and early 1980s in Nottingham and Edinburgh. I have no knowledge of the specific actions taken as it is well before the time I worked in either place.

28. When did i) Nottingham and ii) Edinburgh begin to use heat treated factor products and for which categories of patients? Please set out what steps were taken to obtain heat treated products. Please also set out whether steps were taken to recall any stores of unheated products which patients had.

28.1. Question 26-30 relate to a period of time in the late 1970s and early 1980s in Nottingham and Edinburgh. I have no knowledge of the specific actions taken as it is well before the time I worked in either place.

29. Looking back now, what decisions or actions by you, any of the institutions at which you have worked, or any other relevant organisations or individuals, could have avoided, or brought to an end earlier, the use of infected blood products?

29.1. Question 26-30 relate to a period of time in the late 1970s and early 1980s in Nottingham and Edinburgh. I have no knowledge of the specific actions taken as it is well before the time I worked in either place.

30. 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?

30.1. Question 26-30 relate to a period of time in the late 1970s and early 1980s in Nottingham and Edinburgh. I have no knowledge of the specific actions taken as it is well before the time I worked in either place.

Section 4: Treatment of patients at Nottingham and Edinburgh

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

31.1. Question 31 to 36 related to HIV. By the time I started working in Nottingham and Edinburgh was already several years after HIV testing and discussion about results had already taken place. So I am not able to answer these questions.

32. How many patients at i) Nottingham and ii) Edinburgh were infected with HIV in consequence of the treatment with blood products? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

32.1. Question 31 to 36 related to HIV. By the time I started working in Nottingham and Edinburgh was already several years after HIV testing and discussion about results had already taken place. So I am not able to answer these questions.

33. How and when did you learn that patients under your care or i) Nottingham and ii) Edinburgh's care had been infected with HIV?

33.1. Question 31 to 36 related to HIV. By the time I started working in Nottingham and Edinburgh was already several years after HIV testing and discussion about results had already taken place. So I am not able to answer these questions.

34. How and when were patients at i) Nottingham and ii) Edinburgh told that they had been, or might have been, infected with HIV? What if any involvement did you have in this process?

34.1. Question 31 to 36 related to HIV. By the time I started working in Nottingham and Edinburgh was already several years after HIV testing and discussion about results had already taken place. So I am not able to answer these questions.

35. Please describe the processes at i) Nottingham and ii) Edinburgh for HIV testing, including pre-test and post-test counselling.

35.1. Question 31 to 36 related to HIV. By the time I started working in Nottingham and Edinburgh was already several years after HIV testing and discussion about results had already taken place. So I am not able to answer these questions.

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

36.1. Question 31 to 36 related to HIV. By the time I started working in Nottingham and Edinburgh was already several years after HIV testing and discussion about results had already taken place. So I am not able to answer these questions.

37. How many patients at i) Nottingham and ii) Edinburgh were infected with hepatitis C?

37.1. See answer to Question 7.

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

38.1. See answer to Question 6.

39. When did i) Nottingham and ii) Edinburgh begin testing patients for hepatitis C? Please describe the processes at i) Nottingham and ii) Edinburgh for HCV testing, including pre-test and post-test counselling. What involvement did you have in this process?

39.1. See answer to Question 6.

40. Were the results of testing for HIV and hepatitis C notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

40.1. I have no knowledge of HIV testing as this had happened before I worked in Nottingham or Edinburgh. In relation to HCV testing in Nottingham, patients were told about the results at the next outpatient clinic visit or sooner if they attended for treatment or assessment.

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

41.1. When I first started in Nottingham I don't think there was a systematic approach to taking blood samples form patients. There was no storage of plasma or serum samples that I was aware of in the haematology department. When Dr Dolan arrived he initiated a much more organised approach to follow up of patients with bleeding disorders.

41.2. In Edinburgh there had been a much more organised approach to haemophilia follow-up which had been in place for a number of years before I arrived. Serum samples had been stored on all patients who attended the haemophilia centre. I am not sure exactly when this started but it was certainly in place by the early 1980s. I think the storage of samples was regarded as "good practice" and seen as part of the routine care of patients. I'm not sure if patients were specifically told about this in an explicit way and there was no written consent taking for blood tests then (as is still the case these days for many blood tests).

42. Did i) Nottingham and ii) Edinburgh have a bank of stored samples? If so, was that storage undertaken with patients' knowledge and consent?

42.1. There was no bank of stored samples in Nottingham.

42.2. In Edinburgh there was an extensive bank of stored samples. See answer to last question in relation to patient consent.

42.3. My understanding of this (and other banks of samples in the UK) is that the doctors running many of the larger haemophilia centres in the UK thought that keeping serum banks would be potentially useful to investigate a range of issues in patients with bleeding disorders who received treatment with blood products. There was a lot of debate about viruses and also the factors which contributed to the formation of inhibitors in patients with haemophilia. In the late 1970s, as immunological abnormalities in patients with haemophilia began to be observed, there was an emerging view that this was due to some ill-defined immunomodulatory effect of

concentrates. In retrospect, many of these changes were actually due to HIV infection but it was not for many years that this was confirmed.

42.4. Without the banks of samples, the retrospective longitudinal study of viruses and correlation with clinical information would not have been possible. Much of the work which contributed to my MD thesis was performed on stored samples (which is also the case for the two haematology lecturers who preceded me) so an enormous amount of information which has been of benefit to patients has been derived from the study of stored serum banks. In many ways the doctors who developed the banks of samples made an important contribution to the care of their patients. It is, perhaps, unfair to be overly critical of them for not taking written consent from patients as this approach did not exist anywhere in medicine in this era. Nowadays this would be regarded as routine.

42.5. As an example, it was common practice in many haematology departments to collect extra samples from patients with a variety of conditions for laboratory-based research. This included leukaemia research. I am sure that there was no consent from individual patients. I am also sure that this was regarded as contributing to the "greater good" of patients in terms of increasing the understanding of their underlying conditions. When judged by contemporary standards, however, this practice would not be acceptable nowadays and has been superseded by properly organised biobanks with ethical approval and appropriate consent and governance.

43. Were patients under your care/under the care of i) Nottingham and ii) Edinburgh 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?

43.1. The approach to "consenting" patients for treatment and how this is appropriately recorded in the clinical record has evolved considerably in the course of my career. In the 1980s there was very little formality to the consent process, apart from consent forms which patients would sign before surgery.

43.2. This is not to say that patients were not given information including the pros and cons of various treatment options, but their receipt or understanding of the information as

well as their consent to a variety of treatments was not generally recorded in the medical notes.

43.3. In the course of my training in haematology I spent a lot of time looking after patients with haematological malignancy. There was no recording of patient consent in relation to chemotherapy or even major procedures such as bone marrow transplantation until relatively recently. So, it is perhaps not surprising, that there was no systematic approach to recording consent to treatment for patients with haemophilia in the 1980s. Even in my career since 2000, when we have moved to an era of "shared decision making" with patients/parents and sharing of much more information and uncertainty, explicit consent for a range of treatments for bleeding disorders is not recorded as a "signed consent" process.

43.4. As an example, we spend a lot of time counselling parents of young children with newly diagnosed bleeding disorders about the pros/cons of different approaches to treatment before agreeing on a particular approach. This would be recorded in the clinical record as "the pros/cons were fully explained of treatment X, Y and Z. After a lengthy discussion we agreed to Y. The parents were in full agreement with this and all their questions were answered in the course of the discussion". This wouldn't be routinely accompanied by a signed consent form, even today.

44. Were patients under your care or under the care of i) Nottingham and ii) Edinburgh 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?

44.1. I have no knowledge of HIV testing in Nottingham or Edinburgh as this had happened before my arrival. My involvement in HCV testing in Nottingham is outlined in my answer to Question 6.

45. The enclosed document is a complaint made to the General Medical Council against Dr Peter Jones in 2003 [WITN3365016_001]. The complaint contains a letter dated 28 March 2003 in which Mr L R Fenwick, Chief Executive of The Newcastle Upon Tyne Hospitals NHS Trust outlines the findings of his investigation into the patient's concerns (pages 25-26). Without providing any information that would identify the patient, please explain:

a. the basis for your view, expressed by Mr Fenwick in his letter, that it is unlikely that individual patient consent for HCV testing would have been sought at the relevant time; and

b. when to your knowledge consent for HCV testing commenced at Newcastle.

45.1. a) See answer to Question 43. My view was based on my experience of working in other hospitals in the late 1980s and early 1990s in relation to the practices of obtaining consent which were widespread at the time.

45.2. b) Verbal consent for HCV testing started as soon as the first serological tests for HCV were available. I base this observation on discussions I've had with patients had over the years when I've asked them what they recalled about HCV testing previously.

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

46.1. As a haematology registrar (in Nottingham) or haematology lecturer (in Edinburgh) I did not take any decisions about 'previously untreated patients'. This would have been a Consultant-level decision.

47. How was the care and treatment of patients with bleeding disorders and HIV/AIDS managed at i) Nottingham and ii) Edinburgh? In particular:

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

b. What treatment options were offered over the years?

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

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

47.1. In Nottingham, as a haematology registrar, I was not involved with the care of patients with HIV. In Edinburgh the care of patients with HIV was provided by the HIV team based in the department of infectious diseases, so again, as lecturer in haematology I was not involved in the follow-up or treatment.

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

48.1. I don't recall any patients with chronic hepatitis B infection.

49. How was the care and treatment of patients with bleeding disorders and hepatitis C managed at i) Nottingham and ii) Edinburgh? In particular:

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

b. What treatment options were offered over the years?

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

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

49.1. I cannot comment on HCV care and treatment in Nottingham as this happened after I had left.

49.2. a) In Edinburgh there was a close working relationship between the haemophilia team and the hepatology team in relation to the assessment of liver disease and the treatment options.

49.3. b) Interferon treatment was offered to all patients. Subsequently, in those who had not responded to interferon alone, combination therapy with interferon and ribavirin was

offered. Liver transplantation for decompensated liver disease was undertaken in one patient whilst I was in Edinburgh. I left the lecturer post in Edinburgh in 1997, so I have no knowledge of treatment with more recent therapies for chronic HCV infection.

49.4. c) Patients were told about response rates and side effects of treatment before therapy was initiated

49.5. d) Treatment was monitored by serial testing of liver function tests (particularly transaminases) and HCV RNA by quantitative PCR.

49.6. For patients with established cirrhosis, there was monitoring for hepatocellular carcinoma (regular ultrasound scan and alpha fetoprotein measurement) and decompensation of liver disease.

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

50.1. In Edinburgh there was a part time social worker who provided support for patients attending the haemophilia centre. Counselling and input from psychology required individual referral.

51. Did i) Nottingham and ii) Edinburgh receive funding from the Department of Health and Social Security or from any other source to help with the counselling of patients infected with HIV?

51.1. I have no knowledge about funding received by Edinburgh or Nottingham for counselling.

52. What, if any, difficulties did you or i) Nottingham and ii) Edinburgh encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

52.1. I have no detailed knowledge about difficulties in funding of treatment for HIV and HCV in Nottingham or Edinburgh. I know that in some places (including Newcastle) there were problems with funding for interferon treatment initially.

53. What, if any, involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

53.1. I had no involvement in clinical trials for HIV or hepatitis.

54. What were the policies at i) Nottingham and ii) Edinburgh with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis? Were you involved with any inquests in relation to patients who had been infected with HIV or hepatitis in consequence of their treatment? If so, please provide details.

54.1. I do not recall any particular policy in relation to death certification in either Nottingham or Edinburgh. I do know there was a major issue with the stigma associated with HIV in the 1980s and 1990s which led to a reluctance to write this on death certificates for fear of this causing problems for the deceased families. I was not involved with any inquests.

55. What were the retention policies of i) Nottingham and ii) Edinburgh in regards to medical records during the time you were practising there?

55.1. I do not know the specific retention policies in relation to medical records.

56. As far as you are able to recall, did you:

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

b. 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 Centres? If so, why, what information and where is that information held now?

56.1. I don't recall separate records for patients in Nottingham or Edinburgh.

57. Please list all research studies that you were involved with at the Nottingham, Edinburgh and Newcastle Haemophilia Centres (or any other relevant positions of employment) insofar as relevant to the Inquiry's Terms of Reference, and please:

a. Describe the purpose of the research.

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

c. Explain what your involvement was.

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

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

f. State the number of patients involved.

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

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

57.1. a-g) I was not involved in any research studies in Nottingham. In Edinburgh I was involved in a range of projects. Some of these were laboratory based research activities and others were clinical projects. The clinical projects were not research projects in the way that the term clinical research is used nowadays. There were more a collation of clinical information about the investigation and treatment of chronic hepatitis C. The projects were approved by the hospital ethics committee. At the time there was not a requirement to seek explicit consent from individual patients, so this was not done. I told many patients over my time in Edinburgh that their clinical information was being used to as part of the work I was involved with. I reassured them that this was done in an anonymised way for any of the publications which resulted. In retrospect this would have been a better to document explicit consent about such research and nowadays this would be a mandatory requirement.

57.2. Publications:

57.2.1. **Hanley JP**, Jarvis LM, Hayes PC, Lee AJ, Simmonds P and Ludlam CA. Patterns of hepatitis G viremia and liver disease in hemophiliacs previously exposed to non-virus inactivated coagulation factor concentrates. *Thrombosis and Haemostasis,* 1998, **79**; 291-295.

57.2.2. **Hanley JP** and Haydon GH. The biology of interferon-α and the clinical significance of anti-interferon antibodies. *Leukemia and Lymphoma* 1998, **29**; 257-268.

57.2.3. Ludlam CA, **Hanley JP** and Hayes PC. Liver biopsy in haemophilia. *British Journal of Haematology* 1997, **97**; 690-691.

57.2.4. Jarvis LM, Davidson F, **Hanley JP**, Healey CJ, Yap PL, Ludlam CA and Simmonds P. Frequency of infection with hepatitis G virus among recipients of plasma products. *Lancet* 1996, **348**; 1352-1355.

57.2.5. **Hanley JP**, Jarvis LM, Simmonds P and Ludlam CA. Development of anti-interferon antibodies and breakthrough hepatitis during treatment for HCV infection in haemophiliacs. *British Journal of Haematology,* 1996, **94**, 544-550.

57.2.6. **Hanley JP**, Jarvis LM, Andrews J, Dennis R, Hayes P, Lee R, Simmonds P, Piris J and Ludlam CA. Investigation of chronic hepatitis C infection in individuals with haemophilia assessment of invasive and non-invasive methods. *British Journal of Haematology* 1996, **94**; 159-165.

57.2.7. **Hanley JP,** Jarvis LM, Andrews J, Dennis R, Hayes P, Piris J, Lee R, Simmonds P and Ludlam CA. Interferon treatment for chronic hepatitis C infection in haemophiliacs - Influence of virus load, genotype and liver pathology on response. *Blood* 1996, **87**; 1704-1709.

57.2.8. **Hanley JP,** Jarvis LM, Andrews J, Hayes P, Simmonds P and Ludlam CA. Treatment of hepatitis C infection in haemophiliacs; the Edinburgh experience. *Haemophilia* 1995, **1**, (Suppl. 4); 36-38.

57.2.9. **Hanley JP**, Dolan G, Day S, Skidmore SJ and Irving WL. Interaction of hepatitis B and hepatitis C infection in haemophilia. *British Journal of Haematology* 1993, **85**; 611-612.

Please provide the same details in relation to any other studies in which you were involved or articles you have published relevant to the Inquiry's Terms of Reference, including:

Your two papers in 1996 with Dr Rosemary Dennis and others on chronic hepatitis C infection in haemophiliacs and Interferon treatment in haemophiliacs.

57.3. This paper reported the experience of interferon treatment for chronic HCV in a group of 31 patients in Edinburgh. 24% of the group cleared the HCV infection.

Your article titled 'Haemophilia And Liver Disease - New Directions in Diagnosis, Management and Treatment', ACP News, 1995 [DHSC0003986_053].

57.4. I was awarded a travel grant by the Association of Clinical Pathologists to attend a meeting about hepatitis C. A stipulation of the award was to provide a report for the ACP news bulletin. This article is a summary of what I learnt at the meeting.

Your article titled 'What is Interferon' in the Haemophilia Society Bulletin, 1995 [HSOC0022987].

57.5. I was asked to write an article about interferon for the haemophilia society bulletin which was aimed at patients and families to aid their understanding.

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

58.1. I think I have already answered this question. I was involved with collection of clinical data which was not regarded, at the time, as the type of research which required express consent by individual patients.

59. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or shared with third parties without their express consent? If so, please explain what data was used, and how/why it was shared.

59.1. No.

Section 5: Current care at the Newcastle Haemophilia Centre ("Newcastle")

60. Please describe:

a. how the provision of care and treatment for bleeding disorders is currently organised at Newcastle; and

b. your current roles and responsibilities at Newcastle.

60.1. a) The haemophilia service in Newcastle is based at the Royal Victoria Infirmary. There is a dedicated haemophilia centre which provides a service for the region serving a population of over 3 million. Newcastle haemophilia comprehensive care centre is staffed by 3 consultant haematologists, 3 haemophilia nurse specialists

(funding has been approved for a 4th nurse specialist), 2 staff nurses, 1 healthcare assistant, 1 physiotherapist, a clinical psychologist and a social worker (post currently vacant). Care is provided for both children and adults. Children are seen within the Paediatric part of the hospital. There is close working with a number of departments. Joint clinics are held with infectious diseases for the care of patients with HIV/HCV. There are also joint clinics with orthopaedics, obstetrics and gynaecology. There is a weekly multi professional team meeting. The service is supported by a coagulation laboratory which performs all the relevant laboratory tests to diagnose and monitor patients with bleeding disorders.

60.2. Patients have direct ask access to the haemophilia centre Monday to Friday during the day. Out of hours children have direct access via Children's Emergency Department and adults go direct to the adult haematology ward for assessment.

60.3. The Haemophilia centre is part of the Department of non- malignant haematology which is within the directorate of cancer services and clinical haematology.

60.4. The service was assessed as part of the UKHCDO/QRS peer review in 2019. The report is available: https://images.qualityreviewservicewm.nhs.uk/wp-content/uploads/2020/04/28112022/20190719-IABD-Newcastle-Final-Report-V1.pdf

60.5. b) I have been Co-Director of the Newcastle haemophilia centre since my appointment in 2001. Previously I took the lead for children but more recently I have mainly looked after young adults.

61. Please outline the treatments currently provided to patients with bleeding disorders at Newcastle.

61.1. For patients with haemophilia A treatments include recombinant factor VIII (including extended half-life products), Emicizumab or DDAVP (for non-severe haemophilia A).

61.2. For haemophilia B recombinant factor IX including extended half-life products are used.

61.3. Patients with von Willebrand's disease received DDAVP or von Willebrand factor plasma derived products. Recently recombinant von Willebrand factor has become available.

61.4. For inhibitor patients Emicizumab is now routine if there is a persistent inhibitor. Bleeding in inhibitor patients is managed with recombinant factor VIIa.

62. Please describe how you typically obtain your patients' consent to treatment. In particular:

a. What information is provided to patients by you or others regarding the risks, benefits and potential side-effects of treatment options?

b. What information is provided to patients by you or others regarding the consequences of forgoing treatment?

c. How is patient consent typically recorded?

62.1. Over the last 20 years the approach to patient consent has evolved considerably. This is in recognition that the care of a patient with a life-long condition requires a shared approach between the patient/family and the haemophilia centre team. So consent isn't viewed as a "one off" signature but more of an ongoing dynamic process between the parties involved. This is perhaps best illustrated by the way we discuss the pros/cons of different approaches to treatment as the options have become wider and the decision-making process more complicated and individualised.

62.2. In terms of the documentation of this process, this is widely documented in the medical record. There is also some formal documentation and patient signatures for example, WITN5572002

63. Do you routinely take blood samples from patients attending Newcastle? If so, what information is provided to patients by you or others about the purposes for which the samples are being taken? Do you obtain patients' consent to the storage and use of the samples and if so, how?

63.1. Blood samples are taken on a regular basis for clinical follow up. The reasons for particular blood tests are explained to patients/parents on an individual basis. Written consent is taken for any genetic testing but not for routine or diagnostic blood tests. There is no storage of samples.

64. If applicable, how many current patients at Newcastle were infected with HIV, HCV, HBV through blood products or were co-infected with HIV and HCV through blood products?

64.1. Currently there are 7 patients with HIV (all co-infected) and 39 patients with previous HCV infection who have responded to treatment. There are now no patients who are still positive for HCV RNA by PCR.

65. What if any involvement do you have in the treatment of Newcastle's patients for HIV and/or HCV and/or HBV? Are there multidisciplinary clinics (e.g. haematology and hepatology), and if not, would such arrangements be beneficial?

65.1. There is a joint clinic in the haemophilia centre for patients with HIV/HCV run by my colleague Dr Kate Talks (Consultant Haematologist and Co-Director Newcastle Haemophilia Centre) and Dr Matthias Schmidt (Consultant in Infectious Diseases)

66. What if any psychological services are available at Newcastle to patients infected with HCV/HBV/HIV?

66.1. Patients are supported by all members of the multi-professional team including Clinical Psychologist and Social Worker.

67. What has been the impact of the infection of patients with HIV and/or hepatitis through blood products:

a. upon patients at Newcastle (without identifying any individual patient); and

b. how treatment is decided, arranged and provided at Newcastle?

67.1. a) There was a devastating impact on patients and families in Newcastle with many deaths in the 1980s from AIDS. Most patients with HIV died before they could benefit from modern antiretroviral therapy. The impact of HCV has been massive also in terms of morbidity and mortality. Many patients and their families have also had to deal with discrimination and stigma.

67.2. b) The management of HIV is led by the infectious diseases team. In recent years there has been increasing involvement of the hepatology team in managing patients with HCV who have not responded to previous treatments.

68. Has the infection of patients with HIV and/or HBV and/or HCV through blood products:

a. changed or influenced your professional practice and approach, and/or that of your colleagues, and if so, how?

b. changed or influenced the practice and approach of your colleagues and if so, how?

68.1. a and b) The impact of contaminated blood has influenced the development of professional practice for myself and other haematologists and all who work in haemophilia centres in a highly significant way. In many ways the multi-professional team working which was pioneered in haemophilia centres has spread out to all areas of the NHS and has also influenced practice in other countries. The importance of being completely patient-focussed and sharing uncertainty as well as working within robust Clinical Governance arrangements have all been influenced by the lessons from the contaminated blood disaster and the downstream consequences. I think it's fair to say that the way vCJD was handled was as a result of the lessons learnt from HIV/HCV.

69. Please provide (to the extent that you are able to from your own knowledge) a chronological account of the introduction of recombinant products in the UK. You may be assisted by consideration of the various UKHCDO minutes enclosed with this letter. Additionally, you may also wish to consider the enclosed documents relate to a judicial review claim made by Peter Longstaff regarding access to funding for recombinant Factor VIII [DHSC0006924_048; DHSC0010313_002 & DHSC0010314].

69.1. I can't recall the exact date when recombinant products were approved for children. I think this had already happened by the time I started in Newcastle in 2000. There was a strong clinical view supported by all the doctors involved in the UKHCDO that all patients should receive recombinant products as soon as possible. There was eventually a phased roll-out from 2003 onwards. I think this was driven by cost rather than any clinical considerations. In Newcastle the roll out was done very quickly as soon as there was approval. In addition there were strenuous efforts to get approval for a particular patient who was declining treatment with plasma derived products. This request was repeatedly declined by local commissioners.

70. The enclosed minutes from a meeting of the UKHCDO Advisory Committee held on 29 November 2004 record a discussion on recombinant products for adults in England [BART0000926]. Whilst you were not present at this meeting, were you familiar with the concept of 'prescribing freedom' referred to on page 2 of the minutes in the context of recombinant Factor VIII products in the UK? If so, please explain this concept as you understood it to be, and how it applied to the rollout of recombinant Factor VIII products.

70.1. I think this referred to being able to prescribe any of the available recombinant products. There was a view (which I agreed with) that it was sensible to have access to all the products in case of supply problems (which subsequently happened with Kogenate).

71. Please explain your involvement, and that of UKHCDO, with efforts to obtain recombinant blood products for patients with haemophilia. What difficulties were encountered and why?

71.1. I have partly answered this in Q69. At a national level the UKHCDO had been lobbying for access to recombinant products for a number of years. This included multiple meetings with Department of Health officials and the issuing of recommendations based on the safety and clinical benefits which were clear to all the doctors involved in the care of patients with haemophilia. At a local level we were constrained by the national position but as I mention above we lobbied on behalf of individual patients.

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

72.1. Yes. There was no clinical justification for the delay in using recombinant products in the UK. They should've been made available for all adults as soon as they were licensed.

73. When were recombinant products available to patients (and which categories of patients) treated at the Newcastle Centre?

73.1. This was as per the national roll out in age bands which happened in 2004/2005.

74. The enclosed minutes of a meeting of the UKHCDO Advisory Committee held on 26 March 2001 record that a policy was agreed for which categories of patients should be treated with recombinant Factor VIII [BART0000937]. Please confirm whether this policy was adopted at the Newcastle Centre and explain which categories of patients were treated with recombinant Factor VIII (if any) and if they were, how these recommendations were decided.

74.1. These minutes are about a meeting which was convened to discuss how to cope with the shortage of recombinant factor VIII which resulted from the unavailability of Kogenate. The Newcastle centre followed the UKHCDO recommendations.

75. Please consider the enclosed minutes from a meeting of The Newcastle upon Tyne Hospitals NHS Trust ("the Trust") and other stakeholders on Recombinant Factor VIII for Haemophiliacs held on Friday 28 June 2002, at which you were present [HCDO0000264_042].

a. What were the 'current safety concerns' raised by Haemophilia Action UK with regard to factor VIII concentrate? How were these concerns addressed by the Trust?

b. Please comment on Ms Grayson's comment that plasma manufacturing companies were 'violating patient safety' and risking further infection amongst haemophilia patients (p1), and Mr Longstaff's comment that a 'black market' of recombinant Factor VIII products existed in Wales and Scotland (p2). To your knowledge, what was the basis for their concerns? Did you share these views?

75.1. a) I think the safety concerns were related to the concern about ongoing use of plasma-derived products. To move to recombinant products was not a decision that was in the gift of the Trust as this was a national decision by the Department of Health.

75.2. b) In 2002 all plasma derived products in use were subjected to virus inactivation. My safety concern was that this did not necessarily protect against some viruses or new pathogens. This was the main argument in favour of recombinant products. I agreed with this (as did all Doctors at this time). The issue about a black-market in recombinant products was aired but there was no evidence that I was aware of that this was happening in Newcastle.

Section 6: UKHCDO

76. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups). Did you usually attend the annual general meetings?

76.1. Following my appointment as Consultant Haematologist in Newcastle I started attending the UKHCD0 National advisory committee. All the comprehensive care centres (CCCs) were represented at these regular meetings. There was also a representative from smaller haemophilia centres. I have been a member of a number of UKHCDO working parties or task forces. A convened a group to draw guidelines for the emergency care of patients with bleeding disorders. I chaired the musculoskeletal working party and we published guidelines on the assessment and management of haemophilia joint disease. Most recently I chaired the peer review working party. For many years the UKHCDO coordinated external audit visits to CCCs. The peer review working party built on this experience and established a joint process with the Quality Review Service (formerly the West Midlands Quality Review Service which is a NHS peer review organisation). The peer review working party brought together representatives from all the professional groups involved in the care of patients with bleeding disorders in addition there were patient representatives and the Haemophilia Society. Together we drew up a set of quality standards which were then used as the basis for period you visit. A total of 37 visits were undertaken and the individual reports as well as an overview reports are available on the QRS web site.

76.2. I have attended most of the annual General Meetings since 2001.

77. During the period that you belonged to UKHCDO, please outline:

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

b. Any personal involvement in the development of policies or advice by UKHCDO which are relevant to the Inquiry's Terms of Reference.

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

77.1. a) The main purpose of the UKHCDO is to improve the care available for patients with haemophilia and related bleeding disorders and their families. It brings together health care professional working in different parts of the UK and promotes good

practice. This is under-pinned by collection of data and the writing of good practice guidelines and recommendations. The UKHCDO also established the collection of the data on the treatment of haemophilia which has evolved into the National Haemophilia Database. Over the years this has been crucial to driving forward improvements in haemophilia care.

77.2. b) I have outlined my involvement in the development of policies and advice by the UKHCDO. I do not think any of these areas are directly relevant terms of reference in relation to infected blood. However, the peer review recommendations are very relevant to promoting high quality care for patients with bleeding disorders in the UK and implementation of the Peer Review recommendations would go a long way to filling the gaps in care which exist in some parts of the UK. The overview report is available: https://qualityreviewservicewm.nhs.uk/news/overview-report-inherited-and-acquired-haemophilia-and-other-bleeding-disorders/

77.3. c) Since my involvement with the UKHCDO, information and advice has been disseminated by email and letter to all UKHCDO members. In addition, the UKHCDO web site has open access to all guidelines. Over the last 20 years the UKHCDO has worked hard to be an open and inclusive organisation. In recent years the annual meetings have been extremely well attended.

Section 7: Pharmaceutical companies/medical research/clinical trials

78. Have you ever:

a. **provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?**
b. **received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture of sale of blood products?**
c. **sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?**
d. **received any financial incentives from pharmaceutical companies to use certain blood products?**
e. **received any non-financial incentives from pharmaceutical companies to use certain blood products?**

f. received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?

g. undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products?

h. provided a pharmaceutical company with results from medical research studies that you have undertaken?

If so, please provide details.

78.1. a) No.

78.2. b) No.

78.3. c) No.

78.4. d) No.

78.5. e) No.

78.6. f) No.

78.7. g) I have been involved with several clinical trials sponsored by the pharmaceutical companies. All these trials have been through an ethical approval process and conducted according to good clinical practice under the research governance framework within the NHS.

78.8. h) No.

79. At any of the institutions at which you have worked, what regulations or requirements or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

79.1. There has been a requirement for a number of years to declare any financial support from pharmaceutical companies in the Newcastle Hospitals declaration of interest register. I have declared any support I have received to attend educational meetings.

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

80.1. Yes.

Section 8: Interaction with the financial assistance trusts and schemes

81. Please explain as fully as you can any involvement you have had in relation to any of the 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 assistance to people who had been infected. Relevant involvement may include:

a. Occupying a formal position with any of the trusts or funds;

b. Providing any advice to any of the trusts or funds, including for the development of any eligibility criteria or policies;

c. Informing patients about or referring patients to the different trusts or funds;

d. Determining or completing any part of applications made by patients.

81.1. a) I have not had a formal position with any of the trusts or funds listed.

81.2. b) I have not been involved in providing advice to any of the trusts or funds listed.

81.3. c) In Newcastle we have made any information about assistance available from all the trusts and funds to eligible patients and their families. Our social worker has provided support for applications and other members of the team have also been involved if required.

81.4. d) I have completed Skipton fund and EIBSS applications on behalf of patients or relatives.

82. The enclosed minutes from a meeting of the UKHCDO Advisory Committee held on 19 September 200 record a discussion about ex-gratia payments for HCV [BART0000928]. Various concerns were raised regarding the way in which the scheme was structured, and the exclusion of some categories of patients from the scheme. Please explain:

a. **The nature of these concerns and any other perceived issues with the ex-gratia payment scheme;**
b. **Whether you shared these views; and**
c. **Any steps taken to address these concerns.**

82.1. There was concern from many members of the UKHCDO that some patients would be excluded from payment and that this was potentially unfair. This was particularly in relation to individuals who were anti HCV antibody positive but HCV RNA negative by PCR. It was felt that the impact of previous HCV infection, even for individuals who had spontaneously cleared the virus, was being underestimated by the criteria being used to determine eligibility for payment. For example, some patients suffered considerable anguish in the years of uncertainty about whether they would suffer any ill effects from the previous HCV infection. This included an impact on both physical and mental health. In addition, some patients took very significant decisions in relation to personal relationships and whether to have children on the basis of the anti-HCV antibody results. To exclude them from any compensation scheme seemed very unfair. In other words, there was a view (which I supported) that it was an over-simplification to view the impact of HCV infection just in terms of liver damage. Apart from the voicing this concern at UKHCDO meetings, I wrote to the Skipton fund on behalf of individual patients. I do not think the Skipton fund rules allowed sufficient flexibility in relation to a fair assessment of the overall impact of hepatitis C in some patients.

Section 9: vCJD

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

83.1. I became aware of a variant CJD from the medical journals I was reading in the 1990s. From an early stage there was a concern that vCJD might be transmitted through bloods and blood products.

84. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so, please answer the following questions:
a. **What steps were taken/put in place a process at Newcastle, or any of the institutions at which you have worked, for informing patients about the risks of or possible exposure to vCJD?**

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

c. **The enclosed minutes from a meeting of the UKHCDO held on 26 June 2009 discuss how information surrounding the risks of vCJD should be communicated to patients [page 3 of HCDO0001030]. Did you agree with this view? Please describe your/Newcastle's approach to communicating information about vCJD to patients.**

d. **Please consider the enclosed minutes from a meeting of the UKHCDO Advisory Committee held on 16 February 2004 [BART0000930]. The minutes record a discussion on vCJD in which it was stated that 'patients were aware of the risk of vCJD from blood products and this was a source of anxiety to them.' Did any of your patients or their parents ever raise concerns surrounding this risk with you? If so, what steps did you/ Newcastle take to manage their concerns?**

84.1. a-d) I started working in Newcastle in early January 2001. This coincided with information about batches of BPL products having been manufactured from a plasma pool which included donations from blood donors who subsequently developed variant CJD. After discussion with other members of the haemophilia centre team I took the decision to write to all patients to let them know about this information and share with them all the available details. Some patients and parents were understandably very worried about this and they were offered support by myself and other members of the haemophilia team. Some patients who had lost relatives as a result of HIV or hepatitis C infection were particularly upset. Some patients/parents wanted to know all the details whereas others preferred not to receive any additional information. Patients were given the choice of either receiving information face-to-face in clinic appointments or by letter. I had many conversations about variant CJD with individual patients/parents. Most of these conversations were sharing the enormous uncertainty about risks of vCJD. It has only been with the passage of time and the lack of any cases of vCJD in the recipients of plasma products a degree of reassurance has become possible.

84.2. Patients/parents received support from all members of the haemophilia team.

85. What measures were put in place in terms of information sharing and risk at any of the institutions at which you have worked in relation to vCJD? In answering this question, you may wish to consider the enclosed minutes of a meeting of the Working Party on Paediatric FFP held on 1 July 2002 [NHBT0043645_004] at which a discussion occurred about the knowledge of the risk of vCJD transmission by blood products and the risk levels associated with various blood products. Further, you may be assisted by the enclosed letter from Professor Jeffries to you dated 13 October 2003 concerning vCJD risk assessment and communication of potential exposure to patients.

85.1. In line with the national recommendations any recipients of the implicated batches were considered "at risk of secondary transmission for public health purposes". This led to issues around disposal of surgical instruments or quarantining of endoscopes.

85.2. The issue discussed in NHBT0043645_004) was not related to haemophilia but the issue of the use of blood products in children and whether MB (Methylene Blue) FFP should be used. My colleague Dr Wallis was the transfusion lead and presented a compelling argument that MB FFP was not a good option at this time which myself and the others involved in the discussion supported. The minutes represent an accurate summary of the discussion.

86. Please consider the enclosed letter from Dr Hill to you dated 14 February 2001 [NTHT0000005_003]. As far as you can recall:

a. Please explain the context of this letter. If your original letter to Dr Hill is in your possession, please provide a copy.

b. Upon commencing your position as a consultant haematologist at Newcastle, what were the 'difficulties' you encountered, as described by Dr Hill? What steps were taken by you/Newcastle to resolve these issues?

c. Please explain the advice given by the Department of Health regarding patient notification, and whether, in your opinion, it was the correct course of action. What could or should have been done differently?

86.1. a) I enclose the letter I wrote to Dr Hill at WITN5572003. I was a newly appointed Consultant and I asked him for advice.

86.2. b) I think the "difficulties" refer to previous decisions about how to communicate concerns about vCJD to patients/families. I don't think these difficulties were unique to Newcastle.

86.3. c) This happened before I was appointed so it's difficult to say if I would have acted differently. My general view is that all information should be openly shared with patients.

Section 10: Look-back and tracing exercises

87. In as much detail as you are able to, please explain your knowledge and involvement in hepatitis (of any kind) look-back or tracing exercises. You may be assisted by the enclosed minutes of a meeting of the UKHCDO held on 3 October 2011, which discusses plans for an HCV look-back exercise by all UK Haemophilia Centres [HCDO0000510].

87.1. In Newcastle every effort has been made to identify all the patients with bleeding disorders who received plasma products which were potentially contaminated with HCV. When HCV testing was first available all patients registered with the centre at the time were offered testing. Subsequently there have been several systematic look-back exercises driven by the UKCHDO. This has involved trawling historical records recurrently to identify anyone who may have slipped through the net. Most recently there has been another effort to this. Some patients have moved and where possible they are identified by the NHS strategic tracing system and contacted. If there is no response, the GP is notified and the importance of offering testing for HCV highlighted.

88. In as much detail as you are able to, please explain your knowledge and involvement in HTLV-III/HIV look-back or tracing exercises.

88.1. A similar approach has been taken for HIV testing.

89. In as much detail as you are able to, please explain your knowledge and involvement in vCJD look-back or tracing exercises. You may be assisted by the enclosed letter dated 28 October 2007 in which Dr Chia wrote to you seeking information in connection with a patient's exposure to blood products carrying a potential risk of vCJD transmission [WITN1850015].

89.1. When the information about batches of concentrate which had been contributed by donors who subsequently developed vCJD became available, the recipients of the batches were identified form historical records. All patients were contacted and offered counselling and information about their exposure.

Section 11: Other Issues

90. 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.

90.1. I am not aware of any complaints made about me.

91. 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.

91.1. I would like to thank the inquiry for asking me to provide a statement. I hope my statement is helpful. The impact of contaminated blood on the haemophilia community has been beyond description. This was a true disaster and I hope the inquiry will shed light on the reasons it happened and put in place recommendations to ensure a similar event does not happen in the future. I am fortunate that my medical career coincided with huge improvements in the safety of treatment for bleeding disorders. I have been privileged to work at several haemophilia centres and I have learnt much from patients and families with haemophilia and other bleeding disorders. I am in awe of how patients and families with haemophilia have coped with all the adversity associated with contaminated blood. In many ways they have been let down and I hope this inquiry will bring justice for the haemophilia community. I would also like to pay tribute to the staff at haemophilia centres and my colleagues in the UKHCDO who have done so much to improve the quality of care for haemophilia in the UK and around the world.

91.2. A final comment about the approach to support for patients with bleeding disorders. I have been shocked on many occasions about how patients/families with bleeding disorders have suffered hardship as a result of how the benefits system has been applied. The worst example of this was a young man (who did not have virus infections) who was pursued by the DWP and had to appear in court on a charge of fraud. I appeared in court to give evidence on his behalf as did his mother. He was relieved to be acquitted by the magistrates. This was a terrible example of a patient with a bleeding disorder being "criminalised" because of his medical condition. The reason for this is that the DWP could not understand a condition which led to a marked variation in disability (depending on whether bleeding had occurred). So this young man was frantically trying to live a normal life, needed support to do so but was then persecuted by the authorities as a result! This persecution also extended to his mother who had to appear in court also. I mention this as the most extreme example I can give of how patients with haemophilia have been unfairly dealt with. I hope the public Inquiry will make some recommendations to avoid this type of experience in the future.

Statement of Truth

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

Signed: GRO-C

Dated: 19/4/2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
November 2016 (EHL) August 2019 (Emicizumab)	Consent forms for treatment with EHL and Emicizumab	WITN5572002
30th Jan 2001	Letter from John Hanley to Frank Hill	WITN5572003