Witness Name: Janet Ann Shirley
Statement No.: WITN3901019
Exhibits: WITN3901020 – 30
Dated:

**INFECTED BLOOD INQUIRY**

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**WRITTEN STATEMENT OF JANET ANN SHIRLEY**

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I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 10 February 2020.

I, Dr Janet Ann Shirley, will say as follows: -

**Section 1: Introduction**

1. My name is Dr Janet Ann Shirley. My date of birth is GRO-C 1948. My address is c/o Advisory, The MDU, One Canada Square, London E14 5GS. My professional qualifications are: MB.BS. DCH, FRCPath., Dip. Hlth. Mgt.

2. I qualified as a doctor in 1971 at the Royal Free Hospital School of Medicine, University of London.

I have held the following positions:

2.1 House Physician Medicine Royal Free Hospital 1971
I worked on the Liver Unit under Professor Sheila Sherlock.

2.2 House Physician Surgery Willesden General Hospital 1972
This was a general surgery post mainly in gastroenterology and gynaecology

2.3 Post Registration HP. Royal Hospital, Richmond 1972-1973
This was a post in general medicine

2.4 SHO Paediatrics Kingston Hospital 1973-1974

This was a general paediatric post in a district general hospital. I worked on the neonatal unit, the children's ward, attended paediatric cases in Accident and Emergency and attended births in case resuscitation of the newborn was required.

2.5 SHO Pathology Kingston Hospital 1974-1975

I rotated through the four pathology disciplines of chemical pathology, haematology, histopathology and microbiology. The haematology component comprised laboratory work in haematology and blood transfusion.

2.6 Registrar Haematology Kingston Hospital 1975-1976

I continued to work in the laboratory but also attended outpatient clinics. There were no haematology inpatients.

2.7 Senior Registrar Haematology Kingston Hospital 1976-1978

I worked in the laboratory, taking on more responsibility for the issuing of reports of blood tests and blood and bone marrow films. I learnt to carry our bone marrow sampling and cross match blood. I managed outpatients and gave advice on the management of inpatients with haematological problems. Haematology inpatients were under the care of the general physicians.

2.8 Senior Registrar Haematology St Thomas Hospital 1978-1980

I rotated through the laboratory, the haemophilia centre, the blood transfusion department, haematology outpatients and haematology inpatients. I also spent a short time at the Blood Transfusion Service at Tooting. I took part in the on call rota for haematology patients and gave advice on the management of haematological problems under the care of other departments.

2.9 Consultant Haematologist at Frimley Park Hospital NHS Trust, February 1980 – May 1997. I was responsible for providing a clinical and laboratory haematology service to the population served by the trust:

- Developed a clinical haematology service, including chemotherapy services for patients with haematological malignancies, enabling patients to be treated locally;
- Developed an associate haemophilia centre enabling patients to be treated locally. Prior to this, patients with haemophilia were registered at a number of main haemophilia centres in London, Oxford, Southampton and Lord Mayor

Treloar Hospital and had to travel long distances for treatment if they had a bleed;

- Recruited a second haematologist;
- Introduced specialist nurse practitioners for anticoagulant and chemotherapy services;
- Secured funding to improve the technology and develop the haematology laboratory service;
- Set up and chaired the Hospital Transfusion Committee;
- Provided postgraduate education and training of medical, laboratory and nursing staff; and
- Audited the provision of on call services, outcomes of acute leukaemia patients treated locally and anticoagulant patient management.

2.10 Clinical Director for Pathology at Frimley Park Hospital NHS Trust, 1991 – 1997: I was responsible for providing the strategic direction for the laboratory services, representing pathology at the Hospital Management Board and managing the laboratory resources, including staff and facilities:

- Implemented an extension to the working week;
- Collaborated with the North Hampshire Hospital and the Royal Surrey County Hospital to appoint a Consultant Immunologist;
- Achieved CPA(UK)Ltd accreditation for the entire laboratory service; and
- Lead clinician for Frimley Park Hospital during the merger of pathology services with the Royal Surrey County Hospital.

2.11 Medical Director and Consultant Haematologist at King Edward VII Hospital, June 1997 – November 2000. I was responsible for managing the medical workforce, medical advice to the Hospital Board and clinical governance. I also provided a clinical haematology service, and I was the professional head of the laboratory and lead clinician for cancer services:

- Implemented a hospital wide clinical governance framework;
- Improved links with NHS Trusts and implemented linked medical posts;
- Worked with local NHS organisations to transfer acute medical services to the Royal West Sussex Trust;
- Provided an outpatient, day case and inpatient service for haematology patients;
- Lead clinician for cancer services linking in to the Central South Coast Cancer Network and the St. Luke's Cancer Network;

- Postgraduate education and training of junior medical staff, nurses and PAMS; and
- Professional head of the laboratory at King Edward VII Hospital. Achieved a 10% saving whilst maintaining the quality of the service.

2.12 Consultant Haematologist at Royal Surrey County Hospital NHS Trust, April 2001 – January 2011. I was responsible for the provision of the coagulation and anticoagulant services:

- Provided services for patients with thrombophilia, bleeding disorders, myelodysplasia and myeloproliferative disorders;
- Responsible for blood transfusion until April 2004;
- Developed clinical guidelines and protocols for patients with thrombotic and bleeding disorders, myeloproliferative disorders and myelodysplastic syndromes; and
- Liaised with haemophilia comprehensive care centres to deliver local care for patients with bleeding disorders.

2.13 Associate Medical Director at Royal Surrey County Hospital NHS Trust, April 2001 – November 2006. I was responsible for the Clinical Governance Unit, research governance, patient information and clinical audit and effectiveness:

- Set up the Trust Clinical Governance Unit;
- Managed the implementation of the NHS Research Governance Framework;
- Set up the Clinical Audit committee. Responsible for ensuring that the audit requirements of the National Service Frameworks, the National Confidential Enquiries and the National Institute of Clinical Excellence were met;
- Formulated and implemented the trust Patient, Carer and User Information Strategy; and
- Chaired serious untoward incident panels, investigated complaints and concerns about colleagues' performance.

3. I was not a member of any of the committees or groups relevant to the Inquiry's Terms of Reference apart from being an Associate Haemophilia Centre Director from 1981 until 1997. I attended several of the meetings of the UK Haemophilia Centre Directors. I took part in the 8Y study. Frimley Park Hospital was designated an Associate Haemophilia Centre between 1980 and 1981. Patients with haemophilia and other bleeding disorders could therefore be treated locally for bleeds and attend for routine follow up appointments at Frimley Park Hospital without having to travel to

the Haemophilia Reference Centre (later designated Comprehensive Care Centres) where they were registered. As the consultant haematologist responsible for their care at Frimley Park Hospital, I liaised with the relevant Haemophilia Reference Centres. I was not involved in drafting any of the directives or advisory documents. I would however have received advice and directives from the UK Haemophilia Centre Directors' Organisation regarding the treatment of patients with bleeding disorders.

4. I have not provided evidence to, or have been involved in, any other enquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus (HIV) and hepatitis B virus (HBV) and hepatitis C virus (HCV) infections or variant Creutzfeldt-Jakob disease (vCJD) in blood or blood products.

**Section 2: Decisions and actions of the Haemophilia Centre at Frimley Park Hospital ("The Centre") and my decisions and actions at the Centre**

5. Frimley Park Hospital was designated an Associate Haemophilia Centre between February 1980 and October 1981. Associate Centres were small Haemophilia Centres which did not always have the medical and laboratory facilities for comprehensive full time care but which provided treatment for most of their local patients most of the time. Patients attended for regular home treatment supplies or for treatment of minor bleeds but were also under the care of a Reference Centre or other designated Haemophilia Centre for regular tests and treatment of any major problem. Associate Haemophilia Centres had suitable medical staff to give the treatment, correct storage facilities for the concentrate and had to co-operate with the main Centre in record keeping. Major haemorrhages and surgery were still managed at the main Centre where full laboratory backup was available. The Reference Centres at which the patients under my care were registered were: Oxford Haemophilia Centre, Royal Free Hospital Haemophilia Centre and St. Thomas' Hospital Haemophilia Centre. I also managed children who were under the care of the Lord Mayor Treloar Haemophilia Centre near Basingstoke. Patients were asked to attend the main Centre, once or twice each year, for routine tests, such as coagulation factor levels, hepatitis and the presence or absence of inhibitors (Exhibit WITN3901020, pages 7-9 of the Haemophilia Centre Handbook). I sent letters to the Reference Centres after patients' attended my outpatient clinic or were admitted to Frimley Park Hospital describing the patients' attendance or admission, their general health and any problems which they had experienced, the results of any blood tests

undertaken and the details of any treatment given. The Reference Centres would write to me with details of the patients' attendance at their clinic, any problems encountered and any treatment given and the results of the routine blood tests and factor VIII or IX assays performed. The Reference Centres would also explain what treatment was recommended for bleeding episodes and the management of minor procedures, such as dental extractions and, if the patient was on home treatment, what dose of factor concentrate they were on and how they were to receive their supplies of concentrate. If I was concerned about a patient I would contact the Reference Centre by telephone to ask for advice about the patient's management. For the first five years I was a single handed consultant haematologist working with the support of a medical senior house officer and staff in the Blood Transfusion Department.

6. As the consultant haematologist and Director of the Associate Haemophilia Centre my role was to:

    a. Keep a register of the patients seen at the Centre
    b. Prescribe and supervise the use of blood products to haemophilia patients and patients with other bleeding disorders
    c. Liaise with junior medical staff responsible for giving the blood products
    d. Ensure that annual returns were submitted to the Oxford Haemophilia Reference Centre
    e. Review the patients regularly in the outpatient department and ensure that they were reviewed on at least an annual basis at their main Centre
    f. Ensure that newly diagnosed patients were referred to a Haemophilia Reference Centre for registration and assessment
    g. Ensure that blood products were stored in the correct manner in the Blood Transfusion Department
    h. Ensure that the staff in the Blood Transfusion Department knew how to correctly reconstitute the blood products, such as cryoprecipitate and freeze dried factor VIII.
    i. Ensure that the Blood Transfusion Department kept records of blood products received and used and made the correct returns to the National Blood Transfusion Service at Tooting (NBTS Tooting)
    j. Attend the meetings of the Haemophilia Centre Directors whenever possible to liaise with other Centre Directors and keep abreast of developments

7. The Associate Haemophilia Centre at Frimley Park Hospital was not responsible for any actions or policies regarding the importation, manufacture and use of blood products (in particular factor concentrates). I had no involvement in this apart from prescribing the blood products supplied by NBTS Tooting.

8. Selection and purchase of blood products at the Centre

    a. The Centre was supplied with blood products by NBTS tooting. I had no input into decisions about the selection and purchase of blood products. NBTS Tooting supplied the Centre with both NHS and commercial factor concentrates.
    b. I do not know what were the particular reasons or considerations that led to the choice of one product over another at NBTS Tooting although generally I think that cost and availability were issues. Later on the risks of transmitting viruses ( HBV, HIV, NANBH) impacted on the choice of blood products
    c. I do not know what role commercial and/or financial considerations played in the decisions about the selection and purchase of blood products by NBTS Tooting
    d. I had no involvement in these decisions except for ordering the available factor VIII and IX concentrates and cryoprecipitate from NBTS Tooting.

9. There was no relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products. I do not know what influence that had on NBTS Tooting. The pharmaceutical companies sometimes had stands at Haematology conferences and scientific meetings and I would have discussions with them about their products. It did not have any influence on my decisions and actions because I used the blood products recommended by the UK Haemophilia Centre Directors' Organisation and those supplied by NBTS Tooting.

10. The responsibility for the selection and purchase of blood products lay with NBTS Tooting. I have no knowledge of its decision –making. See 8 above.

11. It was my responsibility to decide which products to use for particular patients. The decision was based on the patient's factor VIII or IX level (i.e. whether they were mild, moderate or severe haemophiliacs) and the site and severity of the bleed. I calculated the dose for cryoprecipitate and factor concentrates according to the guideline in the Haemophilia Centre Handbook (WITN3901021, page 21 of the Haemophilia Centre Handbook) .Prior to the publication of the UK Haemophilia

Centre Directors' Organisation AIDS Advisory Document in December 1984 (WITN3901012) I tended to use cryoprecipitate first for mild and moderate haemophilia patients and if this did not lead to a sufficient factor VIII or IX level I would then switch to the factor concentrate provided by NBTS Tooting. For severe haemophilia patients I usually used factor concentrates for bleeding episodes.

12. Other treatments available for people with bleeding disorders (Exhibit WITN3901022, page 37 of the Haemophilia Centre Handbook) were:

    a. Fresh frozen plasma
    b. Cryoprecipitate
    c. Topical thrombin – for small cuts and oozing tooth sockets
    d. Absorbable haemostatics e.g. Sterispon, Surgicel and Oxycel – for large cuts and nose bleeds
    e. Tranexamic acid and Epsicapron – for bitten tongue
    f. Later on DDAVP (Desmopressin) became available for raising factor VIII levels in patients with mild or moderate haemophilia or von Willebrand's Disease thus avoiding the need to give factor VIII concentrates in many instances.

13. For fresh frozen plasma the disadvantages were that large volumes were required, it took a long time to thaw and other clotting factors were given. Also the factor VIII and IX levels were variable. Cryoprecipitate was useful but the factor VIII level varied and therefore the therapeutic response was variable. This meant that if the required factor VIII level for treatment was not obtained it was necessary to switch to factor concentrates. Once it became available DDAVP could be used in some instances rather than factor VIII concentrates but it was not suitable for severely affected haemophilia patients or for major bleeds. The topical treatments in 12c, d and e above were for minor bleeding problems. Therefore they could not have been used in preference to factor concentrates or cryoprecipitate.

14. In the early 1980s I used cryoprecipitate as first line therapy for bleeding episodes in haemophilia patients. If it did not achieve the required factor VIII or IX levels on post transfusion blood tests I switched to commercial or NHS factor VIII or IX concentrate supplied by NBTS Tooting. After NHS heat treated factor VIII and IX products became available in 1985 these were used. It is also possible that NBTS Tooting supplied commercial heat treated factor VIII concentrates but I cannot remember if

this was the case. When DDAVP became available I used this as first line treatment for bleeding problems in patients with mild haemophilia and von Willebrand Disease.

15. Whether patients were on home treatment was decided by their main Centre and not by myself. Supplies of factor concentrates were sent to the Blood Transfusion Department at Frimley Park Hospital for some patients, who picked them up from the hospital. Other patients received their supplies at home. Over time the number of haemophilia patients on home treatment increased.

16. The Centre complied with the decision of the patient's main Centre regarding prophylactic treatment. As far as I can remember the patients on prophylactic treatment were on home treatment. I do not know whether the policy and approach changed over time. The Centre supported patients on home and prophylactic treatment, for example if they had problems with venous access. We did not provide a service for administering prophylactic treatment as I was not supported by a haemophilia nurse.

17. Children with severe haemophilia were usually treated at their main Centre. If they were treated at Frimley Park the decision regarding the use of concentrates was that of their main Centre. For mild bleeding episodes and for children with mild haemophilia cryoprecipitate was the blood product of choice as far as I can recall. Once heat treated concentrates became available they would have been the treatment of choice.

18. Patients with mild and moderate bleeding disorders were treated with cryoprecipitate until heat treated products were available, or with DDAVP. Factor concentrates were used if cryoprecipitate was not successful in treating a bleeding episode.

19. Without access to the haemophilia patients register or the Oxford annual returns I am unable to answer this question. The Oxford returns for Frimley Park Hospital for 1983 (HCDO0000208_004 and HCDO0000208_006) show that four haemophilia A patients, one von Willebrand patient and two haemophilia B patients were treated with factor concentrates. However there would have been patients registered at the Centre who did not receive any factor concentrate or cryoprecipitate because they did not have a bleed that year or who were on home or prophylactic treatment and received their supplies from their main Centre which would have made the returns. I remember that there were about ten children registered at the Centre but I cannot

recall how many adults were registered. Most of the patients registered were mild or moderate haemophilia patients or had von Willebrand's disease.

20. I am not aware of any other viruses, apart from HIV, HBV and HCV being transmitted by blood products to patients at the Centre.

**Section 3: Knowledge of, and response to, risk**

21. I was at St Thomas' Hospital for the last two years of my training. During that time I was attached to the Coagulation Department, which was also the Haemophilia Reference Centre (Exhibit WITN3901020 page 7). I treated haemophilia patients under the supervision of Professor Ingram and Dr Savidge. At that time I was aware that hepatitis B could be transmitted in blood products. I knew that without treatment the life expectancy of severe haemophilia patients was less than 15 years. The life of people with haemophilia was revolutionised by the introduction of cryoprecipitate and later in the 1970s by freeze-dried factor concentrates (WITN3901010). I became aware in the early 1980s that patients who were treated with commercial concentrate produced from American paid donors could develop HIV. It was generally thought that British produced factor concentrates were safer and had a very low risk of transmitting HIV. About the same time I first became aware that factor concentrates could transmit a new type of hepatitis, NANB. The sources of my knowledge were colleagues, scientific papers and the Haemophilia Centre Directors' meetings. From the beginning of 1985 I became aware that heat treatment of factor concentrates could prevent the transmission of HIV and potentially also NANB (HCV) hepatitis.

22. A test for HIV became available in 1985 and patients who had received factor concentrates were tested at the centre. Patients were also tested for HCV once a test became available in 1991 (WITN3901010).

23. I was of the opinion that NHS blood products were safer than commercially supplied products because NHS blood products were produced from a pool of volunteer donors. Commercially produced concentrates were manufactured from paid donors, many of whom were homeless or intravenous drug users and therefore more likely to contract hepatitis and HIV.

24. Where possible I used cryoprecipitate or NHS factor concentrates. However I was reliant on what factor concentrates were received from NBTS Tooting. The UK was

not self-sufficient in the production of factor concentrates so the Blood Transfusion Department at the Centre also received commercial factor VIII concentrates (HCDO0000208_004). Once heat treated factor concentrates became available in 1985 these were used to treat patients.

*Hepatitis*

25. When I became a consultant in 1980 I knew that blood products could transmit hepatitis. However, I also knew that left untreated bleeding episodes in haemophilia patients could lead to severe disability and/or early death. The risks were less with cryoprecipitate than factor concentrates because the pool of donors was small. The risk of transmission of hepatitis with whole blood was very small because of the very limited number of donors. The risk of transmission of hepatitis B was negligible once donors were screened for hepatitis B. I cannot remember when this began. The sources of my knowledge were the same as in 21 above.

26. I tested patients for hepatitis B if I did not know their hepatitis B status. When a test became available for hepatitis C, patients who developed signs of hepatitis were tested for this. Patients would also have had yearly assessments and tests for hepatitis and HIV at their Haemophilia Reference Centre.

27. When hepatitis B vaccination became available newly diagnosed haemophilia patients and those who were negative for hepatitis B were vaccinated. Previously untreated patients (PUPs), mild and moderate haemophilia patients who had a bleeding episode or a surgical procedure were treated with cryoprecipitate unless the bleed was severe and cryoprecipitate did not raise the factor level sufficiently. In this case factor concentrates were used. When heat treated factor concentrates became available these were used to treat all bleeding episodes and cover for surgical procedures.

28. I understood that NANB hepatitis was more severe than HBV. Initially it could only be diagnosed by excluding HBV and hepatitis A. Over time it became more obvious that NANB hepatitis (HCV) could lead to severe liver damage and that almost all haemophilia patients had been infected by the transfusion of blood products.

*HIV and AIDS*

29. As far as I can remember I first became aware of HIV and the risks of transmission from blood and blood products in the early 1980s. By 1985 I was aware that unheated blood products could transmit HIV and that most patients who had developed HIV had been given unheated commercial factor concentrates.

30. By 1985 I was aware that HIV could be transmitted by NHS unheated factor concentrates.

31. I used heat treated factor concentrates when they became available. Following the circulation of the Haemophilia Centre Directors Organisation AIDS Advisory Document (WITN3901012) and before heat treated UK concentrates were available I used cryoprecipitate, unheated UK factor concentrates or heated imported factor concentrates, whichever was available from NBTS Tooting. There was a lot of debate as to whether heated imported factor concentrates had a lower risk of transmission of infection than unheated UK factor concentrates (WITN3901012). Whenever possible I followed the guidance in WITN3901012.

32. When a test for HIV became available I tested haemophilia patients who had received blood products for HIV. I can only remember one patient testing positive for HIV at the Centre.

33. I continued to use factor concentrates in haemophilia patients who had a severe bleeding episode when cryoprecipitate did not raise the factor levels sufficiently in order to prevent severe disability.

34. I have the following to add to my statement of 28 November 2019 and I refer to the page and line numbers of the oral statement of W1303 on 11 October 2019:

    a. Page 69, lines 16-25. The patient's factor VIII level measured at the Centre in February 1983 was 5% (WITN3901002).
    b. Page 71, lines 5-11. It was a very nasty bleed but not life-threatening – see paragraph 10 of my witness statement of 28th November 2019 and the treatment of ileopsoas haemorrhage (WITN3901023, pages 34-35 of the Haemophilia Centre Handbook).
    c. Page 74, lines 14-26. On 17 December 1984 the patient's factor VIII level post transfusion of cryoprecipitate was 32% (WITN3901024). The target level

for the treatment of an ileopsoas haemorrhage is above 40i.u/dl (40%) (WITN3901023, page 35). With cryoprecipitate the volume being transfused becomes a problem if the number of units is increased and the response is unpredictable. Therefore I switched the treatment to NHS factor VIII concentrates and achieved post transfusion levels of 80% and 54% (Exhibits WITN3901025 and WITN3901026). I was aware that the patient had not received any factor VIII concentrates since 1971. At the time I thought that unheated NHS produced factor VIII was safe and not likely to transmit HIV.

d. Page 75, lines 1-25. I did not know that the batch of Scottish factor VIII had been withdrawn until I read this witness statement. NBTS Tooting provided the Centre with factor VIII concentrates which were ordered as required on a daily basis. The Centre had no say in what product or batches were provided.
e. Page 76, line 3. I refer back to my statement in section d above.
f. Page 79. I did not have access to heat treated NHS product or heat treated US commercial product in December 1984. I refer to paragraphs 11, 12 and 13 of my witness statement of 28th November 2019.
g. Page 82. I was not at the meeting of the Haemophilia Centre Directors on 27th September 1984 (BART0002269). On page 12 of these minutes Dr Craske states, '*So far no patients who have only received NHS concentrates have shown HTLV3+ results'*. As I had not received the UK Haemophilia Centre Directors' AIDS Advisory Document, dated 14 December 1984 (WITN3901012), when I treated the patient I thought that unheated NHS factor VIII concentrate was safe.
h. I was a single handed general haematologist in 1984 and my role as the Director of an Associate Haemophilia Centre was only a small part of my responsibilities. I was responsible for the management of all the haematology patients seen at Frimley Park Hospital. This included patients with anaemia, blood count abnormalities, other bleeding disorders, haematological cancers (including leukaemias, lymphomas and myeloma), transfusion problems, acute bleeds and paediatric and maternity problems.
i. Page 86, lines 21-25. For any laboratory test it is necessary to confirm the result on a second sample to make sure that it is not a false positive or a false negative result. This is why the patient was not informed that he was positive for HIV until he attended for the second blood test in October (WITN3901016).
j. Pages 86-94. I was never told whether any of the batches of factor VIII concentrate that I gave the patient were contaminated with HIV.

k. Page 95. The patient was told in March 1985 that he had non A, non B hepatitis. There was no test for hepatitis C at the time so I could not tell him that he had hepatitis C.

*Response to risk*

35. Patients who tested positive for HIV were given the Haemophilia Society booklet on safer sex and the DHSS guidelines on the Prevention of the Spread of Infection of HIV as well as the name and telephone number of the counsellor for HIV patients (WITN3901017). They were then referred to the consultant responsible for patients with HIV infection. As far as I remember I did not inform or educate patients or the public about the risks of hepatitis and HIV. I expected this to be done by each patient's Haemophilia Reference Centre where there was the support and resources to do this.

36. I think that with the resources and the knowledge available to me that my decisions and actions in response to any known or suspected risk of infection were appropriate. With hindsight I think that Associate Haemophilia Centre Directors should have been given more guidance by the Haemophilia Centre Directors' Organisation and more support and guidance by the Haemophilia Reference Centres and the Blood Transfusion Service.

37. I do not know what I could have done earlier to end the use of infected blood products by the Centre since I was reliant on NBTS Tooting for supplies of blood products and I did not have a budget for purchasing commercial heat treated factor VIII concentrates. Also I did not have the necessary knowledge prior to January 1985.

38. The Centre had very few haemophilia patients requiring treatment for acute bleeds. Most of the severe haemophilia patients were on home treatment supplied by their Haemophilia Reference Centre. I was not responsible for the choice of product for these patients. It was unusual for a patient to attend the Centre for the treatment of an acute bleed. As you can see from my witness statement of 28 November 2019, paragraph 8, my initial choice of treatment was cryoprecipitate.

39. I do not recall what arrangements were put in place at the Centre for the supply of heat treated factor VIII by BPL. From BPLL0010362, BPLL0011964 and

BPLL0002371_034 it would appear that I received heat treated factor VIII for patients who tested negative for HIV and that in order to receive such supplies I had to request them from BPL on a named patient basis.

40. The purpose of the liver function tests was to determine whether the heat treated factor VIII was transmitting hepatitis. At the time it was not known whether the type of heat treatment being used would get rid of any hepatitis virus. From my letter it appears that a viral follow up of patients was required for all patients receiving the heat treated factor VIII and that I was sending these results. I cannot recall whether patients were informed of the results of their liver function tests or informed about and asked to consent to the sending of the results to Dr Snape.. During the 1980s most consent was implied or oral and patients were generally given much less information than nowadays when patient consent forms and information leaflets are very detailed.

41. I did not recall that I had entered patients into the 8Y trial until you sent me the details. According to PRSE0004378 and BPLL0006186_002 I entered patients into the 8Y trial. I have not received the Clinical Trial Exemption Application signed by Dr Lane at BPL and dated 28 September 1987. I am unable to provide details of my participation.

42. I do not know anything about other clinicians or other organisations, other than what I have read in the minutes of the Haemophilia Centre Directors' Organisation. I am therefore unable to answer this question. I do however think that funding of the production of factor concentrates in this country was a problem.

43. I do not know whether there was the knowledge prior to 1980 about viral inactivation of blood products. Therefore I am unable to answer this question.

## Section 4: Treatment of patients at the Centre

*Provision of information to patients*

44. I do not recall providing any information to patients with a bleeding disorder about the risks of infection in consequence of treatment with blood products prior to such treatment commencing. In my view it was the responsibility of the patient's Haemophilia Reference Centre (Exhibit WITN3901020).

45. Patients should have been informed about this by their Haemophilia Reference Centre once it became known that there were hepatitis viruses in blood. However, there was the need to balance treatment of severe and life-threatening bleeds against the risk of hepatitis B (only hepatitis A and B viruses were known at the beginning). At the time hepatitis B was thought to be a risk worth taking compared to an early death and/or severe disability if patients were not treated.

46. I do not recall providing information to patients about alternatives to treatment with factor concentrates. I would have explained to the patient what treatment I was recommending. Factor concentrates were the best treatment for stopping bleeds if cryoprecipitate had not worked. Once DDAVP was available I would suggest that this was used to raise the factor VIII level in mild bleeds, mild haemophilia patients and patients with von Willebrand's Disease.

47. The Haemophilia Reference Centre Directors were responsible for starting home treatment.

*HIV*

48. I first discussed AIDS and HIV when the husband of witness W1303 became infected.

49. I learned that a patient under the care of the Centre had been infected with HIV as in 48 above. I do not recall any other patients at the Centre becoming infected with HIV.

50. I informed the patient in 48 above in person and by telephone (WITN3901016 and WITN3901017).

51. I provided information as detailed in WITN3901017. I do not recall telling patients to keep their infection a secret. However given the stigma associated with HIV at the time I suspect that most patients kept their infection secret. If patients were diagnosed with HIV I referred them to the HIV counsellor at the hospital (WITN3901017).

52. Partners of HIV positive patients were tested for HIV (Exhibit WITN3901027, 24 September 1986). Once a patient was diagnosed with HIV partners were offered a test.

53. The same information was given to patients and partners (WITN3901017). See paragraph 35 above.

54. I only recall diagnosing one haemophilia patient as having HIV (the husband of witness W1303). This patient had moderate haemophilia A. However there may have been others under my care who had been diagnosed at their Haemophilia Reference Centre which was responsible for the routine follow up of patients. I cannot answer questions 54 a-e.

*Hepatitis B*

55. The patients were tested for hepatitis B at their Haemophilia Reference Centre. I only recall testing the husband of witness W1303 because he developed signs of hepatitis. His hepatitis B antigen test (HBsAg) was negative (WITN3901018) signifying that he did not have hepatitis B.

56. I did not supply this information. It should have been given to patients who tested positive by staff at their Haemophilia Reference Centre.

57 I do not know how many patients at the Centre were infected with hepatitis B.

*NANB Hepatitis/Hepatitis C*

58 The only patient I recall testing for NANB hepatitis was the husband of witness W1303. I would have told him verbally that this was the cause of his hepatitis as tests for other forms of hepatitis were negative.

59 I informed Dr Rizza at the Oxford Haemophilia Reference Centre responsible for this patient (WITN3901015). I did not provide patients with information about NANB hepatitis. I relied on the Haemophilia Reference Centres as they were resourced to do this.

60 I did not do this. It was the responsibility of the Haemophilia Reference Centres.

61 See 60 above.

62 See 60 above.

63 I do not know how many patients at the Centre were infected with hepatitis C.

*Delay, public health/other information*

64 The only patient I recall having to give the results of testing for HIV and hepatitis was the husband of witness W1303. He was given the result at his next outpatient appointment. I did not call him in before this to give him the results. Outpatient clinics were very busy as the haemophilia patients were seen in the same clinic as all the other haematology patients.

65 We followed the advice given by the microbiology consultant for managing potentially infected blood samples The treatment of patients who had HIV or hepatitis was managed by their main haemophilia centre. The Centre gave patients who were positive for HIV information as in paragraph 35 above.

66 Information about the risks of other infections was provided to patients by their main haemophilia centre.

67 Patients were given the Haemophilia Society booklet on safer sex and the DHSS guidelines on preventing the spread of infection (WITN3901017. Patients were advised to wear a condom (Exhibit WITN3901028).

*Consent*

68. Blood samples were taken to measure factor levels at diagnosis and to measure factor levels after treatment. Patients' main haemophilia centres would take samples at the annual follow-up for viruses and factor VIII or IX inhibitors. The Centre did not routinely store samples except for the viral follow-up of patients who were given heat-treated factor VIII (BPLL0011964). I do not recall what information was given to patients about the purposes for which the blood was taken. I do not think patients were informed about the storage and use of these samples. The samples were only stored so that they could be tested in a batch because of the problems in the laboratory with cleaning the machines (BPLL0011964).

69. In order to treat patients with factor concentrates and other blood products it is necessary to insert an intravenous needle. This cannot be done without the patient

consenting. Patients therefore gave implied and oral consent to this procedure and the transfusion of blood products. It was later in the 1990s that patients gave written consent to the transfusion of blood products. Practice changed as a result of the contamination of blood products by HIV and hepatitis C. In 1995 the UKHCDO agreed that formal written consent should be implemented (HCDO0000495, section 8, page 4).

70. Patients were tested for HIV without their consent. The reason for this was that insurers would not insure people if they said they had been tested for HIV regardless of a negative result. I then informed patients who had tested positive. Patients were told if they were tested for hepatitis or for factor levels. The approach to obtaining consent for testing was implied or oral.

*PUPS*

71. As far as I can remember these patients were treated with cryoprecipitate as first line treatment and then with heat-treated factor concentrates when these became available. Their main centre would have made the decision about how to treat them.

*Treatment of patients who were infected with HIV and hepatitis*

72. The care and treatment of patients with HIV/AIDS was carried out at their main Centre. It was not the responsibility of Associate Haemophilia Centres.

73. Patients who were infected with HIV were seen regularly in my outpatient clinic to check on their health. If they developed problems they were referred to their main centre.

74. The care and treatment of patients with hepatitis B was managed by their main centre.

75. The Centre monitored the liver function tests of patients infected with hepatitis B when they attended outpatient clinics.

76. The care and treatment of patients with NANB hepatitis was managed by their main centre.

77. The care and treatment of patients with hepatitis C was managed by their main centre.

78. The Centre monitored the liver function tests of patients infected with hepatitis C when they attended outpatient clinics.

79. I had no involvement with clinical trials in relation to treatments for HIV and/or hepatitis.

80. I had no involvement in the care and treatment of children infected with HIV and/or hepatitis.

81. Patients infected through blood products were given the contact details of a counsellor (WITN3901017).

82. The Centre was not provided any funding to help with counselling of patients infected with HIV.

83. Counselling was provided by the hospital for patients infected with HIV. Patients infected with HIV were given the contact details of the counsellor appointed by the hospital (see 81 above).

84. The Centre was not responsible for the treatment of people who had been infected with HIV and/or hepatitis C (see 72 and 77 above).

*Research*

85. I entered patients into the 8Y study. I did not enter patients into any other study as far as I am aware.

a. The purpose of the 8Y study was to assess the incidence of NANB hepatitis and the transmission of other viruses in patients receiving a BPL factor VIII concentrate, 8Y, and who have never before received a large pool concentrate (CTX 880110001 A-8).
b. The co-ordinators, Dr C R Rizza and Dr P E A Kernoff, applied for a trial exemption certificate (CTX 880110001 A-8). Institutional Ethical Committee approval and informed patient/parent consent had to be obtained by participating physicians before patients were entered into the trial (Section 8.13 of CTX 880110001 A-8).
c. I obtained local Ethical Committee approval for the research and I obtained informed consent from patients who fitted the study criteria. I entered them into the study, treated them with 8Y concentrate as required, carried out the post

transfusion blood tests required and submitted the results to the lead investigators.

d. The UK Haemophilia Directors' Organisation and the Plasma Fractionation Laboratory, Churchill Hospital, Oxford. (PRSE0004317, page 5, Interim report on 8Y and 9A) were involved in the research.
e. The research was funded by BPL (Section 8.12 of CTX880110001 A-8).
f. 33 patients were entered into the study (PRSE0004378).
g. It was a requirement of entering patients into the trial that informed consent was taken from individual patients before they were eligible to be entered into the trial (see b above).
h. The results of the study were published in 1987 (PRSE0004378).

86. The ethical principles that should guide research are set out in the General Medical Council (GMC) Handbooks, 'Consent: patients and doctors making decisions together' published in 2008 (first published as 'seeking patients' consent' in 1998) and 'Research: The role and responsibilities of doctors', published after 2000. These guides were published after the period in question in order to make sure that doctors applied the correct ethical principles to consent and research. It is possible that not all these principles were applied to research prior to this. I do not recall whether I applied all these principles to the patients that I entered into the 8Y study. However, I have always attempted to be open with patients and inform them about their treatment and investigations and the purpose of any research or studies that they were involved in.

87. I would have sought consent for patients to be involved in the 8Y study. I would have informed them why they were having blood samples taken so regularly to check their liver function and that the aim of the study was to check that heat treatment of the 8Y would prevent infection with NANB hepatitis.

88. At the time we were not aware of issues surrounding patient data (It was before general use of computers) and as far as I can recall we did not specifically mention the use of patient data. The GMC handbook 'Confidentiality: Protecting and providing information' was not published until 2004. As far as I am aware the lead investigators in the 8Y study anonymised the patient data and patient blood test results submitted to them.

89. Patient data was shared with the lead investigators at the UKHCDO, Oxford Haemophilia Centre and the Plasma Fractionation Laboratory, Churchill Hospital, Oxford. This sharing of data was necessary for the study. I also submitted annual returns to the

Oxford Haemophilia Centre of the number and category of patients treated with blood products and the type and amount of blood products used to treat patients with haemophilia A and B and von Willebrand's disease. The returns had no patient details (HCDO0000208_004 and HCDO0000208_006).

90. I have not published any articles or studies relevant to the Inquiry's Terms of Reference. I was a contributor to the 8Y study but not an author.

*Records*

91. I do not remember having to record the death of a patient at the Centre due to HIV or hepatitis. However my practice was to recorded any contributing factor to a patient's death. For example if alcohol was a contributing factor I would record it.

92. The Centre followed the medical records retention policies of the hospital.

93. A record of haemophilia patients and the treatment they received was kept in the Blood Transfusion Department of the hospital. I do not know where this register is now. I assume that it is at Frimley Park Hospital if it has not been destroyed.

94. I did not keep any records or information about any of my patients other than at the Centre.

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

**Section 5: Treatment of patients other than at Frimley Park Hospital (i.e. at King Edward VII Hospital and the Royal Surrey County Hospital).**

96. I was not involved in the care and treatment of, or in decision-making relating to the care and treatment of, patients who had HIV or HCV or HBV in consequence of infected blood products or infected blood at either of these hospitals

97. – 103. See 96 above.

**Section 6: Self-sufficiency**

104. The 1974 Department of Health announcement on self-sufficiency in factor VIII blood products.

a. I became aware of this announcement after I became the director of the Associate Haemophilia Centre at Frimley Park Hospital.

b. I understood self-sufficiency to mean producing enough factor VIII products for all the treatment requirements for patients requiring factor VIII concentrates.

c. My understanding did not change over time.

d. My understanding was that others defined self-sufficiency in the same way.

e. I had no involvement in any arrangements or initiatives designed to help self-sufficiency.

105. I do not know how estimates were made of how much factor VIII blood product would be required for use in England and Wales.

a. My role was to submit returns to the Oxford Haemophilia Centre of the amount of factor VIII blood product used at the Centre (HCDO0000208_004). The only change I am aware of over time was that it was suggested that paper returns sent in the post were changed to electronic returns (HCDO0000497, page 7, paragraph 1).

b. As far as I am aware the role of the UKHCDO was to liaise with the Department of Health and from 1988 with the Central Blood Laboratories Authority (BART0002329, section 9, paragraph 6, page 6). From 1993 the UKHCDO worked with the National Blood Authority (BART0000998, page 4, paragraph v) NBA).

c. I am unable to answer this.

d. I am unable to answer this.

e. I am unable to answer this.

f. I am unable to answer this.

106. I do not know how the annual figures were derived for how much factor VIII blood product had been used over the course of a year. I presume it was based on the annual returns from each haemophilia centre.

a. My role as director of the Centre was to send annual returns of the amount of factor VIII blood product to the Oxford Haemophilia Centre. See 105a above.

b. See 105b above.

c. I am unable to answer this.

d. I am unable to answer this.
e. I am unable to answer this.
f. I am unable to answer this.

107. I am unable to answer this.

108. With regard to achieving self-sufficiency of factor VIII blood products:
a. Whilst I was the director of the Centre at Frimley Park Hospital up until 1997 I do not think that self-sufficiency of factor VIII blood products was achieved. I do not know whether it was achieved after this time.
b. During this time I think that there were funding problems and delays in setting up enough capacity in the Blood Products Laboratory.
c. I cannot answer this – see 108a above.

109. The haemophilia centres submitted annual returns of factor VIII blood products used at their centres to the Oxford Haemophilia Centre which collated all the returns in order to see what the annual usage for that year was. From this it would have been possible to see if annual use was rising and what the trend was. However, the annual use of factor VIII blood products would be impossible to predict accurately. A few factor VIII inhibitor patients who needed a lot of factor VIII in one year because of unpredicted bleeding or major surgery could skew the figures significantly. As factor VIII blood products became safer use would have gone up. Also the more patients who survived beyond teenage years the higher the factor VIII usage became. I do not see how haemophilia clinicians could be blamed for failing to identify the foreseeable increase in the use of such products once they became available as it was difficult to foresee this.

110. Since the majority of patients who became infected with HIV had received commercial factor VIII blood products from large pools of paid blood donors, I personally think that self-sufficiency would have reduced the number of patients infected with HIV. I do not think it would have materially affected the number of patients with HBV as most of these patients were infected during their first exposure to blood products, either UK produced or commercially produced. HCV was not known about until later when non A/ Non B hepatitis was recognised. If self-sufficiency had been achieved during the 1970s I think that the numbers of HIV patients would have been reduced. I don't know whether it would have reduced the number of HCV positive patients.

111. As far as I can remember, I think that England and Wales did achieve self-sufficiency in factor IX blood products. I think that I used NHS factor IX concentrates rather than commercially produced products (HCDO0000208_006).

112. I am not aware that I used any commercially produced factor IX products.

**Section 7: Blood services and BPL**

113. The Centre received blood products from NBTS Tooting. Blood products were ordered as required and returns of usage were made. I had no direct contact with BPL regarding the supply of blood products until 1985. At this time I liaised with Dr Snape for the supply of heat-treated factor VIII for some of the patients I treated (BPLL0011964, BPLL0002371_034 and BPLL0010362).

114. I only know of what the UKHCDO did to liaise with the Department of Health and BPL regarding the production of heat treated factor VIII and IX from attending the meetings and receiving the minutes of the meetings.

115. I had no discussions or meetings or interactions with any blood service (regionally or nationally) and/or BPL in relation to:

a. The risk of infection with hepatitis from blood products.
b. The risk of infection with HIV/AIDS from blood products.
c. The steps to be taken to reduce the risk of infection.

116. I had no involvement with any decisions or actions taken by any blood service (regional or national) and/or BPL in response to the risks arising from blood and blood products.

**Section 8: UKHCDO**

117. I attended the UKHCDO meetings that I could travel to easily from Frimley Park Hospital. I was not a member of any of its working parties, committees or groups. I cannot remember whether the minutes of the meetings were routinely provided to attendees and non-attendees following the meetings but I think they would have been.

118. The UKHCDO

a. I cannot recall all the purposes, functions and responsibilities of the UKHCDO but as far as I am aware it collated all the information regarding the use of blood products to treat patients with inherited bleeding disorders. It also conducted research into the use and complications of blood products and it liaised with the BPL and government about the requirements for blood products, in particular factor VIII and factor IX concentrates and cryoprecipitate. It also sent treatment guidelines for patients with inherited bleeding disorders to members of the UKHCDO and more widely to consultant haematologists. It liaised with the Haemophilia Society, the Haemophilia Nurses Association and the British Association of Social Workers Special Interest Group.

b. There were working parties to deal with specific issues, such as AIDS, hepatitis, von Willebrand's disease, inherited platelet disorders, and patients with factor VIII inhibitors. The working parties consisted of a small group of members with a particular interest in the relevant subject. Each working party had a chairman.

There was a committee made up of the Haemophilia Reference Centre Directors which managed the organisation and decided on the needs of the organisation and what it should be concerned with. The committee elected the chairman who served for a term of three years. A chairman could serve two terms. Representatives of the Haemophilia Reference Centre Directors met with government representatives regarding funding and the production of factor concentrates.

c. I do not know what the relationship was between the UKHCDO and pharmaceutical companies. I was not aware that there was a relationship.

d. Some of the decisions were taken by the Haemophilia Reference Centre Directors or the working groups. Some, such as the reorganisation of haemophilia centres, were taken after discussion with all the members of the UKHCDO. In this case a committee consisting of elected members and an elected chairman was convened to consider the question of re-organisation in more detail and individual centre directors were asked to write to the chairman with their views.

e. The UKHCDO sent advice on the treatment of patients with inherited bleeding disorders to the haemophilia centre directors and in some cases more widely to all consultant haematologists. As far as I am aware the minutes of the meetings were sent to all haemophilia centre directors. I do not know whether information or advice was sent to anyone else.

f. I was not involved in any of the policies, guidance, actions or decisions of the UKHCDO but I would have received information in the minutes and the guidance for treatment sent to haemophilia centre directors.

i. I only knew what was discussed at the UKHCDO meetings and was in the minutes or in treatment guidelines.

ii. See i above.

iii. See i above.

iv. See i above.

v. See i above.

vi. I do not remember receiving anything about sharing information about the risks of infection with blood products with patients and/or their families..

vii. I don't remember receiving anything about obtaining consent for patients for the testing and storage of their blood, for treatment and research although when the GMC published its guidance on obtaining consent I followed this.

viii. See i above.

ix. See i above.

x. I do not remember receiving any information about vCJD exposure.

xi. See i above.

**Section 9: Pharmaceutical companies/medical research/clinical trials**

119. I have never provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products.

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

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

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

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

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

125. I do not know what regulations or requirement or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company as it did not apply to me.

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

127. I have never provided a pharmaceutical company with the results of medical research studies that I have undertaken.

128. This is not applicable to me as I have not received funding from pharmaceutical companies for medical research.

**Section 10: vCJD**

129. I think the awareness of the risks of transmission of vCJD associated with the use of blood and blood products happened after I left Frimley Park Hospital.

130. I did not have any involvement in decision-making about the information that should be provided to patients about the risk of, or exposure to, vCJD and/or in decision-making about the steps which should be taken in relation to patients and their care or treatment. Therefore I cannot answer questions a. to e.

**Section 11: involvement with the financial support schemes.**

131. I had no dealings with the different trusts or funds which were set up to provide financial support to people who had been infected.

132. The Centre advised patients to contact the Macfarlane Trust (Exhibit WITN3901029).

133. The Centre did not have a policy or any guidance in relation to referring patients to trusts or funds for support. If patients needed advice the Centre advised them to contact

the Macfarlane Trust (Exhibit WITN3901029). The Centre also passed on information supplied by the Macfarlane Trust to patients (Exhibit WITN3901030).

134. I do not recollect the Centre being asked provide any information to the trusts and funds about or on behalf of patients who were seeking assistance from the funds or trusts.

135. The Centre did not act as a gateway for determining whether a particular patient met the eligibility criteria for receipt of assistance from any of the trusts or funds.

136. The Centre was not involved in determining applications made by patients for assistance from the trusts or funds.

137. I had no involvement or dealings with the trusts or funds during my work at King Edward VII Hospital or the Royal Surrey County Hospital.

138. I had no dealings with any of the trusts or funds. I have no knowledge of the experiences of my patients in relation to the trusts or funds. Therefore I cannot comment on how well they were run. I do not know whether they achieved their puposes. I do not know whether there were difficulties or shortcomings in the way they operated or in their dealings with beneficiaries and applicants for assistance.

**Section 12: Other issues**

139. I have had no complaints made about me, in so far as relevant to the Inquiry's Terms of Reference, to my employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

140. I know of no other issues that I believe may be of relevance to the Infected Blood Inquiry.

**Statement of Truth**

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

Signed GRO-C

Dated 23rd September 2020

**Table of Exhibits**

| Date | Notes/Description | Exhibit number |
|---|---|---|
| 1980 | Haemophilia Centre Handbook, Cover and pages 7-9 | WITN3901020 |
| 1980 | Haemophilia Centre Handbook, page 21 | WITN3901021 |
| 1980 | Haemophilia Centre Handbook, page 37 | WITN3901022 |
| 1980 | Haemophilia Centre Handbook, pages 34-35 | WITN3901023 |
| 17 December 1984 | Factor VIII assays pre and post transfusion | WITN3901024 |
| 18 December 1984 | Factor VIII assay pre and post transfusion | WITN3901025 |
| 19 December 1984 | Factor VIII assay post transfusion | WITN3901026 |
| 24 September 1986 | Clinical notes | WITN3901027 |
| 8 April 1988 | Clinical notes | WITN3901028 |
| 13 June 1990 | Letter to Dr Tibbott | WITN3901029 |
| 18 August 1989 | Letter to patient | WITN3901030 |