Witness Name: Dr Simon Davies
Statement No.: WITN5590001
Exhibits: Nil
Dated:28th April 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF SIMON DAVIES

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 March 2021

I, Simon Davies, will say as follows: -

Section 1: Introduction

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

1.1. My name is Simon Vyvyan Davies and my date of birth was GRO-C 1958. My professional qualifications are as follows: BSc, MB BS, MD, FRCP, 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. I qualified as a doctor in 1982 after initial training at Guy's Hospital in London, completed general medical training and attained MRCP in 1985, and trained in haematology in Birmingham then Cardiff before my

permanent appointment in May 1995 as consultant haematologist at Musgrove Park Hospital Taunton, with duties at Yeovil District Hospital.

2.2. During my period as a trainee in Cardiff, I worked as a locum consultant haematologist between December 1992 and January 1994, with duties in the haemophilia Centre at University Hospital of Wales. I was director of the haemophilia Centre at Musgrove Park Hospital, Taunton between May 1995 and January 2021, when I retired.

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

3.1. I was a member of the British Society for Haematology between 1987 and 2021. I was a member of the UK Haemophilia Centre Directors (later Doctors) Organisation (UKHCDO) between 1992 and 2021. Between 1995 and 2001 I acted as the South West Region representative for UKHCDO. I was a member of the UKHCDO working party on haemorrhagic diseases in women between 1998 and 2002. I was a member of the South West regional haematology committee between 1995 and 2009 and chaired the committee between 2006 and 2009. I was a member of the haemophilia subgroup of the South West regional haematology committee from 2001 and remained in this group when it became the regional specialist commissioning group (haemophilia). The group later became a haemophilia network group related to the Bristol Comprehensive Haemophilia Care Centre.

4. **The Inquiry is aware of your involvement in the South West Haematologists Group. Please set out the dates of your membership; the nature of your involvement; your fellow members and the purpose of the Group.**

4.1. The South West regional haematologists' committee was originally formed to enable distribution of Regional Health Authority funding for the

development of haematology in the South West, and also served as a networking meeting for the single-handed haematologists found in many South West hospitals until the late 1980's. The financial component of the committee's function appears to have ended in the mid-1990s, prior to my joining the group in 1995. All haematologists in the South West were invited to become members, and meetings were held on a six-monthly basis, usually in Taunton, because of its central geographical location within the region. When I joined the group, it was well-attended by a high proportion of consultant haematologists in the South West and remained a valued meeting to discuss common issues of the day, to pursue collaborative work in clinical trials (mainly in haematological malignancies) and to carry out regional audits of clinical and laboratory practice (e.g., South West regional audit of treatment of patients with Hodgkin lymphoma). The six-monthly meetings were frequently accompanied by a lecture by an invited speaker. A subcommittee of haemophilia treating doctors was established and this would often meet on the same day as the six-monthly regional haematology committee meeting. Attendance at the regional haematology committee fell progressively during the early 2000's, eventually reaching unsustainable levels by 2009 when the group was disbanded. There was, however, agreement among haemophilia treating doctors that there was significant mutual benefit in continuing to meet despite the demise of the RHC. In early meetings of the haemophilia group, we invited attendance by health commissioners and in later years the meetings were organised and facilitated by a succession of specialist commissioning groups related to the evolving NHS structure. Much of the later effort in this group was concerned with implementing the National commissioning of blood products for haemophilia. In parallel, as a group, we were concerned with quality of care and carried out our own audit of haemophilia centres using the prevalent National haemophilia audit tool. Later, when Bristol achieved Haemophilia Comprehensive Care status, the group continued as a haemophilia network group to support evolution of a hub and spoke model for haemophilia care, as currently operates in South West England.

5. **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.**

5.1. I confirm that I have not provided evidence to, nor been involved in, any other enquiries, investigations, criminal or civil litigation in relation to HIV, hepatitis B, hepatitis C, variant CJD in blood and blood products.

Section 2: Decisions and actions of the Taunton Haemophilia Centre ("the Centre")

6. **Please:**

a) **describe the roles, functions and responsibilities of the Centre during the time that you worked there.**

b) **outline the facilities and staffing arrangements for the care of patients with bleed disorders;**

c) **identify senior colleagues at the Centre 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.**

6.1. My answers to questions 6 through to question 127 refer to my time as consultant haematologist and haemophilia centre director at Taunton. I have made some additional comments under question 128 which relates to my period as locum consultant haematologist in the haemophilia

Centre at the University Hospital of Wales Cardiff between 1991 and 1993.

6.2. (6a) The Taunton haemophilia Centre ("the Centre") operated as a local haemophilia treatment Centre as defined in the 1993 health service guidance (HSG (93) 30). Most of the care required by patients with bleeding disorders living within the county of Somerset was provided by the Centre. Exceptions to this included some specialist surgical operations, for which patients were referred to other hospitals (for example the Royal Free Hospital for shoulder joint replacement in one patient). Also, patients with inhibitor problems were always managed principally at a Comprehensive Care Centre (CCC) (including Great Ormond Street Hospital and St Thomas's Hospital, and later, on achieving CCC status, Bristol Children's Hospital/Bristol Royal infirmary). Specialist laboratory work such as molecular genetic analysis was carried out in Sheffield, at the Royal Free Hospital, and in Oxford. Children with haemophilia or related disorders were seen in a joint clinic with paediatricians from 1995, and by about 2000, Bristol Children's Hospital had established visiting paediatric haemophilia sessions in Taunton such that I played no further part in Paediatric haemophilia care. Once the Bristol Centre achieved CCC status, all adult patients from the Centre with severe or moderately severe disease were offered shared care, which the great majority accepted.

6.3. (6b) When I joined the department in 1995, most of the medical elements of haemophilia care were delivered by an associate specialist in haematology (middle grade doctor), Dr. Elizabeth Thompson. Approximately 50% of her role was dedicated to haemophilia and related blood disorders. She ran a weekly clinic which included some children with their parents and saw most daytime patients that required ad hoc treatment or consultation between clinics. She was supported by an experienced nursing sister, who also ran the haematology daycare unit. The laboratory was experienced in the required range of specialist blood testing. There was evidence of excellent collaboration with specialist

medical colleagues in paediatrics, orthopaedics, gastroenterology, HIV medicine, and oral and maxillofacial surgery. There was a shared data collector who submitted regular information to UKHCDO. Access to physiotherapy, social work, were through the standard referral channels within the hospital. Over the period of my responsibility, there were a number of changes to this service, and these are detailed in my answers to question

7. Please describe:

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

b) your work at the Centre 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.

7.1. (7a) When appointed to Taunton I was one of three consultant haematologists in a department that had for many years (since the mid-1980s) had only two consultants in haematology. Prior to my appointment, care of haemophilia and related disorders had been shared between the two consultants Dr Stephen Johnson and Dr Malcolm Phillips, both providing supervision for an Associate Specialist Dr Elizabeth Thompson who ran the day-to-day haemophilia service. She saw most of the outpatients with bleeding disorders including at that stage a significant number of children. On appointment I became lead consultant for haemophilia and director of the haemophilia Centre which covered Taunton and Yeovil hospitals in providing for the care for a population of approximately 450,000 people within West, Central and South Somerset. My role formed a relatively small part (perhaps 20%) of a busy consultant haematologist role, sitting alongside my responsibilities in managing patients with leukaemia and related malignant blood disorders, anaemia and related general haematology disorders, and in supervising and supporting the haematology laboratory

service for Somerset. Dr Thompson continue to work alongside me for several years and provided invaluable support for me in settling into this aspect of my role. As I was able to take on a larger role in haemophilia than had been possible for consultants in previous arrangements, I gradually assumed a significant proportion of the work that had previously been done by Dr Thompson. I developed a closer liaison with the children's department and established a joint Paediatric haemophilia clinic with Dr Timothy French and later with Dr Louise Newbury. Eventually, visiting Paediatric haemophilia specialists from Bristol took my part in these clinics and I stepped back from paediatric haemophilia care. When Dr Thompson retired, she was replaced by an extra trainee and a new consultant with a broader remit in haematology. In this way I became the only doctor with dedicated time for haemophilia care, supported by my two, (later four) consultant haematologist colleagues for out of hours situations or if I was away. When Bristol acquired comprehensive haemophilia care status, I was able to draw increasingly on their support for decision-making in difficult cases then later establishing formal shared care arrangements for the small group of severely affected, and moderately severely affected local patients (numbering between 10 and 15 throughout my tenure in Somerset).

7.2. (7b) When I arrived in Somerset in May 1995 there was an efficient process in place to:

7.2.1. systematically test untested patients for evidence of hepatitis B, C and HIV

7.2.2. regularly re-test patients as part of follow-up procedures, usually on the day of attendance for clinic appointments

7.2.3. vaccinate all patients against hepatitis A and B.

7.2.4. regularly reassess hepatitis B immunity by blood testing with a view to revaccination by booster doses where immunity was suboptimal.

7.3. Patients with hepatitis and or HIV were managed in collaboration with hepatitis and HIV specialists (consultants and specialist nurses in gastroenterology, and genitourinary medicine).

8. **Approximately how many patients with bleeding disorders were under the care of the Centre when you began your work there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so). In answering this question you may wish to consider the Audit Report of Taunton from 1991 [TSFT0000002_086]; the Audit Report of Taunton/Yeovil from 1998 [TSFT0000002_070] and the letter from you to Dr Majumdar dated 16 July 1999 [TSFT0000002_073].**

8.1. Approximate patient numbers under the care of the Centre between 1995 and 2020 were as follows: haemophilia A, 26 to 34 patients (3 to 5 severe, 3 to 5 moderately severe, 20 to 25 mild); haemophilia B, 9 or 10 patients (3 to 4 severe and moderately severe); von Willebrand disease 180 patients, other single factor deficiencies 12 to 14.

9. **To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centre, 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, 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? You may find it helpful to refer to the Audit Report of Taunton from 1991 [TSFT0000002_086].

9.1. (9a) From appointment in Taunton in May 1995 I took the lead in decisions about selection of blood products used in haemophilia care. As an active member of UKHCDO I was aware of national guidance on treatment of bleeding disorders and followed this where practicable throughout. Later in my time in Taunton, National procurement of blood products came in, and products were allocated based on a national agreement: in this phase I was still able to have some influence over product choice for local patients, and always tried to follow the important principle of keeping changes in product within individual patients to a minimum.

9.2. (9b) I believe that the regional health authority and or area health authority may have played a part in decisions on the arrangements for the selection, purchase or use of blood products in the early years of my post, but do not know how this process worked, and never experienced any barrier being placed to prescribing any specific treatment. Prior to national commissioning, regional specialist commissioning of blood product procurement took place, but I do not remember how that process influenced arrangements for the selection, purchase or use of the

products. Other Centres in the same region did not play any part in the Centre's arrangements for the selection, purchase or use of blood products.

9.3. (9c) The main considerations that led to the choice of one product over another were patient safety and effectiveness of treatment. Availability of the product could also be an issue. National guidance by UKHCDO covered these considerations and I followed this where practicable throughout.

9.4. (9d) I do not believe that financial and/or commercial considerations influenced my ability to follow national (UKHCDO) guidance on choice of use of blood products, except in so far as recombinant factors were only introduced in England for all patients in 2003 after specific national funding had been allocated, and I believe that this was some time after initial recommendations by UKHCDO.

9.5. (9e) When a change in National guidance on choice for use of blood products was being implemented, I would make a written request to the hospital trust (via my clinical Director) to make this change. I do not remember such a request ever having been refused or delayed. In fact, we had transferred all haemophilia A patients to recombinant factor VIII by December 1997 and transferred haemophilia B patients in 2003.

9.6. (9f) I have described which products or treatments were generally used for treating the subcategories of hereditary bleeding disorder in my answer to question 10.

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

10.1. There follows a summary of the concentrated blood products used in the Centre for the main categories of inherited bleeding disorder patients between 1995 and 2021.

10.1.1. Haemophilia A (severe): BPL high-purity factor 8 (8SM, replenate) 1995 to 1998, recombinant Factor 8 (helixate, refacto) from 1998. New products for severe haemophilia A were being introduced during the last year of my tenure, but this was in all cases directed by, and prescribed by the Bristol CCC.

10.1.2. Haemophilia A (mild and moderate): as for severe haemophilia A but also including DDAVP.

10.1.3. Haemophilia B: BPL high-purity factor 9 (NHS 9A, replenine, alphanine), recombinant factor 9 (benefix) (from 1998), NB benefix was not effective in preventing bleeding in all patients, and two patients reverted to replenine and alphanine respectively). New products for severe haemophilia B were being introduced during the last 2 years of my tenure, but this was in all cases directed by, and prescribed by the Bristol CCC.

10.1.4. Von Willebrand's: DDAVP, BPL intermediate purity factor VIII (8Y), haemate P, wilate

11. What was the relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre 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.

11.1. Between 1995 and 2007 I regularly saw representatives of pharmaceutical companies related to haemophilia and to other aspects of clinical haematology. Visits from most companies were at a maximum of twice per year and took place at my office in the haematology department, Musgrove Park hospital on an appointment basis. In

general, these were 10-to-15-minute visits and usually of educational value as representatives would bring copies of peer-reviewed articles relevant to their products. Many of the companies would offer patient educational information, some of which was offered to patients if felt to be of a satisfactory quality. I attended several international conferences as a result of sponsorship for hotel accommodation and travel from pharmaceutical companies, all of which was declared to the Trust hospitality register, and which complied with NHS standards of business conduct. The international conferences attended between 1995 and 2021 and the sponsors are listed below:

11.1.1. 1997 ISTH Florence sponsored by Aventis Behring.

11.1.2. 2003 ISTH Birmingham, UK sponsored by Aventis Behring.

11.1.3. 2006 World Federation of haemophilia, Vancouver, Canada sponsored by Bayer.

11.1.4. 2012 World Federation of haemophilia, Paris, France sponsored by Bayer, Novo and Grifols.

11.1.5. 2012 ICTHIC Bergamo, Italy, sponsored by Leo.

11.2. When I became Clinical Director for Haematology and Oncology in 2007, I chose to stop seeing representative of pharmaceutical companies mainly because of time limitations in my programme. I did not resume offering appointments to representatives for the remainder of my tenure, but instead asked that any representatives that contacted my secretary be asked to e-mail me, following which some would be asked to e-mail peer-reviewed literature about their products. I would also see a number of representatives at local or national meetings where organisers had allowed them to set up stands as part of a trade exhibition.

11.3. I do not feel that my relationships with the companies supplying and manufacturing blood products influenced my decisions on purchase and use of blood products at any time.

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

12.1. Responsibility for selection and purchase of blood products lay with the Centre until National procurement began.

13. Please describe your relationship/the Centre's relationship with the local Regional Transfusion Centre. Please explain whether the Regional Transfusion Centre supplied the Centre with cryoprecipitate and with NHS factor concentrates and whether (and if so to what extent and with what frequency) there were shortages or other difficulties in obtaining sufficient supplies. Please confirm whether the Regional Transfusion Centre had any involvement in supplying commercial factor concentrates or whether those were obtained from the pharmaceutical companies directly.

13.1. Bioproducts laboratory (BPL) manufactured several products used at the Centre in patients with haemophilia, as detailed in my answer to question 11. I do not know if they came to the hospital via the regional transfusion centre (RTC) in Bristol throughout, but I am aware that this was the route of supply for at least part of the period between 1995 and 2021. Cryoprecipitate was supplied to the hospital by the RTC although the Centre did not use this product for treatment of patients with haemophilia and related disorders during my tenure in Taunton. I do not remember that there were shortages or difficulties in obtaining sufficient supplies of BPL factor concentrates or cryoprecipitate. Commercial factor concentrates were obtained from the pharmaceutical companies directly.

14. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions? To what extent, if at all, were patients offered a choice as to which products to use?

14.1. Decisions on selection of products for individual patients at the Centre were made by me in discussion with the patient and followed national (UKHCDO) guidelines. Occasional patients had decisions on selection of blood products made elsewhere, such as children being managed by Bristol Children's Hospital, and two patients whose treatment had been started elsewhere and were continuing to have input to their care by a Comprehensive Care Centre elsewhere (both complex patients). In later years, patients with severe and moderate haemophilia who transferred to shared care with Bristol had their care prescribed by colleagues at the Comprehensive Care Centre.

15. What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders? What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Centre 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?

15.1. I began my consultant role in haemophilia in the 1990s and am not well-informed about the alternative treatments to factor concentrates that were available in the 1970s and 1980s, and their advantages and disadvantages. From the 1990s onward we would use DDAVP in preference to factor concentrate wherever possible (and clinically appropriate) in mild or moderately severe haemophilia A patients to reduce the risk of infection transmission. The same applied to von Willebrand disease. An increasing proportion of dental and other surgical patients with haemophilia were managed without factor concentrates or DDAVP, but with local haemostatic treatments only, through the course of my career in Taunton, with the aim of reducing any risk of transmission of infection and avoiding side-effects from DDAVP. The evolution of

subcutaneous preparations of DDAVP was also helpful in reducing the side-effects of this drug, when compared with the original intravenous formulation.

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

16.1. From May 1995 onward the Centre used DDAVP in preference to factor concentrate wherever possible (and clinically appropriate) in mild or moderately severe haemophilia A patients in order to reduce the risk of transmission of infection. The same applied to von Willebrand disease. An increasing proportion of dental and other surgical patients with haemophilia were managed without factor concentrates or DDAVP, but with local haemostatic treatments only, through the course of my career in Taunton, with the aim of reducing any risk of transmission of infection and avoiding side-effects from DDAVP. The evolution of subcutaneous preparations of DDAVP was also helpful in reducing the side-effects of this drug, when compared with the original intravenous formulation.

17. What was the Centre's 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? Did the policy and approach change over time and if so how?

d) How, if at all, was the policy and approach informed by discussions had with external parties?

17.1. (17a) The Centre did not use cryoprecipitate for the treatment of patients with inherited bleeding disorders during my tenure in Taunton. It was used for patients with acquired bleeding disorders, notably for cases with life-threatening coagulation disturbance characterized by low levels of plasma fibrinogen.

17.2. (17b) The Centre encouraged home treatment for all patients with severe bleeding disorders and this had been introduced before I began in Taunton.

17.3. (17c) The Centre encouraged prophylactic treatment for most patients with severe bleeding disorders during my tenure in Taunton. If this was started in childhood (for example a newly diagnosed case of childhood haemophilia) the choice of product and protocol would be discussed with and implemented by colleagues at the Children's Hospital in Bristol. In adults, prophylaxis began in some individuals before I came to Taunton. In others it was started after a serious bleed (for example a central nervous system bleed) or a series of bleeds affecting one joint (a so-called "target" joint). Some of these cases returned to on-demand therapy after a period of prophylaxis. Others remained on prophylaxis long-term, based on an assessment of the risk of (and the consequences of) further episodes of bleeding. The approach taken did not change during my time in Taunton.

18. What was the Centre's policy and approach in relation to home treatment? Did the policy and approach change over time and if so how?

18.1. The Centre encouraged home treatment for all patients with severe bleeding disorders, as a means of achieving excellent prophylaxis and thereby reducing the impact of haemophilia on the day-to-day life of a patient and their family. The policy was unchanged throughout my tenure in Taunton.

19. What was the Centre's policy and approach in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

19.1. The Centre encouraged prophylactic treatment for most patients with severe bleeding disorders during my tenure in Taunton. If this were started in childhood (for example a newly diagnosed case of childhood haemophilia) the choice of product and protocol would be discussed with and implemented by colleagues at the Children's Hospital in Bristol. In adults, prophylaxis began in some individuals before I came to Taunton. In others it was started after a serious bleed (for example a central nervous system bleed) or a series of bleeds affecting one joint (a so-called "target" joint). Some of these cases returned to on demand therapy after a period of prophylaxis. Others remained on prophylaxis long-term, based on an assessment of the risk of (and the consequences of) further episodes of bleeding. The approach taken did not change during my time in Taunton.

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

20.1. The approach of the Centre to the use of factor concentrates for children was guided by national (UKHCDO) guidelines and by advice from colleagues in the Children's Hospital in Bristol. This policy and approach did not change significantly between 1995 and about 2000, following which I played no role in managing paediatric haemophilia cases locally.

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

21.1. The approach of the Centre to treatment of patients with mild or moderate bleeding disorders followed National (UKHCDO) guidelines. The major principle was that wherever safe and effective alternatives to

factor concentrates were available, these should be used in preference. I believe that this was followed throughout.

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

22.1. I am not aware that any viruses or infections (other than HIV, HCV and HBV) were transmitted to patients at the Centre in consequence of the use of blood products.

23. Please describe the relationship between the Haemophilia Centres at the Westgrove Hospital and at the Yeovil District Hospital.

23.1. In answering this question, may I first assume that "West Grove Hospital" is a typographical error and that this should read "Musgrove Park Hospital (Taunton)"? In what follows I will describe the relationship between the Haemophilia Centres at Musgrove Park Hospital (Taunton) and at Yeovil District Hospital. The haemophilia service in Taunton and Yeovil was organised from Musgrove Park Hospital where the consultant haematologists are based. Most elements of the Somerset haemophilia service were delivered at Musgrove Park Hospital with the following exceptions, which were delivered at Yeovil District Hospital:

23.1.1. Some patients residing in East Somerset had some (occasionally all) of their outpatient reviews in my weekly clinic at Yeovil District Hospital.

23.1.2. Very occasional emergency treatments of patients with haemophilia (etc.) occurred at Yeovil District Hospital as the patients had been taken to the accident and emergency department there. Yeovil District hospital is 33 miles from Taunton.

23.1.3. Occasional minor surgical (including dental) treatment on patients with haemophilia (etc.) occurred at Yeovil Hospital with consultant haematologist input from Taunton.

23.1.4. To allow for treatments as in (b.) and (c.) small stocks of a limited range of specialist blood products were kept at Yeovil District Hospital.

Section 3: Knowledge of, and response to, risk

General

24. When you began work as a Consultant Haematologist at the Centre, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

24.1. When I began work as consultant haematologist in Taunton, I had already gained broad experience of haemophilia and related bleeding disorders as a trainee in Birmingham and Cardiff and also in particular as a locum consultant in Cardiff. I had worked as a locum consultant for approximately 12 months at the large haemophilia Centre at the University Hospital of Wales and had first-hand experience of the whole range of infections and other complications of haemophilia (and related disorders) and their treatment. I had had the benefits of the mentorship of Dr Has Dasani, an experienced expert in haemophilia, throughout my period as a locum. Dr Dasani had worked as a middle grade doctor with Professor Arthur Bloom for many years prior to Prof. Bloom's sudden and tragic death immediately prior to my taking up the locum position. I was also fortunate enough to receive several months teaching as a senior registrar from Prof. Bloom. I had previously attended a course on coagulation disorders at the Royal Free Hospital in London which included specific teaching on the risks of infection with blood products. Other sources of knowledge then, and later, were through reading and

attending meetings. In these ways I kept up to date with the evolving knowledge base on transfusion-transmitted infections in this patient group.

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

25.1. In a small Centre with approximately 10 severely affected patients with haemophilia, local decision-making was largely by discussion between me and local medical and nursing colleagues, always guided by national (principally UKHCDO) guidelines. I would occasionally make use of my network of contacts in the specialist haemophilia centres for further advice, and later when Bristol became a comprehensive care centre. I was grateful for the ready access which they gave me and my colleagues to 24-hour, 7-day specialist advice.

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

26.1. I believe that my experience as a trainee and locum consultant gave me a clear understanding of the relative risks of infection from commercially supplied factor concentrates and NHS factor concentrates. My training emphasised the importance of understanding in detail the geographical source of the plasma, whether donors were paid, the size of the plasma pool from which batches of concentrate were manufactured, and the manufacturing process including the viral inactivation steps that were used in the production of any concentrate that I or the Centre prescribed.

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

27.1. During my training and my consultant career, I kept up to date with relevant scientific and medical developments in knowledge by reading a

broad range of journals regularly and by attending local, national and occasional international meetings. Latterly web-based educational material became widely available and was valuable in expanding and maintaining my knowledge base. Journals I read regularly included: Blood, British Journal of Haematology, Haemophilia, Haemostasis and Thrombosis, Journal of Thrombosis and Haemostasis, New England Journal of Medicine, The Lancet, British Medical Journal.

Hepatitis

28. When you began work as a Consultant Haematologist at the Centre, 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?

28.1. (28a) When I began work at the Centre, because of my training and previous consultant experience, I believe that I was aware of the risks of transmission of viral hepatitis from blood and blood products.

28.2. (28b) When I began work at the Centre, because of my training and previous consultant experience, I believe that I was aware of the nature and severity of the different forms of blood-borne viral hepatitis.

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

29.1. My knowledge of hepatitis related to blood products came from my training in general medicine in the 1980s and from my training in haematology in the 1980s and 1990s. Experience gained as a locum consultant in the haemophilia Centre at the University Hospital of Wales in Cardiff added greatly to this knowledge.

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

30.1. I did not carry out any further enquiries and/or investigations in respect of the risks of the transmission of hepatitis.

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

31.1. By 1995, when I joined the Centre, a thorough programme of testing for hepatitis B and C had been instituted. In order to reduce the risk to further patients of being infected with hepatitis, hepatitis B vaccination was carried out in non-immune individuals, with booster vaccination as guided by national guidance at the time; exposure of patients to the minimum number of batches of plasma-derived blood products was encouraged; blood products were reserved for situations where no alternative existed; and when funded, adoption of recombinant therapy in place of plasma derived products was done in a timely manner.

32. 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?

32.1. Because of my training and previous experience in haemophilia, I believe that I had a broad understanding of the nature and severity blood-borne viral hepatitis at the start of my consultant career. I was also grateful for the support of excellent colleagues in gastroenterology/hepatology for management of the cases of viral hepatitis which I encountered.

HIV and AIDS

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

33.1. When I began work at the Centre, because of my training and previous consultant experience, I believe that I was aware of all the relevant aspects of current knowledge on HIV (HTLV3) and AIDS and their relationship to blood and blood products.

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

34.1. I do not recall exactly when I first heard of the association between AIDS and the use of blood products. Given that the earliest reports were in the literature in the early 1980s, and that I began training in haematology in 1985, I believe that I must have read or heard about this association while I was a general medical trainee studying for the membership of the Royal College of Physicians and working in teaching hospitals in London.

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

35.1. My involvement in haemophilia care started in the 1990s, by which time measures had been in place for several years to identify all individuals affected by HIV, to begin treatment and to implement measures to prevent any further infections.

36. What, if any, actions did you and/or the Centre take to reduce the risk to your patients of being infected with HIV?

36.1. My training in haemophilia care (in the early 1990s) emphasised the importance of avoiding blood product usage wherever satisfactory alternatives existed. While working at the Centre I always followed this approach, and in addition, where plasma-derived products were used, our approach was to minimise the number of batches to which any individual patient was exposed. Introduction of recombinant factors removed the remaining theoretical risk of transmission of HIV from the heat and solvent detergent treated factor concentrates that were in regular use when I joined the Centre.

37. Did the Centre continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

37.1. By the time that my consultant career began, large changes had already been made to the practices within haemophilia care aimed to prevent any further transmission of HIV by the medium of contaminated blood products. I am not able to answer this question for Taunton as it relates to aspects of haemophilia care from some years before I began working at the Centre in May 1995.

Response to risk

38. Did you or your colleagues at the Centre take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps? What information was provided to patients, and when, about such risks?

38.1. By the time that my consultant career began, large changes had already been made to the practices within haemophilia care aimed to prevent any further transmission of HIV by the medium of contaminated blood products. I am not able to answer this question for Taunton as it relates to aspects of haemophilia care from some years before I began working at the Centre in May 1995.

39. What, if any, actions did you and/or the Centre take to reduce the risk to your patients of being infected with HIV? What changes (if any) did you make to the way in which patients were treated?

39.1. By the time that my consultant career began, large changes had already been made to the practices within haemophilia care aimed to prevent any further transmission of HIV by the medium of contaminated blood products. I am not able to answer this question for Taunton as it relates to aspects of haemophilia care from some years before I began working at the Centre in May 1995.

40. Did the Centre continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?

40.1. By the time that my consultant career began, large changes had already been made to the practices within haemophilia care aimed to prevent any further transmission of HIV by the medium of contaminated blood products. I am not able to answer this question for Taunton as it relates to aspects of haemophilia care from some years before I began working at the Centre in May 1995.

41. When did the Centre 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.

41.1. I do not know when the Centre began to use heat-treated factor products as this change occurred several years before I was appointed to the Centre in 1995. I have been shown the report of an audit in 1991 which indicates that BPL 8SM and monoclate (both of which were heat-treated high-purity products) were in use at the Centre in 1991 alongside BPLVIII which I believe was not heat-treated.

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

42.1. I do not know when the Centre began to use heat-treated factor products and as such, cannot judge whether heat-treated products should have been made available earlier. These changes occurred many years before I started to work in the Centre.

43. Did you or your colleagues at the Centre revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

43.1. I do not know whether colleagues at the Centre had reverted to treatment with cryoprecipitate in the period in the 1980s when HIV transmission cases were being identified.

44. Do you consider that your decisions and actions, and those of the Centre in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

44.1. I do not know whether colleagues' decisions and actions were adequate and appropriate as they were taken many years before I joined the Centre.

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

45.1. I do not know which decisions or actions taken by the Centre could and/or should have been avoided or ended earlier, as these events took place many years before I joined the Centre.

46. 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?

46.1. I do not know what actions or decisions, or policies of other clinicians or other organisations played a part in or contributed to the scale of infection in patients with bleeding disorders. Neither do I know what, if anything, could or should have been done differently by these others.

47. Do you consider that greater efforts could and/or should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?

47.1. I do not know whether greater efforts could and/or should have been made to inactivate viruses in blood or blood products prior to 1980.

Section 4: Treatment of patients at the Centre

Provision of information to patients

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

48.1. Prior to commencing treatment for a bleeding disorder, the approach taken at the Centre was to give a full explanation face-to-face with the patient or parent, based on the understanding of risks and benefits of the treatment prevalent at that time. This was documented by hand in the patient's medical record.

49. 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.

49.1. The explanation given as part of the consent process for a new patient or new product for a patient at the Centre would include a discussion of alternatives to treatment with factor concentrates, where these were clinically appropriate in terms of safety and efficacy.

50. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients before they began home treatment/home therapy?

50.1. During my time in Somerset, I did not start any adult patient on home therapy. Children starting home therapy, and their families, were counselled by the paediatric haemophilia team from Bristol Children's Hospital, and I do not know what information was given.

HIV

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

51.1. During my time at the Centre, I did not deliver a diagnosis of AIDS or HIV to a patient.

52. Please describe how and when you learned that patients under your care/the care of the Centre had been infected with HIV.

52.1. When I started in Taunton in 1995 there was one patient with HIV under my care. The patient moved away from Somerset (and the UK) not long

afterwards, I believe in 1997. There were no further patients with HIV under my care between 1995 and 2021.

53. Please describe the arrangements that were made for the testing of the patients. Were they tested without their knowledge? What if any arrangements were made at the Centre for pre-test counselling?

53.1. Patients were tested regularly for HIV with their consent. When I started in Taunton patients were used to having regular hepatitis and HIV testing as this had been standard practice for some years previously. Regular HIV testing was discontinued when patients moved over to recombinant therapy.

54. What if any arrangements were made at the Centre for pre-test counselling?

54.1. It was the practice at the Centre to discuss any HIV test prior to taking a blood sample, explaining why the test was recommended and asking the patient how they would like to be informed of the result.

55. How and when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by phone? Were they seen individually or in groups? What if any involvement did you have in this process?

55.1. There were no new HIV positive results at the Centre between 1995 and 2021. In principle, if a positive test result had been obtained, the patient would have been asked to come to the hospital for a face-to-face discussion with a consultant haematologist followed by a same day visit to the HIV clinic.

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

56.1. Between 1995 and 2021 I did not convey a new HIV diagnosis to any of my patients. I am aware that several HIV diagnoses had been made at the Centre in the 1980s and do not know the exact wording that would have been used in conveying the diagnosis at this time.

57. What was the Centre's/your policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?

57.1. I do not remember if the Centre had a policy regarding testing partners/family members of people known or suspected to be infected with HIV. If that question had arisen, I would have taken advice from my specialist HIV consultant and nursing colleagues.

58. What, if any, information or advice was provided by you or colleagues at the Centre to partners or family members of people who were at risk of infection with HIV or were infected with HIV?

58.1. I do not remember if the Centre had a policy regarding the provision of advice and information to partners or family members of people who were at risk of infection with HIV or were infected with HIV. If the question had arisen, I would have taken advice from my specialist HIV consultant and nursing colleagues.

59. What if any arrangements were made at the Centre for post-test counselling?

59.1. The Centre's approach to post-test counselling for HIV tests was as follows: before samples were taken patients were asked how they would wish to be contacted in the event of a positive result. In the event of a positive result the patient would be contacted, and arrangements would be made for a face-to-face discussion with a consultant at the Centre, followed by a same day visit to the HIV clinic. This situation did not arise between 1995 and 2021.

60. How many patients at the Centre were infected with HIV in consequence of the treatment with blood products? In answering these questions you may wish to consider the Audit Report of Taunton from 1991 [TSFT0000002_086]. 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?

60.1. One patient with severe haemophilia A attending the Centre in 1995 was infected with HIV. The patient moved away from the Centre (and from the UK) shortly afterward. I have been shown an audit report from Taunton from 1991, prior to my starting at the Centre which indicates that two patients had died of AIDS before 1991. I do not know the nature of the bleeding disorder which these two patients suffered from. (TSFT0000002_086)

61. Was work undertaken at the Centre to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached.

61.1. I am not aware that any work was undertaken at the Centre to establish the time during which patients seroconverted to HIV.

Hepatitis B

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

62.1. No patients were infected with hepatitis B in consequence of their treatment with blood products at the Centre, to my knowledge.

63. **How many patients at the Centre were infected with hepatitis B? You might find it helpful to consider the Audit Report of Taunton from 1991 [TSFT0000002_086].**

63.1. There were no hepatitis B infection positive patients attending the Centre or registered with the Centre between 1995 and 2021. I have been shown an audit report from Taunton from 1991 and there were no hepatitis B infection positive patients attending the Centre at that time. (TSFT000002_086)

NANB Hepatitis/Hepatitis C

64. **Were patients 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 if any involvement did you have in this process?**

64.1. Awareness within haemophilia centres of transfusion transmitted NANB hepatitis preceded my career in haematology by many years. All Taunton patients with NANB hepatitis underwent testing for hepatitis C when this became available in the early 1990s. All hepatitis C positive patients were made as fully aware as possible about the potential

adverse consequences of their hepatitis and the treatment options available.

65. When did the Centre begin testing patients for hepatitis C and over what period of time were such tests first carried out? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What if any involvement did you have in this process?

65.1. I have been shown an audit report (TSFT000002_086) which indicates that the Centre began testing for hepatitis C in 1990 or 1991 which preceded my appointment in Taunton. I do not know about the process that was used at the Centre for communicating a diagnosis of hepatitis C at that time. I communicated one new positive diagnosis of hepatitis C between 1995 and 2021 (in 2019) and arranged that I saw the patient to discuss the diagnosis with a hepatology specialist nurse in attendance. The nurse then supported the patient by making herself available on the telephone, arranged a consultant hepatologist appointment within a few days, and with medical and specialist nurse colleagues, supported the patient through a course of anti-viral treatment.

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

66.1. I do not know what information was conveyed to the patients who were found to be positive for hepatitis C prior to my starting in Taunton in 1995. The practice at the Centre from 1995 was that all patients were made aware of the potential adverse consequences of their hepatitis, notably cirrhosis and hepatoma, and of the evolving available treatment options.

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

67.1. I believe that the programme of testing for hepatitis C at the Centre was started in 1990 or 1991 and that the Centre team believed that most patients had been tested before my appointment in Taunton. I am aware from audit data in 1996 (TSFT000002_015) and my own recollection, that a small number of individuals who had missed testing during this initial programme of testing, emerged over many years afterward. In two cases the diagnosis was made by the general practitioner in conjunction with a gastroenterologist and one patient declined testing until 2019, despite repeated offers by the Centre and by the GP. I was aware of only one untested individual at the time I left the Centre. The patient was at risk for having acquired hepatitis C from blood products given for haemophilia in the 1970s but did not attend appointments at the Centre. The patient lived locally but refused all attempts by the Centre and the GP to arrange hepatitis C testing.

68. How many patients at the Centre were infected with hepatitis C in consequence of their treatment with blood products? You might find it helpful to consider the Audit Report of Taunton from 1991 [TSFT0000002_086] and the South West Haematologist's Group HCV Audit Questionnaire dated March 1996 [TSFT0000002_015].

68.1. In 1996 I completed an audit report for the South West haematologists group stating that 16 patients were hepatitis C positive and that eight were untested at that time. By 2016 as a result of several patients moving away, and a number who had died, I recorded 7 hepatitis C positive patients attending the Centre. Of the patients who had died, 1 had a cause of death related to hepatitis C (hepatocellular carcinoma). Between 2016 and 2021 2 further patients had died, cause unrelated to hepatitis C, and 1 more hepatitis C positive patient had been identified.

Delay/public health/other information

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

69.1. The results of testing for HIV and hepatitis (of all kinds) were notified to patients promptly.

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

70.1. In deciding what information or advice to provide to patients or what treatments to offer to patients at the Centre, an assessment was made of the patient's needs based on our understanding of their medical condition.

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

71.1. Variant CJD risk was discussed with patients who had received UK sourced blood products between 1980 and 2001 once this risk became apparent. The process undertaken at the Centre is detailed below (questions 118 a to d).

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

72.1. Regarding transmissibility to others, I do not know the exact message that was given at the time of a diagnosis of hepatitis C when most diagnoses were made in 1990 and 1991. I note from the 1996 audit (TSFT 000002_086) submission that at that time condom use was only recommended for casual sexual partners of HCV positive individuals. I believe that this was on the understanding that hepatitis C transmission,

were this to occur in a long-term partner, would have occurred many years previously, as it was believed that most infections in this patient group occurred in the 1970s and 1980s. I do not remember discussing transmissibility with patients, although I feel sure that this would have come up in conversation during some consultations.

Consent

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

73.1. Blood samples were taken at each follow-up visit for viral testing (hepatitis B, C, HIV), for liver function testing and for full blood count (a test for anaemia). Viral testing was intended to identify any new transmission of hepatitis or HIV, and, in immunised individuals, to check ongoing immunity to hepatitis B. Samples were not stored, but consent to the above testing was obtained verbally at each visit.

74. Did the Centre have a bank of stored samples? If so, was that storage undertaken with patients' knowledge and consent?

74.1. The Centre did not have a bank of stored samples.

75. Were patients under your care or under the care of your colleagues at the Centre 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?

75.1. All patients gave fully informed consent before being treated with factor concentrates or other blood products. In recent years this was recorded using a standard written consent form.

76. Were patients under your care ever 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?

76.1. I am not aware that any patient was tested for HIV without consent. I believe that occasional patients were tested for hepatitis without fully informed consent in recent years when hepatitis testing became very widespread within haematology units.

PUPS

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

77.1. All previously untreated patients in Taunton or Yeovil were treated under the direction of the haemophilia team at Bristol Children's Hospital. I played no part in the selection of treatment nor in the administration of treatment to these patients.

Research

78. Please list all research studies that you were involved with during your time as a consultant at the Centre 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.

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.

78.1. I was involved in a small local study of adding amantadine treatment to interferon plus ribavirin treatment for patients with hepatitis C, starting in 2001.

78.2. (78a) The research aimed to identify any improvement in clearance of hepatitis C and increase in response rate to therapy attributable to amantadine.

78.3. (78b) The research was organised by my colleague Dr Stirling Pugh, consultant gastroenterologist. He obtained local ethical approval.

78.4. (78c) Some of my patients were recruited to the study. They were all patients known to Dr Pugh previously because they had been referred to his clinic for management of hepatitis C.

78.5. (78d) I do not know of any other organisations or bodies that were involved in the research.

78.6. (78e) I do not know how the research was funded.

78.7. (78f) I do not know how many patients were involved in total as patients with hepatitis C without blood disorders were being recruited. I think that four of my patients were involved.

78.8. (78g) Consent would have been taken by Dr Pugh as the study investigator.

78.9. (78h) I do not think the research was published. I have performed a quick Internet search which supports this.

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

79.1. I am not in a position to comment on whether patients were involved in research studies without their express consent. For the amantadine study referred to in question 78, I think this is very unlikely given the experience in research and excellent reputation of my colleague Dr Pugh. All clinicians engaged in research at Taunton hospital were required to complete research training (GCP training) including regular update training sessions. This training always emphasised the importance of fully informed consent There were no other research studies in the Centre.

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

80.1. Patient data held by the Centre was not used for the purpose of research or any other purpose without patients' express consent. However, I do

not know whether Centre data from the haemophilia national database (previously Oxford haemophilia database) was used without patients' express consent prior to the relatively recent discussions about consent requirements for this database.

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

81.1. Patient data held by the Centre was not shared with third parties without patients' express consent. However, I do not know whether Centre data from the haemophilia national database (previously Oxford haemophilia database) was shared with third parties without patients' express consent prior to the relatively recent discussions about consent requirements for this database.

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

82.1. I have not published any articles or studies insofar as they were relevant to the Inquiry's Terms of Reference.

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

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

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

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

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

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

83.1. (83a) There was only one patient with HIV/AIDS and haemophilia in Taunton during my tenure. This patient was already receiving specialist care from colleagues in genitourinary medicine when I arrived in Taunton. The patient left the area (and the country) before 1998.

83.2. (83b) The single patient with HIV/AIDS I encountered at the Centre was receiving antiretroviral therapy, but I do not know which drug or drugs were being used.

83.3. (83c) I do not know what information was provided to HIV/AIDS patients about the risks and benefits of specific treatments and side-effects as I have experience of only one patient. This patient was already on treatment when I began working at the Centre and left the area after a short time.

83.4. (83d) In the one case in which I was involved, HIV/AIDS care was provided by a specialist consultant in genitourinary medicine in Taunton.

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

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

b) What treatment options were offered over the years?

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

84.1. I did not encounter any patients with hepatitis B and haemophilia while working in Taunton.

84.2. (84a) As with hepatitis C, any patient with hepatitis B and haemophilia would have been referred to colleagues in gastroenterology/hepatology.

84.3. (84b) I did not encounter any patients with hepatitis B and haemophilia while working in Taunton.

84.4. (84c) I did not encounter any patients with hepatitis B and haemophilia while working in Taunton.

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

85.1. As with hepatitis C, any patient with hepatitis B would have been under the care of a gastroenterologist, and specialist nurses in hepatology and their care would follow the standard protocols of the hepatology team.

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

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

b) What treatment options were offered over the years?

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

86.1. When I started working in Taunton, almost all patients with NANB hepatitis had been tested for hepatitis C. For responses to subsections 86a, 86b, 86c, please refer to my answer to question 87 on the management of hepatitis C at the Centre.

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

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

b) What treatment options were offered over the years?

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

87.1. (87a) Any patient with hepatitis C was referred to a consultant gastroenterologist. For many years this was Dr Stirling Pugh, and in recent years two gastroenterology colleagues, Dr Timothy Jobson and Dr Rudi Matull, saw all hepatitis C cases in conjunction with a team of hepatitis specialist nurses.

87.2. (87b) The following treatment options were offered over the period 1995 to 2021: interferon alone, interferon combined with ribavirin, interferon combined with ribavirin and amantadine, pegylated interferon, and more recently, other antiviral combinations.

87.3. (87c) Counselling on treatment for hepatitis C was carried out by the consultant gastroenterologists and the specialist hepatology nurses who supported patients very thoroughly during their therapy.

88. Please consider the correspondence between you and Dr Creagh dated May 1996 [TSFT0000002_013 and TSFT0000002_014]. Please explain the context of this correspondence. What was intended by the phrase "I was hoping to generate some ammunition for people having funding difficulties". What was the outcome of the South West Haematologists Group - Hepatitis C in Coagulation Disorders Audit? Did the results of the Audit have an impact on the availability of funding for treatment in the South West Region?

88.1. I have been shown correspondence between Dr Creagh and myself in 1996 (TSFT0000002_013 and TSFT0000002_014). In my letter to Dr Creagh dated 22 May 1996 I was referring to my understanding at that time that not all Centres had funding for treatment of hepatitis C using alpha-interferon.

88.2. I reported the results of the "South West haematologists group – hepatitis C in coagulation disorders" audit to a meeting of the South West regional haematologists at Lyngford House, Taunton, on 9 October 1996. The minute from the group meeting reads as follows: "Dr Simon Davies presented the results of the Regional Audit. There is a variation in the rate of seropositivity which may reflect the amount of cryoprecipitate used. There are still several patients in the Region who have not been tested. Most Centres are organizing PCR genotyping and most Centres are managing patients in collaboration with gastro-enterologists or hepatologists in line with best practice. There seems (sic.) to be patients who are eligible for alpha interferon therapy but have not yet been started and it was questioned whether funding was a problem. However as a general principle most units in the South West did not see this as a problem as they already had wide use of alpha interferon in clinical haematology. In all there are 150 HCV positive patients in 7 Centres and it is likely that they are going to represent a significant burden of liver disease in the next 10-20 years."

88.3. I do not remember whether the results of the audit had an impact on the availability of funding for treatment in the South West region. As stated in the minute, lack of funding for interferon alpha for these patients appears to have been the exception rather than the rule. It is possible that alpha interferon was less easily available for the wider group of hepatitis C patients with other risk factors.

89. Please consider the letter from you to Dr Morkane dated 2 November 2000 [TSFT0000002_076] wherein you state that "*At present the patients eligible for combination therapy between Alpha Interferon and Ribavirin are being*

***offered a place in a locally organised clinical trial (observational study of Alpha Interferon, Ribavirin and Amantadine) albeit that full ethical approval is awaited.*" Please explain whether the full ethical approval was obtained and if so when? Were your patients involved in this trial aware that full ethical approval had not been obtained when they were enrolled? Did your patients involved in this trial provide their informed consent? You also state that you received a questionnaire from the Haemophilia Society with a "*number of very detailed and probing questions about [your] approach to therapy, availability of funding etc etc*" but that you "*declined to return the questionnaire*". Please explain why you declined to return the questionnaire to the Haemophilia Society?**

89.1. I have been shown a document which I wrote to Dr Morkane about hepatitis C therapy in 2000 (TSFT0000002_076). Full ethical approval was obtained by Dr Stirling Pugh for the amantadine study, as described in my answer to question 78. Dr Pugh will have obtained informed consent from the haemophilia patients who participated.

89.2. I do not remember why I declined to return the questionnaire, referred to in the same letter, to the Haemophilia Society.

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

90.1. All patients infected with hepatitis C were reviewed by the hepatology team. In some cases, without liver disease, a protocol for ongoing monitoring was communicated to the Centre, and we would check appropriate blood tests and carry out appropriate clinical monitoring alongside haemophilia reviews at the Centre. In those cases with liver disease, regular outpatient review was carried out by the hepatology team following their own protocols.

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

91.1. I was not involved in the care and treatment of any children infected with HIV or hepatitis.

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

92.1. The approach of the Centre to any patient under our care, for any condition, would be to consider all possible avenues of support to them and their families. This might, on a case-by-case basis, lead to referrals to a wide variety of specialist medical and non-medical services including counselling, psychological support and social work support.

93. Did the Centre 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?

93.1. As far as I am aware, the Centre did not 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. Such funding may, however, have been made available to colleagues in genitourinary medicine who were involved in seeing patients with HIV and AIDS in Taunton.

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

94.1. I do not remember experiencing any difficulties in obtaining sufficient funding for the treatment of people who have been infected with HIV and/or hepatitis C.

95. 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.

95.1. I was not involved in clinical trials for HIV. My only trial experience with hepatitis was a trial of adding amantadine to ribavirin and interferon in hepatitis C. I refer to my answer to questions 78 and 79 for more detail.

Recombinant products

In answering the following questions you may be assisted by consideration of the various UKHCDO minutes enclosed with this letter as well as the following documents: Letter from Deborah Anthony to you dated 5 May 1997 [HCDO0000275_116]; Fax enclosing memorandum from Dr Archibald Prentice to you dated 29 May 1997 [BWCT0000059]; Letter from Professor Ludlam to Deborah Anthony dated 29 May 1997 [HCDO0000275_136]; Letter from Professorn Ludlam to UKHCDO Directors including you dated 21 August 1997 [HCDO0000275_200]; Email from Dr Frank Hill to UKHCDO Directors including you enclosing revised advice from the UKHCDO Advisory Committee dated 18 May 2001 [HCDO0000013_042]; Email from Margaret Ghlaimi to UKHCDO Directors including you enclosing the government Press Release dated 12 February 2003 [HCDO0000109_008]; and Minute of the Haemophilia Sub-Committee of South & West Haematology Committee meeting on 12 April 2001 at which you were present [TSFT0000002_081 and TSFT0000002_082]

96. 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.

96.1. I have been shown a number of documents related to the discussions regarding introduction of recombinant coagulation products.

(HCDO0000275_116, BWCT0000059, HCDO0000275_136, HCDO0000275_200, HCDO0000013_042, HCDO0000109_008, TSFT0000002_081 and TSFT0000002_082). My recollection of the sequence of events leading to the introduction of recombinant therapy in the UK is not very clear despite having read these documents. As I understand it, recombinant factor VIII was licensed as a treatment for haemophilia A in August 1994. UKHCDO published guidelines on the treatment of haemophilia in 1997, recommending that recombinant products should be used in preference to plasma derived factor VIII and factor IX. Following publication of these guidelines, there was a gradual process of transfer of patients to recombinant therapy, which accelerated after provision of specific funding for children in 1998, and specific funding for adults from 2003. Thus, as I recall, all eligible patients had been offered, and most had started, on recombinant therapy by 2005 to 2006.

97. 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?

97.1. I had no personal involvement in lobbying government departments or other high-level actions in pursuit of recombinant therapy for patients with haemophilia. I, like all haemophilia Centre directors, was a member of UKHCDO, which was a powerful advocate for recombinant therapy in the discussions in the UK.

98. At the Fifth Meeting of the UKHCDO Executive Committee meeting on 3 February 1997 [HCDO0000460] you stated that "*no purchasers in the South-West supported recombinant products on the grounds of expense but one or two patients, were however, receiving them.*" At the Seventh Meeting of the UKHCDO Executive Committee meeting on 20 August 1997 [HCDO0000462] you stated, in relation to the South-West, that "*no purchasers had committed themselves to recombinant products but one or two people [did] receive them*". On what basis were the small number of

patients in the South-West receiving recombinant products? Who were "the purchasers" you were referring to?

98.1. I have been shown a number of documents, the minutes of UKHCDO Executive committee meetings on 3 February 1997 and 20 August 1997 (HCDO0000460, HCDO0000462). I do not know the basis on which the "small number of patients" (otherwise expressed as "one or two people") were receiving recombinant coagulation factors at that time. There were a number of trials of recombinant factor at this time and earlier, so it is possible that the patients I referred to had been, or were at that time, participating in a clinical trial. Alternatively, it is possible that some NHS organisations were funding recombinant factor prior to specific allocation of funds for this purpose.

99. **When were recombinant products available to patients (and which categories of patients) treated at the Centre? In answering this question please refer to the correspondence between you, Mr Peter Sharpe and Mr Eric Thomas dated November 2003 [TSFT0000002_084 and TSFT0000002_085] and to the completed form regarding the product usage at Taunton submitted to Dr Frank Hill in September 2003 [HCDO0000108_150, p7].**

99.1. I have been shown a number of documents, relating to the introduction of recombinant products in Taunton. (TSFT0000002_084, TSFT0000002_085, HCDO0000108_150). The Taunton documents referred to transfer of patients with haemophilia B from plasma derived factor IX to recombinant factor IX therapy, starting in November 2003. It is my recollection that all factor VIII administered to haemophilia A patients at the Centre was recombinant factor VIII by this time. Monthly returns to the National haemophilia database from the Centre should indicate the dates of commencement of recombinant products and could be reviewed to access this information. I do not have access to this data.

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

100.1. I do not know whether sufficient quantities of recombinant products were available to treat all patients with haemophilia and thus to allow an earlier introduction than that which occurred. I also do not know if an earlier introduction, if quantities of recombinant factors had allowed, would have been affordable with funds available to the National Health Service at that time, given all the other calls on health service funding that existed.

Records

101. What was the Centre's policy 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.

101.1. The Centre did not have a formal policy about recording information on death certificates when a patient had been infected with HIV or hepatitis. As I recall, in the small number of cases where I was involved, the Coroner's advice was sought in each case. I believe that specific reference to the role of infected blood products was made on the death certificate in each case.

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

102.1. The policies of the Somerset NHS Foundation trust and Yeovil District Hospital NHS Foundation trusts were that medical records of patients with haemophilia and related hereditary bleeding disorders were to be kept indefinitely. I found that a set of medical records had been microfiched a few years before I retired, and, after having the case notes reconstituted, contacted the appropriate Information Governance

colleagues in both Taunton and Yeovil Trusts to reinforce the requirement that the paper-based case notes and all electronic records must be kept available on an indefinite basis. This was agreed. I believe that there remains a risk that paper records will be destroyed in the future and if that cannot be avoided, that great care must be taken to extract all the relevant details about diagnosis and treatment in this group of complex patients.

103. 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 Centre? If so, why, what information and where is that information held now?

103.1. (103a) The Centre did not maintain separate files for some or all patients, neither did I.

103.2. (103b) I did not keep records or information (e.g., information being used for the purpose of the search) about any of my patients at my home or anywhere other than the Centre.

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

104.1. I do not hold records or information about any of my patients.

Section 5: UKHCDO

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

105.1. I joined UKHCDO in 1992 as a locum consultant in haematology working at the haemophilia Centre, University Hospital of Wales. I do not recall whether I attended any meetings of the executive group (comprising directors of larger haemophilia centres) at that time.

105.2. I had an approximately 2-year period between the above post and before taking up my permanent position in Taunton in 1995, when I did not participate in UKHCDO business. In 1995 I began to work in haemophilia care again and soon afterward I was asked to begin attending UKHCDO Executive group meetings as a representative for South West England, as there was no Comprehensive Care Centre (CCC) or similar large haemophilia Centre in the South West at that time. This entailed attending meetings of UKHCDO Executive committee in London several times per year and afterward feeding back to colleagues at South West Haematology Committee meetings. I would also canvas South West colleagues for opinions to enable me to represent them. I participated in a working party on haemorrhagic disorders in women for several years as I had published on this topic as a trainee. I usually attended annual general meetings of UKHCDO.

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

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

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

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

d) The relationships between UKHCDO and pharmaceutical companies.

e) How decisions were taken by UKHCDO.

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

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

- the importation, purchase and selection of blood products;
- the manufacture of blood products;
- self-sufficiency;
- alternative treatments to factor products for patients with bleeding disorders;
- the risks of infection associated with the use of blood products;
- the sharing of information about such risks with patients and/or their families;
- obtaining consent from patients for the testing and storage of their blood, for treatment and for research;
- heat treatment;
- other measures to reduce risk;
- vCJD exposure; and
- treatments for HIV and hepatitis C.

106.1. (106a) I saw the purpose of UKHCDO as being to maintain and improve standards of care for patients with haemophilia and related blood disorders. I believed that the function of UKHCDO was to establish standards and to write guidance for all clinicians involved in the care of persons with haemophilia and other disorders; to scrutinise the care of persons with haemophilia and related disorders within the UK and to ensure universal high standards were being maintained; to lobby the Department of Health and government of the day on issues pertinent to haemophilia and related disorders. I saw the responsibilities of UKHCDO as being to ensure that all clinicians involved in UK haemophilia care were kept informed on relevant issues in this very specialised area of medicine; to ensure that all data submitted to UKHCDO was stored confidentially and used responsibly; to ensure a transparent relationship with the pharmaceutical industry to ensure that all guidelines on choice of therapeutic products were free from bias.

106.2. (106b) I had no significant involvement in policy development within UKHCDO beyond opportunities to comment on drafts brought to the executive committee prior to publication. I was not part of any of the policy and guidelines writing groups of UKHCDO.

106.3. (106c) UKHCDO had several working groups which studied, then provided recommendations on, specific areas within haemophilia care and related matters. Some groups were of the "task and finish" type and had a short existence, usually closing after one- or two-years following production of a new or updated guideline document. Other groups had much longer lives and this reflected both the nature of the topic in their remit and the rate of change of the scientific and political background to that topic.

106.4. (106d) I understood that UKHCDO, not only where raising funds was concerned, but also when writing guidelines, was always careful to ensure that there could be no bias toward individual pharmaceutical

companies. I believe that UKHCDO sustained an excellent reputation for probity.

106.5. (106e) Decisions were made by UKHCDO by what I saw as democratic processes, often by voting at the Executive committee (the committee of comprehensive care centre (CCC) directors) or by taking topics to the annual general meeting for debate and voting by a wider group of clinicians.

106.6. (106f) Information and advice from UKHCDO was publicised by several means: by circulating minutes of AGMs to all members of UKHCDO; by letters from the chair of UKHCDO to all members of UKHCDO; by circulating minutes of Executive committee/CCC directors meetings; by onward transmission of information by CCC directors to the local haemophilia centres in their geographical area; by publishing guidelines in medical journals and latterly also by online early publication prior to printing.

106.7. (106g) I acted as the South West region representative on UKHCDO executive committee between 1995 and 2001. As such, I played a part in all decisions made by that group over that time period. I did not, however, participate in any writing groups for guidelines that were produced during that time. I did not take a leading role in any specific policy area, apart from my participation in the working party on haemorrhagic disorders in women.

Section 6: Pharmaceutical companies/medical research/clinical trials

In answering these questions please consider the Declaration of Interest on the UKHCDO Reply Form regarding the placing of contract for Recombinant Factor VIII submitted by you on behalf of the Centre [HCDO0000110_146]

107. 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.

107.1. (107a-h) I did not provide advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products. I did not receive any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture of or sale of blood products. I did not sit on any advisory panel, Board, committee or similar body of any

pharmaceutical company involved in the manufacture or sale of blood products. I did not receive any financial incentives from pharmaceutical companies to use certain blood products. I did not receive any non-financial incentives from pharmaceutical companies to use certain blood products. I did not receive any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company. I did not undertake medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products. I did not provide a pharmaceutical company with results from medical research studies that I had undertaken.

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

108.1. I have never received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products.

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

109.1. I have never sat on any advisory panel, Board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products.

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

110.1. I have never received any financial incentives from pharmaceutical companies to use certain blood products.

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

111.1. I have never received any non-financial incentives from pharmaceutical companies to use certain blood products.

112. 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.

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

113. 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?

113.1. My employer, Somerset NHS Foundation Trust, and its predecessor organisations, required all staff to comply with NHS standards of business conduct. I did so throughout my career.

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

114.1. I have never undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products.

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

115.1. I have never provided a pharmaceutical company with results from medical research studies that I have undertaken.

116. 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?

116.1. I have never provided a pharmaceutical company with results from medical research studies that I have undertaken.

Section 7: vCJD

117. 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?

117.1. I believe that I first became aware of concerns about the possibility of transmission of vCJD associated with the use of blood and blood products in 1997 when UKHCDO recommended discontinuing the use of UK-sourced blood products because of concerns that vCJD had entered the blood donor population in the preceding years.

118. 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 to inform patients about possible exposure to vCJD and to provide information to them about vCJD?

b) What steps were taken to tell patients of possible exposure to vCJD?

c) What steps were taken to provide information to patients about the risks of vCJD?

d) 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?

118.1. I do not remember having any involvement in UKHCDO recommendations as to what information to provide to patients about vCJD. It is possible that I attended UKHCDO executive committee meetings where this topic was discussed, but I have no specific recollection of this.

118.2. (118a) I wrote a letter on 21 September 2004 to all Centre patients who had received British-sourced factor VIII, factor IX and related products between 1980 and 2001. I used the pro forma letter which had been created by UKHCDO. This letter included an explanation of the situation regarding vCJD at that time and included an offer to meet me to discuss the situation. The patients were also asked if they wished to know about their individual risk of having been exposed to vCJD and if so, whether they were prepared to receive a letter about this or whether they would prefer a face-to-face meeting to discuss this. I conducted approximately 20 consultations that were specifically related to discussion of individual vCJD risk. Further discussions took place in routine haemophilia clinic review appointments.

118.3. (118b-d) Each patient who was being informed about vCJD was seen by me, and I gave counselling and advice to the best of my ability.

119. What measures were put in place at the Centre from a public health perspective, in relation to the care and treatment of patients? If patients at the Centre were identified as at risk for public health purposes, did that impact detrimentally upon them in terms of their ability to access treatment and care (whether at the Centre or elsewhere?).

119.1. I took advice from the Trust's clinical ethics committee, regarding the most appropriate means by which patient records could be marked in order that decisions could be made regarding quarantining of surgical instruments and endoscopes in patients who were considered "at risk for variant CJD on public health grounds". This group discussed the matter on three separate occasions. It was decided that a clinical alert marker would be placed on the record alerting the user of the medical record to "important infection-control information" and directing the user to an envelope filed in the notes that contained the individual vCJD exposure risk assessment form. This was felt to balance the need for patient confidentiality and avoidance of stigma with protection of NHS staff carrying out exposure prone procedures.

119.2. Discussions with endoscopy services and public health colleagues took place and a protocol was written. I am aware that several patients in this group had endoscopies, having been identified as being "at risk for variant CJD on public health grounds". I am not aware that any endoscopy or surgery was delayed or prevented inappropriately.

Section 8: The financial support schemes

120. 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, EIBSS) which were set up to provide financial support to people who had been infected?

120.1. I did not have any involvement with Macfarlane trust, Eileen trust, the Macfarlane and Eileen trust, Caxton foundation or EIBSS. I received notification from UKHCDO about the Skipton fund where it was recommended that I review local cases to assess possible eligibility and to enable the patients or their relatives to be encouraged to apply to Skipton fund if this had not already been done. We wrote to all eligible patients. I later supplied information on blood test results and other

clinical data at the request of several patients who were making these applications.

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

121.1. As set out in my answer to question 120, I informed several patients about Skipton fund.

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

122.1. The Centre did not have a policy or any guidance in relation to referring patients to the trusts and funds for support.

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

123.1. As set out in my answer to question 120, I supported several patients in their applications to the Skipton fund.

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

124.1. I do not believe that the Centre acted as a gateway for determining whether patients met eligibility criteria for the receipt of assistance from any of the trusts and funds.

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

125.1. Other than the applications to Skipton fund as set out in my answer to question 120, I do not believe that the Centre was involved in determining applications made by patients for assistance from the trusts or funds.

126. 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?

126.1. As set out in my answer to question 120, I had limited dealings with Skipton fund (and no other funds) and was not aware of any adverse comment or opinion on the operation of this fund.

Section 9: Other issues

127. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

127.1. There were no complaints made about me (insofar as relevant to the enquiry's terms of reference) to my employer, to the general medical Council, to the health service ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

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

128.1. re: Cardiff

128.1.1. I was a locum consultant in haematology at the University Hospital of Wales in Cardiff between December 1992 and January 1994. I was a senior trainee in the Department of Haematology (Lecturer in Haematology) and, after the sudden death of Professor Arthur Bloom, I was approached by Professor Alan Burnett, Head of Department, and asked if I would be prepared to step in to act as locum consultant pending the appointment of a substantive consultant haematologist. At this time, I had very limited experience in haemophilia care: I had completed a pre-examination course in blood clotting and bleeding disorders at the Royal Free Hospital London the previous year and had been attached as a trainee to the haemophilia Centre under Professor Bloom's supervision for a few months before his death. I had had a limited exposure to the care of patients with bleeding disorders during my registrar posts in Birmingham between 1985 and 1990 as I did not work at the haemophilia Centre in Birmingham where most patients were treated. I therefore accepted the position of locum consultant haematologist on the understanding that I would be strongly supported by the haemophilia team, notably by the very experienced middle grade physician, Dr Has Dasani. This turned out to be the case, and I gained valuable experience in the Department over the following year before a permanent appointment, Dr Eddie Hampton, was made. I then returned to my position as a Lecturer to complete my training in haematology and moved to Taunton in May 1995.

128.1.2. I have read the witness statement and the transcript of the oral evidence given to the Inquiry by Professor Peter Collins, who succeeded Dr Hampton as consultant in Cardiff in 1996. In these statements, he suggests that I had counselled patients newly diagnosed with hepatitis C in conjunction with Dr Has Dasani. I have no specific recollection of doing so, but accept

that this was probably the case, as it was in all haemophilia centres at that time. I would need to have access to patient medical records from that time to refresh my memory of the approach I would have taken and the form of words I would have used in the communication: having contacted the University Hospital, Cardiff, I was informed by Kathryn Lewis from the Department of Corporate Governance that this is not possible. In an email reply to me dated March 4th, 2021 she said:

"I have been asked to look into your question about having sight of records from your time at UHW. Unfortunately, we are unable to allow access to records to those who are not employed by the UHB and any document that relates to a patient would require expressed consent. I have checked with the Inquiry who have given the following response: "We are not able to facilitate the sharing of data between a third party and an individual required to give evidence to us without the specific consent of the patient. Even where consent is obtained, the third-party document provider may not agree to such a request. It is the Inquiry's understanding that patient medical records cannot be used in this way without specific consent from the individual to whom they pertain.""

128.2. In terms of the broader remit of the enquiry, with reference to my time in Cardiff, I do not have anything to add to the comprehensive evidence given by Professor Collins.

128.3. In closing, I should like to take the opportunity to commend Dr Has Dasani for his devoted work with patients with haemophilia and related disorders and their families, and for the tremendous support that he gave me in my role as a locum consultant haematologist in Cardiff.

Statement of Truth

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

Signed GRO-C

Dated 28/4/2021