Witness Name: Dr Paul Giangrande
Statement No.: WITN3311003
Exhibits: WITN3311004 - WITN3311011
Dated:23.10.20

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF DR PAUL GIANGRANDE

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

I, Paul Giangrande, will say as follows: -

Section 1: Introduction

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

1.1. Name: Dr Paul Leo Francis Giangrande

1.2. Address: My address and date of birth are known to the Inquiry

1.3. Qualifications:

1.3.1. BSc in Pharmacology (First Class), University of Manchester: 1976
1.3.2. MB, ChB with Honours, University of Manchester: 1979
1.3.3. MRCP (UK): 1982
1.3.4. MRCPath: 1986
1.3.5. MD: 1991

1.3.6. FRCPath: 1995

1.3.7. FRCP London: 1996

1.3.8. FRCP Edinburgh: 1997

1.3.9. FRCP Ireland: 1999

1.3.10. FRCPCH: 1997

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. July 1979: Qualified in Medicine (MB ChB with Honours), University of Manchester

2.2. Aug 1979-January 1980: House Surgeon to Prof. I. Sellwood, University Hospital of South Manchester

2.3. February 1980-July 1980: House Physician to Prof P. Adams, Manchester Royal Infirmary

2.4. August 1980-July 1981: Senior House Officer (SHO) in Pathology, University Hospital of South Manchester (three months in each of haematology; microbiology; chemical pathology; and histopathology)

2.5. August 1981-January 1982: SHO in Renal Medicine to Prof. K. Peters, Hammersmith Hospital & Royal Postgraduate Medical School, London

2.6. February 1982-July 1982: SHO Endocrinology/Metabolic Medicine to Prof. V. Wynn, St Mary's Hospital, London

2.7. August 1982-July 1983: Assistentartz, Kantonsspital Basel, Switzerland (six months in Internal Medicine with Prof. W. Stauffacher and six months in Haematology with Prof. B. Speck)

2.8. August 1983-November 1984: Registrar in Haematology, Westminster Hospital, London (under Prof. J. Barrett)

2.9. December 1984-November 1987: Lecturer (Hon. Senior Registrar) in Haematology, Westminster and Charing Cross Medical School, University of London, on rotation to Westminster Hospital, Charing Cross Hospital and Queen Mary's Hospital, Roehampton.

2.10. December 1987-December 1989: Clinical Research Fellow at Royal Free Haemophilia and Thrombosis Centre, London (under Dr P. Kernoff)

2.11. January 1990-March 1991: Research Fellow, Hemophilia and Thrombosis Center, Milan, Italy (under Prof. P. Mannucci)

2.12. April 1991-May 2015 Consultant Haematologist, Oxford University Hospitals NHS Trust (based in Oxford Haemophilia & Thrombosis Centre at the Churchill Hospital). I retired at the end of May 2015.

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 UK Haemophilia Centre Doctors' Organisation (UKHCDO) throughout my time in post in Oxford although I never held a senior elected office within that body.

3.2. My primary engagement outside the hospital throughout my time in Oxford was with patient organisations. I was elected to the senior medical position within the World Federation of Hemophilia (WFH) from 2000-2008 inclusive. I also served as Chairman of the Medical Advisory Group of the European Haemophilia Consortium (EHC) from 2013-2018 inclusive. All my work for the WFH and EHC was performed on a voluntary basis (without salary or fees).

4. **Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus.**

    4.1. I gave evidence to the Lindsay Tribunal in 2001. I have not been involved in any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus.

5. **Please consider the transcript of the evidence which you gave to the Lindsay Tribunal, which is attached to this letter [LIND0000330]. Please confirm whether the contents of that oral evidence are true and accurate. If there are any matters contained within your oral evidence that you do not consider to be true and accurate, please explain what they are.**

    5.1. I no longer recall the detail of the evidence that I gave to the Lindsay Tribunal nor recall the number of patients infected with HIV in the UK. Please refer to my answer to 63b below.

6. **Please provide a copy of any written evidence that you provided to the Lindsay Tribunal. If you do not hold any such evidence, but know or suspect that it may exist elsewhere, please state where this may be found.**

    6.1. I do not have copies of any written evidence or statements that I may have provided to the Lindsay Tribunal.

7. **The questions below focus, as appropriate, on your time as a Registrar and Lecturer (Honorary Senior Registrar) in Haematology at the Westminster Hospital between 1983 and 1989, as a Clinical Research Fellow at the Royal Free Hospital between 1987 and 1989 and the Milan Haemophilia Centre ("the Milan Centre") between 1990 and 1991, and as Consultant and Director of the Oxford Haemophilia Centre ("the Oxford Centre") from 1991. Some questions focus on the Westminster Hospital and the Oxford Centre, but if you have**

information concerning other hospitals and centres relevant to the period or issue to which the question relates, please include that in your response.

Some of the questions set out below relate to events that would have taken place before you began work at the Oxford Centre, but the Inquiry assumes that, as a consultant at and director of the Centre over many years, you will have some knowledge of its policies and practices before you began working there. Please answer these questions as best as you can; if you do not have the information necessary to answer them, please say so.

Section 2: Decisions and actions of the Westminster Hospital and the Oxford Centre and your decisions and actions

8. In relation to your work at the Westminster Hospital please:

a. describe the facilities, organisation, roles, functions and responsibilities of the Westminster Hospital during the time that you worked there and how they changed over time, and provide (if you can) an account of the history of the treatment of patients with haemophilia and other bleeding disorders at the Westminster Hospital during this time;

8.1. I started work at the Westminster Hospital in August 1983. It is now 37 years since I started work there and therefore my recollections are qualified by that passage of time and therefore they may not be accurate. However, to the best of my recollection there were two consultants, three junior doctors (registrar and two senior registrars), a transfusion laboratory, a small research laboratory and two clinic rooms where outpatients could be treated. There was a single departmental nurse. The department admitted a few patients to beds on one of the upper floors.

8.2. The head of department was Prof. John Barrett. The other consultant, Dr James, was responsible for the transfusion laboratory and I believe was one of the founders of the Anthony Nolan bone marrow donor register.

8.3. The Westminster and Charing Cross Hospitals were linked as a single medical school under the Riverside Health Authority, which also encompassed several smaller hospitals like Queen Mary's Hospital in Roehampton. I spent 15 months at Westminster Hospital as a Registrar but after my promotion in 1994 I was sent to Charing Cross Hospital and then Queen Mary's: I returned to Westminster again for a few months towards the end of 1987.

8.4. Westminster Hospital was designated as a haemophilia centre but Charing Cross Hospital and Queen Mary's Hospital were not. St Thomas' Hospital was located just a few hundred yards away from the Westminster. I only remember one patient with haemophilia at the Westminster Hospital. He was a middle-aged man with haemophilia B who used to come in periodically to self-infuse with factor IX concentrate.

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

8.5. My roles at the Westminster Hospital included care of inpatients; liaison between our laboratory and doctors in other departments regarding blood results; provide reports on blood films and bone marrow aspirates; liaise with GPs and doctors in other hospitals by phone or letter; dealing with outpatients who would come in for procedures like infusions of chemotherapy or venesection; and teaching medical students.

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

8.6. I had never treated or even encountered a patient with haemophilia before starting work at Westminster Hospital in August 1983. I only recall one patient with haemophilia who came to the hospital for self-infusion. I was not involved with the investigation or counselling of any patients there with haemophilia and infections like HIV or hepatitis C.

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

8.7. The two consultants in the haematology department at Westminster Hospital during my time there were Prof. Barrett and Dr James. After the latter retired, he was succeeded by Dr Donald McCarthy.

9. Please describe the work and roles that you undertook at (a) the Royal Free Hospital and (b) the Milan Centre as a Senior Research Fellow.

9.1. My work at the Royal Free Hospital was almost exclusively laboratory-based research, the aim of which was to gain a higher academic qualification (MD). My supervisors were Dr Peter Kernoff and Dr (later Prof) Alison Goodall. I was duly awarded the MD in 1991. As far as I recall, I was not involved in the routine management of patients with bleeding disorders whilst at the Royal Free. The one clinical role which was assigned to me was to supervise the treatment of two patients with severe haemophilia A enrolled in an international, multicentre clinical trial of recombinant factor VIII (the product which would later be licenced as Kogenate).

9.2. My work at the Milan Centre was exclusively laboratory-based. I played no part in the clinical management of patients. Prof. Mannucci was my boss but my day-to-day supervisors were Dr Marco Cattaneo and Dr Franco Pareti.

10. In relation to your work at the Oxford Centre please:

a. describe the facilities, organisation, roles, functions and responsibilities of the Oxford Centre during the time that you worked there and how they changed over time, and provide (if you can) an account of the history of the Oxford Centre and its activities during this time;

10.1. More accurate information can be obtained from the centre than I can provide and therefore I would suggest contacting the centre for this information.

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

10.2. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. When I started work in Oxford in April 1991, Dr Charles Rizza was in charge and I replaced Dr James Matthews who had just retired. Dr Rizza retired in October 1993 and, after a series of locum doctors, Dr David Keeling joined me as the second consultant in July 1995. We shared similar clinical duties relating to patients with bleeding disorders, including reviewing outpatients; providing advice over the phone to patients or other doctors; assessment and treatment of bleeding episodes; liaison with our laboratory; provision of on call service at night and weekends; and supervision of inpatients. A significant change came in around 2004, when the Trust asked us to take on responsibility for the diagnosis and treatment of outpatients with deep vein thrombosis. Although definitive figures could be given by the Unit, following this change and over time, I believe that the number of patients with thrombotic problems that were seen in the department exceeded the number of patients with bleeding disorders.

10.3. I was the clinical lead until 2000 but after that David Keeling and I alternated in this role on a three-yearly basis

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

10.4. By the time I started work in Oxford in April 1991, I believe that all the patients infected with HIV would have already been identified and counselled. Many of the patients exposed to hepatitis C would also have

been identified. Other specialist colleagues (see below) provided ongoing monitoring treatment related to these infections.

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

10.5. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. However, I believe that Dr Joan Trowell was the liver specialist in Oxford who would have looked after our hepatitis patients until around 2006 when she retired. This role was then filled by Dr Jane Collier. I believe that both ran regular outpatient clinics in the Haemophilia Centre and would have admitted patients to the gastroenterology ward at the John Radcliffe if necessary.

10.6. Our patients with HIV would have been followed up by specialists in infectious diseases My recollection from 25 years ago as it is that for the first few years that I was in Oxford, Dr (later Prof) Tim Peto was in charge but in or around 1995, Dr (later Prof) Chris Conlon was appointed and he looked after these patients throughout the rest of my time in post. However, more definitive information may be available from the Trust.

11. Approximately how many patients with bleeding disorders were under the care of (a) the Westminster Hospital and (b) the Oxford 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).

11.1. I cannot say: please contact the respective organisations.

12. To the best of your knowledge, what policies were formulated at (a) the Westminster Hospital and (b) the Oxford Centre regarding the selection, purchase and use of blood products (in particular factor concentrates)

during the time that you worked there? What, if any, involvement did you have in the formulation and application of these policies?

12.1. I am not able to provide any information regarding Westminster Hospital. You should approach Prof. (A). John Barrett for further information: he is still active professionally. I was a junior trainee and had no role in the selection or ordering of any products. The system in Oxford is explained in the answer to question 13.

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

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

13.1. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature and more accurate information may be available directly from the respective organisations. However, I believe that in Oxford, from 1991 to around 1995, factor VIII and IX concentrates would have been provided by BPL (BioProducts Laboratory, which was an integral part of the NHS).

13.2. From around 1995 to 2004, I believe that concentrates would have been procured through competitive open tenders operated by the Trust's procurement department. Mike Potter from the Trust's procurement team would discuss with both consultants and the departmental manager to establish the number of units that would need as well as the broad requirements for products. The procurement department would then attend to the tender process. Trust management would decide on which product was acquired from the tendering process.

13.3. From 2004 I believe that there were national tenders for the purchase of coagulation factor concentrate run by government agencies appointed by the Department of Health. I was not involved in this.

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

13.4. Please see my response to 13 a above.

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

13.5. Please see my response to 13 a above.

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

13.6. Please see my response to 13 a above.

e. What involvement did you have?

13.7. Please see my response to 13 a above.

In respect of the Oxford Centre, you may be assisted by your evidence to the Lindsay Tribunal at pp.18-19 of the Transcript [LIND0000330].

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

14.1. I am not able to provide any information regarding Westminster Hospital. During the period I was in post in Oxford, there was a gradual but continuous improvement in the products available for the treatment of haemophilia. We started out with intermediate purity concentrates, moved

on to high purity plasma concentrates and finished up with recombinant ones.

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

15.1. Please see my answer to 13 a.

16. If the responsibility for the selection and purchase of blood products at (a) the Westminster Hospital and/or (b) the Oxford Centre lay with an external organisation, please specify which organisation and provide as much information as you can about its decision-making.

16.1. Please see my answer to 13 a.

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

17.1. Desmopressin (also known as DDAVP), which is still used in clinical practice today.

18. What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at (a) the Westminster Hospital and at (b) the Oxford Centre? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

18.1. Desmopressin is of clinical value but can induce side effects.

19. What was the policy and approach at (a) Westminster Hospital and (b) the Oxford Centre as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?

19.1. To the best of my knowledge, I have never used cryoprecipitate, or even seen it used for the treatment of haemophilia in the UK.

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

19.2. Please see my response to the stem of 19 above

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

19.3. Please see my response to the stem of 19 above.

20. What was the policy and approach at (a) the Westminster Hospital and (b) the Oxford Centre in relation to home treatment? Did the policy and approach change over time and if so how?

20.1. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. I do not think that home treatment was provided by Westminster Hospital.

20.2. Home treatment was already established in Oxford when I started in 1991. Patients could either collect product themselves or it would be sent to them by courier.

21. What was the policy and approach at (a) the Westminster Hospital and (b) the Oxford Centre in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

21.1. I do not know at Westminster Hospital.

21.2. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. However, I believe that in Oxford, prophylaxis was not yet established as routine when

I started there in 1991. I do not recall when prophylaxis was introduced, but it may have been around 1995. This information could be available from the UKHCDO database.

22. What was the policy and approach at (a) the Westminster Hospital and (b) the Oxford Centre in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?

22.1. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature and so more accurate evidence should be sought from the respective institutions. However, in principle children would be the first to have improved therapies such as recombinant factor VIII and IX. Prophylaxis would have first been offered to children and then later offered to adults

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

23.1. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. However, people with mild or moderate haemophilia usually only require treatment infrequently, typically after injuries or for surgery or other invasive procedures such as dental extractions.

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

24.1. I am not aware of any.

25. In your evidence to the Lindsay Tribunal [LIND0000330] you said: *"I can state with confidence that no patient treated with blood products at the Oxford Haemophilia Centre after the introduction of heat-treated concentrates has ever been suspected or identified of developing Hepatitis C."*

a. Does that remain your view? Explain the reasons for any change of view.

25.1. I am grateful for being provided with a transcript of the evidence that I gave to the Lindsey Tribunal as I can no longer recall what I said. However, this remains my view. To be clear: I was only talking about patients treated in Oxford and specifically those treated with the NHS (BPL) products treated at 80°C for 72 hours.

b. On what basis did you reach this view?

25.2. Please see my response to 25 a. Patent monitoring.

c. Does the reference to the introduction of heat-treated concentrates refer to both commercially produced concentrates and those produced from plasma from UK voluntary donors? (You may be assisted by your evidence, in response to questions drawn from your statement to the Tribunal, at p.19 of the Transcript.)

25.3. Please see my answer to 25 a. I only have knowledge of the use in Oxford of NHS concentrates treated at 80°C for 72 hours .

d. Many commercially heat-treated products were, initially, treated at a lower temperature than BPL's 8Y concentrate. Were such commercially treated concentrates used by the Oxford Haemophilia Centre? If they were, do you remain confident that these products did not transmit HCV? (Again, you may be assisted by your evidence, in response to questions drawn from your statement to the Tribunal, at p.19 of the Transcript.)

25.4. The stem of d relates to factual matters that should be within either the knowledge of the manufacturer of the product or the Oxford Centre.

e. **Please explain whether you have similar confidence about HIV not being transmitted to patients at the Oxford Centre following the introduction of heat-treated concentrates.**

25.5. Please see my answer to d above.

f. **Do you have the same confidence that no patients at the Westminster Hospital were infected with HCV and/or HIV following the introduction of heat-treated concentrates?**

25.6. I am not able to answer this question.

Section 3: Knowledge of, and response to, risk

General

26. When you began work as a Registrar in Haematology at the Westminster Hospital, 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?

26.1. My knowledge would have been informed from teaching, medical journals and lectures.

26.2. I cannot give any specific dates.

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

27.1. I was a very junior doctor at the time and have no recollection of any such measures.

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

28.1. My knowledge would have been informed from teaching, medical journals and lectures. I cannot give any specific dates.

29. What decisions and actions were taken at the Westminster Hospital and/or by you to minimise or reduce exposure to infection?

29.1. I have no recollection of any such decisions or actions. I was in a junior training position and certainly not in position of authority in the department.

Hepatitis

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

30.1. For most of my time as a senior registrar I was not actually working at Westminster Hospital but at Charing Cross Hospital and Queen Marys Hospital in Roehampton, where to my best recollection, no patients with haemophilia were treated.

30.2. My knowledge would have been informed from teaching, medical journals and lectures. I cannot give any specific dates.

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

31.1. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. I was a junior doctor at the time and so I do not believe that I instigated any enquiries or investigations myself.

32. What, if any, actions did you, or others at (a) the Westminster Hospital and (b) the Oxford Centre, take to reduce the risk to patients of being infected with hepatitis (of any kind)?

32.1. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. However, I cannot provide information about Westminster Hospital. I started work in Oxford in April 1991, when I believe that all patients were already being treated with BPL's heat-treated coagulation factor concentrates.

33. What liver function tests and/or other forms of monitoring were undertaken at (a) the Westminster Hospital and (b) the Oxford Centre, and how did that change over time? What was the purpose of such testing and monitoring?

33.1. I am being asked to provide recollections of matters which start nearly 30 years ago and therefore my recollections are historical in nature. I have no recollection of tests carried out in Westminster Hospital.

33.2. In Oxford I believe that basic liver function tests (transaminases, bilirubin, albumin) would usually be measured as part of a haemophilia review. Patients with liver disease would be followed up by a liver specialist, who would then decide if further tests and investigations would be required.

34. 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?

34.1. My knowledge would have been informed from teaching, medical journals and lectures. I cannot give any specific dates.

HIV and AIDS

35. 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 Westminster Hospital? How did your knowledge and understanding develop over time?

35.1. When I started work at Westminster, I was not aware of any such risk. I believe that I first learned about AIDS in 1982 when working at St Mary's Hospital in west London I believe that there were cases in the hospital and there were educational lectures for staff on AIDS.

35.2. I believe I became aware of the discovery of HTLV-III (HIV) in 1984 and the subsequent development of an antibody test and heat-treated concentrates thereafter.

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

36.1. I think that I would have first become aware that there might be an association between AIDS and the use of blood products at the UKHCDO annual meeting in October 1983.

37. What, if any, enquiries and/or investigations were carried out at the Westminster Hospital in respect of the risks of transmission of HIV or AIDS? What was your involvement? What information was obtained as a result?

37.1. I do not know.

38. What, if any, actions were taken at the Westminster Hospital to reduce the risk to the patients of being infected with HIV?

38.1. I do not know.

39. Did you and your colleagues at the Westminster Hospital continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

39.1. I do not know what concentrates were used. This information should be available from the UKHCDO database.

40. You were present at a meeting of the UK Haemophilia Centre Directors on 17 October 1983, replacing your colleague, Dr A.J. Barrett [PRSE0004440]. The meeting included a discussion of whether to revert to the use of cryoprecipitate. The minutes record Professor Bloom stating that, *"at present there was no proof that commercial concentrates were the cause of AIDS."* The minutes record that: *"After discussion it was agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way."*

a. Please provide any account that you are able to give of the discussion that took place, and the reasons for the conclusion recorded in the minutes.

40.1. I have no recollection of the discussion referred to which took place 37 years ago.

b. State what your views were on the matters discussed, and whether your colleagues at the Westminster Hospital agreed.

40.2. Please see my response to a above.

c. Why, in your understanding, was there no general, nation-wide reversion to the use of cryoprecipitate in light of the emergence of HIV?

40.3. I do not know.

d. The minutes record Dr Chisholm explaining that in her region, there were *"problems in getting large amounts of commercial concentrates whereas she could get unlimited supplies of cryoprecipitate."* Other Directors were reported to have had the same problems. What was your experience at the Westminster Hospital of the amount of cryoprecipitate and commercial concentrates that were available for potential use with your patients? Would sufficient cryoprecipitate have been available to maintain existing methods of treatment for some or all groups of patients had a decision been taken to revert to the use of cryoprecipitate.

40.4. To the best of my knowledge, I have never used cryoprecipitate for the treatment of haemophilia or seen it used in the UK for that purpose. I do not know whether sufficient cryoprecipitate would have been available to treat some or all patients, had a decision been taken to revert to the use of cryoprecipitate

Response to risk

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

41.1. Heat-treated concentrates had already been in routine use in Oxford for some years by the time I started work as consultant haematologist there in April 1991.

42. When did you begin to use heat treated factor products and for which categories of patients? From where did you obtain heat treated products? Did you experience difficulties in obtaining such products?

42.1. I do not know when heat-treated concentrates were first used at the Westminster Hospital, I was a junior trainee at the time and had no involvement in any discussions about this matter. The UKHCDO database

may be able to provide information about when these concentres were used at the Westminster.

42.2. I believe that heat-treated concentrates would have already been in use in Oxford by the time I started work as a consultant haematologist there in April 1991.

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

43.1. I am not able to comment on this.

44. Insofar as you have not addressed these matters above, did you 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?

44.1. I do not recall seeing cryoprecipitate being used in the treatment of haemophilia in this country and was not trained to use it as a treatment for haemophilia.

45. Do you consider that your decisions and actions, and the steps taken at (a) the Westminster Hospital and (b) the Oxford 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.

45.1. I am not able to comment with regard to Westminster Hospital. I was not involved in policy-making discussions.

45.2. I was not working in Oxford in the mid-1980s.

46. Looking back now, what decisions or actions by you and/or at (a) the Westminster Hospital or (b) the Oxford Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

46.1. I do not feel able to contribute any useful comments. I was a junior trainee in the mid-1980s with very little involvement in the field of haemophilia. By the time I became a consultant in Oxford in April 1991, the risk of infection with HIV or hepatitis C had been contained by the introduction of heat-treated concentrates and improved donor screening.

47. 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?

47.1. I do not feel able to contribute any useful comments. I was a junior trainee in the mid-1980s with very little involvement in the field of haemophilia. By the time I became a consultant in Oxford in April 1991, the risk of infection with HIV or hepatitis C had been contained by the introduction of heat-treated concentrates and improved donor screening.

48. 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?

48.1. I am not able to comment and this question as I only qualified in 1979.

Section 4: Treatment of patients

Provision of information to patients

49. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at (a) the Westminster Hospital,

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

49.1. I am not able to comment with regard to Westminster Hospital.

49.2. By the time I became a consultant in Oxford in April 1991, the risk of infection with HIV or hepatitis C had been contained by the introduction of heat-treated concentrates and improved donor screening.

50. What information, if any, did you provide to your patients about the risks of chronic and/or serious liver disease?

50.1. This would have been covered by the liver specialists (see my answer to Q 10d).

51. 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.

51.1. I am not able to comment with regard to Westminster Hospital.

51.2. At Oxford, for patients with mild haemophilia and certain types of von Willebrand disease there would have been a potential option of using of desmopressin (DDAVP). Tranexamic acid could also be used which is not a substitute for concentrate but it makes clots more stable and can reduce the total amount of concentrate used.

52. 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?

52.1. I do not believe that I was involved in this as I believe that this was nurse led. The focus of training for home treatment would have been on the practical aspects. I anticipate that this would have included teaching the practical skills (e.g. how to reconstitute concentrate and injection technique) as well as emphasising the importance of sterility, how to store products and how to keep records of treatment.

HIV

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

53.1. To the best of my recollections, I do not think I ever had to break the news to any patient that they had been infected with HIV as I think that they were already aware that they had been infected.

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

54.1. I am not able to comment on this as I was not working at the Westminster Hospital at the time when commercial assays became available.

55. What if any arrangements were made for pre-test counselling?

I do not know. See my answer to Q 54.

56. 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?

56.1. I do not know. See my answer to Q 54.

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

57.1. I do not know. See my answer to Q 54.

58. What was the 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?

58.1. I do not know. See my answer to Q 54.

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

59.1. I do not know. See my answer to Q 54.

60. What if any arrangements were made for post-test counselling?

60.1. I do not know. See my answer to Q 54.

61. How many patients at the Westminster Hospital were infected with HIV? 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?

61.1. I cannot provide answer to questions to a-e inclusive above. The UKHCDO database may be able to provide this information. As regards Q 61f, no children with haemophilia were treated at Westminster Hospital.

If you are able to provide the same information for the Oxford Centre, please do so.

61.2. I am not able to provide any information about how HIV testing was arranged in Oxford and how patients were counselled. I started work there in April 1991 and my recollection, as it is, is that the patients had been informed of their HIV status before I had started work at Oxford.

62. Was work undertaken at Westminster to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached. If you are able to provide the same information for the Oxford Centre, please do so.

62.1. I do not know whether any such work was undertaken at Westminster Hospital. My recollections of this at Oxford are now from nearly 30 years ago and therefore I have no specific recollections. I believe, however that when I started work in Oxford, it had been the practice to transcribe laboratory results on to a flow chart in the clinical records. This would include results of HIV tests which should have given some indication of the time of seroconversion.

63. You co-authored two published studies that provide figures for the number of patients with haemophilia who were infected with HIV: "Mortality before and after HIV infection in the complete UK population of haemophiliacs" (*Nature*, vol. 377, 7 September 1995, 79-82) ("the *Nature* letter") [HCDO0000264_095], and "Mortality individuals with haemophilia" (*AIDS*, 2004, 18:525-533) ("the *AIDS* paper") [HCDO0000254_384].

a. The two articles contain different figures for the number of male patients with haemophilia who were infected with HIV-1. The *Nature* letter refers to 1,227 infected between 1979 and 1986 *"as a result of transfusion therapy"*. The *AIDS* paper refers to 1,246 infected *"from clotting factor concentrate"* in the *"early 1980s."* Explain the reasons for the difference between these two

numbers, and state which you consider to be a more accurate measure of the number infected with HIV-1 as a result of the use of blood products.

63.1. Prof. Sarah Darby, Professor of Medical Statistics at the University Oxford, was the lead author of both papers and analysed the data. I am now not able to assist beyond speculation as I do not have access to the relevant data and information upon which the papers were based.

b. In your evidence to the Lindsay Tribunal [LIND0000330], you stated that *"In the UK, we know that 1,229 people with haemophilia were exposed to HIV"* (pp.16-17 of the Transcript). Please explain why this number differs from those referred to above, and state which you consider to be the most reliable.

63.2. I gave oral evidence to the Lindsay Tribunal in 2001 and the paper referred to above as "the AIDS paper" had not been published then (it was published in 2004).

c. Would the cited figures exclude, as a result of the limits of the study, any other patients who were infected as a result of the use of blood products? If so, explain which patients have been so excluded, and whether you are aware of the scale of infection in those groups. (You may be assisted by the evidence that you gave to the Lindsay Tribunal, and in particular, pp.9-10 of the Transcript [LIND0000330]).

63.3. Please see my answer to 63a.

d. In respect of the *Nature* letter, please explain how robust you consider the following conclusions to be (and why):

(i) the figure for the number of patients with severe haemophilia who were infected (1,020),

63.4. Please see my answer to 63a.

(ii) the figure for the number of patients with moderate/mild haemophilia who were infected (207),

63.5. Please see my answer to 63a.

(iii) the median estimated date of seroconversion for the two cohorts of patients (October 1982 and December 1982 respectively),

63.6. See my answer to 63a. See my answer to Q63e below.

(iv) the range of dates for seroconversion (June 1979-October 1986, and October 1979-March 1986)

63.7. See my answer to 63a. See my answer to Q 63e below.

(v) the conclusion that 85% of deaths in seropositive patients are likely to have been caused by HIV.

63.8. See my answer to 63a.

e. **Also in respect of the *Nature* letter, explain how the median estimated dates of seroconversions, and the date ranges for seroconversions were calculated.**

63.9. See my answer to 63a.

f. **Are you aware of any reason why the conclusions presented in the *Nature* letter and the *AIDS* patient should be revised, caveated, or otherwise treated with caution (for example, because of subsequent research or critiques; if so and if you disagree with those later critiques explain why)?**

63.10. Please see my answer to 63a. Also the question would be better directed to the author listed under 'address for correspondence' for each manuscript as any critiques would have been sent to them in line with usual practice.

64. You also co-authored the paper "Mortality Rates, Life Expectancy, and Causes of Death in People with Haemophilia A or B in the United Kingdom Who Were Not Infected With HIV", *Blood* (2007), 110:815-825 [PRSE0001620]. Are you aware of any reason why the conclusions presented in this paper should be revised, caveated, or otherwise treated with caution? (for example, because of subsequent research or critiques; if so and if you disagree with those later critiques explain why)?

64.1. Not that I am aware of.

Hepatitis B

65. Were patients at the Westminster Hospital and at the Oxford Centre who were infected with HBV informed of their infection and if so, how? What information was provided to patients infected with HBV about the infection, its significance, prognosis, treatment options and management? What involvement did you have in this process?

65.1. I do not recall ever dealing with a haemophilic patient in London with hepatitis B. In Oxford, I recall a couple of patients with persistent hepatitis B infection. A specialist hepatologist provided advice on monitoring and treatment.

66. How many patients at the Westminster Hospital and the Oxford Centre were infected with HBV?

66.1. See my answer to Q 65 above.

NANB Hepatitis/Hepatitis C

In respect of the questions that follow, you may be assisted by the evidence that you gave to the Lindsay Tribunal, and in particular, pp.6-9, 11, 13-14 and 18 of the Transcript [LIND0000330].

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

67.1. I cannot provide any information about Westminster Hospital.

67.2. I cannot provide any details about how the issue of NANB hepatitis was handled before I started in Oxford. Dr Joan Trowell was the gastroenterologist who followed up the Oxford patients in the 1980s, before diagnostic tests for hepatitis C became available.

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

68.1. Although I am being asked about specific matters that occurred almost 30 years ago my best recollection is that by the time I started in Oxford in April 1991, many of the patients had already been tested by Dr Matthews (my predecessor) and Dr Rizza. After I arrived, this continued to be dealt with mainly by Dr Rizza. By the time Dr Rizza retired at the end of October 1993, I believe that all our regular patients had been tested. I only recall having to tell very few patients that they had been infected .

69. In your evidence to the Lindsay Tribunal [LIND0000330, p.9], reference is made to a protocol and check list, referred to as "PG1" (which suggests that it was an exhibit to your witness statement). Please provide this protocol if it is still in your possession, or provide details about where it may be held if it is not. Please explain what the protocol and check list contained, and by whom and for what purpose they were intended to be used.

69.1. I do not have a copy of this document but a copy of it should be contained in the clinical records of patients at Oxford. The checklist was introduced in order to document what each patient exposed to HCV had been told about the condition by any of the medical disciplines that were seeing the patient.

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

70.1. See answer to Q 69 above.

71. How many patients at (a) the Westminster Hospital and (b) the Oxford Centre were infected with HCV?

71.1. I cannot provide any information about Westminster Hospital and I no longer have access to the data from Oxford.

72. In your evidence to the Lindsay Tribunal, you stated that it was estimated that in the UK *"probably 3,000 were exposed to Hepatitis C"* (pp.16-17). What was the basis for that estimate, and how robust do you now consider it to be? Has any further work been done, to your knowledge, to establish a more precise number?

72.1. It is now 19 years since I gave evidence to this Tribunal. I have no papers relating to this in my possession. Any answer would be speculation now and therefore of little assistance to the Inquiry but at the time my answer would have been based on peer reviewed studies and articles in medical and scientific journals.

Delay/public health/other information

73. 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.

73.1. As I have previously said, by the time I started work in Oxford in 1991 patients who had been infected with HIV and many of those who had been infected with HCV had been informed of the diagnosis. I have no reason to believe that there was any significant delay in informing patients with severe haemophilia who were on regular treatment and followed up closely by the centre. I cannot say how quickly patients with mild or moderate haemophilia or with mild von Willebrand disease were informed as they were generally treated infrequently, did not always maintain contact with the centre and did not always keep their changes of address updated.

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

74.1. This was not an issue for me, given that I first started work as a consultant in Oxford in April 1991 and decisions had already been taken by others with regard to information and advice provided to patients diagnosed with HIV and/or HCV.

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

75.1. Vaccination against hepatitis A was recommended. vCJD was also the subject of discussions: see section 7.

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

76.1. This was an area which was primarily covered by the experts in hepatology and infectious diseases

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

77.1. As I have previously said, by the time I started work in Oxford in 1991 patients who had been infected with HIV and many of those who had been infected with HCV had been informed of the diagnosis. Patients with severe haemophilia were on regular treatment and followed up closely by the centre. I cannot say how quickly patients with mild or moderate haemophilia or with mild von Willebrand disease were informed as they were generally treated infrequently, did not always maintain contact with the centre and did not always keep their changes of address updated.

78. At the 19th meeting of the UKHCDO Executive Committee on 5 June 2000 [HCDO0000474], there was a discussion about HIV and HCV testing following which *"it was agreed to continue to test for HIV and HCV at least annually"*. Was it intended that all patients would be tested at least annually for HIV and HCV? What was the purpose of the continued, routine testing? What information was provided to patients about it?

78.1. In Oxford, we offered HIV and HCV testing on an annual basis to establish if the patients had been infected with HIV or HCV whether this be through the use of recombinant blood products or otherwise.

Consent

79. How often were blood samples taken from patients attending (a) the Westminster Hospital, and (b) the Oxford 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?

79.1. I cannot provide any information about Westminster Hospital.

79.2. In the case of Oxford, blood samples would usually be taken at routine follow-up appointments. These appointments would be offered every six months in the case of patients with severe haemophilia. The patients would be told what blood tests were being taken.

79.3. Plasma samples sent to our own coagulation laboratory for inhibitor screens were often retained but I am not aware that there was any specific aim in mind regarding this. To the best of my knowledge this was an established practice before I started at Oxford in 1991. I do not recall specific consent being sought from patients for such samples to be retained.

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

80.1. To the best of my recollection, my usual practice would be to have detailed discussions with new patients or parents about treatment options before starting treatment and, to the best of my recollection, my usual practice was to summarise these discussions in a letter following that discussion.

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

81.1. During my time in Oxford, consent for HIV and HCV testing would always be sought by me before taking a blood sample. In the case of HIV, when I started work in Oxford in April 1991 there was already a special form in use for HIV tests on which the clinician had to indicate that consent had been provided.

PUPS

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

82.1. To the best of my recollection of between 25 and nearly 30 years ago, when I started work in Oxford in April 1991, BPL's 8Y was the concentrate used for haemophilic patients and this was used across the board from the PUPs to our older patients. I believe that PUPs were the first in at the Centre to be treated with recombinant FVIII which I think was used from 1995. I think that I enrolled one or two PUPs in an international multicentre clinical trial (approved by our local ethical committee and institution) of the second-generation recombinant FVIII product Kogenate FS (made by Bayer) which began in 1998. This product contained no albumin and so it was widely viewed as an improvement on previous products.

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 (a) the Westminster Hospital, and (b) the Oxford Centre? In particular:

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

83.1. I have no information about Westminster Hospital.

83.2. Patients in Oxford would have been referred for specialist advice and follow up to a hepatologist or infectious diseases expert.

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

83.3. The care would have been provided by the infectious diseases team, which should be able to answer this question.

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

83.4. I am not able to answer this question as these treatments were only provided by the infectious diseases team

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

83.5. Please see my answer to b and c above.

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

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

84.1. I do not recall ever dealing with a haemophilic patient in London with HBV. In Oxford, there were a couple patients with persistent hepatitis B infection who had access to care from a hepatologist.

b. What treatment options were offered over the years?

84.2. See my answer to Q 84a above.

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

84.3. See my answer to Q 84a above.

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

84.4. See my answer to Q 84a above.

85. How was the care and treatment of patients with NANB hepatitis managed at (a) the Westminster Hospital and (b) the Oxford Centre? In particular:

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

85.1. I cannot provide any details about how the issue of NANB hepatitis was handled before I started in Oxford.

b. What treatment options were offered over the years?

85.2. I cannot answer this question, which refers to an era before I started work in Oxford.

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

85.3. I cannot answer this question, which refers to an era before I started work in Oxford.

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

85.4. I cannot answer this question, which refers to an era before I started work in Oxford.

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

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

86.1. All haemophilia patients who had been infected with HCV would have been referred to a hepatologist for further follow up and, if necessary, treatment.

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

86.2. Please see my answer to 86a.

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

86.3. I am not able to answer this question as these treatments were only provided by the hepatology team.

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

86.4. Please see my answer to 86a

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

87.1. As far as I can recall, children in Oxford would have been treated by the same teams as those who looked after adults.

88. What if any involvement did you and/or colleagues at (a) the Westminster Hospital and/or (b) the Oxford Centre and/or patients under your care have with any clinical trials in relation to treatments for HIV and HCV? Please provide details.

88.1. I cannot provide any information about Westminster Hospital.

88.2. I cannot provide any information about clinical trials in Oxford as I was not involved. If patients were involved in any clinical trials relating to HIV or HCV, this would have been through other departments.

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

89.1. Some of this information relates to circumstance nearly 30 years ago. However, to the best of my knowledge, when I started work in Oxford in 1991, there was a social worker who would offer support to patients infected with HIV. I believe that the social worker was employed by Oxfordshire County Council and was in post until the late 1990s. After that, to the best of my knowledge, no particular social worker was allocated to these patients but there would have been several others in the hospital who could be called in for support. The nurses also offered valuable support to the patients. Their support was much appreciated by the patients. I recall that one of the longest-serving nurses was also a trained psychotherapist.

90. In your evidence to the Lindsay Tribunal [LIND0000330], you stated that, in retrospect, you thought that it would have been helpful to put in place internal procedures to assist staff at the Oxford Centre in helping patients with HCV and HIV (p.18).

a. Is this a correct interpretation of your evidence, and do you remain of that view?

90.1. I do think that it would have been helpful to have had internal procedures to assist staff at the Oxford Centre in helping patients with HCV and HIV in the early years after I started at Oxford.

b. Please provide further details of what such internal procedures could, helpfully and practically, have covered.

90.2. In retrospect, I think rotation of staff would have been helpful, either to other roles within the Haemophilia Centre or to other departments. Insisting on staff leaving on time at the end of the day and not allowing staff to work late on a regular basis would also have helped to reduce the burden as well as

making sure all leave was taken and weekends were not eaten into. Social events, like meals out together, help bring a team together. Towards the end of my time in Oxford, the hospital introduced an awards scheme to recognise the contribution of staff: a scheme like this would have been helpful earlier.

c. Are you aware of any haemophilia centre that did put in place such procedures?

90.3. Not that I can recall.

d. Did you put in place any such procedures in the Oxford Centre following your evidence to the Lindsay Tribunal in 2001? If not, why not?

90.4. No, we did not introduce any such measures after I gave evidence in 2001. The general prospects for effective treatment of patients had evolved and improved by then.

91. Did any of the institutions at which you worked 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?

91.1. Not that I am aware of.

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

92.1. I do not recall hearing any complaints from my colleagues in the infectious diseases department about securing funding for treatment, although I seem to recall hearing that when direct acting antiviral agents for hepatitis C were introduced that funding was limited, resulting in a 'waiting list' for treatment.

High Purity products

93. Please set out your involvement in the debate about the need for and/or use of high purity products for HIV positive patients. Did you use such products for HIV positive patients at any of the hospitals at which you worked and if so which?

93.1. I am being asked to recall matters in some cases for over 30 years ago. However, I believe I would have followed the developments and publications in the field whilst I was working in research posts in London and Milan and my research at the Royal Free Hospital in 1988/9 touched on this issue. I seem to recall that there was some evidence that the use of high-purity plasma-derived products was associated with better preservation of CD4 lymphocyte count and that it was recommended that these products be used.

Recombinant products

94. Please provide (to the extent that you are able to from your own knowledge) a chronological account of the introduction of recombinant products in the UK. (You may be assisted by consideration of the papers, "Treatment of haemophilia in the United Kingdom, 1981-1996", *Haemophilia* (2001), 7, 349-359 [HCDO0000012_173], "nvCJD and Blood Products in the UK"(seemingly presented at the 35th Haemophilia Symposium, Hamburg 2004 –please confirm whether this is correct) [GLEW0000067], and your article in Haemophilia Society, *Bulletin* , December 1995, p.8 [HSOC0022988]).

94.1. These are historical articles. I am unable to better the content of these now as these were published between 19 and 25 years ago. Any response would only be a repetition of this information.

95. Please explain your involvement, and that of UKHCDO, the Recombinant Users Group, relevant pharmaceutical companies and the Haemophilia Society, with efforts to obtain recombinant blood products for patients with haemophilia. What difficulties were encountered and why? You may be assisted by:

a. **The correspondence relating to one of your patients, for whom you recommended recombinant products in 1996 [HSOC0017402_001 to HSOC0017402_009; HSOC0017764 and HSOC0017403]. You are not asked to comment about the specific details of this patient, but it would assist if you could explain the extent to which the matters referred to in this correspondence were typical, and what – if any – progress was made in overcoming them.**
b. **A publication by the Haemophilia Society, dated 23 May 2001, "Recombinant – the case for extending provision to adults", in which you are quoted at p.3 [HSOC0006031]**
c. **The minutes of the First (Extraordinary) Meeting of UKHCDO Executive Committee held on 30 January 1996 [HCDO0000456]. Please provide an explanation of the tensions that are referred to in that meeting about the role of the UKHCDO, and in particular the Chair, Dr Colvin.**
d. **The following media reports in which (among others) you are quoted: "Money, or their lives…" *Independent*, 17 September 1996 [HSOC0003936]; "A bloody disgrace" *Daily Mirror* , 19 August 1996 [HSOC0027078]; "Haemophiliacs praise Irish stance on safety" *New Scientist*, 7 February 1998 [DHSC0040895_074]; "Doctors get to grips with new variant of CJD" *Hospital Doctor* , 14 May 1998 [BPLL0016004_007] transcript of BBC Radio 4 *The World Tonight*, 3 April 2002 [DHSC0041379_024]**

95.1. I was an advocate, with others, of recombinant products. My views were expressed in an invited review I wrote to propose the case for recombinant products to an international audience in 2003 (WITN3311004)

95.2. In my view, there were three obstacles to the immediate introduction of recombinant factor VIII (which became available earlier than recombinant FIX) in the UK.

95.2.1. Lack of consensus among medical community. This difference of opinion appears in the minutes of the First (Extraordinary) Meeting

of UKHCDO Executive Committee held on 30 January 1996 [HCDO0000456].

95.2.2. Cost of recombinant FVIII which was approximately twice that of plasma-derived products. The addition of VAT at 17.5% on top of the base price was a further burden. However, the commissioners who covered our core area were always very helpful.

95.2.3. It is my opinion, but I have no evidence to support this contention, that concerns about the future and viability of BPL's fractionation facility may have delayed the authorisation of the use of commercially sourced recombinant FVIII by the Department of Health.

96. The Inquiry understands that VAT was charged on recombinant products from 1995 as they were not classified as blood products (see article in the Haemophilia Society, *Bulletin*, December 1995, p.3, and also your own article in the same edition at p.8 [HSOC0022988]). You are quoted as expressing opposition to this policy: see (as an example) "A bloody disgrace" *Daily Mirror,*19 August 1996 [HSOC0027078].

a. Explain your opposition and your role in the campaign against the charging of VAT on such products.
b. Was the campaign successful, and if so when?
c. In your view, what was the effect of the decision to charge VAT on recombinant products? In particular, did it limit the amount of patients receiving such products, and if so for how long and with what effect?

96.1. I am being asked for recollections relating to a newspaper article that I did not write of 25 years ago. However, my view is that the imposition of VAT at 17.5% was an unwelcome additional burden on the overall cost of providing these blood products. Whilst blood products (including conventional coagulation factor concentrates) are exempt from VAT, medicines are not and recombinant FVIII was classed as a medicine. A

legal challenge was brought by the manufacturers but this failed and I believe that it is still the case today that VAT is chargeable except in a particular circumstance referred to below.

96.2. Some years later a loophole was identified. It emerged that recombinant products would attract no VAT if distributed directly to patients at home and this stimulated the universal adoption of home delivery in the UK. VAT is still payable on recombinant concentrates used in hospital.

97. In your view, should recombinant blood products have been made available to all patients with haemophilia earlier than they were? If so, why, and when?

97.1. It is my view that recombinant products should have been made available to all patients by the middle of 1997. The UKHCDO published guidelines in early 1997 (a statement was initially issued several months earlier in 1996) advocating recombinant FVIII for all patients (WITN3311005) with haemophilia A It was only in the financial 2004/5 that all patients with haemophilia A in the UK were treated with recombinant FVIII.

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

98.1. I no longer have access to the data in Oxford following my retirement.

Research

99. Please list all research studies that you were involved with during your time at the Westminster Hospital, the Royal Free Hospital, the Milan Centre and the Oxford Centre.

99.1. As I no longer have access to Trust records, I am unable to provide a list of all clinical trials and other studies that I was involved with in Oxford. I can certainly provide a complete list of my publications (WITN3311006) and these include results of formal clinical trials, epidemiological studies and

reviews. However, it is likely that there are other studies I was involved with but which did not result in publications bearing my name as a co-author.

In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please:

a. Describe the purpose of the research.

99.2. Publication 7: This was the core of my research work for my MD thesis and was carried out at the Royal Free Hospital in London. This was an *in vitro* study of lymphocyte activation in 64 subjects with haemophilia and 21 normal subjects. Conclusion: "These findings do not support the hypothesis that lymphocytes of haemophiliacs are affected directly by the regular administration of intermediate purity concentrates so as to accelerate the progression of HIV disease."

99.3. Publication 10: A study of the pharmacokinetics and thrombogenicity of a high-purity plasma-derived factor IX concentrate manufactured by BPL (subsequently licenced as Replenine). 19 patients recruited from various treatment centres in the UK. The importance of this study is that it helped to prove that there was a lower risk of thrombosis associated with the use of high-purity FIX concentrate compared intermediate purity products which were still available.

99.4. Publication 29: histopathological study of *post mortem* brains of 33 patients who were treated at 3 UK haemophilia centres with clotting factor concentrate of predominately UK donor source during the years 1962-1995. No evidence of spongiform encephalopathy was found and the immunocytochemistry was negative for prion protein in all cases. "It is concluded that, at present, there is no evidence for the transmission of nvCJD via clotting factor concentrate to patients with haemophilia."

99.5. Publication 33: A study of the pharmacokinetics of a brand of recombinant factor VIII manufactured by Baxter (Recombinate). 30 patients recruited

from four treatment centres in the UK. This product was already licenced for routine clinical use at the time of this study. The specific aim of the study was to compare factor VIII assays using chromogenic assays (which were new at the time) with conventional one-stage factor assays. This had implications for labelling of potency as well as monitoring of patients.

99.6. Publication 46: International multicentre study of the use of a second generation (albumin free) recombinant factor VIII concentrate (Kogenate FS, manufactured by Bayer) in 31 previously untreated patients (PUP) and minimally treated patients (MTP). The removal of albumin was a clear improvement on the first-generation product. PUP studies were required by licencing authorities such as the FDA and EMA.

99.7. Publication 54: This was a study to determine whether there was any evidence of transmission of various porcine virus associated with the use of porcine FVIII (used to treat patients with inhibitors). I was only involved in the analysis of the data after samples had been collected in the USA, Canada and two haemophilia centres in the UK (no patient from Oxford was involved in this study). No evidence of pathogen transmission was found. However, this plasma-derived product was not heat-treated and the company withdrew the product from the market and it was replaced by a recombinant version about a decade later.

99.8. Publication 67: International multicentre study of the pharmacokinetics of NovoSeven (manufactured by Novo Nordisk). This product was already licenced at the time for treatment of patients with inhibitors. 12 children and six adults were studied. This study documented a significantly higher clearance and shorter half-life in children which had important implications for dosing.

99.9. Publication 72: This clinical trial evaluated the safety and efficacy of a brand of recombinant FVIII (ReFacto, Wyeth) which was already licenced and in routine clinical. This was an open-label, multicentre, post-marketing surveillance study in which 60 patients received prophylaxis or on-demand

treatment for 6 months or 50 exposure days (EDs), whichever occurred first. The purpose of the study was simply to confirm safety and efficacy. Post-licencing surveillance studies are positively encouraged by the regulatory authorities nowadays.

99.10. Publication 84: International multicentre study of NovoSeven (manufactured by Novo Nordisk). This product was already licenced at the time for treatment of patients with inhibitors. The aim of this study was to see whether it could be given by subcutaneous injection. Sixty patients were enrolled. Unfortunately, absorption after subcutaneous injection was poor and so the concept was not taken any further.

99.11. Publication 85: International study in 16 patients of a new pegylated recombinant FIX concentrate manufactured by Novo Nordisk. 16 subjects studied. Half-life was five times longer than normal factor IX-a huge improvement. This product is now licenced as Refixia.

99.12. Publication 94: International multicentre study of a pegylated version of NovoSeven (manufactured by Novo Nordisk), designed to try and extend its half-life. 23 patients were enrolled. Unfortunately, there was no benefit in terms of preventing bleeds and so the concept was not taken any further.

99.13. Publication 107: International study in 13 patients undergoing surgery using a new pegylated recombinant FIX concentrate manufactured by Novo Nordisk. Confirmation of efficacy in setting of surgery is required by licencing authorities such as FDA and EMA. This product is now licenced as Refixia.

99.14. Publication 108: Phase III international, multicentre clinical trial of a long-acting FVIII product manufactured by Novo Nordisk. 186 adult and adolescent patients enrolled. Study documented prolonged half-life, good efficacy and safety and the product is now licenced as Esperoct.

99.15. Publications 9/13/17/19/20/94: these were immunological studies carried out by senior scientists in the University of Oxford on the immune response to HIV

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

99.16. All clinical trials of new therapeutic products which I was involved with in Oxford received prior ethical committee and institutional approval. My work at the Royal Free Hospital (publication 7) also received prior ethical committee approval.

c. Explain what your involvement was.

99.17. I was the local designated Principal Investigator for the clinical trials referred to above, which included taking responsibility for treating patients recruited to the study according to the approved protocol.

99.18. In the case of publication 7, my roles were to analyse blood cells in the laboratory using a flow cytometer and monoclonal antibodies to quantify lymphocyte activation of lymphocytes and to correlate the results with treatment records.

99.19. The primary purpose of work described in publication 29 was to determine whether prions were present or not in brain sections and this was undertaken by Prof. Ironside and Dr Bell at the CJD Surveillance Unit in Edinburgh. My role in the study was to provide details of treatment which the subjects from Oxford had received.

99.20. In the case of publication 54, I was approached by the company which manufactured porcine FVIII (Speywood) after the samples had all been collected and tested. My role (together with Dr Craig Kessler in the US) was to provide clinical input to the analysis and conclusions.

99.21. The immunological studies (Publications 9/13/17/19/20/94) reported the results of *in vitro* laboratory work carried out by senior scientists in the University of Oxford on blood samples provided by some of our haemophilic patients. I was only peripherally involved in this research, helping to identify suitable patients to study and provide details of previous treatment received but I was not involved in the laboratory work.

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

99.22. Most clinical trials in the field of haemophilia are international multicentre studies. The names of centres participating in studies are usually listed in a publication and the co-authors also give an indication of the main other hospitals involved in a study.

99.23. The screening of brain sections for prions described in publication 29 was undertaken by Prof. Ironside and Dr Bell at the CJD Surveillance Unit in Edinburgh.

99.24. The testing of samples for antibodies to porcine pathogens reported in publication 54 was carried out by the UK Veterinary Laboratories Agency (a UK government body)

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

99.25. Clinical trials of therapeutic products are funded by the manufacturing company (listed in answer to Q 99a above). In Oxford, a contract would have been drawn up between the hospital and the company and the company would have paid the hospital a fee and also had to provide evidence of insurance cover. No fees were ever paid to physicians involved in clinical trials.

99.26. The research described in publication 7 was carried out with support from the Special Trustees of the Royal Free Hospital, the Haemophilia Society and the Peter Samuel (Royal Free Fund).

99.27. The immunological studies (Publications 9/13/17/19/20/94) carried out in Oxford were largely funded by the Medical Research Council and Wellcome Trust.

f. State the number of patients involved.

99.28. I cannot provide details of how many patients from Oxford were recruited but the total number for each study is listed in my answers to Q 99a above.

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

99.29. I do not now have access to any documentation relating to patient consent. However, patients (or parents/guardians in the case of minors) would have given written informed consent in all clinical trials I have listed above. Signed consent would also have been provided before taking blood samples for the research work at the Royal Free Hospital described in publication 7. Scrutiny of the consent form is a component of ethical committee approval.

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

99.30. A complete list of my publications (WITN3311006) is attached.

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.

99.31. The epidemiological studies I was involved with appear as numbers 14, 16, 23, 25, 41, 52, 68, 69 and 78 in my list of publications, the scope of the research will be obvious from the title of each manuscript. All these studies analysed data derived from the UKHCDO national database.

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

100.1. Not in the clinical trials I conducted.

100.2. The source of data used for epidemiological studies I was involved with (listed below in answer to Q 104) was the UKHCDO national database. Patients did not give written consent for their data to be entered on the national database and this was still the case until I retired. All studies, however, received ethical committee approval in advance.

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

101.1. Please see my answer to 100.

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

102.1. Patient data for research would only be shared between people specified in the ethical committee approval.

103. What, if anything, did you tell your patients about this request and your response to it?

103.1. Please see my response to 100-102 above.

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

104.1. A complete list of my publications is attached (WITN3311006)

Transfusion

105. The questions above have focused on the care and treatment of patients with bleeding disorders. What role, if any, did you play in advising or treating patients receiving blood transfusions in (a) the Westminster Hospital and (b) the Oxford Centre?

105.1. This is a generic rather than specific answer due to the generic nature of the question. I cannot recall any specific patient case. However in my career as a clinician, I would have prescribed blood packs and blood products (fresh frozen plasma, platelets etc) for transfusion. The Oxford Haemophilia Centre is an outpatient facility with no beds and so not an area where a blood transfusion can be given. Patients with haemophilia who required admission would be admitted under other clinical teams (such as orthopaedics, infectious diseases, gastroenterology) and it would be the teams from those other departments who would prescribe blood should that be required.

If you did play a role:

a. Over what period of time were you involved, and what was your role?

105.2. Please see my response to the stem of 105.

b. How frequently (approximately) did you speak to patients about the risks of blood transfusion and/or the risks of blood products (other than products used in the treatment of patients with bleeding disorders) and in what kinds of circumstances?

105.3. Please see my response to the stem of 105.

c. What (if any) information did you typically provide to patients about the risks of infection from transfusion?

105.4. Please see my response to 105. This is a generic question with no focus relating to a particular time or category of patient. I am being asked to give a specific answer to a generic question for a period that spans nearly 40 years which is not possible.

d. What (if any) information did you typically provide to patients about the risks of infection from blood products (other than products used in the treatment of patients with bleeding disorders)?

105.5. Please see my answer to 105c.

e. What discussions did you have with colleagues about the risks of transfusion?

105.6. Please see my answer to 105c

f. Who was responsible for providing information to patients about the risks of infection from transfusion–the treating clinicians, you as haematologist responsible for the blood bank or some other person?

105.7. I was never responsible for a blood bank. I believe that ultimately it is the responsibility of the blood transfusion service to provide blood and blood products that are fit for purpose.

Records

106. What was the policy at (a) the Westminster Hospital, and (b) the Oxford Centre as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?

106.1. I am not able to provide any information regarding Westminster Hospital.

106.2. I cannot answer this question as the Oxford Haemophilia Centre has always been an outpatient facility with no beds and so no patient would die at the Centre. Further when patients died in hospital in Oxford, death certificates were completed by doctors on the admitting clinical team (e.g. gastroenterology or infectious diseases).

107. What were the retention policies of (a) the Westminster Hospital, and (b) the Oxford Centre in relation to medical records during the time you were practising there?

107.1. I am not able to provide any information regarding Westminster Hospital.

107.2. When I was a consultant in Oxford, I believe that there was a policy of retaining clinical files on all our patients (including patients who died). I cannot recall the specifics of this now and suggest contacting the relevant institution.

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

108.1. Although I cannot recall specifics as I am being asked to recall administrative procedures which may include those from nearly 30 years ago, to the best of my knowledge the Oxford Haemophilia Centre maintained separate clinical files on site for patients seen there. These patients could call in to be seen at any time and without notice or telephone for advice. For many years, patients were also seen on site out of hours for emergencies (saving them a visit to the A & E department). For these reasons, instant access to the patients' clinical records was required. I assume that these records are at the Oxford Haemophilia Centre.

109. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere

other than the hospital where you worked? If so, why, what information and where is that information held now?

109.1. No.

Section 5: UKHCDO

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

110.1. I was a member of UKHCDO throughout my time in Oxford. I was a member of various working parties at different times (I cannot remember precisely when) including the Adverse Events; Hepatitis; Paediatric; Bleeding Disorders in Women; and Musculoskeletal Working Parties. I was never elected to senior office within UKHCDO (Secretary/Treasurer/Vice Chairman/ Chairman) and never sought election to one of these positions.

110.2. Although I have no recollection of the meetings and how may I attended, I think that I attended most of the UKHCDO meetings until 2000.

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

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

111.1. The aims and purpose of the organisation are set out its the constitution. From a practical point of view, the organisation provided a forum for clinicians working in the field of haemophilia to meet up on a regular basis and discuss current issues, both medical and administrative. Working Parties also produced evidence-based guidelines, which were useful and I believe that some were adopted by colleagues abroad.

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

111.2. A more accurate answer to this question could be obtained from the UKHCDO. I am being asked to recollect general matters some of which stem from nearly 30 years ago. As far as I can recall, when I took up my post in Oxford 1991, a representative from each haemophilia centre would be able to attend meetings of the 'Executive Committee' and would be able to contribute in discussions. A new constitution was implemented in or around 2002 which I am sure can be obtained by the Inquiry.

111.3. As regards membership of working parties, people would be invited to apply to the Chairman whenever a vacancy became available. The Chairman would then make a recommendation to the rest of the group in due course and these were invariably accepted. Working Parties produced very useful evidence-based guidelines, which were frequently referred to by colleagues abroad.

c. The relationships between UKHCDO and pharmaceutical companies.

111.4. I am not aware that UKHCDO had any close links with pharmaceutical companies.

d. How UKHCDO was funded.

111.5. I do not know.

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

111.6. This is a very general question and therefore I can only answer accordingly. I think that Working Party guidelines would usually be published in major medical journals. Important notices would be sent out by the Secretariat staff or Chairman either by post or email.

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

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

111.7. I was a member of the UKHCDO Working Party which published "Guidelines on the selection and use of therapeutic products to treat haemophilia and other hereditary bleeding disorders" in 2003 (Haemophilia Vol 9, pages 1–23) (WITN3311007).

ii. the manufacture of blood products;

111.8. None

iii. self-sufficiency;

111.9. None

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

111.10. The 2003 UKHCDO publication on selection and use of products to treat haemophilia to which I contributed as a co-author, includes information about the use of desmopressin (also known as DDAVP), tranexamic acid and fibrin sealants.

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

111.11. I was always an advocate of recombinant products at UKHCDO meetings. The 2003 UKHCDO publication on selection and use of products to treat haemophilia referred to in Q 111 f (i), to which I contributed as a co-author, includes discussion on the topic of risks of infection associated with blood products.

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

111.12. The 2003 UKHCDO publication on selection and use of products to treat haemophilia referred to in Q 111 f (i) states: "Patients with haemophilia are very well informed about their condition, its treatment and the potential hazards of therapy and it is, therefore, appropriate that their views are taken into account when therapeutic decisions are being considered. In addition, the product information leaflet should always be consulted."

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

111.13. None

viii. heat treatment;

111.14. None

ix. other measures to reduce risk;

111.15. The 2003 UKHCDO publication on selection and use of products to treat haemophilia referred to in Q 111 f (i) also refers to the merits of vaccination against hepatitis A and B.

x. vCJD exposure;

111.16. Whilst my comments relate to matters nearly 20 years ago, I do not recall the UKHCDO having a policy on this.

xi. treatments for HIV and hepatitis C (including the guidelines on treatment for chronic liver disease).

111.17. I was co-author of UKHCDO guidelines on the diagnosis and management of chronic liver disease published in Haemophilia in 1995 and 2001 (WITN3311008). These came out of discussions among the UKHCDO Working Party on Chronic Liver Disease in Haemophilia.

When addressing this question, please include a description of your involvement in the production of UKHCDO's Recommendations.

112. Please describe the work of the Adverse Events Working Group, and your role in it. You may be assisted by referring to the decision of the 17th Meeting of the UK Regional Haemophilia Centre Directors Committee on 5 September 1994 [HCDO0000452] in which it was agreed that the Working Group should be reconvened, with you in the Chair.

112.1. Again, you are asking me to recollect matters from over 25 years ago. As far as I can recall much of the key work was carried out by Rosemary Spooner in Oxford centre. As far as I can recall the general process was that every three months an 'orange card' would be sent out to the haemophilia centres seeking notification of the following: new inhibitor, HIV transmission, hepatitis B or C transmission, thrombosis, transfusion reaction or 'other'. There was also a 'nothing to report' box to tick if none of these applied. My role was to draft a short summary of returns for each UKHCDO meeting and also to prepare an annual summary for the UKHCDO annual report. New inhibitors cases were passed on to the UKHCDO inhibitor working party. Allergic reactions were reported to manufacturers as well as to the regulatory agencies through the 'yellow card' system if the reporting clinician had not already done so. My role in collating adverse events came to an end when Rosemary Spooner retired and the UKHCDO database moved to Manchester in 2002.

113. At the 18th meeting of the UKHCDO Executive Committee on 11 February 2000 (minutes enclosed [HCDO0000473]) there was a discussion about issues that had been raised by the Department of Health and the Department was reported to be "anxious for information" about social services support.

a. What kind of information was being sought by the Department of Health and for what purpose?

113.1. I do not remember.

b. What information was provided to the Department of Health by UKHCDO?

113.2. I do not remember.

c. Reference was made in the minutes to support being withdrawn from some patients. What, if any, steps were taken by UKHCDO to address this issue?

113.3. I do not remember.

d. To what extent did patients under your care receive support from social services and how did that change over time?

113.4. When I started work in Oxford in 1991, I believe that there was an allocated social worker to support patients infected with HIV. I think that this social worker was employed by Oxfordshire County Council and this continued until the late 1990s. After that, rather than an allocated social worker, there were several within the hospital who could be called in for support. In addition, the nurses offered social work type support beyond what would normally be expected of a nurse. Their support was much appreciated by the patients.

National Haemophilia Database

114. Please describe the establishment and operation of the National Haemophilia Database, its purpose and objectives, your involvement in it, the range and kind of data recorded in the Database and how data is collected and organised. (You may be assisted by the following, as well as the documents cited in later questions in this section: "Work Undertaken by Rosemary JD Spooner on behalf of the United Kingdom Haemophilia Centre Directors, 1968-1996" [HCDO0000010_001], Minutes of the First Meeting of the Information Technology Working Party, 13 December

1996[HCDO0000002_170], "Treatment of haemophilia in the United Kingdom,1981-1996" *Haemophilia* (2001), 7, 349-359 [HCDO0000012_173]).

114.1. The history and work of the national haemophilia database is set out in great detail in HCDO0000010_001: "Work Undertaken by Rosemary JD Spooner on behalf of the United Kingdom Haemophilia Centre Directors, 1968-1996". I am not sure that my recollections of nearly 25 years ago can improve upon this.

115. Please explain how the work of the National Haemophilia Database has been funded over the years; how it is currently funded; and what, if any, financial contributions have been offered or made by (a) pharmaceutical companies and (b) the Department of Health.

115.1. This information can be obtained from those running the database. My recollection of funding from between 20 and 30 years ago is that it was mainly funded from by the Oxford Haemophilia Centre. Whilst I cannot now be specific there may have been occasional small payments from UKHCDO. I do not recall any contribution from pharmaceutical companies or specific contribution from the Department of Health.

115.2. I am not able to provide detailed information about how the database is funded now.

a. You are reported in the minutes of the 18th Meeting of the UK Haemophilia Centre Directors' Organisation Executive Committee, 11 February 2000, as being *"wary"* of commercial funding of the National Haemophilia Database [HCDO0000473]. Did this accurately express your view then? Why did you hold that view? Did your views change?

115.3. It is now 20 years since this meeting and I have no recollection of it. I think that my comment in the exchange referred to above may have been related to funding for UKHCDO in general and not just the database. My view is

that UKHCDO as an organisation should not accept funding from pharmaceutical companies and for the database in particular.

116. Please explain how the question of patient consent in relation to the National Haemophilia Database has been approached over the years. (Amongst the documents enclosed with this letter, you may wish to consider: section 7 of the minutes of the 18th meeting of the UKHCDO Executive Committee on 11 February 2000 [HCDO0000473]; minutes of UKHCDO Data Management Group on 8 August 2000 [HCDO0000013_286]; section 11 of the minutes of the 1st meeting of the UKHCDO Advisory Committee on 11 September 2000 [GGCL000089]; section 12 of the minutes of the 1s t AGM of UKHCDO on 29 September 2000 [GGCL000085]; section 3 of the minutes of the meeting of the UKHCDO Data Management Group, 7 February 2002[HCDO0000005_014]) Please address in your response the extent to which there have been differences of opinion and approach amongst haemophilia centre directors in relation to this issue.

116.1. During my time at Oxford, from 1991 to 2015, written consent was not requested from patients for their data to be entered and stored on the UKHCDO national database.

116.2. After the introduction of the Data Protection Act, and after some discussion within the UKHCDO, the group agreed that patients would be informed that their data were being collected and stored but consent would not be sought. A leaflet was produced on behalf of UKHCDO for patients explaining this situation, which was distributed to haemophilia centres. As far as I can recall, we handed out the patient information leaflet to patients in Oxford. Further again as far as I can recall, most patients in Oxford were already aware of the existence of the national database. During my time in Oxford, I do not recall any patient expressing concern to me about their data being on a national database or asking me to delete it.

117. In the Minutes of the 27th meeting of UKHCDO Directors on 29 September 1995 [HCDO0000495], reference is made to a letter that you sent to Dr Colvin

in which you, *"wondered to what degree the data should be released outside the UKHCDO"*, and noted that you were receiving requests for information regarding individual patients. A discussion of the legal position followed. Please explain what concerns you had on this point at this time. Please also outline the way in which material from the database was used, and how and why that changed over time. (You may also be assisted by the exchange of correspondence between you and Dr Colvin in October 1995, at BART0000648_025 and BART0000648_026).

117.1. I am being asked to recall specifics about a letter that was written and a meeting that took place 25 years ago neither of which I recall writing or attending respectively. As far as I can now recall, the exchange of letters with Dr Colvin related to a query that revolved around the issue of who owned information on the UKHCDO database. Patients at Oxford could request copies of their medical notes or data held on the hospital computers. Again as far as I can recall, Dr Colvin wanted the UKHCDO database to be separately registered, which I believe it was. Therefore requests for information held on behalf of UKHCDO would have been referred to UKHCDO for processing and authorisation.

118. In the minutes of the 18th meeting of the UKHCDO Executive Committee on11 February 2000 (at section 13 headed Annual Returns) [HCDO0000473] it was recorded that information about Hepatitis C in haemophilia patients had been requested by the Department of Health. Please explain what information was sought by the Department of Health and for what purpose, and what information was provided by UKHCDO to the Department of Health.

118.1. I do not know: please contact wither the UKHCDO or the Department of Health.

<u>Section 6: Pharmaceutical companies/medical research/clinical trials</u>

119. Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation

and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.

119.1. Yes. As far as I can recall, I provided advice to Bayer and Novo Nordisk relating to educational courses. I also provided advice to Speywood, after they discontinued manufacture of Hyate:C in or around 1996.

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

120.1. Yes. See answer to 121.

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

121.1. Yes. I have sat on advisory boards convened by CSL Behring (formerly Armour), Novo Nordisk and Bayer. I have also been a member of Data Safety Monitoring Boards convened by Bayer, CSL Behring and Pfizer. From the records which I have been able to locate, I am able to say that I received £9986 in 2013/14 and £10670 in 2014/15. I retired from the NHS and practise at the end of May 2015. In my retirement I have been engaged in similar work.

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

122.1. No.

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

123.1. No.

124. 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.

124.1. No.

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

125.1. My Trust introduced a requirement for declarations of interest some years ago. I believe this was in around 2004 when the new consultant contract was introduced. I have complied with this.

125.2. UKHCDO also requested periodic submissions of declarations of interest and I complied with this.

125.3. For the last 15 years or so, it has been a requirement to provide a brief summary of disclosures of interest at the end of manuscripts submitted to journals for publication and in an opening slide when giving a lecture at conferences.

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

126.1. I have given extensive details of clinical trials I have carried out for pharmaceutical companies in response to Q 99. All of these received both

ethical and institutional approval in advance. I never received any fees from companies for conducting such studies.

a. You are referred to in a letter, dated 29 May 1984, from Armour Pharmaceutical Company Limited to the Medicines Division of the Department of Health and Social Security as someone who was requested to be added as an *"additional investigator"* in respect of the heat treated Factorate CTX product [ARMO0000148]. Please explain what role you played in this matter, and what the outcome of your work was.

126.2. Again you are asking me to recollect something specific, this time from 37 years ago. I have no recollection of what is referred to in this letter.

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

127.1. No (apart from results relating to clinical trials conducted in the hospital on behalf of companies which had received ethical committee and institutional approval).

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

128.1. Throughout my time as an NHS consultant, I have never carried out research for pharmaceutical companies which had not received ethical committee and institutional approval.

129. The Inquiry has obtained a document, an internal Cutter/Bayer UK memorandum dated 28 July 1989 [BAYP0000016_011], which records a visit to the Royal Free in July 1989. The memorandum reports concerns that a patient may have been infected with HBV as a result of the use of the product Koate HS. The document refers to concerns that Dr Kernoff had in respect of this matter. You are referred to in the document, which records you

observing that Dr Kernoff's concerns should be seen within the context of his involvement in civil law suits. You are not asked to comment about the specific details of the patient referred to in the letter, but it would assist if you could please provide an account of this matter, your role in it, and your view of how

(a) Dr Kernoff, and (b) the representatives of the relevant pharmaceutical company (Cutter) dealt with the issues raised.

129.1. I have no recollection of this matter or discussion, which dates back 31 years.

Section 7: vCJD

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

130.1. Again you are asking for my specific recollection matters starting 35 years ago. I have no specific recollections but research would show the following:

130.1.1. 1984/85: Bovine Spongiform Encephalopathy (BSE, also known by the popular name of "mad cow disease") appears in UK cattle.

130.1.2. 1990: Chief Medical Officer (CMO) says beef is safe to eat and a photograph is published in the media of the then Minster for Agriculture (John Gummer) feeding a hamburger to his daughter.

130.1.3. 1996: Spongiform Encephalopathy Advisory Committee (SEAC) announces probable link between BSE in cows and vCJD in humans and a publication in line with this appears in the Lancet. This would have suggested to me for the first time that infection could be passed on by blood transfusion.

130.1.4. 1997: BPL withdrew two batches of FVIII after two blood donors who had contributed to the plasma pool used for fractionation developed vCJD.

130.1.5. 2001: BPL informed haemophilia doctors in the UK that a donor who contributed plasma in 1996 had developed vCJD. His plasma had been used to manufacture batches of FVIII and IX as well as other products which were issued in 1997 and 1998.

130.1.6. 2004: First case report is published of vCJD in a recipient of a blood transfusion. The recipient died five years after receiving a blood transfusion from a donor who subsequently developed vCJD.

130.1.7. September 2004: Department of Health instructs UK Haemophilia Centres to write to patients to advise them that anyone who had received factor concentrates made from British plasma in the period 1980-2001 should be considered to be at increased risk of developing vCJD.

131. Please describe your involvement in decisions as to what in formation to provide to patients about vCJD, both in your roles at the Oxford Centre and with the UKHCDO. Please address in your answer: (i) concerns raised in 1997-1998 about possible exposure of patients using blood products to vCJD, following the identification of plasma donor with vCJD, (ii) similar concerns raised in 2000-2001, (iii) the 2004 notification process, (iv) the 2006 notification process, and (v) the 2009 notification process. Please also answer the following questions:

a. What discussions took place (a) within UKHCDO, (b) with other organisations (including the Haemophilia Society, CJD Incidents Panel and UK Health Departments) and (c) within the Centre?

131.1. I have never been involved in discussions with the CJD Incidents Panel or UK Health Departments.

131.2. My views at the relevant times, as well as a summary of views within UKHCDO and the involvement of the UK Haemophilia Society, are set out in the letters sent to patients in December 1997 [WITN3063002] and January 2001 [WITN3063004] as well as the document prepared by Karin Pappenheim (then Chief Executive of the UK Haemophilia Society) and myself for a World Federation of Hemophilia conference in 2001 [DHSC0006838_071].

131.3. In so far as I can now recall, I am not aware that the haemophilia centre in Oxford was consulted in advance about the 2004 notification exercise. As far as I can recall, a template letter was provided which we were obliged to add our names to but we could not alter the text.

131.4. I was not involved in any discussions about the 2006 and 2009 notification. At this stage I no longer attended UKHCDO meetings.

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

131.5. As far as I can now recall the steps taken throughout the period of interest would have been as described in the article published in Haemophilia in 2010 (WITN3311009): Millar CM, Connor R, Dolan G, Lee CA, Makris M, Wilde J, Winter M, Ironside JW, Gill N, Hill FGH. Risk reduction strategies for variant Creutzfeldt–Jakob disease transmission by UK plasma products and their impact on patients with inherited bleeding disorders. Haemophilia Vol 16: pages 305-315 (2010).

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

131.6. This has already been answered. Copies of letters to patients in Oxford in 1997 and 2001 have been provided and the 2004 notification exercise has been explained in answer to Q 131 b above.

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

131.7. Copies of the letters sent to patients in Oxford in December 1997 [WITN3063002] and January 2001 [WITN3063004] have been provided. The letter sent out in December 1997 concluded with an invitation to patients to come to a meeting where they would have an opportunity to ask questions.

131.8. The 2004 notification exercise has been explained in answer to Q 131 b above. In the 2004 exercise, patients with bleeding disorders would have been notified, provided with written information and given an opportunity to discuss and find out whether they had received UK sourced plasma clotting factors in the specified time period (and were therefore considered 'at-risk'), as well as being given an option to find out whether or not they had received implicated batches.

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

131.9. The letters to patients in Oxford in December 1997 [WITN3063002] set out information about vCJD in paragraphs 2, 3 and 4. That letter concluded with an invitation to patients to come to a meeting where they would have an opportunity to ask questions. The letter of January 2001 [WITN3063004] also included some basic information about vCJD in the opening paragraph set this out clearly. I no longer have access to copies of letters sent out in the 2004 notification exercise and so I cannot provide any information about what they said about vCJD.

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

131.10. As far as I can recall there was no external counselling or support available through the hospital apart from the haemophilia centre staff.

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

131.11. As far as I am aware the Department of Health imposed various precautions. I do not know on what evidence they were based. Please refer to the answer to 131b and the articles referred to in that answer.

132. In answering these questions, you may be helped by considering letters that you and David Keeling sent to a patient concerning the risk of vCJD in December 1997 [WITN3063002] and January 2001 [WITN3063004]. You may also be helped by a document prepared by you and Karin Pappenheim, then Chief Executive of the UK Haemophilia Society, entitled "The UK Experience Treater and Patient Association Perspectives" [DHSC0006838_071]. Please explain the purpose of this paper, we understand that it was presented by you and Karin Pappenheim at the 2nd WFH Global Forum on the Safety and Supply of Haemophilia Treatment Products, 24-25 September 2001, Montreal.

***a.* In the document, you state that the *"contribution of the media in this case was not at all helpful."* Please explain further what you meant by that.**

132.1. DHSC0006838_071 appears to be a summary of a talk at the 2001 Global Forum of the World Federation of Hemophilia (WFH). I do not recall the specifics of the presentation of this paper almost 20 years ago. However, as far as I can now recall, this was a patient-centred meeting held in Montreal every two years and is an opportunity for people with haemophilia and physicians to meet and discuss current topics including research or administrative issues.

132.2. I believe that the intention of the comment is evident from its context from the paragraph about how and when patients should be told: "The preferred

option would have been to have held personal discussions with individual patients at their routine six-monthly reviews. Clearly, there was no clinical need to inform patients about the problem immediately. However, the knowledge that the news would break in the media required a prompt response."

b. **You also state the following: *"It also subsequently transpired that a number of* batches *of other blood products (such as albumin) implicated in this product recall had been distributed around the UK and indeed other countries round the world. To my knowledge, no attempt was made to inform the recipients of these products of the problem."***

Please provide any further details that you have of these events, including how you became aware of them, and what steps, if any, were taken to try to identify and inform the recipients of these products of the risk associated with them. Are you aware of any patients becoming infected with vCJD as a result of these events? If so please provide details.

132.3. Again, you are asking for specific recollections in relation to comments made nearly 20 years ago. I refer to the paper cited (WITN3311009) in answer to Q 131b above.

133. It has been stated in press articles that, in 1997-1998, you informed patients of the risk to them, contrary to guidance and in contrast to some of your colleagues in other centres: see, "CJD variant ' threatens haemophilia sufferers'" *Guardian*, 16 December 1997 [HSOC0010002_003], "Infected blood has ruined the lives of many haemophiliacs. So why are they denied safe, synthetic alternative?" Guardian, 8 February 2001 [NHBT0042344]. Please state whether this is an accurate summation, and provide further details of your approach. If you did act contrary to guidance, please explain what that guidance was and why you did not follow it.

133.1. You are asking me to comment on references to me in press articles from 22 and 23 years ago that I have no recollection of. However, in general terms, the concerns were that if the government would not switch relevant patients to recombinant products it was thought that patients should be offered the possibility of other plasma-derived products made in a territory where BSE/vCJD was not a problem. I do not accept that we in Oxford were out of step with UKHCDO. It clear from the letter between Dr Hay and Dr Ludlam in January 1998 [HCDO0000133_188] that it was UKHCDO policy to switch away from BPL products (see also my answer to Q 135 below).

a. You may be assisted in answering this by considering the letter, dated 3December 1997, that you and David Keeling wrote to a patient about nvCJD, and the withdrawal of products by BPL [WITN3063002]. Please state whether you sent other such letters to other patients. If you did so, explain which patients were selected to receive such letters, and why.

133.2. You are asking me to comment on a letter from 23 years ago that I now have no specific recollection of. However, in general terms this letter would have been sent to patients who were receiving BPL products at the Oxford Centre at the time. I anticipate that the only people who would not have been contacted would be the parents of the youngest patients because they would already have been receiving recombinant products.

b. In the letter dated 3 December 1997, you state that the recipient did not appear to have received blood products made from the concentrates withdrawn by BPL. State whether you identified any patients that had received these products and, if so, what information and advice you provided to them (including whether this was provided in person or in writing).

133.3. I no longer have access to patient files at the Oxford Haemophilia Centre and am not able to answer this question.

134. You are also quoted in the *New Scientist* on 25 July 1998 (p.12) [DHSC0042543_052] criticising what you considered to be delay in the decision

to implement the filtration of white blood cells during blood donations. Does it remain your view that this decision was taken too slowly?

134.1. I cannot now recollect my views which formed the basis of comments in an article from 22 years ago. However, my general view is that the filtration of white blood cells should have been introduced in 1996 after the recognition that vCJD in humans and BSE in cattle were caused by the same pathogen. Four cases of vCJD infection transmitted by blood transfusion had been identified by the end of 2004, from three apparently healthy donors who later developed vCJD. Plasma can be, and was, imported from the USA but it is not possible to import blood and so all blood transfused at this time was still derived from UK volunteer donors.

135. In a letter dated 21 January 1998 [HCDO0000133_188], Dr Hay wrote to Dr Ludlam about "Implementation of our Recommendation on CJD". The letter describes the responses of various centres to the recommendation. In respect of Oxford, Dr Hay wrote that he suspected that the Centre was using *"significant amounts of 8Y, which may present them with a financial problem."*

Please:

a. Explain what the recommendation was and the reasons for it.

135.1. As far as I can recall the recommendation was to switch from BPL products (all then manufactured using British plasma) to comparable products made in the USA where BSE/vCJD was not a problem.

b. Set out what you recall about the difficulties which the Oxford Centre had in complying with the recommendation. Explain, insofar as you are able to do so, how this compared to other centres.

135.2. The Oxford Centre was able to offer the patients the opportunity to switch products in so far as I can recall without difficulty.

c. Do you agree with Dr Hay's view that some centres were *"not fully sold on the policy"* and on his references to *"financial problems"* or *"revenue consequences"*? Please explain your reasons.

135.3. As far as I can recall I believe that the additional funding required to switch products was provided at Oxford.

135.4. As regards Dr Hay's statement that he thought Oxford might not be "fully on board" with the policy of switching products, the explanation may be that Oxford had a history of using BPL products in preference to commercial concentrates manufactured in the USA using plasma from paid donors. However, at the relevant time, given the potential risk of continuing to use products made from British plasma, switching to the alternative product seemed appropriate under these circumstances.

You may be assisted in answering this question by considering the letter, dated 3 December 1997 and referred to above, that you and Dr Keeling wrote to a patient concerning nvCJD and possible treatment changes that would result from it [WITN3063002].

136. On 16 January 2007, Dr Hay sent to all UKHCDO members details of a fourth case of vCJD transmitted by transfusion of whole blood [HCDO0000131_006; HCDO0000131_007; HCDO0000131_008 and HCDO0000131_009]:

a. It appears that UKHCDO decided that there was no need for patients to be notified directly about this news. Is this correct, to the best of your knowledge. Are you aware of the reasons for that decision?

136.1. I do not recall any discussions about this case.

b. Dr Hay anticipated that patients might contact their centres as a result of reports appearing in the press. Did that happen and if so to what extent and what concerns were voiced by patients?

136.2. I do not recall receiving any telephone calls about this case.

137. On 15 May 2009, Dr Hay and Professor Hill wrote to all Haemophilia Comprehensive Care Centres and Treatment Centres about implementation of public health measures in respect of bleeding disorder patients at risk for vCJD [CVHB0000011_017]. Did the Oxford Centres comply with the requests set out in the letter?

137.1. To the best of my knowledge I believe that the Oxford Centre complied.

138. In a letter dated 15 April 2010 [HCDO0000616_007], you wrote to Dr Hay regarding two patients who had mistakenly been informed that they were at risk of developing vCJD. You are not asked to comment upon the circumstances of those patients, but to set out the extent to which the mistaken notification of at risk status was a problem more generally; how it was addressed (whether by UKHCDO or others); and whether there were systematic steps that could have been taken which would or might have avoided the problem of patients being incorrectly told that they were at risk.

138.1. These are general comments on what could arise. There could be confusion around batch numbers which did not distinguish clearly between batches made with US and British plasma. Then there is the sharing of products. Haemophilia centres keep good records of vials issued to individual patients but if one of these is passed on to someone else (e.g. a brother or cousin) without the patient informing the centre the records at the centre will be inaccurate. Similarly, it is not uncommon for large haemophilia centres to send out vials of concentrate for treatment of a patient with a bleed in a local hospital. The haemophilia centre will record the name of the patient for whom the product was intended. If not all the vials are used, it is possible that a different patient may be treated later on with some of those same vials.

139. The article that you co-authored, "Mortality Rates, Life Expectancy, and Causes of Death in People with Haemophilia A or B in the United Kingdom Who Were Not Infected With HIV", *Blood* (2007), 110:815-825 [PRSE0001620], recorded that there was no evidence of any death from vCJD or conditions that could be confused with it in the period of the study (1977-1998, with follow up to 1 January 2000). Please state whether you now have any reason to doubt that conclusion for that period. Please also state if you became aware of any deaths from or related to vCJD after that date within that cohort of patients.

139.1. I have no reason to doubt the conclusion that there was no evidence of any death from vCJD, or conditions that could be confused with it, in the period of the study (1977-1998, with follow up to 1 January 2000) for that period.

139.2. A case report (WITN3311010) relating to one of the patients in Oxford was published in 2010 ("Variant CJD infection in the spleen of a neurologically asymptomatic UK adult patient with haemophilia". Peden A, McCardle L, Head MW, Love S, Ward HJT, Cousens SN, Keeling DM, Millar CM, Hill FGH, Ironside JW. Haemophilia Vol 16, pages 296-304).

Section 8: The Haemophilia Society

140. Please provide details of your involvement with the Haemophilia Society. In particular, please describe the work undertaken by you as a member of the Society's Medical Advisory Panel, insofar as relevant to the Inquiry's Terms of Reference.

140.1. I served on the UK Haemophilia Society Medical Advisory Panel for several years. This typically met a couple of times each year and our role was to provide advice on current medical and administrative matters. In addition, I wrote articles for their newsletter on several occasions and gave lectures at several annual meetings.

Section 9: The financial support schemes

141. What if any involvement did or do 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? Please provide as much detail as you can.

141.1. I do not believe that I had any dealings with the Eileen Trust, Caxton Foundation, or EIBSS. I did complete Part 1 and 2 forms for stage 1 and 2 payments from the Skipton Fund. I had occasional dealings with the Macfarlane Trust but most of the liaison was done by the nurses, who asked me write letters or fill in forms from time to time.

142. You are listed as a member of the Hepatitis C Working Party to the Haemophilia Society, which produced a report dated June 2002 [SKIP0000031_082].

a. Please describe your role and responsibilities as a member of the Working Party

142.1. This question relates to matters 18 years ago and therefore I can only give my general recollections. I was invited to join the group by the UK Haemophilia Society. The remit was to come up with costed proposals for financial assistance to recognise the loss and suffering of people with haemophilia who had been infected with hepatitis C. We came up with a model with five levels of compensation which are set out in the report [SKIP0000031_082]. The aim was to use this report to lobby government through the Department of Health to accept these recommendations.

b. Please refer to the letter from you to Dr Hugh Nicholas dated 24 October 2003 when answering this question [DHSC0004421_005]. Please expand on the concerns you held about the lack of support for individuals who have naturally cleared HCV, the co-infected and the bereaved. Did you receive a

response from the Department of Health, and if so, what reasons were provided for their exclusion from the Fund?

142.2. Patients who cleared the infection, have no lasting injury. However, initial testing for HCV only involved antibody tests. Around 20% of people exposed to hepatitis C clear it spontaneously. They will not develop liver damage and they remain immune. However, when patients were initially counselled about their HCV antibody tests, the natural history of HCV was not fully understood and no distinction could be made between those who had persistent infection and those who had cleared it. Tests in the early days simply did not permit a clear distinction in many cases, especially if liver function tests were normal. Antigen (PCR tests) became available about two years later.

142.3. The issue relating to HIV/HCV coinfected patients is set out in my letter and I have nothing more to add.

142.4. I no longer have any of my old papers and do not recall whether I ever received a reply to my letter. I would hope that the Haemophilia Society has copies of the correspondence or at least a written record of subsequent meetings I had with the Society with feedback from me on the response.

c. **Were any of the Working Party's other proposals not implemented by the Department of Health in the establishment and running of the subsequent Fund?**

142.5. I am not able to answer this question.

d. **The Working Group report concluded that certain types of expenses provided in the Canadian Scheme would not be appropriate in the UK context (see page 10). The Group also diverged away from the Canadian Scheme in terms of payment levels. Please explain why the Working Group did not consider such expenses/payment levels appropriate. Did you agree with this position?**

142.6. I cannot recall details of our discussions on these points.

e. On 11 July 2001 you wrote to Dr Frank Hill requesting the release of UKHCDO data in order to assist the work of the Working Party [HCDO0000013_019]. Was this data released, and if not, why not?

142.7. Yes, the data were provided and appear in section 12 on page 7 of the report.

143. Please consider the following documents relating to the fee imposed on patients of the Oxford Centre for the completion of Skipton Fund forms and answer the following questions: SKIP0000031_106 and SKIP0000031_108.

a. Are you aware if any other haemophilia centres imposed similar fees on their patients?

143.1. I do not know.

b. Were patients refunded the fee in the event of an unsuccessful application?

143.2. I do not know.

c. Did the Skipton Fund reimburse patients for this fee, regardless of the outcome of their application?

143.3. I do not know.

d. Why did you decide that a fee would be charged?

143.4. The time involved required for completing the forms was considerable.

e. Did this practice continue? If it came to an end, please identify when and explain why.

143.5. No charge was made for completion of Part 1 forms. A charge was made for Part 2 forms. No decision was taken to stop or reverse this decision.

f. In your opinion were the requirements for patients to complete a form and provide medical evidence fair and reasonable? Did you provide any feedback to the Skipton Fund and/or the Department of Health as to the content of the forms and requirements for applications?

143.6. I think the requirements for patients to complete a form and provide medical evidence were fair and reasonable

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

144.1. My understanding is that patients would be informed but this would mainly have been by the nurses.

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

145.1. As far as I am aware, there was no formal policy or guidance in relation to referring patients to the trusts and funds for support.

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

146.1. As far as I can generally recall, the organisations may have occasionally sought additional specific details but more usually letters were written and forms completed which would have been shown to the patients before being sent off.

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

147.1. As far as I can recall generally, most of this was done by the nurses who would liaise with the various bodies on behalf of the patients. I would have been asked to write letters or sign forms from time to time.

148. Did the Oxford 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.

148.1. Not that I am aware of.

149. Was the Oxford 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.

149.1. I am not aware of the staff being involved in determining applications made by patients for assistance from the trusts or funds.

150. 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?

150.1. I did not have close or frequent dealings so I cannot answer this question.

151. What, if any, dealings have you had with EIBSS? Have there been difficulties or shortcomings in the way in which it operates or takes decisions or in its dealings with applicants for assistance?

151.1. As far as I can now recall, none.

Section 10: HCV Lookback

152. What role, if any, did you play in the National HCV Lookback Exercise on behalf of the Department of Health between 2010 and 2013, using the National Haemophilia Database? Insofar as it is within your knowledge, please provide details of this exercise, its purpose and objectives, how it was undertaken, whether and if so to what extent it achieved its objectives, and your involvement in it. (You may wish to consider the enclosed documents: Summary Note of Third Meeting between the Haemophilia Alliance and UK Health Departments held on 19 November 2010 [HCDO0000272_004]; Dr Hay's letter to UKHCDO members dated 7 July 2011 [ABMU0000019]; an undated letter headed "Dear Colleagues ... RE: Hepatitis C Look-back Exercise" [ABMU0000020]; section 9 of the minutes of Combined 37th Advisory Committee and 11th Annual General Meeting of UKHCDO on 12 November 2010 [HCDO0000509]; section 8 of the minutes of the Combined 41st Advisory Committee and 12th Annual General Meeting of the UKHCDO on 3 October 2011 [HCDO0000510]).

152.1. I was not involved this so I cannot comment.

Section 12: Other Issues

153. The Inquiry has obtained a letter written by Professor P.M. Mannucci to Dr James Smith of the Plasma Fractionation Laboratory ("PFL") in Oxford, dated 3 October 1990 [BPLL0005814_004]. The letter concerns the provision of 8Yconcentrate from the PFL to Professor Mannucci. The professor suggests that Page 47 "*'smuggling'* [the word is placed in inverted commas in the letter] *is the simplest way to avoid the emotional reactions of the customs when they see the word plasma."* Professor Mannucci suggests that you may be *"one possible smuggler."*

a. Please state what, if anything, you know of the matters discussed in the note.

153.1. I do not know what Professor Mannucci is referring to in a letter that refers to me 30 years ago. I never "smuggled" blood or blood products for Prof. Mannucci during my time in Milan and this was confirmed by Prof. Mannucci in an email to me dated 5th October 2020 (WITN3311011).

b. Please explain what, if anything, you were asked to do in respect of these matters, and what you did in fact do.

153.2. Please refer to my answer to 153a above.

c. Please state what considerations you took into account before doing what you did.

153.3. Please see my answer to 153a above

d. Please state whether there were any other occasions on which you transported blood products internationally and, if you did, whether you complied with all relevant formalities.

153.4. In June 2012, managers at my hospital in Oxford were contacted by the authorities in Tbilisi (Georgia) about a prominent citizen with mild haemophilia who had developed inhibitors. They requested that a doctor with expertise in the field of haemophilia fly out with a supply of products which could be used to treat the patient. After the hospital had received a large advance payment, I flew out with a supply of FEIBA® (a plasma-derived concentrate used in the management of patients with haemophilia and inhibitors). This was declared upon arrival to the customs officials and it was clear that I was expected. I did not have to fill in any forms and I was accompanied to a waiting car.

154. 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.

154.1. I have never been referred to, or investigated by, the General Medical Council (GMC) or Health Service Ombudsman.

154.2. I was named in a civil suit for compensation brought against my employing Trust around twenty years ago after a laboratory report issued by the Oxford Haemophilia Centre incorrectly reported that a lady was not a carrier of haemophilia. She went on to have a boy with severe haemophilia. The claim was settled out of court and the Trust paid compensation.

155. 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.

155.1. Nothing to add.

Statement of Truth

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

Signed GRO-C

Dated 23rd October 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
2003	Review article advocating use of recombinant products	WITN3311004

1997	UKHCDO guidelines on product selection	WITN3311005
2020	List of my publications	WITN3311006
2003	UKHCDO guidelines on product selection	WITN3311007
1995 & 2001	UKHCDO guidelines on chronic liver disease	WITN3311008
2010	Risk reduction strategy for vCJD transmission	WITN3311009
2010	Case report: prions in spleen	WITN3311010
5 October 2020	Email from Prof. Mannucci	WITN3311011